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Feasibility of a digital palliative care intervention (Convoy-Pal) for older adults with heart failure and multiple chronic conditions and their caregivers: a waitlist randomized control trial

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Abstract

Background Although older adults with heart failure (HF) and multiple chronic conditions (MCC) frequently rely on caregivers for health management, digital health systems, such as patient portals and mobile apps, are designed for individual patients and often exclude caregivers. There is a need to develop approaches that integrate caregivers into care. This study tested the feasibility of the Social Convoy Palliative Care intervention (Convoy-Pal), a 12-week digital self-management program that includes assessment tools and resources for clinical palliative care, designed for both patients and their caregivers.

Methods A randomized waitlist control feasibility trial involving patients over 65 years old with MCC who had been hospitalized two or more times for HF in the past 12 months and their caregivers. Descriptive statistics were used to evaluate recruitment, retention, missing data, self-reported social functioning, positive aspects of caregiving, and the acceptability of the intervention.

Results Of 126 potentially eligible patients, 11 were ineligible and 69 were deceased. Of the 46 eligible patients, 31 enrolled in the trial. Although 48 caregivers were identified, only 15 enrolled. The average age was 76.3 years for patients and 71.6 years for caregivers, with most participants being non-Hispanic White. Notably, 4% did not have access to a personal mobile device or computer. Retention rates were 79% for intervention patients, 57% for intervention caregivers, and 60% for control participants. Only 4.6% of survey subscales were missing, aided by robust technical support. Intervention patients reported improved social functioning (SF-36: 64.6 ± 25.8 to 73.2 ± 31.3) compared to controls (64.6 ± 27.1 to 67.5 ± 24.4). Intervention caregivers also reported increased positive perceptions of caregiving (29.5 ± 5.28 to 35.0 ± 5.35) versus control caregivers (29.4 ± 8.7 to 28.0 ± 4.4). Waitlist control participants who later joined the Convoy-Pal program showed similar improvements. The intervention was well-rated for acceptability, especially regarding the information provided ($3.96 \pm .57$ out of 5).

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Conclusions Recruiting informal caregivers proved challenging. Nonetheless, Convoy-Pal retained patients and collected meaningful self-reported outcomes, showing potential benefits for both patients and caregivers. Given the importance of a patient and caregiver approach in palliative care, further research is needed to design digital tools that cater to multiple simultaneous users.

Trial registration ClinicalTrials.gov Identifier NCT04779931. Date of registration: March 3, 2021.

Keywords Digital health, Palliative care, Aging, Heart failure

Key message

Digital health can increase access to palliative care for older adults and their informal caregivers.

Background

Family, loved ones, friends, and formal caregivers referred to as a social convoy, [1-3] provide care for nearly 74,000 older adults who will die each year from advanced heart failure (HF) [4]. Although one in four adults will develop heart failure (HF) in their lifetime, HF is most prevalent in older adults and is estimated to increase 8.5% in the coming years [5]. In addition, the majority of older adults with HF also have multiple chronic conditions (MCC) resulting in complex care regimens, reduced functional capacity, frequent hospitalizations, poor guality of life, and increased risk of mortality [6-8]. Older patients with HF and MCC experience significant physical and psychological symptom burden and progressive dependence on their convoy [9, 10]. For the months or years leading to death, palliative care provides an interdisciplinary and patient-family-centered approach to address the physical, psychological, emotional, and spiritual suffering of patients and convoy [11]. However, few people with HF and MCC receive palliative care due to a shortage of specialty-trained palliative care providers, particularly in ambulatory settings [12–14].

To address this need, digital health, [15] including telehealth, wearable devices, and mobile applications (mHealth), provides modern opportunities for patients and their convoy to engage in palliative care but is relatively underexplored [16]. Digital health uniquely enhances healthcare by catering to different patient needs, increasing intervention reach, and offering remote functionalities, [17] suggesting that digital health can deliver palliative care resources in ambulatory settings earlier in the disease trajectory or as a bridge until specialty palliative care is available. However, digital systems are not typically designed with a patient and family-centered (e.g. multiple users) approach in mind. An estimated 40-65% of convoy caregivers are interested in using technologies to support and monitor the health of their loved ones, [18, 19] yet digital systems are typically designed for individual users rather than integrating the patient's convoy [20, 21]. As older adults with HF and MCC increasingly rely on the support of others to help manage their health, there is a critical need to foster approaches for effective integration of the convoy in palliative care-specific digital health.

To help improve the self-care, social support, and quality of life of older adults with HF/MCC and their convoy, we developed and refined the Social Convoy Palliative Care (Convoy-Pal) mobile intervention [22, 23]. Convoy-Pal is a 12-week mobile intervention to deliver self-management tools and palliative care resources in the participants' homes. This study tested the feasibility of delivering the Convoy-Pal intervention to older adults with HF and MCC and their convoy.

Methods

Study design

We conducted a single-site waitlist randomized control trial to test the feasibility of the Convoy-Pal intervention (Fig. 1). We selected a waitlist approach to assess the feasibility of implementing the intervention, including



Fig. 1 Convoy-Pal Feasibility Pilot Study Flow

randomization and retention of a control arm, while also allowing additional users to provide feedback on the technology [24]. Feasibility was assessed via benchmarks used in our previous patient-caregiver trials [25-27] and relevant recommendations [28] for recruitment (>30% of eligible patients will enroll), attrition (< 20%), and data collection completeness (<10% missing data) on measures of quality of life, social support, positive aspects of caregiving, self-efficacy, and intervention acceptability (>3 on User Version of the Mobile Application Rating Scale). All study protocols were approved by the Colorado Multiple Institutional Review Board (IRB 18-0973), and the trial was registered (NCT04779931). Routinify was approved by the University of Colorado Office of Information Technology's Security & Compliance team to deliver the mobile intervention.

Recruitment and enrollment

We identified potentially eligible patients who were ≥ 65 years of age and had been hospitalized for heart failure $(HF) \ge 2$ times in the last 12 months from UCHealth, an academic-community health system in Colorado, using the electronic health record system's (EHR) data delivery services provided by Health Data Compass, a health warehouse for UCHealth and other clinical partners to identify potential research participants [29]. Patients must have met the following additional inclusion criteria to participate in the study: self-report of multiple chronic conditions (MCC) by the number of diagnosis > 2and a disease burden score>2 on the Disease Burden/ Morbidity Assessment by Self-Report [30, 31] indicating the presence of MCC that limit activities of daily of living, community-dwelling in the United States, and English speaking. Patients with a self-reported diagnosis of dementia or diagnosis of a severe mental health problem (e.g., schizophrenia, bipolar affective disorder, or other psychotic illness) or who received care from the Palliative Care Clinic at UCHealth in the last year were excluded. Participants were not excluded due to limited technology access. We provided Convoy-Pal with data-enabled connectivity to interested participants who did not have internet access.

All patients meeting the initial study inclusion/exclusion criteria were sent an email or mailed letter describing the study. The letter included an opt-out phone number. Patients who did not opt out of the study were contacted by research staff via phone to describe the study and determine eligibility. To identify the patient's social convoy, during the phone screen, patients were asked: *"Could you please tell us all the people who help you with your heart condition or your daily life?"* and followed up with examples if needed. We contacted potential convoy caregivers for participation with the patient's permission. Convoy caregivers included any family, friends, or social support that the older adult identified who were at least age 18, were English-speaking, and could provide informed consent.

We planned to recruit up to 40 patients based on the rationale that feasibility is typically established for mobile solutions in disease management with a median sample of 33 participants [32], and other digital tool feasibility studies focused on self-management, older adults, and caregivers at the time the protocol was developed established feasibility using 17–40 participants [33, 34, 35]. We estimated that 30% of screened patients would be eligible to participate, > 30% of those eligible would enroll in the trial, and on average 2 convoy caregivers per patient would also participate in the study. Research staff obtained electronic informed consent from all study participants.

Data collection and randomization

Baseline visits were conducted via phone, Zoom, or in person at a UCHealth location, depending on the participant's preference and technology access. Based on their scheduling needs, we conducted baseline visits with patients and convoy caregivers separately or together. Patients were then randomized 1:1 to the intervention arm or waitlist control; convoy participants were randomized to the same group as the patient. During the baseline visit, participants completed their initial assessments. Intervention participants were then provided an overview of the Convoy-Pal tool and sent Convoy-Pal equipment and materials via mail. Once the equipment arrived, the research assistant offered additional tutorials via Zoom and technical support as needed during the trial. Upon completing the 12 weeks (3 months), participants were asked to complete their follow-up assessments and return the equipment. The research team provided mailing supplies and assistance, and only one kit was not returned. Waitlist control participants completed baseline assessments and were recontacted at 11 weeks to complete follow-up assessments at week 12 (3 months). If the control participant wanted to try the intervention, they were mailed the Convoy-Pal equipment and materials. Waitlist control participants had 12 weeks to use the tool and complete another round of follow-up assessments at 6 months. Participants were compensated for completing each assessment. We estimated < 20% attrition and <10% missing data for outcome measures. These benchmarks align with recent assessments of clinical trial reporting guidelines for palliative care [36].

Convoy-Pal intervention

The co-design development and initial usability testing of Convoy Pal with older adults and their caregivers are

described elsewhere [22, 23]. Convoy-Pal is a 12-week intervention that uses the Routinify platform [37] to deliver self-management tools and palliative care resources in the participants' homes (Fig. 2). The Routinify platform includes a tablet, charging stand, and smartwatch, with additional options for mobile phone access and a website portal. Participants and their convoy were given access to Convoy-Pal features, tools, and resources and shared between users. Convoy-Pal features were automated over the 12 weeks but were adjusted if needed by the study staff. Aligning with self-management interventions, during the first week, Convoy-Pal provided users the opportunity to assess health and caregiving needs and set corresponding individual goals for the intervention. The goal-setting process was prompted by the tablet and users were asked to identify health priorities and values. Based on these values, users were guided to select a goal (e.g. spend more time with family and friends, walk more, eat healthy options, talk with their doctor) or create their own. Strategies and resources for achieving goals were then provided. For self-monitoring, common physical and psychological symptoms were captured via self-repot weekly, along with smartwatch tracking of steps, heart rate, blood pressure, and skin temperature. Users could review an overview of their symptom reports and smart watch data on the tablet and website dashboard. Each week, users were prompted to complete a different palliative care assessment related to symptoms, advance care planning, spiritual needs, anticipatory grief, health team concerns, and social support. Assessments were specific to the patient or caregiver. Based on user responses, Convoy-Pal replied with a message of encouragement (e.g. it sounds like you have a lot of friends and family to lean on right now) or prompted a credible palliative care resource (e.g. based on your responses, Convoy-Pal can help you connect to supports). For example, if users reported low social support, Convoy-Pal provided resources on finding a support group for social support. If participants reported low satisfaction with their health care team, resources on preparing for visits, asking questions, and improving patient-provider communication were provided. Patients and caregivers shared access to each other's information dashboard via the system portal and mobile app.



Fig. 2 Convoy-Pal Features

Study measures

Quality of life (patients and caregivers)

We assessed quality of life with the Rand Short Form 36-item Health Survey (SF-36). The SF-36 is reliable and has high internal consistency ($\alpha = 0.72-0.94$) among individuals will cardiovascular disease [38]. There are 8 domains, including current physical and mental health, limitation of activities due to health, and functional items such as housework and mobility. A single total score was calculated by averaging the 8 domain scores, and scores ranged between 0 and 100; higher scores indicate improved QoL.

Social support (patients and caregivers)

The PROMIS Social Support measures are reliable, have high internal consistency ($\alpha = 0.95-0.97$) in populations with chronic health conditions, [39] and assess three support domains: companionship, emotional support, and instrumental support. The total combined score of the 14 items ranges from 0 to 70, with higher scores indicating better social support.

Self-efficacy (patients and caregivers)

We measured self-efficacy using the PROMIS self-efficacy for managing chronic conditions scales, which measures an individual's confidence in their ability to successfully perform specific tasks or behaviors related to their health in various situations. The measure includes five domains of self-efficacy calibrated across diverse chronic conditions with high internal consistency ($\alpha = 0.96-0.97$) and cross-sectional validity [40]. We focused on managing emotions, medications and treatment, and daily activities domains. Items were scored on a 5-point Likert scale, with higher scores indicating more self-efficacy.

Positive aspects of caregiving (caregivers only)

We used the 9-item Positive Aspects of Caregiving scale to evaluate the positive emotions arising from providing care. Each item was rated on a 5-point Likert scale, yielding scores from 9 to 45, where higher scores indicate a greater positive outlook on the caregiving experience. PAC is shown to be reliable and have high internal consistency ($\alpha = 0.89$) in diverse populations [41–44].

Acceptability and information quality (patients and caregivers)

Acceptability of Convoy-Pal was evaluated using the User Mobile Application Rating Scale (uMARS) survey, [45] which assesses four subscales to determine quality: 1) engagement with the app, 2) functionality and users' perceived functioning of the app, 3) aesthetics, and 4) users' perception of the quality of information. The uMARS has high internal consistency ($\alpha = 0.9$) among mHealth users [45]. The subscales are assessed on a 1 to 5 Likert scale, with 1 considered inadequate and 5 considered excellent. To focus on the quality of the palliative care content provided, we focused on the overall uMARS score and information quality subscale score among all participants following the completion of Convoy-Pal. Details regarding the use and usability of the intervention technology are pending review elsewhere. We estimated that participants would rate Convoy-Pal on average > 3 out of 5.

Statistical analyses

We used descriptive statistics to summarize the recruitment and retention of participants and calculated the percentage of missing data from pre-to-post intervention for self-report measures. In addition, we descriptively analyzed trends in self-reported quality of life, self-efficacy, social support, and positive aspects of caregiving outcome measures by calculating mean and percentage change with confidence intervals from pre-to-post tests to provide preliminary score distributions to inform future work. Finally, we reported the mean acceptability score for all participants who received the intervention. Descriptive statistics are reported as mean (SD) and median (min, max) or frequency (%). Our study was not designed to detect effects on these measures. All analyses are performed using R Statistical Software (version 4.2.0, R Foundation for Statistical Computing, Vienna, Austria, http://www.R-project.org/).

Results

Recruitment and enrollment

Please see Fig. 3 for a CONSORT Diagram. Our team mailed 557 patient recruitment invitations; we were unable to contact 249 due to disconnected phones and wrong numbers (56%) or unable to contact after 3 attempts (44%). 180 declined participation due to a lack of interest in participating (70%), too busy to participate (13%), the severity of the patient's illness (10%), and difficulty using technology (7%). Of the 126 patients screened for eligibility: 9% did not meet eligibility criteria due to selfreport of dementia or no HF, blindness, or non-community dwelling and 55% were recently deceased according to a family member. We scheduled baseline visits with 46 patients (37% of patients screened eligible), and during this time we identified 48 caregivers of which only 2 convoys (2 caregivers per 1 potential patient) were identified, not the average of 2 per patient as anticipated. Informally, patients would note that their caregivers "were very busy" or they "didn't want to bother them" with the study. In other cases, the caregiver wanted to participate but not the patient. Overall, the trial achieved a 67% recruitment rate among eligible patients (>30% benchmark) enrolling 31 patients and 15 of their caregivers (N=46) who



Fig. 3 Enrollment, Randomization, and Follow-Up in the Convoy-Pal Trial

were then randomized to immediate intervention (n = 19 patients, n = 7 caregivers) or waitlist control (n = 12 patients, n = 8 caregivers).

Participant characteristics

Patients (n=31) were a mean of 76 ± 4 years of age, half were female (50%), most were White (78%), married (64%), and all had at least some college education or higher. Caregivers (n=15) were a mean of 71 ± 14 years of age, primarily White (82%), married (82%), and most had some college education or higher (73%). Caregivers were spouses or partners (53%), children (27%), or siblings/ friends (20%). Most participants used a cell phone and computer (95%), and some used a tablet (58%). Almost all participants used their cell phone (75%) or computer (65%) daily, yet 4% did not have access to a personal computer or mobile device. A full description of patient and convoy caregiver participants is detailed in Table 1.

Retention

The study maintained a 67% retention rate overall, including the waitlist control group. Among immediate intervention participants, 79% of patients and 57% of caregivers completed the intervention and 3-month followup surveys. Among waitlist control participants, the trial retained 60% of participants at the 3-month follow-up. However, 1 patient-caregiver dyad dropped immediately after randomization to the control group, and 2 patientcaregiver dyads completed their follow-up closer to the 6-month mark. Among waitlist control participants n=5patients and n=3 caregivers opted to try the Convoy Pal intervention and completed 6-month follow-up surveys. Recorded reasons for dropout included loss to followup, particularly in the waitlist control group, or declining health of the patient or caregiver. Overall, attrition was higher than the 20% expected particularly in intervention caregivers and the control group.

Survey completion and patient and convoy caregiver outcomes

Only 4.6% of measure items were missing from survey data for all participants and time points, meeting the <10% benchmark. Surveys took an average of 32 min to complete at baseline, 39 min at the 3-month follow-up for the immediate intervention group, and 35.6 min at the 6-month follow-up for the waitlist control group. A description of average responses for each measure at each time point by intervention and control is reported in Table 2 for patient participation and Table 3 for caregiver participants. Internal consistency was high ($\alpha > 0.89$) for all measures at baseline for both patients and caregivers.

Patients in the immediate intervention group reported improvements in several quality-of-life domains on the

Table 1 Participant characteristics

	Total n (%) ^a	Total n (%) ^a		
	Caregivers ^b (N=15)	Patient ^c (N=31)		
Age				
Mean (SD)	71.6 (11.2)	76.3 (6.10)		
Gender				
Female	6 (54.5)	14 (50.0)		
Male	5 (45.5)	14 (50.0)		
Race & Ethnicity				
White	9 (81.8)	22 (78.6)		
Hispanic	2 (18.2)	2 (7.1)		
Other	0 (0)	4 (14.3)		
Marital Status				
Married or domestic partnership	9 (81.8)	18 (64.3)		
Widowed	0 (0)	3 (10.7)		
Divorced, Separated, or never married	2 (18.2)	7 (14.3)		
Education				
High school graduate or less	3 (27.3)	0 (0)		
Some college	3 (27.3)	15 (53.6)		
College graduate	0 (0)	6 (21.4)		
Post graduate	4 (36.4)	7 (25.0)		
About how often do you use a cell phone	?			
Several times a day	8 (72.7)	19 (67.9)		
About once a day	2 (18.2)	2 (7.1)		
Several days per week	0 (0)	5 (17.9)		
Never or No cell phone	0 (0)	3 (10.7)		
About how often do you use a computer?	,			
Several times a day	8 (72.7)	18 (64.3)		
Several days per week	0 (0)	3 (10.7)		
Every few weeks or less/No computer	2 (18.2)	7 (25.0)		
About how often do you use a tablet?				
Once or several times a day	3 (27.3)	8 (28.5)		
Several days per week	3 (27.3)	3 (10.7)		
Every few weeks or less/No table	4 (36.3)	15 (7.1)		
Once a month or less	0 (0)	2 (7.1)		

 $^{\rm a}$ Total participants are reported and categories were collapsed due to small cell size

^b n = 11 of 15 caregivers chose to respond

^c n = 28 of 31 patients chose to respond

SF-36, including physical functioning, role limitations, energy/fatigue, social functioning, and general health. They also reported increased self-efficacy related to managing emotions, medications and treatments, and daily activities. However, scores on the PROMIS quality of social support subscales decreased. In the waitlist control group, patient participants reported declines in quality of life, self-efficacy, and social support from baseline to 3 months. However, participants who chose to participate in Convoy-Pal after the control period

Table 2 Patients assessments

	Control			Intervention		Total Intervention	
	Baseline (N=12)	3 Months (N=7)	6 Months (N=5)	Baseline (N=18)	3 Months (N=15)	Pre- (N=30)	Post- (N=20)
RAND SF-36							
Physical functionii	ng						
Mean (SD)	31.4 (22.8)	29.0 (24.8)	42.1 (26.9)	47.6 (24.4)	48.7 (30.0)	40.5 (25.3)	46.6 (28.6)
Missing	1 (8.3%)	0 (0%)	0 (0%)	1 (5.6%)	0 (0%)	2 (6.7%)	0 (0%)
Role limitations du	ie to physical health						
Mean (SD)	31.3 (40.1)	25.0 (43.3)	35.7 (40.5)	31.3 (34.8)	33.3 (38.6)	30.4 (36.2)	34.1 (38.2)
Missing	0 (0%)	0 (0%)	0 (0%)	2 (11.1%)	0 (0%)	2 (6.7%)	0 (0%)
Role limitations du	le to emotional prob	blems					
Mean (SD)	63.3 (48.3)	46.7 (50.6)	61.9 (44.8)	63.0 (37.7)	71.1 (39.6)	60.9 (41.9)	68.2 (40.5)
Missing	2 (16.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (3.3%)	0 (0%)
Energy/Fatique			, , , , , , , , , , , , , , , , , , ,	. ,		. ,	. ,
Mean (SD)	44.6 (20.4)	35.0 (12.7)	47.1 (20.8)	44.1 (14.5)	47.3 (20.9)	43.6 (17.4)	47.3 (20.4)
Missina	0 (0%)	0 (0%)	0 (0%)	1 (5.6%)	0 (0%)	1 (3.3%)	0 (0%)
Emotional well-be	e (e · · ·)	- (- /- /	- (-,-)		- (-,-,		
Mean (SD)	85.3 (10.6)	74.4 (20.1)	81.7 (11.0)	79.3 (9.51)	80.8 (14.2)	80.8 (12.4)	81.1 (13.0)
Missina	0 (0%)	0 (0%)	0 (0%)	1 (5.6%)	0 (0%)	1 (3 3%)	0 (0%)
Social functioning	0 (0,0)	0 (070)	0 (070)	1 (31376)	0 (070)	. (3.370)	0 (070)
Mean (SD)	646(271)	67 5 (24 4)	768 (264)	646 (258)	73 2 (31 3)	658(271)	744(292)
Missing	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (6 7%)	0 (0%)	1 (4 5%)
Pain	0 (070)	0 (070)	0 (070)	0 (070)	1 (0.770)	0 (070)	1 (1.376)
Mean (SD)	517(238)	47.0 (25.3)	546 (165)	60 3 (29 7)	578(312)	56.0 (27.8)	568(270)
General health	51.7 (25.6)	17.0 (20.0)	3 1.0 (10.3)	00.5 (25.7)	57.0 (51.2)	50.0 (27.0)	50.0 (27.0)
Mean (SD)	20.0 (7.07)	55.0 (15.0)	583(176)	467(317)	593 (267)	494 (265)	590(233)
Missing	10 (83 3%)	2 (40.0%)	4 (57 1%)	12 (66 7%)	8 (53 3%)	21 (70.0%)	12 (54 5%)
PROMIS Self-Effica	10 (05.570)	2 (10.070)	1 (37.170)	12 (00.770)	0 (00.070)	21 (70.070)	12 (3 1.3 / 6)
Managing Emotic	ns (8a) T-Score						
Mean (SD)	514(653)	481(105)	523(704)	50.4 (5.93)	537(676)	50 5 (7 03)	53 2 (6 71)
Missing	1 (8 3%)	0 (0%)	0 (0%)	0 (0%)	1 (6 7%)	0 (0%)	1 (4 5%)
Managing Medico	itions and Treatmen	t (8a) T-Score	0 (070)	0 (070)	1 (0.770)	0 (070)	1 (1.376)
Mean (SD)	50 7 (6 01)	50.9 (7.44)	525 (691)	454 (685)	48.8 (5.71)	474 (726)	50.0 (6.22)
Missing	1 (8 3%)	0 (0%)	0 (0%)	1 (5 6%)	1 (6 7%)	1 (3 3%)	1 (4 5%)
Managing Daily A	ctivities (8a) T-Score	0 (070)	0 (070)	1 (3.070)	1 (0.770)	1 (3.570)	1 (1.570)
Moan (SD)	44 0 (6 87)	113 (851)	46.6 (8.01)	111(736)	153 (687)	137(7)5)	457(707)
Missing	1 (8 306)	0 (0%)	40.0 (0.01)	1 (5 6%)	43.5 (0.82)	1 (3 306)	4J.7 (7.07)
PROMIS Quality of	Social Support	0 (070)	0 (070)	1 (3.070)	1 (0.770)	1 (3.570)	1 (4.570)
Companionshin (1a) T-Score						
Moan (SD)	53 3 (7 88)	526(702)	52 0 (7 50)	520(024)	517(0.22)	521(858)	521(854)
Missing	1 (8 30%)	0 (0%)	0 (0%)	0 (0%)	1 (6 706)	0 (0%)	1 (4 5%)
Emotional Suppor	T(0.570)	0 (070)	0 (070)	0 (070)	1 (0.7 %)	0 (0 %)	1 (4.3%)
Moon (SD)	577 (6 20)	540(961)	572 (664)	521 (761)	52 9 (6 OE)	5/1 (751)	52 2 (6 1 2)
Missing	1 (9 204)	0 (004)	J2.3 (0.04)	0 (0%)	1 (6 70()	0 (00()	1 (4 E04)
Instrumental Cum	1(0.370)	0 (0%)	0 (0%)	0 (0%)	1 (0.7 %)	0 (0%)	1 (4.3%)
Maan (SD)	EO 1 (4 OE)	E6 E (0.02)	E6 4 (0 60)	EA 2 (6 06)	ED E (0.67)	EE 6 (7 0 2)	
Missing	27.1 (4.72) 1 (9.204)	0 (004)	30.4 (9.00) 0 (004)	24.2 (0.90) 0 (004)	J∠JJ (8.07)	0 (004)	JJ.8 (8.95)
IVIISSING	1 (0.3%)	U (U%)	0 (0%)	U (U%)	1 (0.7%)	0 (0%)	1 (4.3%)
Iniormational Sup	puri (ou) 1-Score	60 4 (11 2)		EG 2 (7 72)		EQ (0 1 1)	EE 3 /7 35)
Miccia a	1 (0 20/)	0.4(11.2)	24.2 (0.24)	SU.∠ (7.73)	22.7 (7.79)	⊃o.∪ (ö.11)	22.3 (7.25)
iviissing	1 (0.5%)	U (U%0)	U (U%0)	U (U%)	1 (0.7%)	0 (0%)	1 (4.5%)

	Control			Intervention		Total Intervention	
	Baseline (N=12)	3 Months (N=7)	6 Months (N=5)	Baseline (N = 18)	3 Months (N=15)	Pre- (<i>N</i> = 30)	Post- (N = 20)
uMARS							
Information Mean	Score						
Mean (SD)			4.42 (0.60)		3.44 (1.48)		3.75 (1.34)
Missing			1 (14.3%)		2 (13.3%)		3 (13.6%)
Total Score							
Mean (SD)			3.40 (0.49)		2.76 (0.82)		2.96 (0.78)
Missing			1 (14.3%)		2 (13.3%)		3 (13.6%)

reported improvements in physical functioning, role limitations, energy/fatigue, emotional well-being, social functioning, pain, and general health, comparing their 3-month assessment to 6-month follow-up. Among all patients who participated in Convoy Pal, improvements in average percentage change were found in quality of life $(1.34\pm16\%)$, particularly in the social function domain $(20\pm46\%)$, self-efficacy $(3.41\pm10\%)$, but not social support (-0.311±8.70). Convoy caregivers in both groups reported worsening quality of life and social support with little change in self-efficacy at all points in time. However, while caregivers in the control group reported decreased positive aspects of caregiving from baseline to 3 months, caregivers who participated in the intervention reported a 16% increase in positive perceptions of caregiving.

Acceptability and information quality of Convoy-Pal

Among all users, the overall acceptability of the Convoy-Pal was rated fairly by patients (2.96 ± 0.78) and convoy caregivers (2.94 ± 0.48) , just under the mean > 3 benchmark. However, the information quality of the intervention was highly rated for patients and caregivers $(3.75 \pm 1.34; 3.96 \pm 0.57)$, respectively). Based on free text responses by participants, some participants indicated frustration using the tablet, felt they did not have adequate orientation or training for using the tablet, misunderstood the purpose or intention of the app, and had issues with the watches.

Discussion

Convoy-Pal was designed to add palliative care resources to self-management tools for both patients and multiple caregivers, the social convoy. This is one of the first studies to attempt to recruit and enroll patients and the social convoy into a palliative care intervention, as most trials target patients only or dyads [46]. Based on the evaluation of trial data collection and acceptability, Convoy-Pal was able to collect palliative care outcomes data among patients and caregivers and provide tailored resources that were highly rated by users. While recruitment, retention, and technical components were a challenge, participants reported benefits in social functioning and positive aspects of caregiving after participation.

Overall recruitment from letters mailed was low. Due to the study's attempt to identify older adults with advanced HF and MCC and delays in vital status data in the electronic health system, many potential patients died between the time of the data pull to recruitment and phone numbers were often out of date. In addition, many individuals declined participation because the patient was too sick, back in the hospital, or too complex to participate. While 70% of people contacted opted out of the study for a simple lack of interest, only 7% expressed concerns about the technology. Research on patient and caregiver interest in, adoption, and engagement with palliative care-specific digital health remains limited, yet technology concerns were not a major barrier to participation among this older population. Convoy Pal is a mobile platform providing low-touch assessment and resources that could be disseminated broadly but adopted only by those most interested in digital options. Care in the setting of serious illness is complex, and it will be essential to determine which tools can be delivered in a digital format and when hybrid or in-person options are preferred. There is also great potential for adding Convoy-Pal features to industry-based platforms like Routinify. These platforms are generally created to support aging in place, distributed by aging networks (area agencies on aging) and PACE programs, but often lack palliative care resources. Convoy-Pal provides a new opportunity to offer palliative care resources directly to patients and convoy caregivers in the community rather than needing a clinical referral.

Consistent with other studies, [47] recruiting caregiving dyads, convoy caregiver identification, and recruitment presented a unique challenge to the study. First,

Table 3 Convoy assessments

	Control			Intervention		Total Intervention	
	Baseline (N=8)	3 Months (N=5)	6 Months (N=3)	Baseline (N=6)	3 Months (N=4)	Pre (<i>N</i> = 14)	Post (N = 7)
RAND SF-36							
Physical functi	ioning						
Mean (SD)	66.9 (34.8)	58.3 (33.3)	77.0 (23.9)	88.8 (10.3)	80.0 (23.5)	74.6 (30.3)	78.3 (22.2)
Missing	0 (0%)	0 (0%)	0 (0%)	2 (33.3%)	0 (0%)	2 (14.3%)	0 (0%)
Role limitation	ns due to physica	ıl health					
Mean (SD)	68.8 (43.8)	50.0 (43.3)	45.0 (51.2)	95.0 (11.2)	81.3 (23.9)	76.9 (36.0)	61.1 (43.5)
Missing	0 (0%)	0 (0%)	0 (0%)	1 (16.7%)	0 (0%)	1 (7.1%)	0 (0%)
Role limitation	ns due to emotio	nal problems					
Mean (SD)	83.3 (35.6)	55.6 (50.9)	80.0 (44.7)	72.2 (25.1)	83.3 (19.2)	76.2 (30.5)	81.5 (33.8)
Energy/Fatigu	е						
Mean (SD)	53.1 (25.2)	38.3 (20.8)	44.0 (23.6)	63.8 (13.1)	52.5 (23.3)	59.2 (17.7)	47.8 (22.4)
Missing	0 (0%)	0 (0%)	0 (0%)	2 (33.3%)	0 (0%)	2 (14.3%)	0 (0%)
Emotional we	ll-being						
Mean (SD)	81.5 (19.8)	86.7 (8.33)	76.8 (14.5)	82.7 (10.0)	71.0 (13.6)	83.7 (15.2)	74.2 (13.6)
Social function	ning						
Mean (SD)	73.4 (22.6)	83.3 (19.1)	72.5 (22.4)	79.2 (20.4)	84.4 (12.0)	81.3 (18.8)	77.8 (18.5)
Pain							
Mean (SD)	71.3 (25.9)	70.8 (42.2)	69.5 (21.2)	69.6 (18.9)	61.9 (13.9)	71.3 (23.2)	66.1 (17.7)
General health	1						
Mean (SD)	71.3 (23.2)	70.0 (NA)	80.0 (NA)	80.0 (7.07)	70.0 (NA)	81.0 (9.62)	75.0 (7.07)
Missing	4 (50.0%)	2 (66.7%)	4 (80.0%)	4 (66.7%)	3 (75.0%)	9 (64.3%)	7 (77.8%)
PROMIS Self-Ef	ficacy						
Managing Em	otions (8a) T-Sco	ore					
Mean (SD)	53.9 (12.1)	51.9 (7.09)	49.9 (10.2)	52.8 (6.41)	49.4 (0.500)	53.4 (9.08)	49.7 (7.19)
Managing Me	dications and Tr	reatment (8a) T-Sco	ore				
Mean (SD)	53.0 (8.21)	58.9 (2.94)	52.5 (13.6)	56.7 (4.76)	56.3 (5.82)	56.1 (5.93)	54.2 (10.4)
Managing Da	ily Activities (8a)	T-Score					
Mean (SD)	52.4 (9.31)	53.1 (1.67)	54.8 (10.5)	58.0 (4.15)	55.4 (7.36)	55.7 (7.03)	55.0 (8.68)
PROMIS Qualit	y of Social Sup	oport					
Companionsh	nip (4a) T-Score						
, Mean (SD)	53.3 (6.88)	47.3 (3.23)	55.2 (11.7)	55.0 (7.55)	54.7 (10.2)	53.2 (7.58)	55.0 (10.4)
Emotional Sug	oport (4a) T-Scor	e					
Mean (SD)	56.7 (6.73)	52.8 (7.97)	55.4 (9.35)	55.1 (6.24)	54.6 (5.53)	54.5 (6.64)	55.1 (7.44)
Instrumental	Support (4a) T-So	core					
Mean (SD)	59.6 (7.76)	53.0 (9.32)	51.8 (9.83)	54.0 (13.3)	53.6 (6.45)	55.6 (10.8)	52.6 (8.05)
Informational	Support (6a) T-S	Score					
Mean (SD)	59.7 (12.7)	57.4 (18.6)	58.5 (10.3)	58.3 (5.93)	58.3 (5.97)	59.0 (10.3)	58.4 (8.16)
Short – Positive	e Aspects of Ca	aregiving (S-PAC)				
Overall	•						
Mean (SD)	29.4 (8.70)	28.0 (4.36)	30.4 (15.3)	29.5 (5.28)	35.0 (5.35)	29.9 (5.61)	32.4 (11.6)
Self-Affirmatic	on						
Mean (SD)	22.3 (5.57)	20.3 (3.06)	21.8 (11.0)	21.5 (4.18)	24.5 (4.04)	22.2 (3.95)	23.0 (8.29)
Outlook on Lif	e	····/	× · · · /	× /	· · · · /	· ·	
Mean (SD)	7.13 (3.60)	7.67 (1.53)	8.60 (4.34)	8.00 (1.90)	10.5 (1.91)	7.71 (2.46)	9.44 (3.43)
uMARS		× ,			· · ·		/
Information N	1ean Score						
Mean (SD)			4.00 (0.43)		3.94 (0.72)		3.96 (0.57)

	Control			Intervention		Total Intervention	
	Baseline (N=8)	3 Months (N=5)	6 Months (N=3)	Baseline (N=6)	3 Months (N=4)	Pre (<i>N</i> =14)	Post (N=7)
Missing			2 (40.0%)		0 (0%)		2 (22.2%)
Total Score							
Mean (SD)			2.64 (0.074)		3.17 (0.54)		2.94 (0.48)
Missing			2 (40.0%)		0 (0%)		2 (22.2%)

Table 3 (continued)

many patients were hesitant to identify their convoy and would limit identification to only one potential caregiver rather than the full convoy [48, 49]. Second, caregivers are often busy with multiple priorities and cannot always participate [50]. Lastly, the logistics, including time, to recruit and consent two participants, let alone the full convoy, resulted in onboarding delays [51]. The intervention may benefit from creative solutions that enroll different types of caregivers across the convoy, at different times, with different Convoy-Pal tools.

While Convoy-Pal patient participants randomized to the immediate intervention were likely to complete the trial, intervention caregivers and waitlist control attrition were high. However, our retention rates are comparable to trials recently reported in a systematic review of studies among patients with cancer and their family caregivers (average retention rate 69%; range 16%-100%) [52]. These high attrition rates reflect a need for additional support to retain control groups and caregivers. This also aligns with our previous findings reporting that older adults are likely to complete the trial once onboarded to a technology intervention [53]. This underscores the need for high-quality enrollment procedures and technology support for both the patient and the convoy.

Participants highly rated the quality of the information provided via Convoy Pal, but overall acceptability was lower than anticipated, mainly related to the execution of the specific digital components. First, we identified a potential issue with participants' understanding of the uMARS items. The original uMARS was specific to the term "mobile app," yet Convoy-Pal was a mobile intervention with multiple access points and tools. Participants reported that they did not know what app the survey referred to, potentially indicating an issue in the survey wording rather than the intervention. The uMARS has now been updated to include different types of digital solutions and modifications for specific interventions when applicable [54]. Lower than expected overall acceptability may also speak to the need for a triaged approach that would include asynchronous tools, hybrid options, and referral to clinical services if needed, such as specialty palliative care or seniors/primary integrated options. With self-management, assessments, and resources, Convoy-Pal may be an initial approach to monitoring individual and caregiving needs to increase care and support as needed.

This study had several limitations. First, we did not include non-English speaking participants, and our sample lacked racial and ethnic diversity due to the limited scope of this work. The challenges we experienced in the recruitment of participants from historically underrepresented backgrounds were reflective of more general challenges to recruitment. Further complicating our race and ethnicity reporting, 15% of trial participants chose not to answer demographic questions. Future iterations of the application should consider translation and cultural adaptation to improve access to palliative care resources for historically underserved populations. Second, it was difficult to recruit multiple informal caregivers limiting our understanding of multiple users engaging with Convoy-Pal. Third, recent guidelines suggest that potentially a minimum sample of 70 participants is required to examine the feasibility on process outcomes such as acceptance and participation rates [55]. Fourth, considering trial challenges, adaptations to our onboarding approaches, identification of caregivers, and technological components may have resulted in improved feasibility outcomes. Lessons learned from this study should be incorporated into the next steps. Therefore, our sample did not meet this guideline for feasibility interpretation. Lastly, challenges with the extraction of data from the platform limited our ability to examine specific resources accessed by participants.

Conclusions

The identification and recruitment of multiple informal caregivers for research trials and palliative care are challenging. However, once enrolled, Convoy-Pal was able to retain patients, collect self-report outcomes, and demonstrate potential benefits for both older patients and their caregivers. Because palliative care is a patient and caregiver approach to serious illness care, more research is needed to design digital palliative care tools for multiple, varied ages, and diverse simultaneous users. We will incorporate finding from this work into our next steps which include further testing of Convoy-Pal with enhanced methods for caregiver identification and enrollment and integration with hybrid palliative care support.

Abbreviations

Convoy-Pal The Social Convoy Palliative Care Intervention Social Convoy This refers to an identified caregiver, such as a family member, friend, or social support

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Authors' contributions

All authors made substantial contributions to the conception and design of the work (JDP, SB, DB, RB, JK); the acquisition of data (JDP, JG, GH); data analysis (LD, RG, GH); interpretation of data (LD, JDP, RG, DD); or have drafted the work or substantively revised it (all authors).

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Availability of data and materials

Data can be made available by request to the corresponding author.

Data availability

The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate

All study protocols were approved by the Colorado Multiple Institutional Review Board (IRB 18–0973). Routinify was approved by the University of Colorado Office of Information Technology's Security & Compliance team to deliver the mobile intervention. Research staff obtained electronic informed consent from all study participants.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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