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SPECIFIC AIMS

Family care of an older adult is a valued tradition of society and has become an essential element of the US healthcare system with 83% of long term care provided to older adults coming from family members or other unpaid helpers[1]. As the population of older adults grows, almost doubling in size from 2012 to 2040[2], so too will the expectations placed on American families. This is especially true of families who support community living for individuals living with Alzheimer's disease and related dementias (ADRD), which has been defined as "intense caregiving" and is associated with significant daily burdens and an overall threat to the caregiver's quality of life[3]. A robust body of ADRD research demonstrates that interventions aimed at supporting and educating caregivers can significantly improve the quality of care delivery and improve the well-being and quality of life for both caregivers and persons with dementia (PWD)[4]. Despite the fact that over 200 interventions have been found to be effective for dementia caregivers in randomized clinical trials (results confirmed in 7 meta-analyses and 17 systematic reviews), only six have undergone translation efforts resulting in publication[5]. The lack of credible translation of evidence-based interventions into widely available community-based services means that the clear majority of the current 16.1 million family caregivers do not have access to evidence informed long term care supports and services. Thus, *family caregivers remain at risk of the known negative consequences of caregiving despite evidence suggesting that those negative consequence can be remediated*. There is an immediate and critical need to address this issue which is of significant societal impact.

This study is based on a practical approach of applying technology to an existing evidence-based intervention, Resources for Enhancing Alzheimer's Caregiver Health II (REACH II), refined with real-world user feedback and rigorously tested with the goal of creating an online family caregiver support system that has the potential of both scalability and sustainability. The feasibility of our proposition has been established by the creation of the proof-of-concept system ***GamePlan4Care (GP4C)***, demonstrating that modern internet technology can be used to automate key components of REACH II delivery. Such automated REACH II components include active engagement of caregivers in skill-building to address diverse challenges in caregiving and flexible tailoring of the intervention based on participant needs. ***Therefore, GamePlan4Care is positioned for a Phase 1 study to incorporate the full breadth of REACH II material and optimize the user experience for efficacy testing in a randomization clinical trial that engages BSWH clinics and community-based organizations (CBOs) where family caregivers already seek services.***

Two specific staged AIMS are proposed in this study.

AIM 1. **Advance the current proof-of-concept GP4C into a viable delivery system for the REACH II intervention.** Further development will include uploading the full breadth of REACH II education and skill-building materials, usability testing and updates to the user interface/user experience (UI/UX), creating a portal of delivery tools used by Dementia Care Specialist (DCS; i.e., interventionist), and establishing a comparable education-focused online system (Resources4Care; R4C) to be used in comparison to the multicomponent, skills-training GP4C system. Development activities will be conducted by the Baylor Scott & White Health (BSWH) Office of Digital Health with engagement of community-based organizations, family caregivers, and external advisors, with oversight by the GP4C research team.

> **H_1:** *Within 12 months of usability testing with 32 family caregivers, the GP4C research team will reach consensus with the BSWH Office of Digit Health and an external Advisory Committee that GP4C is a viable platform for online delivery of REACH II with* R4C *as an appropriate comparison condition.*

AIM 2. **Compare the relative impact of GP4C and R4C, both of which include access to a Dementia Care Specialist, on a wide range of family caregiver outcomes.** Family caregivers will be randomized to one of the two conditions and will complete an assessment battery at baseline and at the 6-month follow-up. Primary outcome measures will include burden, depression, social support, and caregiver's health and interaction with health care providers. Secondary outcomes will include caregiver stress, positive aspects of caregiving (PAC), cognitive change in care-recipient. The CBOs will designate a "GP4C Champion" to promote the enrollment of 240 family caregivers who have computer access and report regular use of the internet. Use of GP4C & R4C and contact with DCS will be recorded by the system as implementation data.

> ***H_1:*** Family caregivers randomized to the GP4C condition will report greater improvement on primary and secondary outcomes as compared to family caregivers in the R4C condition.

GP4C will fill a critical gap in caregiver support services as an evidence-based, internet-enabled system capable of providing immediate, tailored education and skills training to caregivers who can access live support from a DCS via phone or web-based video. Compared to existing evidence-based interventions, CBOs will face fewer

barriers to scaling and sustaining GP4C, a critical achievement in efforts to serve the growing number of family caregivers who face the challenges of dementia caregivers.

RESEARCH STRATEGY

SIGNIFICANCE

As the population of older adults grows, almost doubling in size from 2012 to 2040, so too will the need for family caregiving. For most family caregivers, caregiving is not a short-term obligation. As reported in the National Academies' report *Families Caring for an Aging America*[6]*,* nearly 70 percent of caregivers in a nationally representative survey had provided 2 to 10 years of care, and 15 percent had already provided care for more than 10 years by the time of the survey. This is significant because caregivers are more likely to suffer the negative consequences of caregiving the longer they are engaged in it. Caregiving is associated with negative psychosocial outcomes such as depression, anxiety, and burden[3]; social isolation and family conflict[7]; and financial strain due to costs of care[8]. Some caregivers also experience negative health outcomes such as poorer self-reported health, more chronic conditions/healthcare utilization, and decreased immune functioning[9]. The data therefore suggests that an average person in their fourth decade of life is expected to eventually spend 5.1 years (or 10% of their remaining life) caring for an older adult, a situation known to have negative consequences to one's health and well-being.

Dementia caregivers, in particular, are likely to experience these negative outcomes. In the United States, an estimated 5.7 million persons are affected by Alzheimer's disease, the most common type of dementia and an estimated 16.1 caregivers provide daily care to family members living with Alzheimer's disease[10]. Compared to non-dementia caregivers, dementia caregivers spend significantly more time providing care, assist with more activities of daily living, face greater impact on work and career, and experience more negative social and emotional consequences[11]. For dementia caregivers, these compounded negative outcomes are associated with increased intensity of caregiving, presence of care recipient problem-behaviors, and lower levels of informal support[12,13].

There are proven management techniques that can address these unique aspects of dementia caregiving and mitigate negative consequences experience by family caregivers. More specifically, interventions that actively engage caregivers in skill-building[14], utilize a multi-component strategy to address different challenges of caregiving[15], and allow for flexible tailoring of the intervention based on participant needs[16] can positively impact family caregivers. Yet, these services remain elusive to the vast majority of family caregivers as caregiving services remain extremely fragmented, poorly adapted to caregiver needs and preferences, and, in the case of technology-based solutions, underdeveloped.

Barriers to the provision of caregiver services have been well documented and include the lack of a reliable infrastructure capable of standing up service programs, failure to provide services in a format and location that can be accessed by family caregivers who often provide continuous supervision of a family member living with dementia, failure to create a workforce versed in "family-centered care", and the absence of a typical third party payer (i.e., commercial health insurance, Medicare)[6]. While strategies to overcome barriers to the provision of caregiver services have been tried, currently evidence-based interventions share a fundamental restriction – *the development and testing environment from which the interventions emerged is not characteristic of real-world service delivery and did not include input from the end users (i.e., providers of caregiving services and family caregivers)*. The failure of current evidence-based intervention to result in meaningful community-based services lead the authors of *Family caring for an Aging America*[6] to call for the "development and testing of dissemination and implementation strategies to enable reach and scaling up of proven programs and integration in existing systems of care." P. 180

INNOVATION

Application of technology as a strategy towards greater reach and scaling has shown promise in the delivery of health care and social services but has been underutilized in efforts to support family caregivers. We propose modern internet technology as a feasibility strategy to scaling currently evidence-based caregiving interventions. More specifically, internet-enabled technology can be part of the solution in efforts to adapt costly and labor-intensive caregiver interventions into more scalable and sustainable formats acceptable to today's caregivers. Innovations demonstrated in this study is the use of modern internet technology in the delivery of an existing, well studied, effective approach to improving the quality of life of dementia caregivers, the Resources for Enhancing Alzheimer's Caregivers Health II (REACH II) intervention. Development activities will focus on the consumer experience and will benefit from access to the latest digital technology in healthcare. Unlike prior approaches to using web-based supports, we will conduct a methodologically rigorous randomized clinical trial

followed by, if appropriate, dissemination of an online version of REACH II to CBOs who will face fewer barriers to scaling and sustaining an evidence-based intervention.

As access to the internet is becoming ubiquitous[17] even among groups with historically low rates of technology adoption (older adults, less educated, lower income, rural)[17,18], technology-based adaptation of caregiver support has emerged as a potential avenue to overcoming barriers of access, scalability, and sustainability. Caregivers have already demonstrated a collective desire to access the internet to gather health information, track their own health indicators, and seek others with similar health concerns[19]. Caregivers believe that technology solutions can bring significant benefits to both them and the care recipients[20]. Once established, technology solutions that make use of automation (which cannot deviate from standardized protocols [implementation fidelity]) can be rapidly scaled with minimal marginal cost. Therefore, it is through technology that the rapidly growing number of family caregivers can gain access to information and support in an easily implemented, standardized, and cost-effective format they find acceptable (and continue using) to potentially reduce the burden of care and enable them to stay in the caregiving role longer.

There are concerns, however, to the quality and utility of information currently being accessed by caregivers on the internet[21]. Utilizing content from evidence-based programs, whose impact on caregiver outcomes has been previously verified using rigorous scientific methodology, offers the strongest likelihood that caregivers will benefit from technology-enabled platforms. Previous research has shown that adaptations of existing evidence-based programs to internet-based applications is feasible and acceptable for culturally diverse groups[22]. For dementia caregiver support specifically, initial work using telecommunications and computer-based interventions have demonstrated the approach to be a viable mode of intervention delivery[23,24]. Many studies have reported significant improvements in caregiver outcomes and caregiver satisfaction and comfortable with telehealth[25]. However, there are concerns about the methodological rigor in the testing of many of these early internet-based caregiver interventions, as many do not use a control condition or assess caregiver compliance with the intervention[21].

In order to expand access to evidence-based education and support through technology, Stevens and Ory have created an internet-based delivery system for one of the most respected family caregiver interventions, REACH II. While REACH II has been made available in both healthcare systems and community-based organizations, it has failed to achieve the scaling and sustainability needed to accommodate family caregivers. The product created by Stevens and Ory, called GamePlan4Care (GP4C), serves as a “proof-of-concept” that modern internet technology can provide family caregivers with access to the highly efficacious REACH II intervention. The result of their efforts is a consumer-friendly website running on a scalable technical architecture that fosters skills-acquisition in the home setting. The system facilitates high levels of exposure to effective caregiving materials all the while circumventing the need for home visits which can otherwise limit intervention access due to factors related to cost, time constraints, and client preferences. Further efficiencies in intervention delivery are achieved using automating the individualization and tailoring process of caregiver materials, automate email outreach to promote caregiver engagement with the system, automate prompts for regular DCS outreach, and automate aspects of fidelity monitoring. Online delivery and automation of core REACH II components reduces the human resources needed for delivering the interventions, promotes standardization (fidelity), and conforms to caregiver preferences by allowing them to engage with the materials at times they choose. Professional support is provided by a Dementia Care Specialist who the caregiver may access by email, phone or web video (by appointment). The availability of real-time, interactive engagement with the online materials by the Caregiver and DCS enhances the therapeutic experience compared to phone-based delivery systems. Since GP4C is based on the REACH II materials, it is culturally appropriate for the three groups included in the REACH II trail (Caucasian/White, AA/Black, Hispanic).

With further development of the existing proof-of-concept, the refined GamePlan4Care system will represent a viable product for REACH II delivery, appropriate for efficacy testing in a randomization clinical trial that engages BSWH clinics and community-based organizations (CBOs) where family caregivers already seek services.

APPROACH

Relevant Experience with REACH II and Web-based Facilitation of Intervention Delivery

The GP4C design and research team assembled in this study is particularly well-positioned to complete all proposed aims. In the role of NIH Program Director (1981-2001), Ory launched the multi-site Resources for Enhancing Alzheimer’s Caregiver Health (REACH I) Initiative[15]. As an early career investigator, Stevens was part of the original REACH I consortium, and emerged as a leading investigator of the REACH II project[26,27].

Since publication of the REACH II outcomes in 2006[27], Stevens has implemented the REACH II intervention within a large integrated healthcare system and in multiple community based organizations (CBOs), including serving as designer and senior evaluator of one of the largest implementations of REACH II in the US[28]. Stevens and colleagues have also created a training and certification program for REACH II.

In September 2016, Stevens & Ory obtained funding from the Texas Alzheimer's Research and Care Consortium (TARCC), a collaborative of seven leading medical research institutes across the state focusing on persons with dementia, to develop TEXAS CARES, a model of memory capable communities in Texas. One of three core objectives of TEXAS CARES was to explore technology as an avenue to increase family caregivers' accessibility to the evidence-based intervention, REACH II. REACH II is a well-known and respected program but is rarely available in both urban and rural Texas communities. GamePlan4Care (GP4C) resulted from this effort as a proof-of-concept that the REACH II intervention was amenable for adaptation into an online, interactive platform that could maintain the therapeutic materials and techniques while reducing the resource demands of delivering the program to family caregivers. Stevens and Ory guided the scientific process of maintaining the integrity of the REACH II intervention according the principles delineated in Table 1.

Table 1: Principles Guiding the translation of REACH II into online system GP4C

The stress-health process model should remain as the theoretical framework for understanding processes by which caregiver stressors ultimately lead to negative outcomes, and a multi-component/multi-modal approach for addressing specific aspects of the model is still warranted.
All REACH II educational and skill training tools should be made available to family caregivers who access online materials via a computer at time and place that is possible/convenient to the caregiver.
Caregiver exposure to educational and skill building content should be tailored to the caregiver's unique needs and caregiving situation using reliable risk assessment tools
Tailoring should be based on caregiver's risk results and presented in a written plan to guide the caregiver and shape the Dementia Care Specialist's therapeutic interaction to promote fidelity to therapeutic content of REACH II
Reassessment of caregiving characteristics that are important to tailoring of materials should occur so that the intervention continues to be tailored to their needs, and caregivers should continue to maintain access to all intervention content as new areas of concern arise
Automated features of the web-based system should be integrated with live support from a trained Dementia Care Specialist (DCS) to promote skills development in the REACH II core therapeutic areas of problem solving skills/ABC of managing dementia behaviors, stress management, mood management, pleasant activities
Caregiver and DCS should engage in at least the minimal number of therapeutic interactions needed to ensure Caregiver has been fully exposed to the therapeutic experience
Access to other services and supports that may be of value to the family caregiver should be facilitated by the online system and interactions with the DCS
The system supporting the online experience should also track caregiver engagement with the site, all DCS interactions with the caregiver, and will alert the DCS to high risks experienced by the Caregiver.

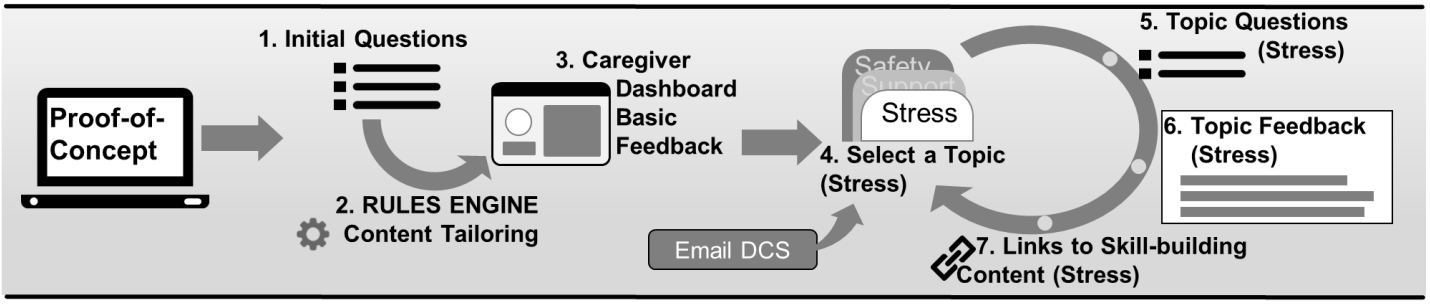
Consistent with Gitlin and Czaja's[29] proposition for adapting evidence based interventions, GP4C maintains REACH II's "active ingredients" which include the theory guiding the intervention and target population while exploring other aspects of the intervention (dosage, duration, modality, setting, etc.) amendable to change. In adapting the REACH II intervention to the GP4C platform, an extensive review of the original REACH II manuals and publications was conducted to identify and protect in translation the immutable aspects of the intervention (including its guiding theory, content, and essential delivery characteristics) that could not be compromised without significantly risking efficacy of the intervention. Conversely, other aspects of the REACH II intervention were judged to be modifiable and include limited changes to content (order/sequence of components, formatting), treatment dosage and duration, modality (format of intervention, use of technology), delivery setting, delivery approach (aspects amenable to tailoring, criteria for tailoring), and staffing requirements. Through this process, the GP4C team defined and were guided by nine principles in the adaptation of REACH II into GP4C (see Table 1). *The current GP4C proof of concept abides by each of these nine principles.*

Stevens and Ory contracted with Clairvoyant Network, LLC. for technological assistance to achieve the desired internet-based system. The system includes a flexible database and server-side code to allow granular information storage and complex data queries. The site was developed using the Microsoft Azure platform which meets all technical safeguards for HIPAA compliance concerning protected health information. A primary development goal to establish a proof-of-concept was to replicate the burdensome process of tailoring the

REACH II materials based on caregiver reported risks. GP4C achieves this goal using condition-based logic and modern internet technology to achieve the following with its users: a) introduce to the system and invite to use a secure sign up on an opening page, b) provide an initial risk assessment based on REACH II RAM, c) offer IMMEDIATE, tailored recommendations drawn from REACH II materials that is formatted in to a plan of care to address both caregiver and care recipient issues, d) invite to email a Dementia Care Specialist (DCS), e) notify the DCS of the user's risk profile and recommendation identified using conditional–based logic. In addition to the tailored recommendations provided in response to the caregiver risk assessment, the caregiver has access to a large library of content adapted from REACH II materials and commonly available online resources.

Figure 1 presents a graphic representation of the GP4C system in its current state of development. As illustrated, the GP4C system replicates a core feature of REACH II, assessing caregiver risks and tailoring supports to those risks. GP4C builds on this core feature by providing the caregiver an opportunity to engage in a similar process (i.e., answer risk assessing questions and get feedback) on each of the target intervention areas (e.g., stress management, depression, burden, self-care and healthy behaviors, social support, problem behaviors) topic areas. As demonstrated in Figure 1, the caregiver has chosen the topic of stress management, which has yielded tailored feedback on managing stress and has linked the caregiver to skills training tools within the GP4C system.

Figure 1: GP4C Current Proof-of-Concept



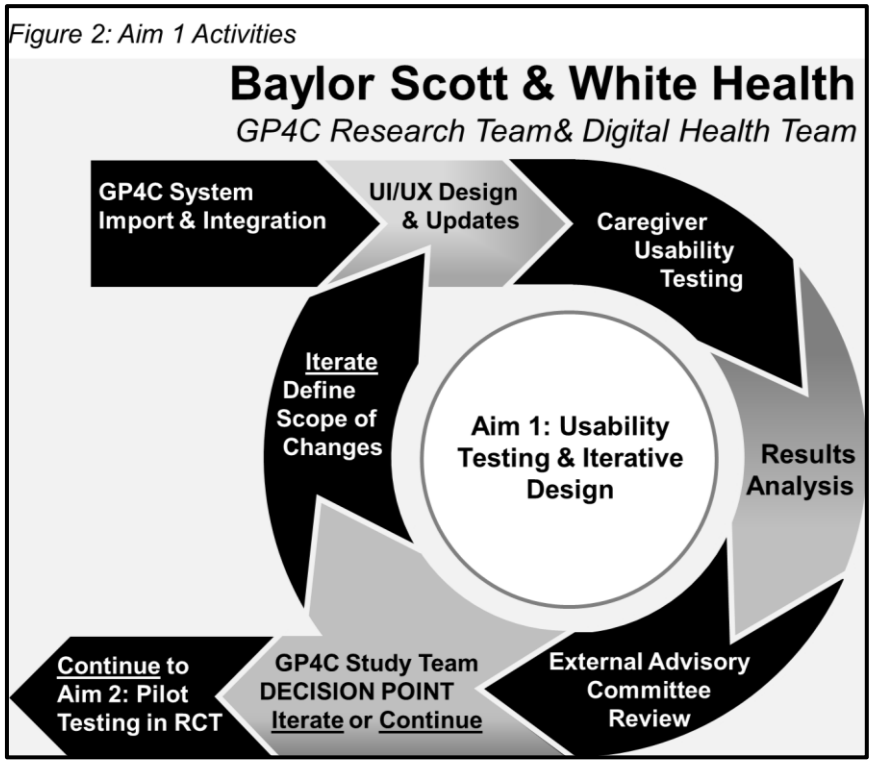
Achieving proof of concepts means that GP4C has technical viability and that desired features, functions, and benefits have been established and demonstrated. Thus, the scope of work delineated in the original TARCC contract to establish a proof-of-concept has been accomplished which was documented in the final report submitted to TARCC. It does not mean that product development has been completed or that the product is market ready. In the case of GP4C, only a limited amount of REACH II therapeutic material has been loaded into the system, and we have not supplemented written information with video content. Nor have we fully achieved integrated support from a DCS via emails and live support via telephone/web video. These activities will be the focus of AIM 1 as we propose to move GP4C from a proof-of-concept to a viable delivery system for REACH II. Stevens and Ory will solicit consultation from dementia caregiving experts from 5 universities who serve on the TARCC Care Steering Committee to complete AIM 1. These five experts have reviewed the TEXAS CARES products created by Stevens & Ory and have agreed to serve as an Advisory Committee to this study. Our CBO partners will be represented in development activities by the president of Alzheimer's Texas and the Directors of each of the AAAs.

AIM 1 – Advance the current proof-of-concept GP4C into a viable delivery system for the REACH II intervention.

GP4C will fully replicate the REACH II intervention upon completion. We propose development is needed to: 1) enhance usability by the caregiver, 2) upload the full breadth of education and skill-building materials, 3) improve the user interface/user experience (UI/UX), and 4) optimize presentation of material so that GP4C operates as an engaging, consumer-driven product suitable for testing in a RCT. Further development is also needed to facilitate DCS/Caregiver interaction and tracking of all therapeutic interactions the caregiver has with the website and DCS (i.e., DCS portal to guide and track service delivery). Lastly, R4C, an on-line education-based minimal intervention strategy will be created to serve as a comparison condition. Following usability testing and a review by the study external advisory committee the GP4C Study team will work with UI/UX designers to inform updates and refine the user-facing elements based on feedback and usability testing results (i.e. problems encountered while performing system tasks). The result will be a comprehensive digital tool to facilitate delivery of the REACH II intervention that is consumer informed.

Figure 2 illustrates the sequence of events that will occur for completion of AIM 1. The GP4C Study team will capitalize on the resources, experience, and expertise of the BSWH Office of Digital Health. The Digital Health Development team is comprised of 35 web, mobile, middle-tier, and database developers with embedded UI/UX designers. The team has considerable experience in the development of clinical applications that interface with both providers and clients including a top medical application in the Apple App Store being used by over 600,000 users. The team is also responsible for developing the software security standards for BSWH and conducting software audits to ensure development and security best practices are maintained.

Figure 2: Aim 1 Activities



The Digital Health Development team will import GP4C code into its development environment, conduct a review of the code, and make updates to take advantage of opportunities to optimize the code for improved functionality, better integration with existing BSWH systems, and better position the system to leverage previously developed software modules to improve GP4C. The UI/UX designers will review and begin updating user-facing elements of GP4C based on industry standards and best practices as well as their own experience designing clinical applications. As prototypes become available, they will be made accessible to the GP4C study team for internal usability testing.

Usability evaluation will occur concurrently to content enhancement via a method of iterative evaluation using concurrent think-aloud technique (Kushniruk & Patel[30]). This method characterizes ease in which a user can complete a task, by what means a user attains mastery of system features, and problems a user encounters while using the system. The GP4C research team will work with the Digital Health Development team to develop a task hierarchy cataloging individual tasks to accomplish within the system and salient design questions appropriate for experimenter prompts. Such tasks will include registering, logging in, answering user assessments, and navigating to education and skill-building content. Participants will be scheduled to test either the technical-related aspects (user interface and design) or content-related aspects (wording/appropriateness of questions and feedback, satisfaction with education and skill-building content) of both GP4C and R4C.

Participants will perform system tasks while vocalizing their thoughts, feelings, and satisfaction with the system. Research staff may prompt the participant with a question to elicit specific feedback regarding that feature. Participants will be engaged in a brief 10-minute interview regarding their overall impression/opinions of their experience with the system and be administered a brief satisfaction survey upon completion of their experience with the online system. User tests will be video/audio recorded, transcribed, and coded for occurrences of user problems and aspects of cognitive processes. Audio recordings from usability testing will be transcribed and coded using a coding scheme that includes categories for information content, comprehensiveness of graphics and text, problems in navigation, overall system understandability. The transcribed audio will also be coded for specific instances of user problems. Results of the usability testing of both content and technical aspects of the system for each participant will be summarized into a report with emphasis on type and frequency of problems encountered.

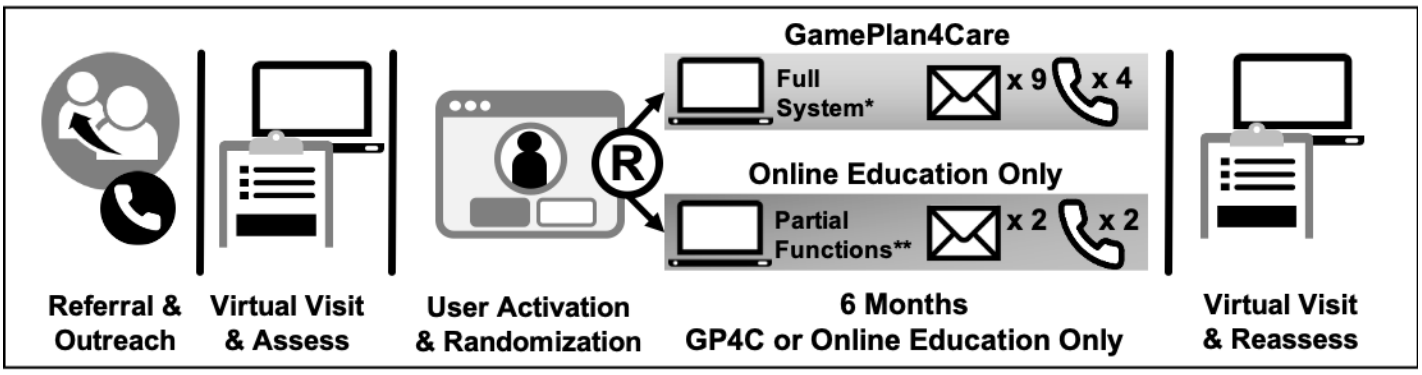
Data will be reviewed by research staff after the completion of 4 participant experiences to identify issues that warrant addressing in subsequent design iterations. Prior to the fourth and final caregiver testing, the external Advisory Committee will be engaged for review and feedback. Recommendations from the external Advisory Committee will be carefully considered by the GP4C research and Digital Health teams with modifications made before the final round of caregiver testing. Upon completion of the 4 cycles of UI/UX, Stevens and Ory will review all findings from caregiver UI/UX, feedback from the External Advisors and consultation from

the Office of Digital Health to judge if GP4C and R4C are sufficiently developed for testing in the proposed randomized clinical trial (AIM 2). In the unlikely event that Stevens and Ory identify significant concerns, additional testing and modifications will be requested from the Office of Digital Health.

Sixteen family caregivers will be engaged in user testing of technical-related aspects of the system and 16 family caregivers will test content-related aspects of the GP4C systems. Since both GP4C & R4C will run from the same platform, the UI/UX activities proposed will apply to both ensuring that both are equally user friendly. However, GP4C will have more functionality. The 32 p*articipants engaged in UI/UX will be selected according to participant eligibility criteria delineated in AIM 2.* To ensure representation of expected users, user testing will include at least 2 family caregivers of the three racial/ethnic groups included in REACH II. Moreover, equal number of participants will come from the urban and rural counties of the target recruitment area used for the RCT (Aim 2; Figure 3). Testing will occur in private office space within the three partner CBOs.

AIM 2: Randomized Clinical Trial of GP4C

GP4C and R4C will be tested as two intervention arms in a randomized clinical trial with 240 dementia caregivers and compared on well-accepted measures of the caregiving experience. See Figure 3 below.



Participants

Multiple strategies will be followed to facilitate recruitment. A list of patients at participating clinics, with a diagnosis of dementia established by charge diagnosis (ICD 9/10) or on the problem list will be forwarded to the PCPs, practice nurses, or likely partnering physicians to review and obtain permission to contact patient/caregiver. Additionally, providers can add to the list for patients/caregivers they think would be a good fit for the study. Once the revised lists is received from the provider, research staff will follow-up with a phone call to confirm eligibility and proceed with enrollment. Participants will also be recruited in partnership with various community-based organizations such as Alzheimer's Texas, Area Agency on Aging (AAA) of the Capital Area, AAA of Central Texas, and the Greater Dallas Chapter of the Alzheimer's Association. Additionally, referrals will be accepted directly to the study team from within the Baylor Scott & White System through a redcap referral link. Eligible participants must be age 18 years or older and providing care and/or supervision for a family member for at least the past 6 months and currently providing an average of 8hrs/wk. of care and/or supervision. Family will be subjectively determined by the caregiver to enable a broader definition of a" "family" member often found in minority communities (e.g., a person not related by blood but who serves in the role of an "aunt" or "grandchild"). The family member, named as the care recipient (CR) in this proposal, must be diagnosed with ADRD (self-report from the caregiver accepted) and is experiencing signs of dementia as verified by the family caregiver on the AD8 informant interview. AD8 is an 8-question interview using a yes/no scoring system[31]. The informant (i.e, family caregiver) is asked if there have been changes in areas of cognition and functioning including memory, orientation, executive function and interest in activities. A score of 2 or greater is the inclusion criteria. Use of this validated tool will provide some evidence of dementia while avoiding the need of direct testing of the CR which would require obtaining informed consent. This approach is more in line with future use of the system by CBOs. Eligible caregivers must demonstrate access to a home computer with internet access to research staff and report using the computer to access the internet at least three times per week, on average. They must not be currently participating in another evidence-based caregiver education and support program. Enrollment is limited to English-speaking caregivers. While the Spanish translation of REACH II has been proven valid, translation of GP4C/ R4C from English to Spanish is not possible within the limited budget of this study

Recruitment and Consenting

Table 2: Recruitment Area

Target Area	Counties	
AAACAP	Bell	Milam
	Coryell	Mills
	Hamilton	San Saba
	Lampasas	
AAACT	Bastrop	Hays
	Blanco	Lee
	Burnet	Llano
	Caldwell	Travils
	Fayette	Williamson
BVAAA	Brazos	Madison
	Burleson	Robertson
	Grimes	Washington
	Leon	Panola
AAAET	Anderson	Rains
	Camp	Rusk
	Cherokee	Smith
	Gregg	Upshur
	Harrison	Van Zandt
	Henderson	Wood
	Marion	
AAAAT	Bowie	Lamar
	Cass	Miller
	Delta	Morris
	Frankling	Red River
	Hopkins	Titus
TEXOMA	Cooke	Grayson
	Fannin	
North Central Texas	Collin	Kaufman
	Dallas	Navarro
	Denton	Palo Pinto
	Ellis	Parker
	Erath	Rockwall
	Hood	Somervell
	Hunt	Tarrant
	Johnson	Wise
Heart of Texas	Bosque	Hill
	Falls	Limestone
	Freestone	Mclennan

Recruitment through physician referral:
PCPs will be made aware of the trial through e-mail, fliers, and other traditional marketing techniques. In addition, project staff will make presentations at meetings of participating medical practices. Some physicians or practices may opt to provide a "blanket" referral for all their patients with dementia and, if so, study team members may reach out directly to recruit participants. Alternatively, PCPs may choose to review their lists of persons with dementia and delete any patients who should not be contacted about the study and/or add any patients/caregivers who they think would be a good fit. Providers can also refer through an ambulatory referral via EPIC. Referrals will be sent to the department of geriatrics, which will then be funneled into the research work que where research staff will be able to outreach.

Referrals will also be solicited through reports ran through data metrics which will help identify patients who have been recently discharged from the hospital and who have an upcoming appointment with their PCP and/or geriatrics. Research staff will then send a message via epic to the provider for patient's upcoming appointment as well as append appointment note to let provider know about the study and sending a referral for the study. Additionally, for patients who have not been enrolled but their provider agreed for research staff to contact, messages will be sent to the providers prior to the patient's upcoming appointment where the provider can talk about the study with the patient/caregiver and send a referral. Research staff will follow-up with a phone call shortly after the visit.

Recruitment through Community-based organizations:
Dr. Stevens has collaborated with the CBOs for over 10 years on multiple research and service programs for family caregivers in Central Texas. Counties served by the Central Texas AAA and AAACAP are presented in Table 2 along with counties served by the Area Agencies on Aging/Councils of Government that overlap with the Baylor Scott & White Service area (Brazos Valley AAA, AAA of East Texas, AAA of Ark. Tex, Texoma AAA, and North Central Texas Council of Governments). Alzheimer's Texas is the primary Alzheimer's focused not-for-profit in Central Texas and provides service to all eligible counties. Our long-term partnership with the named CBOs includes the practice of compensating CBOs for research related activities which are typically outside the core mission of the CBO. Thus, the three organizations will be provided stipends to apply to staff salaries based on services each is expected to provide. Stipends will support the staff person charged to be the organization's "Program Champion". The Program Champion will be fully versed in the study and should be able to answer some basic questions. Program Champions will facilitate referral of interested caregivers to the research team via the secure REDCap site. Referrals will include basic demographic and contact information (See Human Subjects for details). GP4C research staff will conduct a formal screening. Participants will be enrolled in Months 13-48 of the study period (See Timeline.)

Recruitment through existing research studies:

The Dementia Care Study (D-CARE study, site PI: Alan Stevens) funded through the National Institutes of Health (NIH) and Patient Centered Outcomes Research Institute (PCORI) targets the similar population as the current GP4C study. Caregivers enrolled in D-Care study have the opportunity to indicate on their consent form if they would like to be contacted for future research studies. These CGs after completing the DCare study will be contacted by research staff to assess interest and eligibility for participation in GP4C.

Individuals referred for possible enrollment will be contacted by phone within 3 business days of referral for the initial screening interview. Part of confirming eligibility will require the caregiver to demonstrate a functional home computer with internet access. While the GP4C systems will be accessible regardless of connection speed, GP4C research staff will review key computer/internet characteristics over the phone such as use of internet browsers, possible system and software updates and conduct an internet speed test. It is expected that all homes will have at least 1mb/s download speed. Those eligible and expressing interest in the project will be scheduled for a second phone call for consenting and baseline data collection. During the second phone call, participants will review the consent form with study personnel on the phone before providing a digital signature. The REDCap survey feature will allow the consent form to be updated in the participant's record where the consenting staff can add his/her own signature. Participants will then be administered baseline instruments over the phone while following along with their PDF copy.

All data collection systems and services will be based on REDCap, the CTSA-supported data management tool (http://project-redcap.org). While REDCap provides many essential features, its main strength is its open architecture and support for user-designed extensions ("plugins" and "hooks"). Many of the services described below are highly customized REDCap extensions that appear to the user as stand-alone web applications. Through these extensions, we can customize the interface of any REDCap-based web tool to match the workflow of the study activity. After confirming eligibility, study personnel will administer the informed consent procedure, collect intake information, and conduct the baseline assessments over the phone (Aim 2).

Study Design

The proposed study of AIM 2 is a two-group randomized controlled trial that compares the impact of the GP4C system, an online system with functionality designed to be comparable to the REACH II intervention of education, skill building and ongoing support to R4C, an online system of caregiver education. Random assignment will occur after Project Manager (Jordan Reese) confirms that all eligibility criteria have been satisfied and that a valid signed consent form is in the REDCap system. The project's co-investigator and biostatistician, G. Han, will design and oversee the randomization protocol. After randomization, participants will be contacted by study personnel to assist with logging on to the appropriate online system based on their group assignment. At six months following randomization, all participants will be contacted by study personnel to conduct follow up assessments. In addition to measures collected at baseline, the follow-up assessment will include questions regarding participant satisfaction with the online systems and other supports. *Assessments will occur over the phone at baseline and 6 months post baseline.* Project staff conducting the 6-month interview will be blinded to caregiver's condition assignment. Participants will maintain access to the system in which they were assigned through the duration of the project.

GP4C. Participants in the GP4C intervention arm will have access to full system functionality. This includes the ability to answer additional assessment items and receive additional automated, individualized feedback on their responses with links to site educational and skill-building content.

Participants can also access site educational and skill-building content directly by using menu navigation. Each participant will also be assigned a bachelors or masters level Dementia Care Specialist (DCS) who will facilitate caregiver interactions with the online material and provide skill training via telephone or web-based video. Study participants in the intervention arm will receive 9 automated emails and 4 phone calls over a 6-month period (See Table 3).

Replicating the schedule of in-home contacts used in REACH II, each of nine emails will focus on a major topic area covered in the system, encourage the study participant to log into the system to access more information related to the topic, and remind the participant that an interventionist is available for telephonic consultation as needed. Scheduled therapeutic contacts will not be influenced by the degree in which the participant is interacting with the GP4C online materials.

The goal of the telephonic core contacts will be to encourage use of GamePlan4Care to address participant educational and skills-training needs and to assist participants with applying knowledge and skills to their specific caregiving situation through role-playing and problem-solving. If the interventionist receives

negative feedback regarding the participant's ability to use the site, they will attempt to troubleshoot the problem on the phone or invite the participant to a one-on-one training on system use. If there is consistent negative feedback regarding a specific aspect of the system, these observations will be reported to the project team for consideration for possible system updates. The DCS will discuss the value of support groups on all four of the telephone calls, each time referring the caregiver to a complete list of support groups provided by Alzheimer's Texas, including telephone and web enabled video (i.e., Zoom).

While REACH II provided tailored support groups as part of the intervention, our approach encourages the use of existing community resources reducing future barriers to translation of GP4C from a research environment into a service environment. (Alzheimer's Texas will be provided a stipend in Years 2 – 5 to provide support groups.)

R4C. Participants in the R4C comparison will be able to access a standard set of educational materials. Materials will cover all topics included in the education-based comparison condition used in the REACH II trial. We have used the REACH II comparison conditions as a guide. Educational materials on the following topics will be included: 1) General information on Alzheimer's Disease and Dementia, 2) General information on caregiving, 3) Information on caregiving related stress and 4) Home safety. R4C will present one page on each topic and will include active links to two additional online sources on the same topic. System functionality will be limited to a welcome screen with direct navigation to a subset of the educational content by using menu navigation. Study participants assigned to R4C will receive two emails from their DCS encouraging the caregiver to review specific education materials. Each email will be followed by brief "check-in" calls (15-min each) at three months and five months after randomization. This replicates the REACH II control condition.

Treatment Implementation Monitoring

Treatment fidelity assessments will document the degree to which the GP4C and R4C was delivered by the system and research staff and received and used by caregivers[34]. Treatment implementation refers to a class of procedures and process measures that make up treatment delivery, receipt, and enactment[35,36]. Treatment implementation procedures promote the accurate and consistent delivery of the intervention protocol. Process measures document the amount and quality of the treatment delivered. Treatment implementation data will be used to determine if individual caregivers meet treatment compliance thresholds. Distributions on treatment implementation indicators will also be considered in exploratory analysis, which will link "dose" of treatment to outcomes.

Table 3: Schedule of GP4C Therapeutic Activities

Timeline	GP4C Intervention Activities
Week 1 of Enrollment	Login & Initial Assessment Send login credentials Confirm first login Completion of user initial assessment Drafting of domain feedback by DCS
Week 2 of Enrollment	Confirm Dashboard Visit User first visit to dashboard confirmed
Week 3 of Enrollment	Email Contact 1 Topic: Welcome and Setting Goals
Week 4 of Enrollment	Phone Contact 1 Introduction to DCS Orientation to system and therapeutic contacts Clarifying needs/setting goals Review safety issues Action items and next steps
Week 6 of Enrollment	Email Contact 2 Topic: Documentation
Week 8 of Enrollment	Email Contact 3 Topic: Problem-solving
Week 9 of Enrollment	Phone Contact 2 Review new issues/recent changes Assess progress to goals/troubleshoot barriers Review social support issues Action items and next steps
Week 11 of Enrollment	Email Contact 4 Topic: Staying Flexible
Week 13 of Enrollment	Email Contact 5 Topic: Midpoint Review
Week 15 of Enrollment	Email Contact 6 Topic: Empowerment
Week 16 of Enrollment	Phone Contact 3 Review new issues/recent changes Assess progress to goals/troubleshoot barriers Review physical/emotional health issues Action items and next steps
Week 18 of Enrollment	Email Contact 7 Topic: Acknowledging Your Needs
Week 20 of Enrollment	Email Contact 8 Topic: Prioritization
Week 22 of Enrollment	Phone Contact 4 Review new issues/recent changes Assess progress to goals/troubleshoot barriers Review disruptive behavioral issues Discuss closing of intervention and ongoing needs Action items and next steps
Week 23 of Enrollment	Email Contact 9 Topic: Wrapping Up

A number of methods will by employed to ensure treatment implementation according to protocols. The pre-programmed computerized nature of the intervention will ensure a high level of treatment consistency. Initial and booster training will be conducted with CBO points of contact to ensure they are describing the study and

recruiting in a consistent manner to meet study goals. Further, all DCSs will be trained and certified in the REACH II using the training workshop created by Stevens that has been conducted for CBOs across Texas by Birchfield. The project team will conduct weekly meetings with DCSs to discuss cases and special topics related to the GP4C system. Finally, the project team will conduct regular audits of DCS to review documentation and ensure the appropriate number, duration, timing, and content of participant interactions.

Measures and Outcomes

The primary outcome measures will be those that informed the multi-domain quality of life measure utilized in the original REACH II randomized clinical trial. This approach is similar to that used by Nichols and colleagues in two REACH VA studies[37,38]. Burden is considered the signature outcome since it is used for power and sample size estimates for analysis purposes.

Measures include:

- Burden: A 12-item version of the Zarit Caregiver Burden Interview[41]. Each item represents a statement related to some aspect of perceived burden. Caregivers rate each item with higher scores indicating higher rates of burden.
- Depression: A 10-item version of the Center for Epidemiological Studies Depression Scale[39,40]. Each item represents a statement for which respondents indicate how often in the past week they have felt that way in the past week. Total score is computed by summing scores for all items with higher scores indicating higher levels of depressed symptoms.
- Social support: Two subscales of Social Provision Scale (8 items), Reliable Alliance and Guidance will be used to assess availability of support and satisfaction with support from others.
- Self-rated health: A single item of caregiver's perception on his/her own health is included.
- Interactions with health care providers: Medical care management and coordination is measured with a 9-items of NSOC survey for how caregivers manage medical needs for care recipients and provide substantial help with health care activities including interaction with health care providers.

Additional outcome measures will include those that capture a more diverse aspect of dementia care than capture by the QoL REACH II measure and include:

- Caregiver stress: Perceived Stress Scale is a 10-item classic stress assessment, designed to help measure individual stress levels. Individual scores on the PSS can range from 0 to 40 with higher scores indicating higher perceived stress.
- Positive caregiver: Positive Aspect of caregiving (PAC) is measured with eleven items of the favorable aspects of their caregiving experience[46]. The items ask about their mental or affective state related to their caregiving experience, for example, providing help to care recipients has 'made me feel more useful', 'made me feel strong and confident', 'given more meaning to my life', 'enabled me to develop a more positive attitude toward life', and 'enabled me to learn new skills'.
- Cognitive change in care-recipient: A 12-item self-administered questionnaire (NPI-Q), completed by the caregivers about patients for whom they care, that measures the presence and severity of 12 Neuropsychiatric Symptoms (NPS) in patients with dementia, as well as the caregiver's distress.
- Additional process measures will be generated from user logs of the systems to document treatment implementation, including the total duration of time spent on GamePlan4Care. A program evaluation measure, the USE questionnaire, will be provided to caregivers after completion of the 6-month battery has been administrated. The USE questionnaire consisting of 30 items on usefulness, ease of use, ease of learning, and satisfaction will evaluate participant's attitude toward GP4C system.

For participants whose care recipient has passed in the last 6 months, caregiver burden and cognitive change in care recipient will not be assessed at 6 months .

Data Analysis

Caregiver participants will be randomized to the two intervention arms (GP4C and R4C) with the ratio of 1:1. Primary and secondary outcomes, including the Zarit's caregiving burden interview, will be assessed at baseline and 6-month follow-up. Covariates in the analysis include demographic characteristics of the caregivers.

Common descriptive statistics (mean, standard deviation, median, interquartile range for continuous variable; frequency and percentage for categorical variables) will be calculated for all covariates in each intervention arm and the two arms will be compared at baseline. Goals of our statistical analysis will be to evaluate the effectiveness of each intervention arm and to compare the two arms. For each intervention arm, the difference between 6-month follow-up and baseline will be computed. Paired t-test and Wilcoxon signed-rank test will be used to detect significant changes in outcome variables at 6-month follow-up since the baseline. Medians, means, and 95% confidence intervals of the differences will be calculated using both empirical percentiles and normal approximation. The two intervention arms will be compared at each follow-up time and for the whole trial period. We will compare the two arms at 6-month follow-up using the two-sample t-test and Wilcoxon rank sum test for each of the two outcomes.

The Anderson-Darling test will be used to check the normality assumption at baseline and follow-up times for the two outcome variables. If normal assumption is significantly violated then only nonparametric estimates and tests (i.e., median, IQR, empirical confidence intervals, Wilcoxon signed-rank test, and Wilcoxon rank sum test) will be reported, and data transformation, such as log and square root transformations, will be considered to normalize the outcome variables for further model-based testing. The two arms will also be compared incorporating observations baseline and the two follow-ups in longitudinal analysis of covariance (ANCOVA) models having the follow-up time and adjusting for covariates.

Given the fact that participants will be randomized into the two arms, the outcome variables will likely be comparable between the two arms at baseline. As a result, the interaction effect between the treatment arm and follow-up time (while adjusting for covariates) will be tested in the longitudinal analysis to evaluate the difference between the two intervention arms because a significant interaction indicates the caregiver's outcome has followed significantly different trajectories in the follow-up period depending on the treatment arm. Missing values may be possible because 1) some caregivers may be lost to follow-up, and 2) some caregiving recipients can be deceased prior to the follow-up. Missing patterns will be inspected and multiple imputation methods, including regression imputation, propensity score imputation, and MCMC imputation will be considered based on the missing mechanism[47]. All tests will be two-sided and a p-value less than or equal to 0.05 will be reported as statistically significant. Statistical Analysis Software (SAS software, version 9.4; SAS Inc., Cary, NC) will be used to conduct the proposed analysis.

Sample size considerations

Table 4. Sample size and power by effect size

Effect size of 0.28 standard deviation (SD) difference		Effect size of 0.33 standard deviation (SD) difference	
Sample Size	Power	Sample Size	Power
70	.646	70	.777
80	.706	80	.830
90	.757	90	.872
100	.800	100	.905
110	.834	110	.929
120	.868	120	.948
130	.893	130	.962
140	.914	140	.972
150	.931	150	.980

The primary endpoint in this power analysis is the Zarit's caregiving burden score. Assuming 20% attrition rate at the 6-month follow-up, we plan to initially enroll totally 240 family caregivers who will be equally randomized into two will be equally randomized into two arms (120 per arm), and we expect a minimum of 100 caregivers per arm to complete the 6-month assessment. The sample size of 100 in each arm can guarantee 80% power at significance level 0.05 to detect the effect size of 0.28 standard deviation (SD) difference between baseline and 6 months follow-up in a two-sided paired t-test. (See Table 4). Nicholas et al.[38] reported the effect size of 0.33SD of Zarit's score from the REACH VA intervention (also between baseline and 6-month follow-up). While GP4C will use a different delivery strategy than used in the REACH II and REACH VA trials, core therapeutic materials and techniques of the intervention are maintained. Thus, we expect GP4C to have a similar impact on caregiver outcomes as observed in prior REACH II trial. Thus, we conclude that enrolling 120 caregivers per arm (100 available at 6 months) will achieve sufficient statistical power to detect the effectiveness of the proposed interventions, even if the GP4C full functionality intervention is slightly less robust than the original REACH interventions.

Refinement for Future Testing and Dissemination

While Aim 1 usability testing will yield the in-depth feedback needed to produce the best possible version of the GP4C system for testing in the field, 3.5 years of testing to achieve Aim 2 will also produce a considerable amount of feedback regarding its functionality and utility. In order to realize the full value of the project, feedback from GP4C users during Aim 2 project activities (including community partners, interventionists, and caregiver participants) will be used during a final round of iterative design and system updates by the Baylor Scott & White Office of Digital Health. These updates are judged to be critical as they will best position the GP4C for ongoing clinical trials, future cultural adaptations, and eventual dissemination to CBOs.

Timeline of Study Activities

	Year 1				Year 2				Year 3				Year 4				Year 5			
Aim and Activity	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Aim 1: Prepare GP4C for Testing in a RCT																				
• GP4C System Import & Integration w/BSWH IT Systems																				
• Digital Health Team UI/UX Review and Updates																				
• Engage Community Partners for CG Usability Testing																				
• Usability Testing with Dementia Caregivers																				
• External Advisory Committee Review																				
Aim 2: Randomized Clinical Trial of GP4C																				
• Recruitment Materials Development																				
• Engage Program Champion within Community Partners																				
• Interventionist Training																				
• Participant Recruitment & Screening & Consent																				
• Intervention Delivery																				
• Participant 6-month Reassessment																				
Project Completion																				
• Data Analysis																				
• External Advisory Committee Review Preliminary Findings																				
• Post study refinements to GP4C system																				
• Final Report Preparation & Dissemination of Findings																				

Alternative approaches

Successful completion of the two AIMs of this study will advance a proof of concept that the REACH II intervention can be made available online to caregivers and that the burden of intervention delivery can be lessened with web technologies that automate many of the tasks that required human resources. This will fill a significant gap in the availability of online evidence-based services for caregivers. It will not, however, be the only online resource for caregivers. Alzheimer's Navigator® is a content navigation tool that takes user responses to survey questions to direct them outside the site to relevant educational content, mostly related to the planning and provision of care for the care recipient. GP4C provides individual feedback, and link users to internal, tailored content for skill-development related to caregiver self-care and dementia care management. The intervention includes an integrated live-support element with regular interventionist outreach for coaching sessions to facilitate skills acquisition and problem-solving.

Access to the BSWH Office of Digital Health is a significant and unique asset to this project, allowing us to bring GP4C in-house for UI/UX (and hosting). While there are commercial usability laboratories, using resources within the BSWH system provides a more cost-effective approach and ensure secure hosting during the testing phase. We have allotted one year for this process that we believe is reasonable. The BSWH Digital Health Office is committed to having a product within a year.

Recruitment is often a challenge in caregiving studies. Stevens and Ory have a long and strong record of completing research trails as expected. Moreover, Stevens has worked closely with the partner CBOs on number projects. Establishing a "champion" within the organizations will demonstrate our mutual commitment to project success. While our monthly recruitment goals are reasonable given the target recruitment area, BSWH is the largest not for profit healthcare provider in Texas, and we can expand recruitment internally if needed.

BIBLIOGRAPHY

1. Friedman EM, Shih RA, Langa KM, Hurd MD. US Prevalence And Predictors Of Informal Caregiving For Dementia. *Health Aff*. 2015;34(10):1637-1641. doi:10.1377/hlthaff.2015.0510.

2. Ortman JM, Velkoff V a., Hogan H. An aging nation: The older population in the United States. *Econ Stat Adm US Dep Commer*. 2014;1964:1-28. doi:10.1016/j.jaging.2004.02.002.

3. Pinquart M, Sörensen S. Differences between caregivers and noncaregivers in psychological health and physical health: A meta-analysis. *Psychol Aging*. 2003;18(2):250-267. doi:10.1037/0882-7974.18.2.250.

4. Sörensen S, Pinquart M, Duberstein P, et al. How effective are interventions with caregivers? An updated meta-analysis. [Review] [135 refs]. *Gerontologist*. 2002;42(3):356-372. http://www.ncbi.nlm.nih.gov/pubmed/12040138. Accessed November 8, 2012.

5. Gitlin LN, Marx K, Stanley IH, Hodgson N. Translating evidence-based dementia caregiving interventions into practice: State-of-the-science and next steps. *Gerontologist*. 2015;55(2):210-226. doi:10.1093/geront/gnu123.

6. Schulz R, Eden J, eds. *Families Caring for an Aging America*. Washington, D.C.: National Academies Press; 2016. doi:10.17226/23606.

7. Gwyther LP. Social Issues of the Alzheimer's Patient and Family. *Am J Med*. 1998;104(4):17S-21S. doi:10.1016/S0002-9343(98)00024-2.

8. Hurd MD, Martorell P, Delavande A, Mullen KJ, Langa KM. Monetary Costs of Dementia in the United States. *N Engl J Med*. 2013;368(14):1326-1334. doi:10.1056/NEJMsa1204629.

9. Schulz R, Sherwood PR. Physical and Mental Health Effects of Family Caregiving. 2008;44(3):23-27.

10. Alzheimer's Association. 2018 Alzheimer'S Disease Facts and Figures. *Alzheimers Dement*. 2018;14(3):367-429. doi:10.1016/j.jalz.2018.02.001.

11. Ory MG, Hoffman RR, Yee JL, Tennstedt S, Schulz R. Prevalence and Impact of Caregiving: A Detailed Comparison Between Dementia and Nondementia Caregivers. *Gerontologist*. 1999;39(2):177-186. doi:10.1093/geront/39.2.177.

12. Pinquart M, Sorensen S, Sörensen S. Correlates of physical health of informal caregivers: a meta-analysis. *J Gerontol B Psychol Sci Soc Sci*. 2007;62(2):P126-37. http://www.ncbi.nlm.nih.gov/pubmed/17379673.

13. Pinquart M, Sörensen S. Associations of stressors and uplifts of caregiving with caregiver burden and depressive mood: a meta-analysis. *J Gerontol B Psychol Sci Soc Sci*. 2003;58(2):P112-28. doi:10.1093/geronb/58.2.P112.

14. Belle SH, Czaja SJ, Schulz R, et al. Using a new taxonomy to combine the uncombinable: integrating results across diverse interventions. *Psychol Aging*. 2003;18(3):396-405. doi:10.1037/0882-7974.18.3.396.

15. Schulz R, Belle SH, Czaja SJ, et al. Introduction to the special section on Resources for Enhancing Alzheimer's Caregiver Health (REACH). *Psychol Aging*. 2003;18(3):357-360. doi:10.1037/0882-7974.18.3.357.

16. Richards KC, Enderlin CA, Beck C, McSweeney JC, Jones TC, Roberson PK. Tailored biobehavioral interventions: a literature review and synthesis. *Res Theory Nurs Pract*. 2007;21(4):271-285. http://www.ncbi.nlm.nih.gov/pubmed/18236771.

17. Perrin A, Duggan M. *Americans' Internet Access: 2000-2015*. Washington, D.C.; 2015. http://www.pewinternet.org/2015/06/26/americans-internet-access-2000-2015/.

18. Anderson M, Perrin A. *Tech Adoption Climbs among Older Adults*. Washington, D.C.; 2017. http://www.pewinternet.org/2017/05/17/technology-use-among-seniors/.

19. Fox S, Duggan M, Purcell K. *Family Caregivers Are Wired for Heatlh*. Vol 7. Washington, D.C.: Pew Research Center's Internet & American Life Project; 2013. http://www.pewinternet.org/2013/06/20/family-caregivers-are-wired-for-health/.

20. *E - Connected Family Caregiver : Bringing Caregiving into the 21st Century for Caregiving*.; 2011. http://www.caregiving.org/data/FINAL_eConnected_Family_Caregiver_Study_Jan 2011.pdf.

21. Gaugler JE, Kane RL. *Family Caregiving in the New Normal*. London: Academic Press; 2015.

22. Estrada Y, Molleda L, Murray A, et al. Ehealth familias unidas: Pilot study of an internet adaptation of an evidence-based family intervention to reduce drug use and sexual risk behaviors among hispanic adolescents. *Int J Environ Res Public Health*. 2017;14(3):1-15. doi:10.3390/ijerph14030264.

23. Czaja SJ, Rubert MP. Telecommunications technology as an aid to family caregivers of persons with dementia. *Psychosom Med*. 2002;64(3):469-476. http://www.ncbi.nlm.nih.gov/pubmed/12021420.

24. Finkel S, Czaja SJ, Schulz R, Martinovich Z, Harris C, Pezzuto D. E-care: a telecommunications technology intervention for family caregivers of dementia patients. *Am J Geriatr Psychiatry*. 2007;15(5):443-448. doi:10.1097/JGP.0b013e3180437d87.

25. Chi N-C, Demiris G. A systematic review of telehealth tools and interventions to support family caregivers. *J Telemed Telecare*. 2015;21(1):37-44. doi:10.1177/1357633X14562734.

26. Burgio L, Stevens A, Guy D, Roth DL, Haley WE. Impact of two psychosocial interventions on white and African American family caregivers of individuals with dementia. *Gerontologist*. 2003;43(4):568-579. http://www.ncbi.nlm.nih.gov/pubmed/12937335.

27. Belle SH, Burgio L, Burns R, et al. Enhancing the quality of life of dementia caregivers from different ethnic or racial groups: a randomized, controlled trial. *Ann Intern Med*. 2006;145(10):727-738. doi:10.1016/0022-2836(89)90001-6.

28. Stevens A, Cho J, Thorud J, Ory M. *Live Well Our Health Initiative Year 6 6 Month Report*. Fort Worth, TX; 2016.

29. Gitlin LN, Czaja SJ. *Behavioral Intervention Research: Designing, Evaluating, and Implementing*. New York, NY: Springer Publishing Co; 2016.

30. Kushniruk AW, Patel VL. Cognitive and usability engineering methods for the evaluation of clinical information systems. *J Biomed Inform*. 2004;37(1):56-76. doi:10.1016/j.jbi.2004.01.003.

31. Galvin JE, Roe CM, Powlishta KK, et al. The AD8: a brief informant interview to detect dementia. *Neurology*. 2005;65(4):559-564. doi:10.1212/01.wnl.0000172958.95282.2a.

32. U.S. Census Bureau. American FactFinder. https://factfinder.census.gov/. Accessed April 9, 2018.

33. Texas Association of Counties. The County Information Program. http://www.txcip.org/tac/census/. Accessed April 9, 2018.

34. Moncher FJ, Prinz RJ. Treatment fidelity in outcome studies. *Clin Psychol Rev*. 1991;11(3):247-266. doi:10.1016/0272-7358(91)90103-2.

35. Burgio L, Lichstein KL, Nichols L, et al. Judging outcomes in psychosocial interventions for dementia caregivers: the problem of treatment implementation. *Gerontologist*. 2001;41(4):481-489. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2577189&tool=pmcentrez&rendertype=abstract.

36. Lichstein KL, Riedel BW, Grieve R. Fair tests of clinical trials: A treatment implementation model. *Adv Behav Res Ther*. 1994;16(1):1-29. doi:10.1016/0146-6402(94)90001-9.

37. Nichols LO, Martindale-Adams J, Zhu CW, Kaplan EK, Zuber JK, Waters TM. Impact of the REACH II and REACH VA Dementia Caregiver Interventions on Healthcare Costs. *J Am Geriatr Soc*. 2017;65(5):931-936. doi:10.1111/jgs.14716.

38. Nichols LO, Martindale-Adams J, Burns R, Graney MJ, Zuber J. Translation of a dementia caregiver support program in a health care system--REACH VA. *Arch Intern Med*. 2011;171(4):353-359. doi:10.1001/archinternmed.2010.548.

39. Radloff LS. The CES-D Scale. *Appl Psychol Meas*. 1977;1(3):385-401. doi:10.1177/014662167700100306.

40. Irwin M, Artin KH, Oxman MN. Screening for depression in the older adult: criterion validity of the 10-item Center for Epidemiological Studies Depression Scale (CES-D). *Arch Intern Med*. 159(15):1701-1704. http://www.ncbi.nlm.nih.gov/pubmed/10448771.

41. Bédard M, Molloy DW, Squire L, Dubois S, Lever JA, O'Donnell M. The Zarit Burden Interview: a new short version and screening version. *Gerontologist*. 2001;41(5):652-657. http://www.ncbi.nlm.nih.gov/pubmed/11574710.

42. Center for Health Statistics - Division of Health Interview Statistics N. 2016 National Health Interview Survey (NHIS) Public Use Data Release Survey Description. 2016;(June). ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Dataset_Documentation/NHIS/2016/srvydesc.pdf.

43. Teri L, Truax P, Logsdon R, Uomoto J, Zarit S, Vitaliano PP. Assessment of behavioral problems in dementia: the revised memory and behavior problems checklist. *Psychol Aging*. 1992;7(4):622-631. http://www.ncbi.nlm.nih.gov/pubmed/1466831.

44. Jennings LA, Reuben DB, Evertson LC, et al. Unmet Needs of Caregivers of Individuals Referred to a Dementia Care Program. *J Am Geriatr Soc*. 2015;63(2):282-289. doi:10.1111/jgs.13251.

45. Thornton M, Travis SS. Analysis of the reliability of the modified caregiver strain index. *J Gerontol B Psychol Sci Soc Sci*. 2003;58(2):S127-32. http://www.ncbi.nlm.nih.gov/pubmed/12646602.

46. Barber CE, Vega LD. Ethnic Differences in the Experience of Filial Caregiving: A Comparison of Hispanic and Non-Hispanic White Caregivers in Colorado. *Southwest J Aging*. 2004;19:33-54.

47. Schafer JL, Reid N, Keiding N, Louis T, Tong H, Isham V. *Analysis of Incomplete Multivariate Data*. New York: Chapman & Hall/CRC; 1997.