JOURNAL OF INONU LIVER TRANSPLANTATION INSTITUTE

DOI: 10.14744/jilti.2025.02486
J Inonu Liver Transpl Inst 2025;3(Suppl. 1): S127-S133

Review

CARES: Improving Quality of Life for Patients with Chronic Illnesses and their Family Caregivers

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Abstract

CARES, is a novel integrated screening and stepped collaborative care intervention developed for those with chronic illnesses and their family caregivers. This paper provides a history of collaborative care and the findings of Phase I-III trials in oncology and nephrology as well as transplantation. CARES is currently being testing in Hybrid Type I and II effectiveness-implementation cluster randomized controlled trials in oncology and nephrology, respectively.

Keywords: Stepped collaborative care, chronic illness, caregiving, oncology, nephrology, transplant

Please cite this article as "Steel J. CARES: Improving Quality of Life for Patients with Chronic Illnesses and their Family Caregivers. J Inonu Liver Transpl Inst 2025;3(Suppl. 1): S127-S133".

History of Collaborative Care

Collaborative care may be defined as integrated care designed to treat mental health conditions in medical settings.[1] From 1990 to 1996 several collaborative care trials were funded by the National Institute of Mental Health (NIMH) and the Agency for Healthcare Research and quality (AHRQ) were being conducted to improve the management of depression in the primary care setting.[1,2] As a result of these trials, Wagner's Chronic Care Model was developed and the primary goal was to transform the care of patients with chronic illnesses to be proactive rather than reactive (Fig. 1).

The Chronic Care Model includes five key elements critical to improving outcomes.[1] These elements included (1) the delivery system was designed where each patient had proactive follow-up visits or phone contacts, (2) monitoring of adherence and treatment response, (3) a registry was development to track care according to the individual's treatment plan, and (4) self-management training and support was provided to the patient and/or family, and (5) decision support was provided to the physicians to access guidelines, expert systems, and consultation.[1]

A seminal trial, the IMPACT trial, demonstrated the effectiveness of collaborative care in over 1800 patients.[3] Similar to many of the earlier trials, the collaborative care approach included pharmacological treatment of depression with brief psychotherapy, most often problem solving therapy, to manage depression.[3] After this trial, Unutzer and colleagues have further refined the principles of collaborative care to include (1) a patient centered care team, (2) population-based care, (3) measurement-based treatment to target, (4) evidence-based care, and (5) accountable care. Over 90 randomized controlled trials and several meta-analyses have been conducted to demonstrate that

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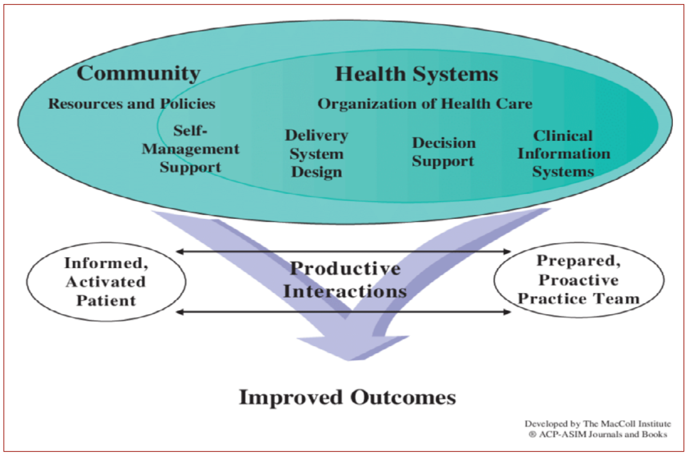

Figure 1. The chronic care model.

the collaborative care model is more effective than usual care for patients with comorbid depression, anxiety, and other mental health conditions. This approach has been shown to be effective across chronic conditions including cancer, diabetes, cardiovascular disease, and HIV.[4] Collaborative care has been also shown to be effective in those from different racial and ethnic groups and under resourced communities.[5] The collaborative care approach has also been demonstrated to be cost-effective in several meta-analyses.[6-9]

CARES: A Novel Stepped Collaborative Care Intervention

For decades the American Society for Clinical Oncology (ASCO), American College of Surgeons' Commission on Cancer (CoC), the National Comprehensive Cancer Network, and the Center for Medicaid and Medicare Services (CMS) have recommended that cancer centers screen and treat symptoms such as distress (depression and anxiety) and pain.[10-13] Despite the recommendations, and incentives (e.g., CMS Oncology Care Model, ASCO accreditation) to screen and treat these symptoms, the current standard of care (e.g., screening and referring patients for treatment) is ineffective at reducing symptom severity, improving patient HRQoL, and/or reducing unplanned health care utilization and costs as was originally intended with the guidelines.[14,15] Many cancer centers still do not routinely screen patients due to the time and resources required.[16]

Further, if patients are screened and have symptoms in the clinical range and are referred to treatment, multi-level barriers (e.g., patient, provider, health care system) exist that prevent the initiation and/or completion of treatment.[14,16] Consequently, the goal to improve patient HRQoL, by screening and referring patients for treatment, has not been relaized.[14] Steel and colleagues developed a solution to solve this problem, an integrated screening and stepped collaborative care intervention, CARES. The screening is integrated with treatment and the treatment is based on the principles of collaborative care.

In the first Phase I randomized controlled pilot trial, Steel and colleagues enrolled 28 patients comparing the intervention (later names, CARES) to an attention-standard of care arm.[17] While the intervention followed the principles of collaborative care, rather than pharmacological treatment being primary, psychotherapy was the primary modality of treatment with adjustments in medications for depression or anxiety if recommended.[17] The intervention initially included a combination of psychoeducation, cognitive-behavioral therapy, supportive-expressive therapy, and collaboration with the patients' psychiatrist, primary care physician, and/or oncologist to adjust or initiate pharmacological treatment.[17] Patients diagnosed with hepatobiliary cancer would receive 3-4 face-to-face sessions when the patient visited their oncologist or surgeon and 5-6 telephone contacts.[17] Patients who were randomly assigned to the intervention arm of the study reported clinically, but not statistically, significant improvements on symptoms of depression and anxiety, disease-related symptoms and treatment side effects, health-related quality of life (HRQL), and modest improvements in peripheral blood leukocytes were observed when compared with the standard of care group.[17]

At the same time as the first trial was conducted, a consensus statement by the National Institute of Health on cancer-related symptoms concluded that the three most common and distressing symptoms for those diagnosed with cancer were depression, pain, and fatigue.[18] It is estimated that approximately 50% of patients report one or more of these symptoms in the clinical range.[19,20] These symptoms are associated with increased morbidity and mortality.[18,21-25]

Steel and colleagues then performed a Phase II trial of CARES funded by the National Cancer Institute. The aim of this study was to examine the efficacy of a collaborative care intervention in reducing depression, pain, and fatigue and improve quality of life.[20] A total of 261 patients with advanced cancer and 179 family caregivers were randomized to a web-based collaborative care intervention or enhanced usual care.[20] The NCI reviewers recommended that family caregivers be included in the study as proxy raters as the patients with hepatobiliary cancers often presented at advanced stages and they were uncertain if patients would be able to complete outcome measures as the disease progressed.[20] We decided to also assess caregiver outcomes not only proxy ratings of patient outcomes. This proved to be an important decision as we have since observed reductions in these caregiver symptoms such as depression and stress with improvements in patient quality of life.

During this trial, we integrated the screening of patients with the treatment. Once a patient was screened the treatment team reached out to the patient to initiate treatment. In this iteration of CARES the intervention included (1) a website with written and audiovisual self-management strategies, a bulletin board, and other resources; 2) visits with a care coordinator during a physician's appointment every 2 months; and 3) telephone follow-up every 2 weeks.20 Primary patient outcomes included measures of depression, pain, fatigue, and health-related quality of life. Secondary outcomes included Interleukin (IL)-1α, IL-1β, IL-6, and IL-8 levels, Natural Killer (NK) cell numbers, and caregiver stress and depression.[20]

At the baseline, 51% of the patients reported 1 or more symptoms in the clinical range.[20] For patients who presented with clinical levels of symptoms and were randomized to the intervention, reductions in depression, pain, and fatigue and improvements in quality of life were observed when compared to those in the enhanced usual car arm at 6 months which included patients receiving educational information and referral to treatment in their community.[20] We also observed in the CARES arm reductions in IL-6, IL-1β, IL-1α, and IL-8 and increases in NK cell numbers when compared to the enhanced usual care arm at 6 months.20 We also observed reductions in caregiver stress and depression were observed at 6 months for caregivers whose loved ones were randomized to the intervention arm.[20]

At the same time, the Symptom Management Research Trials (SMART) trial in the United Kingdom which was a pharmacotherapy-based collaborative care intervention for depression which was found to be effective for those with cancer.[25] Walker and colleagues also recommended the need for integrated screening and evidence-based treatment for those with depression.[20,26]

CARES includes a "stepped" care approach which includes measuring the patients response every 4 weeks and providing individualized treatment (e.g., additional sessions, pharmacotherapy) until symptoms have been effectively reduced.[27] Our novel stepped collaborative care intervention delivers CBT via telemedicine as the primary treatment modality, unlike other collaborative care approaches in which pharmacotherapy is often the primary modality.[28] Moreover, CARES targets not only depression but also pain and fatigue, the three most common and distressing symptoms in those with cancer.28 The duration of treatment is 6-24 weeks depending on the number and type of symptoms the patient reports at the time of screening.[20,26,28] CARES can also include pharmacotherapy to reduce symptoms, if preferred by the patient and the symptoms are not effectively reduced with CBT alone.[20,26,28] The care coordinator collaborate with the oncologist as well as the patients' primary care physician (PCP) and/or psychiatrist in the patients' community to initiate or change medication (Fig. 2).[20,26,28]

In our Phase III trial of CARES we observed that patients randomly assigned to CARES were more likely to initiate treatment (75%) than patients who were referred to a provider (standard of care arm, 4%).[26] Statistically, and clinically meaningful, improvements in HRQoL through reductions in symptom burden as well as lower unplanned health care utilization (e.g., ER visits, 90-day readmissions) and cost savings of $17,085 per patient per year were observed with CARES when compared to SC.[26] A large body of research has found that family caregivers of those caring for loved ones with dementia and more recently cancer, are at increased risk of cardiovascular disease.[29,30] In the general population, treating stress and depression have been shown to reduce risk of cardiovascular related mortality.[31] As a result of our findings from our Phase II trial, we assessed cardiovascular risk in family caregivers as an outcome. We observed that when the patients' quality of life improved with CARES that the family caregivers, of patients randomized to CARES, also had reductions in lifetime risk of

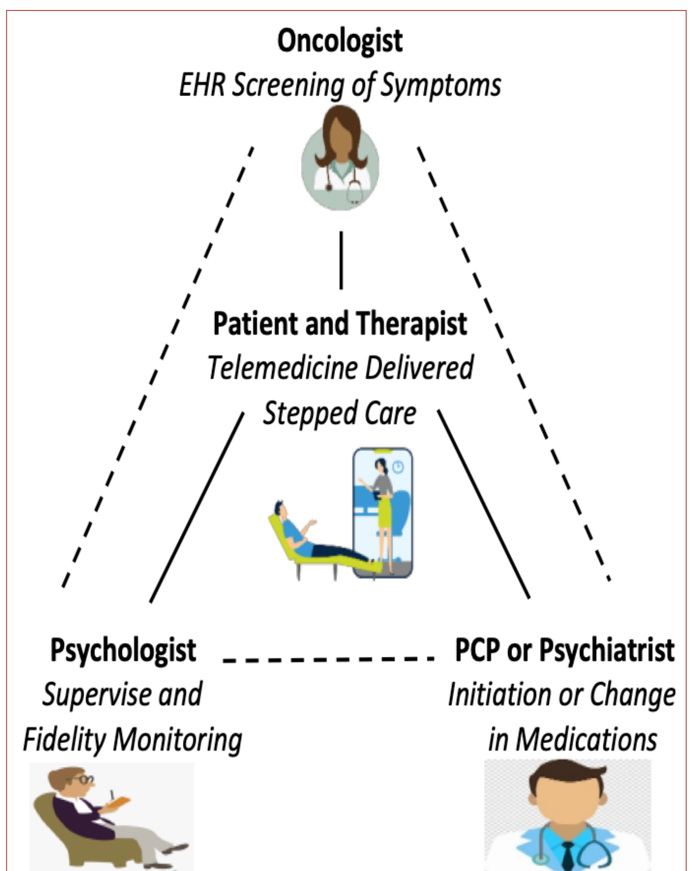

Figure 2. Novel collaborative care approach.

cardiovascular disease as measured by the American College of Surgeons ASCVD risk calculator.[26]

While we believed integration, of screening and treatment, is critical for patient initiation of treatment, and ultimately better patient HRQoL, we found through a pilot of implementing the electronic health record (EHR) screening, the importance of an evidence-based treatment in addition to integrated screening and treatment. Consecutive patients were screened December 12, 2022 and January 15, 2025 using the EHR using a 3-step process to reduce health disparities (e.g., patient portal, tablet at the front desk, and/or verbal administration by the medical assistant).[32] Patients who screened positive were automatically referred to the treatment team who had therapeutic orientations including humanistic and psychoanalytic approaches. Patients' symptoms were assessed every 6 months.[32]

Of 169 patients were contacted by the treatment team, 21 (12.4%) reported thoughts of death or wanting to harm themselves on the PHQ-9, however only 1 (<0.05%) had active suicidal ideation.[32] A total of 56 (36.1%) initiated treatment. A significant reduction over time was observed with depressive symptoms at baseline 14.5 (SD=6.7) to 13.8 (SD=8.3) at 6 months to 11.3 (SD=7.1) at 12 months.[32] Similarly, reductions in anxiety from 14.9 (SD=4.3) on the GAD-7 to 11.8 (SD=7.6) at 6 months to 9.7 (SD=7.1) at 12 months were observed.[32] A trend was observed over time in which patients reported a decrease in pain intensity and interference from 6.2 (SD=1.1) on the PEG to 2.1 (SD=2.6) at 6 months to 0 (SD=0). Of those who initiated treatment, no significant differences were observed on depressive symptoms or anxiety.[32] Due to the lack of expertise in pain management by the treatment team, patients with cancer-related or chronic pain were referred to specialized treatment for pain based on reported etiology. While the sample size was small and so the conclusions should be interpreted cautiously, robust evidence-based interventions are warranted to observe clinically meaningful changes in symptoms.[32]

Traditionally, new psychosocial and/or health interventions have been tested in a staged approach which has focused on ensuring that interventions perform well in ideal conditions before considering translation to real-world practice.[33,34] As a result, translation from the research to practice setting is associated with significant delays.[33,34] Experts argue that the process of moving evidence-based interventions from the research to clinical or real-world practice setting can be expedited by using "hybrid" type trials that blend elements of effectiveness (Phase IV) and implementation research (Fig. 3).[33,34] Based on the findings of our Phase III trial and clinical pilot testing integration without

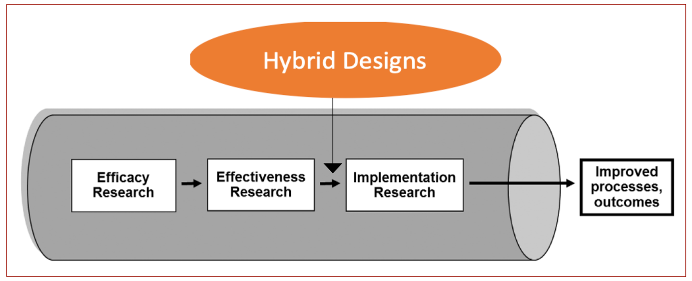

Figure 3. Traditional Research Pipeline and Hybrid Design.

evidence-based treatment, we proposed a Hybrid Type I effectiveness-implementation cluster randomized trial which is currently underway. We will employ the EHR and non-EHR screening (for community cancer centers who may not have Epic) which takes patients approximately 2 minutes to complete, in the patient's health portal prior to their appointment. Studies that use patient portals to screen patients have been shown to result in health disparities.[35-37] As a result, we have added two additional steps (e.g., tablet at the front desk and verbal administration while rooming patients). If a patient reports symptoms in the clinical range are then automatically sent to the CARES treatment team. The medical team does not need to perform any action or place an order to connect the patient with the treatment team.

The proposed study will employ a Hybrid Type I effectiveness-implementation cluster randomized design which will not only examine effectiveness but will also begin to examine the "implementability" of CARES including cost- saving and effectiveness. We will evaluate, using the recently updated RE-AIM framework, the uptake of CARES by patients and health care providers and anticipated barriers to and facilitators of its successful integration into practice.38-41 The findings of this study will provide the necessary information for cancer centers, or other stakeholders (e.g., CMS), to better understand the effectiveness, and cost- savings and effectiveness, of CARES under real world conditions. We anticipate that we will uncover several important barriers to adoption, implementation, and maintenance (e.g., sustainment), necessitating additional implementation strategies to be operationalized/tested in future hybrid type II/III trial.[33,34] This proposed pragmatic trial meets the Readiness Assessment for Pragmatic Trials (RAPT) criteria and is the next logical step in moving CARES from research into clinical practice.[42]

While the focus on improving patient HRQoL is imperative, demonstrating cost- and effectiveness is beneficial for the potential adoption and sustainability of CARES in clinical practice. The Hospital Readmissions Program (HRP) was introduced in 2012 in the U.S. as unplanned readmissions were resulting in higher rates of morbidity, mortality, and healthcare costs. Since that time, several strategies have been tested to reduce unplanned readmissions secondary to the negative effect of these unplanned readmissions on patient morbidity, hospital revenue (e.g., lower reimbursement, penalties), operations, and CMS Quality Star Rating. In 2015, episode-based payment models were introduced and readmissions within 90-days also resulted in lower reimbursement rates. Two of the symptoms, depression, and pain, have been long associated with higher rates of emergency room visits, unplanned readmissions, and longer length of stay in the hospital.[7-8,36] Therefore, in our Phase III trial we focused on 30- and 90-day readmissions as well as associated events (e.g., emergency room visits, length of stay in the hospital) and activity based costs linked to these unplanned health care events.[9] For the proposed effectiveness-implementation trial, we plan to further evaluate the cost savings with a larger and more "real world" sample as we have added additional program costs including fidelity monitoring, leveraged by artificial intelligence, and case tracking software to be able scale up CARES efficiently. Further, we will also evaluate overall cost-effectiveness using cost per quality-adjusted life year based on established benchmarks that we did not include in the Phase III trial.[9,83] We will also assess financial toxicity and cost coping and while it is unlikely that we will observe a reduction in a short period of a year, it will provide important information across cancer types and stages.

The findings from this study have the potential to shift the paradigm of screening and treatment nationwide resulting in improved patient centered outcomes for those diagnosed with cancer. The evaluation of the facilitators and barriers of CARES in a real-world clinical setting will critically inform future implementation and allow for the development of best practices for cancer centers across the nation who want to implement CARES. The goals of the study reflect the mission of the NCI which includes testing strategies to overcome barriers to the adoption, effectiveness, scaling-up, and sustainability of evidence-based interventions focused on improving HRQoL of patients with cancer.

The CARES intervention has been demonstrated to be efficacious not only in the setting of oncology but also nephrology and renal transplant. We have tested CARES in Phase II and III trials in patients with end stage kidney disease on in center hemodialysis. The Phase II trial demonstrated the feasibility of CARES and preliminary efficacy in reducing depression, pain, and/or fatigue. Patients met weekly with a therapist for eight sessions, each 45-60 min, during HD sessions via a video-conferencing platform. Of 10 patients screened, 100% screened positive for at least one symptom, 100% of eligible patients consented, and eight (of 10) completed the intervention (mean age 59 years, 50% male, 50% African American).43 Satisfaction with the intervention was high, and seven of the eight patients completed all eight prescribed sessions. Preliminary results indicate improvement in SF-36 Physical Component, and four of the six patients (67%) with clinically elevated pain at baseline reported improvement at follow-up.[43]

As a result of the findings from our Phase II trial, a parallel-group, single-blinded, Phase III randomized clinical trial was conducted to test the stepped collaborative care intervention to reduce fatigue, pain, and/or depression.[44] The stepped collaborative care intervention group received 12 weekly sessions of cognitive behavioral therapy delivered via telehealth in the hemodialysis unit or patient home, and/or pharmacotherapy using a stepped approach in collaboration with dialysis and primary care teams.[44] The attention control group received 6 telehealth sessions of health education. In the intention-to-treat analyses, when compared with controls, patients in the intervention group experienced statistically and clinically significant reductions in fatigue and pain severity at 3 months.[44] These effects were sustained at 6 months.[44] Improvement in depression at 3 months was statistically significant but small.[44]

Patients awaiting kidney transplant also carry a high symptom burden which has been associated with waitlist inactivation, mortality, and poorer post-transplant outcomes. However, few studies have tested the effects of symptom management interventions in this population. The Phase II randomized controlled trial designed to test the efficacy of CARES-Transplant versus standard of care (SC).[45] Nineteen patients (mean age = 65±6 years, 74% male, 90% White) and 8 caregivers were randomized to CARES or standard of care (screening and referral to treatment).[45] Reductions in pain intensity and interference were observed for CARES while patients in the SC arm had increases in pain intensity and interference.[45] Similar trends were observed for fatigue and depressive symptoms.[45] Lower rates of transplant-related complications, fewer emergency room visits and 90-day readmissions were also observed.[45] A moderate to large effect size was observed for changes on caregiver reported depressive symptoms and sleep quality.[45] The findings of this pilot study warrant a Phase III trial to test the efficacy of CARES-Transplant.[45]

The novel integrated screening and stepped collaborative care intervention (CARES) has been demonstrated to be efficacious across chronic illnesses including cancer and end stage kidney disease, including those awaiting transplant. The teams are currently moving the intervention from research into clinical practice with two implementation studies spanning over 70 cancer center clinics as well as in dialysis clinics across six states. The findings from this trial will contribute to understanding the effectiveness of the CARES intervention but also to the barriers and facilitators to implementing CARES into clinical practice across medical settings.

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