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Health coaching to improve self-care of informal caregivers of adults with chronic heart failure – iCare4Me: Study protocol for a randomized controlled trial

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ABSTRACT

Background: Persons with chronic heart failure are living longer. These patients typically live in the community and are cared for at home by informal caregivers. These caregivers are an understudied and stressed group.
Methods: We are conducting a two-arm, randomized controlled trial of 250 caregivers of persons with chronic heart failure to evaluate the efficacy of a health coaching intervention. A consecutive sample of participants is being enrolled from both clinic and hospital settings at a single institution affiliated with a large medical center in the northeastern US. Both the intervention and control groups receive tablets programmed to provide standardized health information. In addition, the intervention group receives 10 live coaching sessions delivered virtually by health coaches using the tablets. The intervention is evaluated at 6-months, with self-care as the primary outcome. Cost-effectiveness of the intervention is evaluated at 12-months. We are also enrolling heart failure patients (dyads) whenever possible to explore the effect of caregiver outcomes (self-care, stress, coping, health status) on heart failure patient outcomes (number of hospitalizations and days in the hospital) at 12-months.
Discussion: We expect the proposed study to require 5 years for completion. If shown to be efficacious and cost-effective, our virtual health coaching intervention can easily be scaled to.
support millions of caregivers worldwide.

1. Introduction

Informal caregivers have been called the “hidden victim” of illness [1]. Caregiving is demanding and stressful for those who provide extraordinary, uncompensated care for loved ones, friends and neighbors, often daily for years [2,3]. This stress may exceed the caregiver's ability to adapt [4], and many eventually become care recipients themselves as years of stress and deferred self-care put them at risk for illness [5–7]. Self-care refers to those behaviors a person undertakes to maintain their health and manage illness [8]. Engaging in self-care may improve health status [9], defined as physical functioning and mental well-being [10].

Caregivers of adults with heart failure (HF) are understudied. HF is extremely common (14.5% of US adults ≥65 years) [11]. The annual cost associated with informal caregiving of persons with HF in the US was estimated at $3 billion in 2010 [12]. Most HF patients remain in the community through the end of their lives, depending on informal caregivers to assist them [13]. The trajectory of illness in HF is highly variable, which limits the use of palliative care and respite services [14]. As a consequence, HF caregivers report significant stress and poor self-care [15]. Without identifying ways to improve self-care in HF caregivers, we risk losing these burdened caregivers to their own health issues.

Support interventions can encourage self-care by helping caregivers to focus on their own needs and values [16]. Health coaching can improve self-care and outcomes in patients [17,18], but studies of caregivers are limited. Caregiving duties often confine caregivers to the home and many are unable to attend in-person sessions [19], so support interventions delivered by telephone and the Internet become appealing. Leveraging the growing availability and declining costs of –

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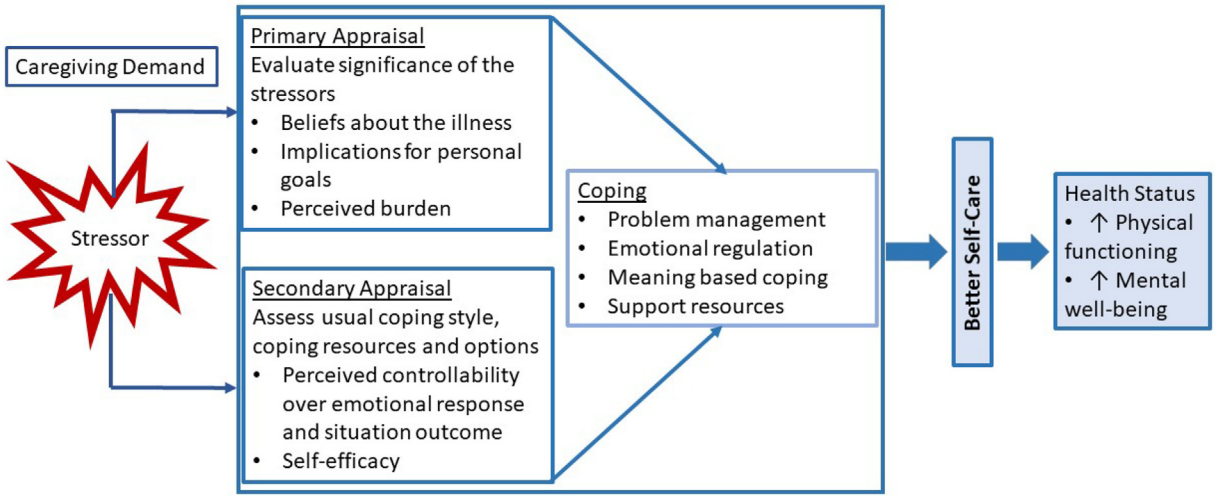

Fig. 1. Transactional model of stress and coping. Caregiving demand is a stressor that initiates a process of primary appraisal (e.g., perceived burden) and secondary appraisal (e.g. controllability) in caregivers. These appraisals lead to coping efforts, which are supported with our ViCCY (Virtual Caregiver Coach for You) intervention. ViCCY is anticipate to promote caregiver coping and improve self-care (e.g., eat better, sleep more, exercise), which will improve caregiver health status. An intervention that improves caregiver outcomes may improve heart failure patient outcomes, but patient outcomes are not shown here.

along with increasing receptivity of older adults to – technology [20], we developed a live, virtual support intervention (ViCCY ["Vicky"] – Virtual Caregiver Coach for You), that we will evaluate in HF caregivers compared to health information alone. Our approach is unique in that we target stress and self-care concurrently, which we anticipate will be more powerful than interventions addressing either issue alone because self-care is lower in stressed populations and self-care can potentiate stress reduction approaches [21]. Other areas where relatively little is known include the cost-effectiveness of support interventions for caregivers [22–24] and the effect of caregiver support on patient outcomes.

The content of ViCCY is based on the Transactional Model of Stress and Coping (Fig. 1) [25]. The conceptual model illustrates that stressful experiences such as caregiving demand – circumstances that give rise to real or perceived stress – are construed as person-environment transactions. Primary appraisal of demand involves assessment of its significance, which results in perceived burden. Secondary appraisal involves assessment of the resources available to cope with it. These appraisals lead to the coping effort. Without successful coping, self-care is poor, which can compromise caregivers' health status. Our virtual support intervention ViCCY addresses both appraisal and coping. Because stress does not affect all people equally, the intervention is tailored to individual appraisals and the factors most likely to influence demand and perceived burden [26].

The purpose of this single-center phase II randomized controlled trial is to test the efficacy of our virtual health coaching intervention on the self-care of HF caregivers. The specific aims of the trial are to (1) compare the efficacy of ViCCY vs. health information in improving self-care and (2) estimate the cost and cost-effectiveness of ViCCY. We hypothesize that, at 6 months after enrollment in the iCare4Me trial, caregivers randomized to ViCCY will have improved outcomes and at 12 months we will see evidence of cost-effectiveness compared to those receiving health information alone. An exploratory aim is to examine the effect of caregiver outcomes on HF patient outcomes, as caregiver burden and stress are associated with higher rates of hospitalization for patients with HF [27]. Therefore, we hypothesize that, at 12 months after enrollment in the iCare4Me trial, HF patients whose caregivers improve vs. not improve in self-care – regardless of group – will have better outcomes.

2. Methods

2.1. Study setting

We are enrolling a consecutive sample of informal HF caregivers identified from the University of Pennsylvania (Penn) Heart and Vascular Center (PHVC), the largest out-patient HF clinic in the Philadelphia region and from the Hospital of the University of Pennsylvania. These sites use a single, integrated electronic medical record (EMR) with the level of financial data needed to address our cost-effectiveness aim. The clinic and the hospital serve a population that is diverse in age, gender, socio-economic status, and race.

2.2. Eligibility criteria

Clinical staff identify qualifying caregivers and determine their interest in speaking with research staff about the study. If a caregiver agrees to speak with research staff, a research assistant explains the study. Those interested in participating are screened for inclusion criteria (Table 1) with standardized testing (e.g., Health Self-Care Neglect scale [28]) and interview (e.g., Telephone Interview for Cognitive Status [TICS] [29]). Eligible caregivers are fully informed about what the study entails and asked to sign a consent form.

Table 1
Heart failure care partner inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
1. Informal caregiver providing care at least 8 h/week 2. Evidence of poor self-care on screening (e.g., Health Self-Care Neglect scale [28] score ≥ 2) 3. Able to complete the protocol, e.g., adequate vision and hearing, able to read and speak English 4. Living within 50 miles of the research office if enrollment is not able to be completed at a local site	1. Cognitive impairment (Telephone Interview for Cognitive Status [TICS] [29] score < 25) 2. Participation in another support trial 3. Untreated major psychiatric illness (e.g. schizophrenia) 4. Inability to use the technology 5. Patient is enrolled in hospice or palliative care

2.3. Interventions

All participating caregivers receive a tablet device with mobile connectivity, an embedded camera capable of full 2-way duplex video, and real-time audio transmissions. Technology experts have trained research staff to set up the devices during an in-person visit and ensure that the system is functioning well before research procedures begin. Availability of the Internet is limited on the tablets to allow the caregivers to only access health information content through carefully chosen websites. Internet sites that offer self-care content (e.g., relaxation and meditation techniques, content on diet, exercise, etc.), support for caregivers, and education about HF were identified and programmed into the tablets and described in the Caregiver Manual. In this manual, caregivers are provided with step-by-step directions on how to use the tablet and given the research office phone number in case technology issues occur. A printed copy of the manual specific to the appropriate intervention arm is mailed to each participant following randomization. Participating caregivers in both study arms are encouraged to spend at least 30 min weekly using the Internet sites for six months and receive monthly reminders to do so. These websites are the only content provided to caregivers in the control group, although all caregivers and patients are offered support from clinic social workers. This active comparator, the provision of education, was chosen to make it possible to determine if the experimental intervention is superior to education alone [30]. After six months, we pick up the tablet devices to minimize bleeding into the follow-up period.

2.3.1. ViCCY intervention

Caregivers in the ViCCY intervention group, in addition to health information, receive 10 sessions of virtual health coaching over 6 months. HF patients do not receive an intervention. As shown in Fig. 2, sessions with the health coach are front-loaded, occurring weekly initially and decreasing in frequency over time. Sessions are more frequent initially because early and intense contact with the coach builds the relationship, engages the participant in the treatment program [31], and maximizes outcomes [32]. ViCCY sessions are provided entirely by video-conferencing technology. A secure cloud account is set up for the ViCCY sessions. Health coaches are expected to call caregivers within two days of receiving the assignment and schedule the first session within one week of the call.

ViCCY incorporates the factors essential in caregiver interventions [33]; it is a psychosocial approach that is personalized and tailored to be flexible; is multidimensional, providing support for coping with perceived stress while fostering self-care; and is sufficient in dose, based on our pilot work. We refined our approach based on caregiver input to focus on relieving stress rather than intensifying demand and burden, thereby promoting caregivers' ability to respond to stressors with adaptive coping. We aim to build motivation to gain the knowledge and skills needed to achieve self-identified health goals [34]. We focus on identifying personal values, solving problems, and transforming goals into action using a combination of psychological and behavioral interventions [35].

Table 2 details how the conceptual model is used in ViCCY. Prior to the first session, caregivers assess their needs using the Carer Support Needs Assessment Tool v2; needs are reassessed at sessions 5 and 9 [36]. Goal-setting and action-planning are discussed based on personal needs. Intervention content is standardized, guided by a manual with session outlines, prompts, and a list of specific content to be covered in each call, but also tailored to allow the coach to focus on caregiver needs, addressing unique and varying individual characteristics, preferences, and goals [37]. For example, as material is covered, it is then carried forward to subsequent sessions with questions (e.g., after session 4 on sleep, the caregiver is asked about sleep in subsequent sessions). Any topic that continues to be problematic is addressed again in a subsequent session.

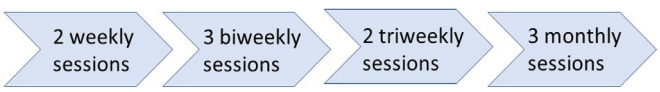

Fig. 2. Graphic illustration of the front-loaded sessions with the health coach. Early sessions occur weekly and decrease in frequency over time. All sessions end within 6 months.

We use motivational interviewing and health coaching methods in the ViCCY sessions [38]. Observations are presented to the caregiver in a way that builds confidence, motivates action, and enhances self-care by breaking the cycle of negative self-perception and emotions with the knowledge, skills, and beliefs needed to engage in healthy behaviors [39]. Information (e.g., reasons for specific patient behavior) is given only if and when the caregiver is receptive to it.

A series of sessions is provided because in preliminary studies, we found a direct relationship between the number of sessions provided and the effect obtained [40,41], with 10 sessions of health coaching typically being a sufficient dose [42]. Consistency is important for trust building, behavioral change, and growth [18], so one health coach is assigned to work with each caregiver for the full 6-month intervention period. Because maintaining contact is important to the success of stress reduction interventions [43], the assigned health coach checks in with caregivers between intervention sessions. We provide booster sessions to any caregiver in the ViCCY arm who requests additional support during the 6-month intervention interval [42]. We track the number of sessions provided to each caregiver and plan to test for differential effectiveness based on the dose received. All contacts are tracked, therefore if what was intended as a brief check-in call lasts > 5 min, the time and content (e.g., brief call becomes an intervention session), it is tracked for use in the analysis.

2.3.2. Recruitment, training, and oversight of health coaches

Applicants with experience in health coaching, knowledge of the HF patient population, and comfort with technology were hired to engage caregivers in creating and maintaining a culture of health in their personal lives. Recruitment of health coaches involved word of mouth and the assistance of the Wisdom of the Whole Coaching Academy www.wisdomofthewhole.com. Location was not an issue in recruiting because the intervention is virtual, so three experienced health coaches living across the US were hired and trained together, in person over a two-day interval. Skill in motivational interviewing was augmented as needed with online continuing education provided by the University of Colorado [44].

Treatment fidelity is carefully monitored as detailed in Table 3 [45]. All sessions are audio-recorded, with intermittent auditing of selected sessions. The audited sessions are reviewed by two trained independent raters using the Behavior Change Technique taxonomy [46]. Raters assess completeness and thoroughness of the content covered and the therapeutic techniques used, calculating intraclass correlation coefficients as a measure of interrater reliability. Coaches who receive less than moderate ratings receive individual session supervision. If a coach receives a low rating on any session, she is required to undergo additional training and suspended from coaching study participants until the deficiencies are remedied. In addition to documenting what occurred in each session using standardized reporting forms, the health coaches complete a checklist of Mechanisms of Action that links with the behavior change techniques used [47,48]. The mechanisms reflect what the coach was trying to achieve with the intervention. For example, the coach may try to build optimism with a particular intervention or intend to reinforce a particular response. Listening to the recording, we can identify the intervention but the rationale for doing it is captured in the Mechanisms of Action checklist. We track all training time and time spent in the sessions for use in the cost-effectiveness analysis.

Table 2
Overview of the 10-session program in self-care for caregivers of persons with heart failure.

Time period	Activities	Theoretical dimension addressed
Session 1 • Assessment • Mutual education	Assess caregiving demand (e.g., patient behaviors, communicating with providers, feeling isolated) [91]. Provide "mutual education" and cross-learning—caregivers educate the coach about the nature of their issues and the coach educates the caregiver about the purpose of health coaching and how self-care can help the caregiver. Use the Carer Support Needs Assessment Tool (CSNAT) [36] to identify needs and set goals. This assessment sets up discussions of the discrepancy between goals and self-care behavior, ambivalence about self-care, and action planning.	Caregiving demand and support resources
Session 2 • Caregiving as a stressful experience • Focus on heart failure and what the caregiver wants to know	Assess beliefs about caregiving and personal goals to determine how caregiving demand impacts burden and personal goals. Assess perceptions of controllability and self-efficacy in dealing with specific situations. Teach how to itemize and prioritize questions before meetings with providers. Identify interpersonal and community resources available to provide respite and support.	Primary appraisal (significance of the stressor) Secondary appraisal (assess coping resources and options)
Session 3 • Self-care and the benefits of pleasurable and productive activities	Discuss the benefits of self-care. Brainstorm about potential ways to incorporate self-care into the current situation. Assess structural and contextual factors influencing self-care (e.g., social determinants of health). Identify resources needed. Teach practical skills to activate self-care and encourage a sense of health ownership (e.g., self-monitoring of thoughts and behavior).	Self-care to support coping
Session 4 • Getting better sleep	Teach about the importance of sleep in coping. Even a single night of poor sleep can make you unproductive and prone to poor decisions, unsafe performance, anger, and depression.	Self-care to support coping
Session 5 • Recognizing thought distortions and their impact on stress levels	Introduce problem solving and automatic thoughts occurring as a triggered response to an action or event. Emphasize self-care as a pleasurable and healthy method of coping. Teach that avoidant coping styles (e.g., denial) are not helpful [92]. Encourage perceptions of controllability and self-efficacy as they are associated with engaged coping styles. Reassess needs using the CSNAT [36].	Coping: Emotional regulation
Session 6 • Changing automatic thoughts and improving coping	Discuss the influence of thinking on coping. Discuss useful coping strategies such as humor, seeking support, exercise, and focused problem solving. Discuss action planning, emphasizing skills that can help deal with problems. Encourage gratitude to decrease stress and improve wellbeing [93]. Identify if spiritual beliefs are important to the caregiver; if so, encourage. Elicit ways to find satisfaction with caregiving.	Coping: Problem management and meaning-based coping
Session 7 • Relaxation techniques	Teach relaxation exercises (e.g., guided imagery, controlled diaphragmatic breathing, and meditation) and reinforce to promote emotional regulation.	Coping: Emotional regulation
Session 8 • Building confidence	Assess self-efficacy or confidence in relation to self-care and coping. The most effective way of developing a strong sense of efficacy is through mastery experiences. Performing a task successfully strengthens self-efficacy, so build in opportunities to perform tasks successfully.	Secondary appraisal (self-efficacy)
Session 9 • Evaluating implementation and effectiveness of interventions, moving towards discharge	Reinforce key content previously covered (i.e., heart failure, the nature of stress, the importance of self-care, self-monitoring, thought distortions and how to change them, problem-solving, confidence, and relaxation). Emphasize the importance of self-care to build resilience in coping. Reassess needs using the CSNAT [36] and address unmet needs now.	Coping resources
Session 10 • Closing session	Build on previously discussed skills. Address agenda items raised by the caregiver. Reinforce self-care practices and confidence in the ability to practice the skills taught over the past few months.	Coping resources

2.4. Outcomes

The main analysis of intervention efficacy is performed at 6-months, with self-care as the primary outcome. We chose to assess the primary aim at 6 months based on prior psychosocial intervention studies [49]. We will assess very early effects at 3-months; assess short-term effects at 6-months; and assess the longer-term effects of ViCCY vs. health information at 12-months. We chose a 12-month follow-up interval for the cost-effectiveness analysis to allow for a full year of event accrual.

2.5. Sample size

We plan to enroll 250 HF caregivers (125 caregivers per study arm) to achieve over 90% power to detect significant overall differences in longitudinal profiles between the groups on the primary outcome. We estimated group differences in the Health Self-Care Neglect Scale [28] at 6 months of D = 1.12. We anticipate 20% attrition based on our prior experience. Using an alpha of 0.05, a design with three major assessment points (baseline, 3- and 6-months), and 100 participants per group (200 total) achieves 99% power to test the overall between-group effect (intervention vs. control without regard to changes over time), 99% power to test the overall time effect, and 90% power to test the group x time interaction effect.

We project identifying 90 unique HF caregivers each month from our enrollment sites. Based on our prior research [50], we anticipate that 70% of these (63 caregivers) will be eligible, and 15% will enroll. Thus, we estimate enrolling at least 10 caregivers per month. We have conservatively allowed 30 months for enrollment.

Based on our prior studies, we anticipate enrolling a diverse sample, with many in vulnerable racial, socio-economic, and geographically disadvantaged groups [50]. Most caregivers will be spouses but some will be adult relatives or friends. Although the sex distribution of HF patients is about equal [51], we expect to enroll more female than male caregivers because most HF caregivers are female [52] and support interventions are more appealing to women [53]. Enrolling at least 50 male caregivers is a goal so that sex-related differences in intervention efficacy and outcomes can be assessed.

We will address our exploratory aim assessing the relationship between HF caregiver and HF patient outcomes by enrolling all willing HF patients cared for by an eligible and enrolled caregiver. Not all patients

Table 3
Methods of Process Evaluation to Ensure Treatment Fidelity.

Goal	Strategies
Study Design Ensure that the treatment dose (number, frequency, length of contact) is adequately described and the same for each participant	• Provide all participants with consistent access to health information • Provide all intervention group participants with 10 doses of ViCCY over six months • Use a detailed treatment manual with session agendas and checklist of points to cover to enhance treatment quality and consistency • Ask all participants to track their use of the health information websites
Plan for Implementation Setbacks (e.g. coach drops out)	• Hire three health coaches and maintain a pool of qualified coaches so that new ones can be trained if needed • Track attrition (Research Assistants, coaches, participants) and reasons for dropout
Coach Training Standardize training to ensure that it is conducted similarly for all health coaches. Train coaches to well-defined performance criteria.	• Train coaches together using standardized training manuals and the same instructors • Design training to accommodate individual styles while assuring standardization • Specify performance criteria a priori • Provide remedial training immediately when problems are detected
Treatment Delivery Monitor and control for treatment differences	• Monitor all encounters, with deviations from protocol addressed quickly • Assure that a single coach is assigned to provide ViCCY for each caregiver for continuity • Audio-record ViCCY sessions and rate randomly chosen for each coach to rate fidelity • Provide routine supervisory oversight using fidelity ratings to minimize decay or drift • Assure that coaches self-monitor, completing an intervention log after each contact
Treatment Enactment Monitor and control for participant perceptions of coach differences (e.g., warmth, credibility)	• Assess participant perceptions of coach characteristics through intermittent phone calls • Give feedback to coaches and mentor them to rectify concerns • Analyze treatment enactment data after 50%, 75%, and 100% of participants are recruited and compare by group (ViCCY and health information) [94]

will enroll, but we will seek at least 40 caregiver-patient dyads, a number sufficient to provide reliable parameter estimates. If a caregiver agrees to participate but the HF patient does not, we will still enroll the caregiver.

2.6. Allocation

After collecting baseline data, we block randomize the HF caregivers 1:1 to the intervention or control group, stratifying randomization by caregiver sex (male, female) and relationship to the patient (spouse, non-spouse) – factors known to influence caregiving burden, perceived stress, and receptivity to the intervention [54]. The randomization sequence was generated a priori by a statistician independent of the study investigators using a randomly permuted blocks algorithm to ensure equal distribution of these variables in each study arm. Although balance in sample size can be achieved with block randomization, the groups may not be fully comparable on other factors. Initial comparison of the groups will allow us to control for important covariates in the analyses [55].

Investigators and all staff involved in collecting assessment data are blinded to group assignment and will remain so until after the data are locked. All participants are contacted as soon as they are randomized to tell them their group assignment. In addition to this phone call, we mail the appropriate Caregiver Manual with a welcome letter describing the arm to which they are assigned and staff they can contact for more information. The co-investigator responsible for intervention fidelity and the caregiver participants are not blinded. It is not possible to blind the health coaches providing this behavioral intervention.

2.7. Data collection methods

On enrollment, we collect self-report data from the HF caregivers on self-care, stress, coping, health status, relationship quality, perceived burden of caregiving, future time perspective, and work status including lost productivity due to time away from work (absenteeism) and reduced efficiency at work (presenteeism) (Table 4). Self-report instruments with demonstrated cultural-sensitivity and prior validity testing in caregiving samples were chosen, and measures are as brief as possible to minimize burden. Social determinants of health (e.g., income, insurance, employment [56]), demographic characteristics, medicines and illnesses are gathered at enrollment, as is the length of time they have been a caregiver.

At 3, 6, 9 and 12-months post randomization we telephone caregivers and collect self-report data on self-care, stress, coping, health status, and work status. To examine whether caregivers' expectations influence outcomes, caregivers in both groups complete the Outcome Expectancy and Treatment Credibility Scale [57] at baseline and 6 months to facilitate data interpretation. A research journal is provided to aid tracking of health care resource use and cost. Quality-adjusted life years (QALYs) are derived from the SF-36 [58] for use in the cost-effectiveness analysis at 12 months. Timing of follow-up assessments is based on the day of randomization.

With HF patient consent, patient demographic and clinical characteristics are abstracted from the EMR at enrollment. We assess duration of HF, how often the patient has been hospitalized in the prior year, complexity of the illness, and comorbid conditions. Medications and treatments such as a ventricular assist device, continuous positive airway pressure (CPAP), or cardiac transplantation are noted because these issues add greatly to the burden of care. Physician ratings of New York Heart Association functional class as noted in the EMR at enrollment are used to describe HF patients. To minimize subject burden, only the TICS [29] and the SF-36 [58] are administered to HF patients at baseline. The SF-36 is re-administered to patients at 12 months.

Health care utilization of both caregivers and consenting HF patients will be obtained from the EMR for 12 months before and 12 months after randomization using a process of active surveillance done by blinded research assistants. These data are gathered in 30-day increments and validated during routine follow-up calls with caregivers. As EMR data may be incomplete if a person is hospitalized outside the health system, participants are asked to sign a waiver to allow us to request access to medical records if caregivers tell us about health care use outside of the health system when they are telephoned at 3, 6, 9, and 12 months. We will ask about and confirm from hospital records all major categories of resource use including provider visits, hospitalizations, emergency department (ED) visits, diagnostic and therapeutic procedures, ambulance services, and home care services received. In the event of the death of a patient, we will measure time to death from date of the caregiver's enrollment in the study to the date of patient death.

To maximize participant retention, we monitor retention regularly and discuss retention trends at biweekly meetings of the full study team. We try to minimize communication problems by assuring that all reading materials are written at a basic level and print is sufficiently large to accommodate age-related vision changes. We maintain contact

Table 4
Participant survey assessments.

Domain	Questionnaire	# Items	Item responses	Reliability	Validity
Stress	Perceived stress scale [95]	10	5-point scale (0 = never to 4 = very often).	0.84–0.86	Concurrent, predictive, construct
Burden	Heart failure caregiver questionnaire [96]	21	5-point scale (0 = not at all to 4 = extremely).	0.78–0.85	Concurrent, construct
Coping	Ways of coping questionnaire, short form [97].	35	4-point Likert scale (0 = does not apply and/or not used, 1 = used somewhat, 2 = used quite a bit, and 3 = used a great deal).	0.76–0.84	Construct
Self-care	Health Self-Care Neglect (HSCN) scale [28]	10	HSCN is dichotomous	0.76	Content
	Self-Care Inventory(SCI) derived from the Self-Care of Chronic Illness Inventory [98].	30	SCI has 4 scales measuring self-care maintenance (8 items), monitoring (5 items), and management (7 items) as well as a self-care self-efficacy scale (10 items). Each scale score is standardized 0–100 points with higher scores indicating better self-care.	0.67–0.86	Content, Construct
Health status	Medical Outcomes Study Short form (SF)-36 [99].	36	Varied (3-, 5- and 6-pt scale and dichotomous [yes/no]); each component score is standardized 0–100 point scale.	> 0.80	Convergent, Divergent
Quality of the relationship	Mutuality scale [100,101]	15	5-point Likert scale ("not at all" (0) to "a great deal" (4)). Total scale score is computed by averaging all item scores with higher scores indicating higher mutuality.	0.76–0.88	Construct
Perceptions of time and the future	Future time perspective	10	7-point Likert-type scale (1 = very untrue, to 7 = very true)	0.85	Discriminant
Work performance	7-day work performance questionnaire [102].	13	Interview format. Varied (10-point) scale and dichotomous [yes/no] and number hours spent performing paid and unpaid work	0.73	Predictive, Concurrent, Construct

with participants with intermittent telephone contact and quarterly newsletters pushed through the tablets. Participants are remunerated for their time and effort using a market model [59]. Payments are made on electronic cards at each data collection interval, for a total of $200 per caregiver and $25 per patient. The participant timeline is illustrated in Fig. 3.

2.8. Data management

REDCap (Research Electronic Data Capture) is used as the central resource for data processing and management [60]. REDCap provides an intuitive interface for data entry with data validation, audit trails for tracking data manipulation and export procedures, automated export procedures for seamless data downloads to common statistical packages, and procedures for importing data from external sources. We use standard operating procedures to guide all data management activities, such as the naming of variables, data cleaning and handling of missing data. Missing fields are not allowed except in certain pre-specified cases (e.g., income). Data are entered directly into REDCap using encrypted tablets and laptop computers.

2.9. Statistical analysis plan

2.9.1. Aim #1

All analyses will be conducted using intention-to-treat principles. Separate mixed effects regression models will be generated to assess changes in each of the continuous outcomes (self-care, stress, coping, health status, QALYs) over time. We will explore the effect of caregiver outcomes (self-care, stress, coping, health status) on HF patient outcomes (number of hospitalizations and days in the hospital) using generalized estimating equations (GEE) regression models with the Poisson distribution as the working outcome distribution. Time to death will be examined using GEE and frailty type multivariable modeling within the context of equally spaced time intervals. Finally, we will examine the effect of caregiver outcomes on HF patient outcomes in patient-caregiver dyads using multilevel dyadic modeling [61].

2.9.2. Aim #2

To estimate the cost and cost-effectiveness of ViCCY over 12 months, we will test for difference in costs (intervention cost minus cost offsets), QALYs, and the incremental cost effectiveness ratio (the difference in costs divided by the difference in QALYs). Costs will include both the costs of the intervention and implementation (number and length of intervention contacts, time to assess needs and deliver the intervention, technology expenses, supervision time, and initial training). Cost offsets include the costs of health care and the difference in workplace productivity collected for both study groups. QALYs will be used to assess effectiveness. We hypothesize that compared to health information, ViCCY implementation will require more resources, but will reduce other health care use. It is unclear if the changes in health care resource use or labor productivity will fully offset the intervention implementation costs (leading to a finding of dominance: lower cost and greater effect) or if net costs will be positive (leading to a finding of cost-effectiveness). We will follow a micro-costing approach, adhering to accepted standards [62].

Health care use is summarized and converted to payer costs (i.e., a payer's perspective) by use of Medicare fees. Due to the limited time frame of the study, there is no need to discount or adjust for inflation. Medication costs are based on average wholesale prices adjusted to average sales prices [63]. We evaluate the effect of a reasonable range of private sector cost estimates in sensitivity analyses. Labor productivity costs are valued using the static human capital approach [64], multiplying the self-reported changes in work hours and absenteeism by the individual's wage.

Resource utilization and cost comparisons are examined overall and by resource category over four time periods (0–3 months, 3–6 months,

	STUDY PERIOD					
	Enrollment	Allocation	Post-allocation			Close-out
TIMEPOINT**	$-t_1$	0	t_1	t_2	t_3	T_4
ENROLLMENT:						
Eligibility screen	√					
Informed consent	√					
Allocation to group		√				
INTERVENTIONS:						
Health Information						
Health Information and Health Coaching						
MAIN ASSESSMENTS:						
Self-care	√		√	√	√	√
Stress	√			√		√
Coping	√		√	√	√	√
Health status	√			√		√

Fig. 3. Schedule of enrollment, interventions, and main assessments, which occur every 3 months.

6–9 months; and 9–12 months), with the main outcome at one year. Statistical comparisons are performed using GEE with links selected using the Pearson correlation test, the Pregibon link test, and the modified Hosmer and Lemeshow test, and families selected using the modified Park test [65]. Estimates of average total treatment costs and QALYs are generated separately for each group. Differences in cost and QALYs will be used to calculate the incremental cost-effectiveness ratio. Sensitivity analysis is a critical component of an economic evaluation since all assumptions and parameter estimates have uncertain precision [62]. As more than one approach is often available to monetize outcomes, we will calculate a lower and upper bound estimate for the benefit (QALYs) and cost calculations.

2.9.3. Aim #3

For the third aim, we will explore the effect of caregiver outcomes (self-care, stress, coping, health status) on HF patient outcomes. Using a combined sample, we will analyze the number of hospitalizations and days in the hospital using GEE regression models with the Poisson distribution as the working outcome distribution. GEE allows for modeling of the marginal distribution of each outcome variable as a function of the caregiver predictor of interest over time, and accounts for the likely correlations of the repeated outcome measures for each participant. We will use an approach like that used for Aim 1 within the GEE framework.

Patients remaining free from an event will be censored at their last follow-up interview. Kaplan-Meier estimates will be plotted to provide a visual demonstration of time to death by group (categorized caregiver outcomes), and the log-rank test will be used for comparisons. GEE and frailty type multivariable modeling will be applied to time-to-event data within the context of equally spaced time intervals [66,67]. This approach allows for the addition of a random effect to a general Cox proportional hazards model to account for the likely correlation of repeated measures for each study participant while also accounting for censoring. We will report all primary and secondary outcomes separately by sex to enhance the rigor and transparency of our findings.

2.10. Safety monitoring committee

Before enrollment began, we registered the trial with ClinicalTrials.gov (NCT03988621). We established a Safety Monitoring Committee (SMC) with three experts from the University of Pennsylvania who are independent of the protocol. Two are independent clinical investigators and the third is a biostatistician. The SMC reviews the progress of the trial, including assessments of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, and other factors that can affect study outcome. The SMC met prior to the start of the study and will meet again in 2019 and annually thereafter unless an issue arises.

2.11. Ethics and dissemination

The study was approved by the University of Pennsylvania Institutional Review Board as research involving “no more than minimal risk” (Protocol #830235). Risks of participation include fatigue during data collection or during intervention sessions, accentuation of stress due to research procedures, and potential loss of confidentiality. Fatigue during data collection is the most likely risk. If participants are too fatigued to complete all measures, baseline surveys will be gathered by telephone. The research assistants are trained to be sensitive to signals from participants that a break is needed during testing. Participants are informed that they can stop their participation in the study at any time. For anyone who finds data collection too fatiguing, we will offer the option of providing only the most essential data reflecting the key outcome variables (e.g., self-care).

In the final two years of the study the research team will develop a strategic plan for the comprehensive presentation and publication of study findings. The committee will plan the topics, authorship and timing for all manuscripts, abstracts and presentations, as well as review and approve publication requests from collaborators. Dissemination will begin after the intervention period has been completed and analyzed, with results of the primary study aim disseminated as soon as they are available. Three main dissemination lines will be used: (1) press releases; (2) journal publications; and (3) conferences to effectively address the academic and scientific community, health policy makers, and the general public. Results will be shared with all participants.

3. Discussion

This study aims to evaluate the efficacy of a virtual health coaching intervention on informal HF caregiver self-care. Informal caregivers carry the bulk of the responsibility for the care of ill, disabled, and elderly individuals [68]. As a group, informal caregivers have more stress [69], worse self-care [9], poorer health status [6,24], and higher mortality than non-caregivers [52]. Caregivers often feel left alone to cope with problems, which exacerbates their stress [70]. When stressed, caregivers are less vigilant and less motivated to engage in behaviors that will benefit themselves and their charges [71,72].

Few trials of interventions for HF caregivers have been published [73], and of those, most have focused on improving HF caregiver burden, stress, or health status – not caregiver self-care [74,75]. Yet, HF caregivers are typically homebound and often isolated, so they may be among the most stressed caregivers in need of self-care [76]. The home environment may be the best place to deliver an intervention, where distractions are predictable and privacy can be optimized. Home interventions are perceived as convenient, requiring less time commitment, travel costs, and waiting times; duration and timing of sessions can be flexible and accommodate caregiver preferences. Thus, Internet-based virtual approaches may be particularly useful. Live video-streaming is now possible for most people in the US at very low cost, making virtual support a potentially efficacious way to intervene with homebound caregivers.

Using video technology to intervene with caregivers is not new, but it is new in HF caregivers, who are a predominately older population. In spite of mounting evidence that older adults use technology regularly [77], ageism persists and older adults often are assumed to be unable to participate in research using technology [78]. Our study will be one of the first adequately powered trials of a virtual intervention for predominately older caregivers. If efficacious, this approach to the delivery of ViCCY can easily be deployed in any location and with other populations.

Another important element of this RCT is testing of the cost-effectiveness of the intervention. Few cost-effectiveness analyses of support interventions have been performed in any chronically ill population. There is evidence that psychological therapies provided by Internet may be cost-effective [79], but no economic analyses of support interventions have been conducted in the HF population. A Cochrane review examined the cost-effectiveness of home palliative care for adults with advanced illness, including HF, and their family caregivers, but found inconclusive evidence and recommended more study [23].

Our exploratory aim examining dyadic processes is an important innovation. By definition, the caregiving relationship involves at least two people [80]. Prior studies have demonstrated that dyadic processes influence outcomes in both HF patients and their caregivers [81–83]. The vast majority of these studies are descriptive, and no one has tested the influence of an intervention for caregivers on HF patient outcomes. The mechanism by which dyadic processes influence outcomes appears to be related to the quality of the relationship [82]. Relationship quality influences burden [84], emotional distress [85], self-care behaviors [86], decision-making [87], and quality of life in both HF patients and caregivers [88]. It is plausible that the relationship influences HF patient hospitalizations and mortality, but there is little evidence on this topic [27,89,90].

Notable strengths of this study include the use mobile connectivity and tablet devices to deliver the virtual intervention. Support is provided to address technical difficulties that may arise, which increases the likelihood that all participants will receive the full intervention. We use a standardized protocol with some tailoring to fit the needs of each caregiver. The health coaches were carefully chosen and trained with attention to intervention fidelity. We anticipate having a wealth of data available to help to address important questions about caregiver needs, mechanisms of intervention effectiveness, dyadic contributors to outcomes, and the cost-effectiveness of an intervention of this nature.

In summary, the planned RCT began in 2019, with full results anticipated to be available in 2024. If shown to be efficacious and cost-effective, our virtual health coaching intervention can easily be scaled to support millions of caregivers worldwide.

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