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EDITORIAL



THE INSTITUTE FOR  
INTEGRATIVE HEALTH



## Moving Integrative Health Research from Effectiveness to Widespread Dissemination

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**T**HIS PHILANTHROPICALLY BACKED *JACM Special Issue on Effectiveness, Implementation and Dissemination Research in Integrative Health* highlights how research on many complementary and integrative health (CIH) practices has moved beyond efficacy studies to progress further along the implementation and dissemination pipeline. This pipeline moves from “preimplementation” or effectiveness studies to implementation of evidenced-based integrative health approaches into practice, and eventually to widespread dissemination, which spurs sustainment.

Real-world research to help the public, academic researchers, health care and policy decision makers, and other stakeholders understand the optimal uses of CIH practices has never been as important as it is today. The twin crises of increased prevalence of depression and elevated chronic pain, plus high levels of opioid use, have played key roles in the increase in patient and provider interest in nonpharmacologic approaches for health management. In addition to increased interest, the evidence of efficacy for several CIH practices has become solidly established for numerous health conditions.<sup>1–7</sup>

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These forces have led to significant movement toward supporting CIH deployment in health care systems, national health strategies,<sup>8</sup> and national treatment guidelines. For example, several CIH practices have been part of the American College of Physicians (ACP) and American Academy of Family Physicians pain treatment guidelines.<sup>9–10</sup> Three years ago, the nation's largest integrative health care system, the Veterans Health Administration (VA), deemed nine CIH practices to be medical treatment as part of their Whole Health medical transformation,<sup>11</sup> something that no other health care system in the world has done to this degree. Globally, the World Health Organization's Traditional, Complementary, and Integrative Medicine initiative urges member nations to determine how CIH practices can be useful in meeting the WHO goal of universal health care.<sup>12</sup>

Given this increased need for and interest in CIH practices, the growing number of studies demonstrating CIH practice efficacy, and growing national and international policy and health care system support, it is critical that scientists move beyond efficacy studies (for the more well-established CIH practices) to examining effectiveness, implementation, and dissemination of CIH practices in real-world clinical settings.

The authors, along with John Weeks, *JACM*'s Editor-in-Chief at the time, who codeveloped this project, would like to thank the philanthropic investors, The Institute for Integrative Health and the George Family Foundation, for funding this special issue to highlight studies of CIH practice effectiveness, implementation, and dissemination (see organizational logos). Importantly, bringing together these studies in this special issue also allows for a review of the methodological strengths in these studies, which can serve as examples for overcoming existing challenges in CIH research. The authors also would like to thank the Special

Issue Advisory Team, which includes the 12 members shown hereunder, for guiding this issue. Finally, the authors would like to thank Drs. Dave Clark, Emmeline Edwards, Peter Murray, and Helene Langevin, members of National Institutes of Health National Center for Complementary and Integrative Health (NCCIH) leadership, for their excellent commentary on implementation science in CIH.

This special issue includes a wide variety of peer-reviewed articles to showcase how CIH researchers are addressing the three phases of effectiveness, implementation, and dissemination research in several countries across the world (e.g., Taiwan, Australia, Switzerland, and the United States). For example, researchers are conducting *preimplementation/effectiveness* phase studies of multimodel CIH programs available in the hospital or outpatient settings or are examining medical records to determine acupuncture effectiveness among patients with osteoarthritis and coronary heart disease. Other studies examine CIH *implementation*, with one using hybrid designs to simultaneously examine effectiveness and implementation, and another study examining the uptake of clinical guidelines recommending CIH practices. The third group of studies explores CIH practice *dissemination and sustainment* in usual care, with one study examining the business case for CIH practices and another demonstrating CIH practice dissemination across a large health care system.

### Preimplementation or Effectiveness Phase

After an intervention has recognized efficacy and before an intervention is ready for implementation, its effectiveness should be demonstrated. This issue presents five articles examining effectiveness, three of which examine multimodal CIH programs, such as are increasingly being explored in health care systems in response to the complexity of chronic

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conditions. The first, by Vitale and colleagues, examined a 4-week multimodal CIH program they developed to address risk factors of suicide. The multimodal program was an intensive (3 hours/day, 5 days/week) 4-week program comprising acupuncture, yoga, transcendental meditation, dance therapy, music therapy, emotional freedom technique, and other wellness activities. Among 126 veteran participants at risk for suicide, their program showed high engagement and improved participants' suicidal ideation, depression, and hopelessness. In a subset of veterans with history of suicidal ideation or attempt, the program also improved their pain, post-traumatic stress disorder (PTSD)/anxiety symptoms, and stress/coping.

The second study examining a multimodal CIH program, by Dusek and colleagues, utilized an EPIC-based medical record to evaluate the impact of CIH practices on pain intensity in a real-world cohort of hospitalized patients in a large Midwestern Hospital in the United States. The authors found that post- to preintervention pain intensity scores decreased at clinically meaningful and clinically significant levels across the sample of over 3600 unique hospital admissions. Across various clinical populations (including cardiovascular, neuroscience/spine, orthopedic, and oncology), there were differences in the degree of pain relief reported. Importantly, for the first time, this team was able to account for pain medication status at the time of the CIH session. The authors found that patients who were not taking any pain medications at the time of CIH session had the same level of pain reduction as patients who were taking narcotics or nonsteroidal anti-inflammatory drugs or both. The authors conclude that future research is needed to determine optimal implementation and use of CIH practices in hospital settings.

The third multimodal effectiveness study, by Abadi and colleagues, examined a peer-led group-based 9-week pilot program that aimed to teach outpatients "to become empowered to engage in their own health and well-being through mindful awareness practices, self-care strategies, and setting life goals," using whole health concepts, tools, and strategies that are now branded as such and have been implemented in many of the 170 VA medical centers in the United States. Their results showed the class reduced their perceived stress and improved their mental health, quality of life, and patient engagement.

The fourth effectiveness study was a randomized trial of a trauma-sensitive yoga intervention versus a standard PTSD treatment—cognitive processing therapy (CPT), with both being delivered in an PTSD outpatient clinic to women veterans with PTSD due to military sexual trauma. Their study rationale was that CPT can be expensive relative to yoga, and women often ask for CPT treatment alternatives. The yoga intervention focused on interoception (i.e., the sense of the physiological condition of the body and "addresses themes related to establishing safety, individual choice, being in the present moment, and taking effective action"). They found the yoga intervention and CPT control groups had similar "clinically meaningful decreases in PTSD symptom severity and PTSD diagnosis" but that the yoga intervention had higher adherence.

The fifth effectiveness study, by Ton and colleagues, took a different approach by conducting a nationwide matched cohort study to examine the risk of coronary heart disease among patients with and without osteoarthritis, among those

who did and did not receive acupuncture, given patients with osteoarthritis are more likely to develop coronary heart disease than the general population. They used electronic records from Taiwan's National Health Insurance Research Database. Their results showed that the osteoarthritis non-acupuncture cohort had a higher risk of developing coronary heart disease than the osteoarthritis-acupuncture cohort, and the nonosteoarthritis cohort had a higher risk of developing coronary heart disease than the osteoarthritis acupuncture cohort. Given the observational nature of the study, the authors note that randomized controlled trials of patients are needed to confirm their observational findings.

### Implementation Phase

Four articles address CIH practice implementation. Since the field of implementation science's inception over 15 years ago,<sup>13</sup> empirical data on 73 implementation strategies exist, and the field of CIH has not yet reached consensus on which strategies are more important.<sup>14,15</sup> As such, it can be difficult to determine which set of strategies to study or use. Roth and colleagues offer one solution to this dilemma by describing how they applied an "implementation mapping"<sup>16</sup> method to identify theory-driven barriers and facilitators to implementation and strategies to overcome those barriers to guide the implementation of outpatient integrative medicine group visits. The authors write that implementation mapping "is based upon and closely mirrors intervention mapping, a process for designing health behavior interventions" and "offers a systematic process for selecting the implementation strategies needed to overcome barriers to implementation by considering relevant behavioral theories and stakeholder input. Utilizing a systematic process enhances replicability, while utilizing relevant theory enhances potential to identify mechanisms of action of implementation strategies," both of which "are key to enhancing the rigor of implementation science." They used the Consolidated Framework of Implementation Research<sup>17</sup> to guide their efforts and determined numerous implementation strategies, as well as implementation barriers and facilitators.

Two studies further delve into issues of barriers and facilitators to CIH implementation. Bolton et al. examined a key health care innovation implementation factor, that of medical center leadership support. They applied Greenhalgh's Diffusion of Innovation framework<sup>18</sup> to elicit health care leaders' reasons for providing or withholding support for CIH programs at the individual, interpersonal, organizational, and health care system levels, among 48 health care leaders at seven medical facilities that had at least three CIH programs. Their respondents provided numerous but consistent implementation themes at these levels. As such, the authors concluded that efforts to "shift individual attitudes alone may be insufficient for securing leaders' support without attention to broader organizational and system-level contextual issues."

Hunter and colleagues explored the prevalence of integrative oncology programs across Australia and the barriers and facilitators to the implementation of those programs. They used a mixed-methods approach, using a survey among all public and private sector health care organizations that provide clinical care to cancer survivors and focus group interviews and an online survey of cancer survivors to further

contextualize their data. Not surprisingly, they too found numerous barriers and facilitators to integrative oncology service implementation at the system and patient levels, leading the authors to conclude that implementation was “more complex than building the evidence-base and demonstrating value to justify funding” and that “providers require more guidance on clinical governance, business models, local service gaps and inter-professional collaboration.”

National health care policies and clinical guidelines clearly play an important role in supporting health care intervention implementation. However, clinicians often do not follow clinical guidelines for a variety of reasons. In the United States, the ACP produced the 2017 and 2020 low back pain treatment guidelines, which included recommendations for a variety of CIH practices.<sup>9–10</sup> Given the widespread prevalence of low back pain, two very different studies were selected examining the critical issue of the degree to which physicians follow these ACP guidelines. In the first, Goertz and colleagues used a large national survey subset of patients with low back pain to examine their providers’ treatment recommendations, while the second study, by Roseen and colleagues, took a qualitative approach to interview providers on their low back pain treatment recommendations. Goertz’s study examined 1035 people with low back pain among a Gallup poll survey of a demographically representative sample of 12,998 U.S. adults. Among those who consulted a physician, 81% reported the physician recommended drug and nondrug therapies for low back pain. Over a third said their doctors recommended massage, acupuncture, or spinal manipulation, with 68% or more following each of those recommendations. The authors also report on respondents’ use of nonpharmacologic therapies *without* an MD’s recommendation and showed that 41% reported using yoga, stretching, or other exercises; 26% reported using massage and 19% reported using spinal manipulation.

Roseen and colleagues’ study used brief structured interviews with 72 primary care providers in three community-based outpatient clinics to elicit their familiarity with the ACP guidelines and how they managed patients with acute/sub-acute and chronic low back pain. Due to socioeconomic and racial/ethnic disparities in access to and outcomes of low back pain treatment, the authors purposely selected the clinics based on their area-level “disadvantage,” to select an academic primary care group in a high-income neighborhood, a community health center serving predominantly Latinx patients, and a federally qualified health center in a low-income neighborhood. The authors found that most primary care providers reported being familiar with the ACP guidelines, but none advised patients with acute low back pain to use the ACP-recommended nonpharmacologic treatments. For patients with chronic low back pain, 85% of physicians did recommend these treatments, but most recommended physical therapy with few recommending the CIH therapies.

Many researchers now simultaneously examine both the effectiveness and implementation of interventions using hybrid study designs.<sup>19</sup> One such study in this special issue conducted by Siebenhuener and colleagues examined both effectiveness (patient symptoms) and implementation (adherence) outcomes of a mindfulness and relaxation app they developed and tested among cancer patients. They found that the app reduced participants’ distress and sev-

eral other patient-reported outcomes. However, they discovered that participants’ adherence to the app was stronger among those whose distress was at moderate levels or in whom distress increased, while their adherence was reduced among those whose distress improved. To interpret this interesting finding, they posit that their app’s effectiveness (a reduction in distress) actually led people to use it less.

### Dissemination or Sustainment Phase

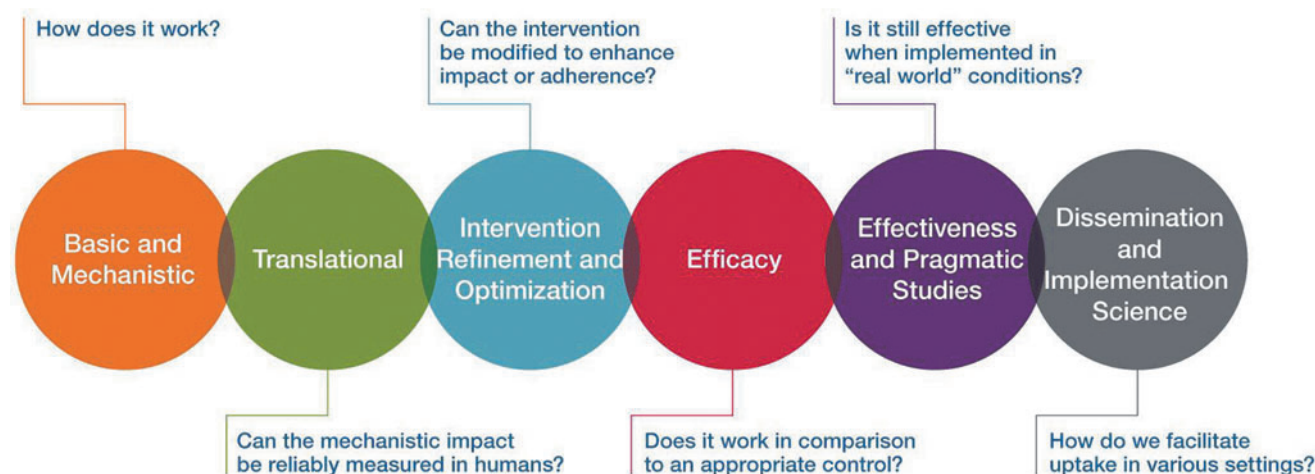
Farmer and colleagues conducted the first in-depth survey of the dissemination of CIH programs across all medical centers in the United States’ largest integrated health care system, the VA. They examined the delivery of 27 CIH and other nonpharmacologic therapies, assessing the type of departments in which they were located and the types of providers delivering them, the visit format, and geographic variations in availability. They found CIH provision in the VA to be widespread, with over 1500 CIH programs being available in 2017–2018. Sites offered an average of 5 CIH practices and 63 sites offered 10 or more such practices. The authors found the five most common CIH practices were relaxation techniques, mindfulness, guided imagery, yoga, and meditation. Importantly, all five of these practices fall under a general “mind–body” category. Given the rise in patients’ interest in nonpharmacologic options to manage their health, the authors concluded that the VA “is well-positioned to meet that demand.”

A key part of sustaining any evidence-based treatment is building the business case for its use. The above-mentioned Taiwan-based study conducted by Ton and colleagues on the effectiveness of acupuncture also examined the costs associated with its use. Understanding the cost implications of any CIH use is essential for building the business case for its sustainment in health care.<sup>20</sup> They examined the average daily hospitalization and outpatient care expenditures of diagnosed osteoarthritis and nonosteoarthritis patients for up to 5 years. They found that patients with osteoarthritis who were treated with acupuncture had lower medical expenditures than either the osteoarthritis nonacupuncture or non-osteoarthritis cohorts.

Finally, the commentary by NCCIH’s leadership provides thoughtful and significant instructional guidance on dissemination and implementation science studies. The commentary begins by stating that NCCIH supports “the full continuum of the biomedical research pipeline, whereby a complementary health intervention moves from basic and mechanistic research, through efficacy trials, through dissemination and implementation.” Not explicitly mentioned, but what is required from this perspective, is a continued evaluation of effectiveness or preimplementation research *after* the efficacy research has been conducted but before the dissemination and implementation research (Fig 1.). The authors then stress the importance of conducting CIH implementation and dissemination studies, and especially studies using *implementation science*.

A goal of conducting dissemination and implementation studies, the authors write, can be “to decrease the time between establishing the evidence base of interventions and the widespread uptake and adoption of these interventions.” The authors clarify that “dissemination research asks, are

## NCCIH Framework for Clinical Research



**FIG. 1.** NCCIH framework for clinical research. NCCIH, National Center for Complementary and Integrative Health.

the relevant clinicians and target population aware of the novel evidence-based intervention(s),” and “implementation science focuses on, how can these novel evidence-based intervention(s) be more widely and rapidly used in practice?” while implementation science studies are those that “that test strategies to address implementation at multiple ecological levels is a high priority to NCCIH.” Informative instructional guidance is provided on the nature of implementation science for researchers who are less familiar with this field, offering that it (1) “assesses more than just barriers and facilitators,” (2) “evaluates specific implementation strategies and characterizes the extent that the intervention is modified within the context of the implementation strategy and health care delivery setting,” and (3) addresses the question, “how can these novel evidence-based intervention(s) be more widely and rapidly used in practice?” The commentary includes informative sections on definitions, the level of evidence needed to begin considering implementing an intervention, how to differentiate implementation science from implementation and dissemination, methods/measures to use, implementation science frameworks, study designs, and apply it all to the field of CIH practices. The NCCIH commentary concludes by noting NCCIH’s future directions and intention to support implementation science among its portfolio of funded research.

Indeed, NCCIH’s desire to support future implementation science is made explicit in language below which is taken from the draft of the 2021–2025 NCCIH Strategic Plan (<https://files.nccih.nih.gov/nccih-strategic-plan-2021-2025-draft.pdf>). “Research has shown that nonopioid pain management interventions can be effective for treating acute and chronic pain. More support is needed to assess the impact of evidence-based health care strategies and clinical practices and procedures when they are included in health care systems. Pragmatic and implementation trials could identify strategies to most effectively implement evidence-based interventions and pain management guidelines.” The authors wholeheartedly affirm NCCIH’s future direction.

This *JACM Special Issue on Effectiveness, Implementation and Dissemination Research in Integrative Health* has provided an opportunity for the field of integrative health research to highlight key studies within the effectiveness, implementation, and dissemination domains of research. It also emphasizes the variety of study designs, methods, measures, and outcomes being assessed across each of these domains. An area of focus for those involved in this research is to coalesce around the optimal ways of conducting CIH effectiveness, implementation, and dissemination research, to move the field forward while also ensuring a high standard of methodological rigor in this research. The work of researchers, who are part of coalitions all using the same outcome measures in studies of integrative health interventions (such as those in the NIH-DoD-VA Pain Management Collaboratory<sup>21</sup> or the BraveNet Practice-Based Research Network<sup>22</sup>), should be shared and widely used. This sharing can encourage a consistent use of outcome measures, the formation of a community of practice of researchers looking to move the needle on the effectiveness of CIH, implementation of evidence-based CIH therapies in routine care settings, and dissemination of best practices widely to ensure sustainment. The overall goal of all CIH effectiveness, implementation, or dissemination research is to improve health of the population. The authors hope you will agree that highlighting these studies and their methodological strengths in this special issue is an important step in that direction.

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