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Title: A Problem Solving Intervention for Hospice Caregivers

PI: G. Demiris

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Study Protocol and Data Analysis

Design

The study was designed as a randomized clinical trial with four groups. Hospice caregivers were randomly assigned to either to a group receiving standard hospice care with the addition of the PISCES intervention delivered face to face (Group 1) or a group receiving standard hospice care with the addition of the PISCES intervention delivered in a hybrid format (first session in person, remaining sessions via video) (Group 2) or a group receiving standard hospice care with the addition of the PISCES*plus* intervention delivered in a hybrid format (Group 3) or a group receiving standard hospice care with the addition of the PISCES*plus* intervention delivered entirely online (Group 4).

Setting and Participants

We partnered with Penn Homecare and Hospice Services. Penn Homecare and Hospice Services is an agency (part of the Penn Medicine system) that is Medicare and Medicaid-certified, accredited by the Joint Commission, licensed in the Commonwealth of Pennsylvania. It serves patients and families in Philadelphia, Chester, Delaware, Bucks and Montgomery counties mostly (total number of counties serves is 20) and is experiencing a growth over the years (20% increase in admissions over the past 5 years). The hospice component of the agency had a total number of 2,970 home admissions, an average daily census of 380 and an average length of service (LOS) of 68 days in 2016

Inclusion criteria for caregivers were the following:

- enrolled as a family/informal caregiver of a hospice patient
- 18 years or older
- with access to a standard phone line or Internet and computer access at home
- without functional hearing loss or with a hearing aid that allows the participant to conduct telephone conversations as assessed by the research staff (by questioning and observing the caregiver)
- no or only mild cognitive impairment—mental status will be assessed using the Short Portable Mental Status Questionnaire;¹ individuals with a score of less than seven (i.e., more than three errors) will be excluded, similar to other studies involving this instrument.
- speak and read English, with at least a 6th-grade education

Enrollment

The hospice admissions staff presented the research opportunity to caregivers upon admission, asking them if they agree to be contacted by the research staff to find out more about the study. The admissions staff then forwarded contact information for caregivers willing to learn more about the study to the research team if they fulfilled the eligibility criteria. The interventionist called and scheduled the initial visit. The interventionist visited the caregiver, discussed the project, obtained informed consent from the caregiver, and documented demographic data. The interventionist opened a numbered sealed envelope, prepared by the team in advance, which assigned caregivers to one of the three groups. This approach ensured that consent is obtained prior to group assignment and caregivers consent to participate in the study, regardless of group assignment. Randomization was stratified by site. Furthermore, we followed a block randomization approach to ensure that treatment groups are not imbalanced with respect to time of the year as season (e.g., holidays) may have an effect on some of the psychometric measures. Upon consent, caregivers were asked to review and prioritize common caregiver concerns using a checklist, as the intervention will focus on the top three concerns or problems. Following this visit, a research assistant called the caregiver to conduct the baseline assessment (including anxiety, quality of life, caregiver reaction and problem solving inventory) over the phone. The research assistant was blinded to the caregiver's group assignment to

eliminate any potential bias. While the pre- and post assessments were conducted by the research assistant over the phone, the consent visit, actual intervention visits/ video-calls and exit interviews were delivered by an interventionist.

Group 1: PISCES delivered face to face

Before departing, the interventionist tentatively scheduled the upcoming three face-to-face visits for caregivers, and leave a manual on problem-solving designed for the lay audience based on “Solving Life’s Problems” by Nezu and D’Zurilla who developed the PST theoretical frameworkⁱⁱ with a special emphasis on hospice and hospice specific examples. The three intervention visits were scheduled with a suggested timeline between days 5 and 18 of the hospice admission.

This timeline was calculated based on average length of stay for our participating hospice agency and also on national level as well as based on the PST recommendations⁸⁶ and previous work on cognitive behavioral interventions in hospice.ⁱⁱⁱ However, this was only a guideline, and the actual timing and scheduling was tailored to the individual caregiver needs and challenges (the visits were scheduled and confirmed based on the caregiver’s feedback and preferences and with the recognition that unexpected and stressful events can lead to frequent rescheduling). Each intervention visit lasted approximately 45 minutes.

The agenda for the first face to face visit for caregivers (suggested timeline 5-7 days after hospice admission) includes an explanation of the purpose of the visit/call, and confirmation of the three specific problems that the caregiver had selected from the concern list during the consent visit. Caregivers’ problem-solving inventory scores and sub-scales indicate their problem-solving style (positive problem orientation, negative problem orientation, rational problem-solving, impulsivity/carelessness and avoidance⁶) and this allows the interventionist to customize the delivery of the intervention. During the first session, the interventionist works on steps one and two of the ADAPT model of the PST, namely “Attitude” and “Defining the Problem and Setting Realistic Goals.” For the first step the focus is on realistic optimism, i.e., acceptance that problems are a normal part of life. This step focuses on promoting visualizing successful problem solving, healthy thinking rules, positive self-talk and using emotions adaptively. The problems identified by the caregiver will be used as examples for exercises and to brainstorm about applying different approaches. The second step of defining the problem focuses on enabling caregivers to seek available facts, describe facts in a clear language, separate facts from assumptions, set realistic goals and identify obstacles to overcome.

During the second visit (suggested timeline 11-13 days after hospice admission) the interventionist covers steps three and four of the ADAPT model. Step three encourages caregivers in being creative and generating alternative solutions. This step involves brainstorming possible solutions to the identified problem, encouraging caregivers to brainstorm many alternatives, defer judgment on these alternatives until a later stage of the intervention and think of a wide range of possible strategies (general) and tactics (more specific). Step four focuses on predicting the consequences and developing a solution plan. This step involves evaluating alternatives and choosing the one that is most likely to effectively solve the identified problem. Making effective decisions involves screening out obviously ineffective solutions, predicting possible consequences, evaluating solution outcomes, and identifying effective solutions/developing a solution plan.

The third visit (suggested timeline 16-18 days after hospice admission) focuses on step five, namely trying out the solution plan and determining if it works. The general goal is to systematically evaluate the solution that caregivers implemented as a result of the previous steps to determine if it was effective in solving (or improving) the identified problem.

Group 2: PISCES delivered in a hybrid format

In this group, participants received the PISCES intervention in three sessions; however, the first session was delivered face to face and the other two via video. The three intervention sessions

were scheduled with a suggested timeline between days 5 and 18 of the hospice admission as in Group 1.

The first session took place in person (suggested timeline 5-7 days after hospice admission) and included an explanation of the purpose of the visit/call, and confirmation of the three specific problems that the caregiver had selected from the concern list. During the first session, the interventionist worked on steps one and two of the ADAPT model of the PST, namely "Attitude" and "Defining the Problem and Setting Realistic Goals." After the first session where the in person encounter allowed for the establishment of rapport between the interventionist and the caregiver, the second session (suggested timeline 11-13 days after hospice admission) and the third session (suggested timeline 16-18 days after hospice admissions) were conducted via live videoconferencing.

Group 3: PISCESplus delivered in a hybrid format

PISCESplus is meant to be an enhanced version of the PISCES intervention including the original problem solving therapy modules as designed for PISCES with the addition of positive reappraisal elements added to the curriculum. The agenda for the first face to face visit for caregivers (suggested timeline 5-7 days after hospice admission) includes an explanation of the purpose of the visit/call, and confirmation of the three specific problems that the caregiver had selected. During the first session, the interventionist works on steps one and two of the ADAPT model of the PST, namely "Attitude" and "Defining the Problem and Setting Realistic Goals." Additionally, at the end of the first session, the interventionist will ask the caregiver to take the time until the next scheduled session to think about and identify some positive aspects of caregiving, whether these are tasks or responsibilities they enjoy, or other elements of the caregiving experience that they perceive as positive or beneficial.

During the second session (suggested timeline 11-13 days after hospice admission) which took place via video the interventionist covers steps three and four of the ADAPT model. At the end of the session the interventionist asked the caregiver to go over the benefits or positive aspects of caregiving that they had identified and asked them to comment as to why they perceive these as positive or beneficial and whether there are ways to maximize the perceived benefits. The interventionists asked the caregiver to take the time until the next scheduled session to record how the appreciation of these positive elements helps them through stressful situations or when they have negative thoughts.

The third session (suggested timeline 16-18 days after hospice admission) which also takes place via video focuses on step five, namely trying out the solution plan and determining if it works. The interventionist concluded the session by briefly discussing the caregiver's perceived positive aspects of caregiving and reiterating the importance of recognizing and celebrating these aspects during the caregiving trajectory.

Group 4: PISCESplus delivered online

In this group the entire PISCESplus is delivered online. The first session is conducted via video and not in person (as is the case in Group 3). The agenda for the first video visit for caregivers (suggested timeline 5-7 days after hospice admission) includes an explanation of the purpose of the visit/call, and confirmation of the three specific problems that the caregiver had selected.

During the first session, the interventionist works on steps one and two of the ADAPT model of the PST, namely "Attitude" and "Defining the Problem and Setting Realistic Goals." Additionally, at the end of the first session, the interventionist will ask the caregiver to take the time until the next scheduled session to think about and identify some positive aspects of caregiving, whether these are tasks or responsibilities they enjoy, or other elements of the caregiving experience that they perceive as positive or beneficial.

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After all three intervention sessions were completed, a research assistant (blinded to the group assignment) called caregivers in all four groups for a post-intervention assessment of anxiety, depression, quality of life and problem solving inventory. This segregation of responsibilities and the blinding of the research assistant to the group assignment aimed to minimize any potential bias. Caregivers received a phone exit interview a few days after the last intervention visit and post intervention assessment phone call.

Treatment Fidelity

To ensure treatment fidelity to the planned interventions, we used the training and treatment fidelity manual refined during previous work. The guide details the training of research staff, the nature of each of the three intervention sessions, and the protocol for administering each of the evaluative instruments. All face to face visits and all video-calls were audio-taped by the research staff and a randomly chosen sample of 10% of all sessions were studied. Thus, the integrity of the intervention protocol was systematically assessed via reviews of audio recordings of these sessions. Tapes were rated by the principal investigator (PI) for overall adherence to the protocol and inclusion of all required elements, as well as to confirm that no contamination took place (e.g., a case where the interventionist provided specific advice for a problem without allowing the caregiver to review and select an option). The research team was required to make adjustments if interventions were violating the intervention protocol. The intervention manual included our intervention monitoring tools (IMTs) that were refined based on recommendations by Radziewicz et al^{iv} to help assure fidelity in individualized intervention studies.

Measures

Measures for Specific Aims 1 and 2:

Generalized anxiety disorder (GAD-7): The GAD-7 is a brief, valid and efficient tool for screening for anxiety and assessing its severity in clinical practice and research. The GAD-7 has been tested and demonstrated high levels of reliability and validity.^v The total score is calculated by assigning scores of 0-3 for each of the seven items. Scores of 5, 10, and 15 are taken as the cut off points for mild, moderate, and severe anxiety, respectively.

Problem-Solving Inventory (PSI): The PSI is a 25 item Likert-type inventory that serves as a measure of problem-solving appraisal, or an individual's perceptions of their problem-solving behavior and attitudes.^{vi} The total score is used as an overall index of problem-solving ability. Reliability and validity of this instrument have been documented extensively (Cronbach's Alpha reported at .85).

Caregiver Quality of Life Index – Revised (CQLI-R): The CQLI-R, a measure of caregivers' quality of life (QOL), includes four dimensions: emotional, social, financial, and physical.^{vii} This four-item instrument was designed specifically for hospice caregivers, and its reliability and validity have been established. The instrument has been used successfully with elderly hospice caregivers.^{viii} Our research team has revised the CQLI instrument for use in oral interviews

using 0 and 10 for each of the four anchors in place of the visual analog scale.^{ix} Cronbach's alpha for the revised instrument (CQLI-R) was 0.769, and test-retest reliability was supported ($r_s = 0.912$, $p < 0.001$).

Nine-item Depression scale of the Patient Health Questionnaire (PHQ-9): The PHQ-9 is a brief tool for assisting clinicians and researchers in assessing and monitoring levels of depression.^x The PHQ-9 assesses symptoms and functional impairment due to depression and derives a severity score. It is based directly on the diagnostic criteria for major depressive disorder in the Diagnostic and Statistical Manual Fifth Edition (DSM-V). It is widely used in practice and has been extensively tested (kappa = 0.65; overall accuracy, 85%; sensitivity, 75%; specificity, 90%). While all other measures described above were also used in our original clinical trial, the PHQ-9 is a new measure we are planning to utilize; we decided to include a depression measure as it has been found to be impacted by the positive reappraisal modules in other studies.

Demographic data: Standard demographic data were collected on patients and caregivers, including age, gender, nativity, education level, marital status, occupation, patient's diagnosis, relationship to patient, location of residence (residing with patient or not), estimate of average time spent on caregiving activities per week, impact on employment (whether caregiver had to decrease work hours or give up employment) and perceived income adequacy (having a comfortable income, having just enough to get by, not having enough to get by). Furthermore, if the patient dies during the subject's participation, that will be recorded along with the date of death (to allow for calculation of timing of death in the context of subject's days in the study).

Table 1 demonstrates the timeline for the collection of these measures.

Table 1: Timeline for data collection

	1 Baseline	2 Pre- Interventio n Assessme nt	3	4	5	6 Post-intervention Assessment	7 Exit interview
Group 1 PISCES delivered face to face <i>Delivered by:</i>	Demo- graphic data F2F <i>I</i>	Measures (PHQ-9, CQLI-R, PSI, GAD- 7) Telephone <i>RA (blinded to group assignment)</i>	PST Session 1 F2F <i>I</i>	PST Sessio n 2 F2F <i>I</i>	PST Session 3 F2F <i>I</i>	Measures (PHQ-9, CQLI-R, PSI, GAD-7) Telephone <i>RA (blinded to group assignment)</i>	Telephon e <i>RA</i>
Group 2 PISCES delivered in a hybrid format	Demo- graphic data F2F	Measures (PHQ-9, CQLI-R, PSI, GAD- 7) Telephone	PST Session 1 F2F	PST Sessio n 2 Video	PST Session 3 Video	Measures (PHQ-9, CQLI-R, PSI, GAD-7) Telephone	Exit interview Telephon e

<i>Delivered by:</i>	<i>I</i>	<i>RA (blinded to group assignment)</i>	<i>I</i>	<i>I</i>	<i>I</i>	<i>RA (blinded to group assignment)</i>	<i>RA</i>
Group 3 PISCESplus delivered in a hybrid format	Demo-graphic data	Measures (PHQ-9, CQLI-R, PSI, GAD-7)	PST+ positive reappraisal Session 1	PST+ positive reappraisal Session 2	PST+ positive reappraisal Session 3	Measures (Measures (PHQ-9, CQLI-R, PSI, GAD-7)	Exit interview Remove video
<i>Delivered by:</i>	<i>I</i>	<i>RA (blinded to group assignment)</i>	<i>I</i>	<i>I</i>	<i>I</i>	<i>RA (blinded to group assignment)</i>	<i>Telephone RA</i>
Group 4 PISCESplus delivered online	Demo-graphic data	Measures (PHQ-9, CQLI-R, PSI, GAD-7)	PST+ positive reappraisal Session 1	PST+ positive reappraisal Session 2	PST+ positive reappraisal Session 3	Measures (Measures (PHQ-9, CQLI-R, PSI, GAD-7)	Exit interview Remove video
	Video	Telephone	Video	Video	Video	Telephone	Telephone
<i>Delivered by:</i>	<i>I</i>	<i>RA (blinded to group assignment)</i>	<i>I</i>	<i>I</i>	<i>I</i>	<i>RA (blinded to group assignment)</i>	<i>RA</i>

I=Interventionist; RA=Research Assistant; F2F=Face-to-Face

Measures for Specific Aim 3

We conducted exit interviews with caregivers in all three groups. Caregivers in Group 1 were asked to provide general feedback about the PISCES intervention. Exit interviews with caregivers in Groups 2, and 3 also assessed caregivers' perceptions of the hybrid delivery platform (face to face and video sessions); caregivers in Groups 3 and 4 were further asked to provide feedback on the positive reappraisal aspects of PISCESplus. Interviews were carried out by the research coordinator and audio-taped based on an interview protocol aiming to examine caregivers' perceptions and satisfaction. Interview questions pertained to satisfaction with this form of interaction, barriers and facilitators to the use of video, and confidence in using this form of interaction, lasted 20 to 30 minutes. The interviews were digitally recorded and transcribed. The QSR Nvivo11 software was used to manage and interpret the data. This software facilitates the organization of emerging ideas, to search and explore in context, and to seek patterns.

Measures for Specific Aim 4:

We conducted a cost analysis and we utilized the demographic data collected on enrollment in the study to allow for comparisons between the groups. These include hospice admission date and diagnosis, patient and informal caregiver age and sex, race, informal caregiver employment status, education and income range, relationship of informal caregiver to patient, and residence of the informal caregiver. We also equipment costs (including equipment price and depreciation), and training costs based on time to train research staff in the use of videoconferencing. The participating hospice agency also furnished the research team with the following client-level data to estimate resource use and costs:

- direct care time for scheduled visits by type of professional
- travel distance and time spent traveling for scheduled visits by type of professional
- direct care time for after-hour calls and visits by type of professional
- travel distance and time spent traveling for after-hour visits by type of professional
- time and travel associated with the installation and maintenance of videophones and addressing potential technical problems
- average salary paid by type of professional
- number and cost of hospital or emergency room visits for patients.

Other Measures

We assessed the quality of the video calls using a previously developed instrument for assessing the technical quality of a “virtual visit” in home care,^{xi} a video-based interaction between health care providers and patients or caregivers. This instrument is a form that will be filled out by the research staff after each video-session with a caregiver in Groups 2 and 3. The form includes identification of the caregiver, date, starting and ending time of the video-call. The main section of the form contains five items regarding the technical quality of the video-call. The first two items refer to the observations made by the research staff in regard the frequency of difficulties with audio and image by the research staff. The next two items address problems with video and sound at the caregiver’s end, as reported to the research staff during the video-call. The last item addresses possible disconnection(s) and their frequency of occurrence. This section allows for the definition of a score for the overall technical quality of each video-call. This instrument has been tested for reliability and validity and used to rate the technical quality of video-calls in home care settings.^{xii}

Data Analysis Plan

Data Analysis for Specific Aims 1 and 2

The primary analyses focused on examining differences between treatment groups in terms of caregiver outcomes during the time of intervention. Changes in caregivers’ scores from baseline to post-treatment will be analyzed using analysis of covariance, with baseline score, site, and whether the caregiver’s patient has died, as covariates. Separate models were run for each outcome (caregiver quality of life, anxiety, depression, and problem-solving ability). For Specific Aim 1 (SA1) to assess the equivalence between PISCES F2F and PISCES in hybrid format, a confidence interval approach was used on the ANCOVA model, with a two-sided 5% level of significance. If the CI of the difference between the two groups falls within the pre-specified range of equivalence, the two interventions will be considered equivalent.^{xiii xiv} The range of equivalence is defined between $-\Delta$ and $+\Delta$. The clinically informed Δ s for the primary outcomes are: CQLI-R = 1.0; GAD-7 = 1.75; PHQ-9 = 2.0; PSI = 2.5, respectively. The analyses of equivalence will be on a per-protocol basis and will be supplemented by secondary sensitivity intent-to-treat analyses.⁵⁵

The analyses for Specific Aim 2 (SA2) focus on pair-wise comparisons between PISCES*plus* and the other treatment groups. A significance level of $\alpha=0.025$ for each comparison was used to account for the multiple (2) comparisons and assure an overall significance level of no more than 0.05 for each outcome. These analyses of superiority was on an intent-to-treat basis, using

multiple imputation to address missing data. ANCOVA and chi-square tests were used to determine whether attrition had an impact on sample composition. Specifically, analyses were computed on baseline demographic characteristics, as well as baseline outcome measures, to determine whether participants who completed all phases of data collection were initially different when compared with persons who did not complete the intervention. Data were analyzed using the Stata statistical package.

Data Analysis for Specific Aim 3

Interview sessions were audio-recorded and transcribed. Data were analyzed using a qualitative thematic coding approach. Data codes were inductively generated. Data analysis was performed by two members of the research team and validity of interpretations was checked by a third member. Transcript data were coded by line and sentence for descriptive (first-level) and theme (pattern) codes.⁶⁵ A list of major thematic elements was extracted by thorough study and coding of the interview transcripts. The analysis was organized into an expanding list of themes, arising from content, concepts, and descriptive categories (the process will be supported by the use of QSR NVivo11, an index-based qualitative analysis software package). The thematic elements was used to develop coding keywords. Each response was coded along a number of salient dimensions, such as topic, thematic content, and general sentiment using the previously abstracted keywords. Data were grouped and reviewed for trends and patterns or ideas that give insight into caregivers' overall satisfaction with the intervention, their perception of the hybrid delivery platform (for Groups 2 and 3) and of the positive reappraisal modules (for Group 3). Perceived benefits and challenges associated with both the focus and content of the intervention and its components as well as the mode of delivery were examined.

Data Analysis for Specific Aim 4

Our cost analysis compared the three intervention groups with respect to total costs. Using the resource use and cost information, and the cost of client-specific hospitalizations and emergency department visits as described earlier, we estimated the total cost of care for each client. These data were used as the dependent variable in four pair wise regression analyses comparing the four groups with respect to total costs incurred over the study timeframe. Analysis of variance methods was employed. We also examined resource use, and compared this between groups. Specifically, we compared the number of after-hours calls and, and the number of hospitalizations and emergency department visits. As these outcome variables are each an event-count, each cannot be truly normal in distribution. Traditional regression methods assume a normally distributed outcome with constant variance. In contrast, count data are discrete and usually involve many observations with identical values and often highly right-skewed due to a few individuals with extreme event counts. We used both Poisson regression and the Zero-Inflated Poisson model for a comparison of the number of after-hour visits and calls. We also controlled for demographic covariates in these models. Direct and indirect costs for the hospice program were computed as the sum of implementation and operating costs. Intervention implementation costs included equipment costs (based on equipment price and depreciation), and staff training costs. Operating costs were measured by staff costs (wages and time) for delivery of the intervention (based on average wages and average time research staff took to do the intervention), and costs of home visits (frequency and duration) by all hospice staff as documented in the record review. Caregiver costs were based on overall informal care time (using income data gather upon admission), intervention time, any time lost from work, and out-of-pocket and travel expenditures related to caregiving as reported by the caregiver during the exit interview.

Table 1: Participant characteristics

Variable	Traditional Pisces		Online Pisces		
	Group 1 (n = 154)	Group 2 (n = 152)	Group 3 (n = 154)	Online (n = 63)	P-value
Caregiver Age [Mean (Std.)]	56.8 (12.7)	58.8 (12.8)	57.4 (12.2)	56.1 (17.2)	0.5664
Caregiver GAD 7 Score [Mean (Std.)]	6.69 (5.4)	5.74 (4.9)	6.32 (4.9)	5.85 (5.2)	0.4236
Caregiver PHQ-9 Score [Mean (Std.)]	7.54 (5.7)	6.6 (5.4)	6.99 (5.3)	6.78 (5.36)	0.5267
Caregiver QOL Score [Mean (Std.)]	27.7 (8.0)	28.5 (8.4)	29.32 (7.2)	28.31 (7.7)	0.4168
Caregiver Status					0.0010
Bereaved	43 (28.7%)	47 (31.5%)	46 (30.9%)	4 (6.4%)	
Active	107 (71.3%)	102 (68.5%)	103 (69.1%)	59 (93.6%)	
Caregiver Diagnosis					<0.0001
Cancer	11 (21.6%)	6 (13.6%)	10 (22.2%)	5 (21.7%)	
Dementia	2 (3.9%)	3 (6.8%)	2 (4.4%)	13 (56.5%)	
Other	38 (74.5%)	35 (79.6%)	33 (73.4%)	5 (21.7%)	
Caregiver Dementia					< 0.0001
No	14 (25.5%)	8 (17.0%)	9 (18.4%)	1 (3.7%)	
Yes	6 (10.9%)	4 (8.5%)	5 (10.2%)	21 (77.8%)	
Don't Know	35 (63.6%)	35 (74.5%)	35 (71.4%)	5 (18.5%)	
Caregiver Gender					0.2271
Male	23 (15.1%)	34 (23.1%)	20 (13.3%)	12 (19.1%)	
Female	129 (84.9%)	113 (76.9%)	130 (86.0%)	51 (80.9%)	
Decline to Answer	0 (0%)	0 (0%)	1 (0.7%)	0 (0%)	
Caregiver Ethnicity					0.1708
Hispanic	7 (4.6%)	8 (5.4%)	11 (7.3%)	9 (14.3%)	
Non-Hispanic	138 (90.8%)	136 (92.6%)	134 (88.7%)	51 (80.9%)	
Decline to Answer	7 (4.6%)	3 (2.0%)	6 (4.0%)	3 (4.8%)	
Caregiver Race					0.3958
Black/African American	64 (41.6%)	56 (36.8%)	53 (34.4%)	23 (36.5%)	
White/Caucasian	72 (46.7%)	82 (54.0%)	79 (51.3%)	28 (44.4%)	
Other	18 (11.7%)	14 (9.2%)	22 (14.3%)	12 (19.1%)	
Caregiver Marital Status					
Single/Never Married/Partnered	37 (25.5%)	38 (26.8%)	25 (18.5%)	20 (32.3%)	
Married/Partnered	67 (46.2%)	69 (48.6%)	76 (56.3%)	33 (53.2%)	
Widowed	23 (15.9%)	16 (11.3%)	20 (14.8%)	2 (3.2%)	
Separated/Divorced	18 (12.4%)	18 (12.7%)	14 (10.4%)	7 (11.3%)	
Decline to Answer	0 (0%)	1 (0.7%)	0 (0%)	0 (0%)	
Caregiver Education					0.4536
Less than High School	2 (1.4%)	1 (0.7%)	2 (1.5%)	0 (0%)	
High School/GED	24 (16.5%)	27 (19.0%)	25 (18.5%)	6 (9.7%)	
Some College/Associate Degree	38 (26.2%)	42 (29.6%)	43 (31.9%)	17 (27.4%)	
Bachelor's Degree	40 (27.6%)	27 (19.0%)	37 (27.4%)	17 (27.4%)	
Graduate/Professional Degree	41 (28.3%)	45 (31.7%)	28 (20.7%)	22 (35.5%)	
Caregiver Relation					

Spouse/Partner	41 (28.3%)	42 (29.6%)	41 (30.4%)	15 (24.2%)	0.8435
Adult Child	70 (48.3%)	69 (48.6%)	74 (54.8%)	38 (61.3%)	
Parent	7 (4.8%)	7 (4.9%)	5 (3.7%)	1 (1.6%)	
Sibling	6 (4.1%)	4 (2.8%)	3 (2.2%)	1 (1.6%)	
Other	20 (13.8%)	20 (14.1%)	12 (8.9%)	7 (11.3%)	
Decline to Answer	1 (0.7%)	0 (0%)	0 (0%)	0 (0%)	
 Care Receiver Gender					
Male	69 (47.9%)	59 (41.6%)	69 (51.9%)	15 (24.2%)	0.0023
Female	75 (52.1%)	83 (58.4%)	64 (48.1%)	47 (75.8%)	
 Care Receiver Ethnicity					
Hispanic	6 (4.2%)	8 (5.6%)	11 (8.3%)	5 (8.1%)	0.6190
Non-Hispanic	136 (94.4%)	133 (93.7%)	120 (90.2%)	55 (88.7%)	
Decline to Answer	2 (1.4%)	1 (0.7%)	2 (1.5%)	2 (3.2%)	
 Care Receiver Race					
Black/African American	63 (40.9%)	55 (36.2%)	50 (32.5%)	25 (39.7%)	0.7531
White/Caucasian	75 (48.7%)	84 (55.3%)	87 (56.5%)	33 (52.4%)	
Other	16 (10.4%)	13 (8.5%)	17 (11.0%)	5 (7.9%)	
 Care Receiver Marital Status					
Single/Never Married/Partnered	19 (13.2%)	18 (12.7%)	12 (9.0%)	10 (16.1%)	0.9220
Married/Partnered	57 (39.6%)	59 (41.6%)	58 (43.3%)	24 (38.7%)	
Widowed	47 (32.6%)	45 (31.7%)	49 (36.6%)	19 (30.7%)	
Separated/Divorced	21 (14.6%)	20 (14.1%)	15 (11.2%)	9 (14.5%)	
 Care Receiver Residence					
Private Home Residence/Adult Group Home	123 (84.8%)	115 (81.0%)	117 (87.3%)	54 (87.1%)	0.0488
Assisted Living Facility/Nursing Home/Skilled Nursing Facility	18 (12.4%)	22 (15.5%)	13 (9.7%)	2 (3.2%)	
Other	4 (2.8%)	5 (3.5%)	4 (3.0%)	6 (9.7%)	
 Caregiver Distance from Receiver					
With you	90 (62.0%)	72 (51.0%)	81 (60.4%)	37 (59.7%)	0.1859
Less than 1 hour away	49 (33.8%)	61 (43.3%)	42 (31.3%)	19 (30.6%)	
More than 1 hour away	4 (2.8%)	8 (5.7%)	10 (7.5%)	6 (9.7%)	
Decline to Answer	2 (1.4%)	0 (0%)	1 (0.8%)	0 (0%)	
 Caregiver Time Caring					
Less than 1 year	42 (29.0%)	46 (32.6%)	40 (29.9%)	13 (21.0%)	0.1432
1-3 years	32 (22.0%)	31 (22.0%)	28 (20.9%)	26 (41.9%)	
3 years or more	69 (47.6%)	62 (44.0%)	65 (48.5%)	22 (35.5%)	
Decline to Answer	2 (1.4%)	2 (1.4%)	1 (0.7%)	1 (1.6%)	
 Caregiver Time Spent Caring per week					
Less than 5 hours	6 (4.1%)	10 (7.1%)	7 (5.2%)	4 (6.5%)	0.7655
5-10 hours	16 (11.0%)	20 (14.2%)	12 (9.0%)	11 (17.7%)	
11-20 hours	22 (15.2%)	13 (9.2%)	20 (14.9%)	9 (14.5%)	
More than 20 hours	100 (69.0%)	96 (68.1%)	93 (69.4%)	37 (59.7%)	
Decline to Answer	1 (0.7%)	2 (1.4%)	2 (1.5%)	1 (1.6%)	
 Caregiver Added Expense					

	Yes	112 (77.2%)	104 (73.8%)	100 (74.6%)	43 (69.3%)	0.9065
	No	32 (22.1%)	36 (25.5%)	33 (24.6%)	19 (30.7%)	
	Decline to Answer	1 (0.7%)	1 (0.7%)	1 (0.8%)	0 (0%)	
Caregiver Work Status						
	Yes	61 (42.1%)	66 (46.8%)	61 (45.5%)	27 (43.5%)	0.8126
	No	83 (57.2%)	75 (53.2%)	73 (54.5%)	35 (56.5%)	
	Decline to Answer	1 (0.7%)	0 (0%)	0	0 (0%)	
Caregiver Work Support						
Cut back on hours or quit work entirely		18 (21.9%)	15 (19.7%)	16 (20.0%)	4 (11.4%)	0.1053
Taken an unpaid leave or any leave under Family Medical Leave Act		5 (6.1%)	4 (5.3%)	6 (7.5%)	1 (2.9%)	
Left one job for a different one		1 (1.2%)	3 (3.9%)	1 (1.3%)	2 (5.7%)	
Used your own sick leave or vacation time		20 (24.4%)	13 (17.1%)	15 (18.7%)	9 (25.7%)	
Taken a job or worked additional hours to earn more money		1 (1.2%)	0 (0%)	2 (2.5%)	2 (5.7%)	
None of these apply		8 (9.8%)	4 (5.3%)	6 (7.5%)	9 (25.7%)	
Decline to Answer		4 (4.9%)	8 (10.5%)	5 (6.2%)	0 (0%)	
Selected More than 1 option		25 (30.5%)	29 (38.2%)	29 (36.2%)	8 (22.9%)	

Table 2. Comparison of 4 groups

Variable	Group 1 Mean (Std)	Group 2 Mean (Std)	Group 3 Mean (Std)	Group 4 Mean (Std)	p-value
Difference (FollowUp-Baseline) GAD-7	-2.54 (4.25)	-1.49 (4.06)	-2.27 (4.56)	-1.52 (5.12)	0.1860
Difference (FollowUp-Baseline) PHQ9	-2.69 (4.29)	-1.56 (4.19)	-1.87 (4.59)	-2.02 (4.14)	0.2752
Difference (FollowUp-Baseline) CLQI	1.14 (6.42)	0.77 (4.82)	0.27 (7.17)	1.15 (5.80)	0.6233

p-value calculated using Kruskal Wallis Test

Table 3. Comparison of Traditional PISCES vs. Online PISCES

Variable	Traditional PISCES Mean (Std)	Online PISCES Mean (Std)	p-value
Difference (FollowUp-Baseline) GAD-7	-2.04 (4.18)	-2.03 (4.74)	0.5638
Difference (FollowUp-Baseline) PHQ9	-2.15 (4.27)	-1.91 (4.44)	0.9848
Difference (FollowUp-Baseline) CLQI	0.96 (5.70)	0.54 (6.76)	0.9169

p-value calculated using Wilcoxon Two Sample Test

Table 4. Within-Group Comparison Baseline vs. Follow-up

Variable	Traditional PISCES Mean (Std)	p-value	Online PISCES Mean (Std)	p-value
GAD-7	-2.04 (4.18)	<0.0001	-2.03 (4.74)	<0.0001
PHQ9	-2.15 (4.27)	<0.0001	-1.91 (4.44)	<0.0001

CLQI	0.96 (5.70)	0.0155	0.54 (6.76)	0.0504
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p-value calculated using Wilcoxon Signed Rank Test

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