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Adaptations to Acupuncture and Pain Counseling Implementation in a Multisite Pragmatic Randomized Clinical Trial

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Abstract

Objectives: As part of a pragmatic effectiveness trial of integrative pain management among inpatients with cancer, the authors sought to understand the clinical context and adaptations to implementation of two study interventions, acupuncture and pain counseling (i.e., pain education and coping skills).

Design: The larger study uses a 2×2 factorial design with inpatients randomized to: (1) usual care (UC), (2) UC with acupuncture, (3) UC with pain counseling, and (4) UC with acupuncture and pain counseling. The study is being conducted in two hospitals (one academic and one public) and three languages (Cantonese, English, and Spanish). The authors conducted a process evaluation by interviewing study interventionists. Analysis included deductive coding to describe context, intervention, implementation, and inductive thematic coding related to intervention delivery.

Results: Interviewees included seven acupuncturists and four pain counselors. Qualitative themes covered adaptations and recognizing site-specific differences that affected implementation. Interventionists adhered closely to protocols and made patient-centered adaptations that were then standardized in broader implementation (e.g., including caregivers in pain counseling sessions; working in culturally nuanced ways with non-English-speaking patients). The public hospital included more patients with recent diagnoses and advanced disease, more ethnically and linguistically diverse patients, less continuity of staffing, and shared patient rooms. At the academic medical center, more patients were familiar with integrative therapies and all were located in single rooms. Providing acupuncture to hospital staff was a key strategy to establish trust, experientially explain the intervention, and create camaraderie and staff buy-in.

Conclusions: Providing nonpharmacologic interventions for a pragmatic trial requires adapting to a range of clinical factors. Site-specific factors included greater coordination and resources needed for successful implementation in the public hospital. The authors conclude that adaptation to context and individual patient needs can be done without compromising intervention fidelity and that intervention design should apply principles such as centering at the margins to reduce participation barriers for diverse patient populations.

Keywords: acupuncture, pragmatic effectiveness, pain, cancer, implementation, inpatient

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Introduction

RANDOMIZED-CONTROLLED TRIALS (RCTs) are designed on a continuum from explanatory to pragmatic.¹ Explanatory RCTs aim for high internal validity to determine the efficacy of an intervention, but findings may have limited generalizability when study participants must meet narrow eligibility criteria, and standardized interventions are difficult to implement in clinical settings.^{2,3} Pragmatic trials have been lauded as a strategy to bridge the translational gap between traditional RCTs and clinical practice.⁴ Aimed at testing realworld effectiveness, pragmatic trials are typically designed to strengthen external validity while maintaining rigorous methodologic features to minimize potential biases.⁴

A challenge in pragmatic trials is the tension between standardized intervention delivery and adaptability for treating heterogeneous patients in varied clinical settings. Intervention fidelity and integrity are accepted as standards for successful study conduct. Yet, variation in intervention delivery is often necessary to be responsive to local contexts.⁵ Explicit evaluation of intervention fidelity, variation, and contextual factors is therefore a critical aspect of understanding study findings, particularly for complex interventions.⁶ Some pragmatic trials include feedback from patients or clinicians as part of intervention evaluation. Complementary and integrative health (CIH) pragmatic trials are less common, and CIH practitioners and their "voices"⁷ have rarely been included in studies of intervention fidelity.

Racial/ethnic minorities and individuals with limited English proficiency are underrepresented in clinical research,⁸ including studies of CIH.⁹ Homogeneous study participants limit the generalizability and relevance of research findings and impede widespread implementation of efficacious therapies. Clinical research that represents broader populations requires adaptation for patients who are linguistically, socioeconomically, and ethnically diverse. Such adaptations to study procedures cannot always be built into the interventions by design and even when they are, they may not be well tailored to an individual patient with intersectional identities and experiences. Process evaluation of complex interventions can include the perspectives of multiple stakeholders and describe study adaptations and tailoring to specific patient populations and study sites.⁶

Pain is common and burdensome for patients with cancer, particularly during hospitalization. One-third of cancer patients report not receiving adequate pain relief.¹⁰ Undertreatment remains a challenging issue, particularly among racial/ethnic minority patients.¹¹ Nonpharmacologic approaches are recommended as part of optimal management for cancer-related pain,^{12,13} but are underutilized in hospital settings. Integrative medicine offered as part of hospital services is promising, with observational studies indicating improvements in patient-reported outcomes in pain, anxiety, and sleep¹⁴⁻¹⁶; cost savings¹⁷; and potential to enhance overall quality of care by addressing gaps in biomedical treatment and empowering patients.^{18,19} As part of a comparative effectiveness trial of integrative pain management among inpatients with cancer, the authors sought to understand the clinical contexts affecting implementation of two study interventions, acupuncture and pain counseling (i.e., pain education and coping skills). Specifically, they describe how study interventions were adapted for local hospital contexts and procedures were tailored to support the inclusion of diverse study participants.

Materials and Methods

Interventions

Acupuncture and pain counseling were offered as part of the pragmatic trial at two hospital sites, one academic medical center and one public hospital. Acupuncture sessions adhered to a treatment manual detailing selection of points, needling procedures, and treatment duration. Pain counseling comprised assessment of the patient's pain, education about pain, and coping skills including diaphragmatic breathing, progressive muscle relaxation, and guided imagery. Both interventions were offered once daily for up to 4 days during hospitalization and delivered in English, Spanish, or Cantonese. Acupuncture was separately offered to staff and hospitalized patients who were ineligible for the study.

Study design and participants

The authors conducted a qualitative process evaluation of how study interventions were implemented at both sites using interviews with study interventionists. They used the Medical Research Council (MRC)⁶ guidance on process evaluation of complex interventions and the Consolidated Framework for Implementation Research (CFIR)²⁰ to structure and guide the process evaluation. These frameworks are widely used to understand how to ensure implementation success across multiple contexts, which was important for implementing the same interventions in two different kinds of hospitals.

All 11 study interventionists (7 acupuncturists and 4 pain counselors who also work as clinical research coordinators [CRCs]) were invited and participated in an in-person interview. Six of the interventionists were employees at the academic health center before the study; remaining interventionists were hired explicitly for the study. All interventionists completed trainings relevant to their clinical and research roles, including institutional trainings on topics such as hospital safety protocols and protection of human subjects and study-specific trainings on intervention protocols and software for data management. Acupuncturists were privileged to practice within their professional scope at the hospital where they would be providing treatments. Onboarding of new study staff also included shadowing at the hospitals and introductions to all relevant hospital staff.

Data collection and measures

Interviews lasted up to 1 h and were audio-recorded and professionally transcribed. Acupuncturists were interviewed by a study team member with professional acupuncture training.^{6,20} Two authors developed an interview guide structured around the four main domains described by the MRC (description of intervention and causal assumptions, implementation, mechanisms of impact, and outcomes), drawing on five relevant domains of the CFIR (intervention characteristics, outer setting, inner setting, characteristics of the individual involved, and the process of implementation).

Analysis

Transcripts were coded and analyzed using thematic analysis,²¹ with ongoing input from all authors. Four authors, with experience in CIH research, developed a structured codebook using Dedoose to code.²² The authors coded deductively specifically for the MRC and CFIR domains described previously, and also inductively for any other intervention delivery/implementation issues stated. Each interview was independently coded by at least two authors followed by full team meetings to discuss and reconcile discrepancies and combine codes into larger themes.

Results

The 11 interventionists' demographics are in Table 1. The following sections first present patient-centered adaptations and then site-specific differences that led to necessary adaptations to the intervention protocol and practices.

Patient-centered adaptations as ongoing process

Study staff made patient-centered adaptations from initial recruitment through the treatment phase. The multilingual study was intentionally designed to be accessible to diverse patients seen at an academic medical or public hospital setting. Given these considerations, interventionists described the importance of tailoring for individual patients with some adaptations so relevant that they iteratively became part of the interventions.

Adaptations made for language, culture, and patient experience. According to the interventionists, many of the language and cultural adaptations originally designed in the study protocol worked well (Table 2, Theme 1.1). For ex-

Characteristic	Pain counselor/ CRC (n=4), n (%)	Acupuncturist (n=7), n (%)	<i>Total</i> (n=11), n (%)
Age, years, mean (SD)	31.5 (10.2)	50.9 (4.1)	43.8 (11.6)
Sex Female Male Transgender	3 (75.0%) 1 (25.0%) —	5 (71.4%) 1 (14.3%) 1 (14.3%)	8 (72.7%) 2 (18.2%) 1 (9.1%)
Race/ethnicity Caucasian/ white	_	3 (42.8%)	3 (27.3%)
Latinx Asian Egyptian Other	3 (75.0%) 1 (25.0%) 	2 (28.6%) 1 (14.3%) 1 (14.3%)	3 (27.3%) 3 (27.3%) 1 (9.1%) 1 (9.1%)
Relevant professional experience, years, mean (SD)	6.0 (6.4)	19.6 (5.0)	14.6 (8.6)

 TABLE 1. DESCRIPTIVE CHARACTERISTICS

 OF INTERVENTIONISTS

CRC, clinical research coordinator; SD, standard deviation.

ample, study documents were available in three languages, and study recruitment and enrollment were conducted by multilingual research staff, most of whom were Chinese and Latinx.

However, language and cultural challenges still needed to be addressed in the moment. During conversations with patients, prepared study scripts did not always work because of differences in patient literacy. In these cases, interventionists would simplify language and use more examples in the patient's preferred language (Excerpt #1). These in-themoment adaptations sometimes led to the research team making permanent protocol changes to be more inclusive. For example, several months into recruitment, study staff realized that talking about acupuncture was more effective if accompanied by a picture of an acupuncture needle. Using the life-sized picture of the needle-which shows how small they are-helped those who were afraid of needles (Excerpt #2). Notably, study staff had all used acupuncture themselves, so were also able to speak about the experience of acupuncture treatment from personal experience.

Adaptation to patients' life context also happened in the pain counseling intervention. One of the coping skills taught in pain counseling was guided relaxation practice. Initially, the script invited patients to think of a "safe space." However, some patients at the public hospital reported that they did not have safe spaces (Excerpt #3). The script of the guided relaxation practice was changed to "a place where you feel comfortable and calm" to be inclusive of patients' experiences without compromising the fidelity of the protocol.

Developing trust. Interventionists highlighted the importance of developing trust with patients (Table 2, Theme 1.2). Specific strategies for developing trust varied depending on whether interventionists were of the same ethnic background. In Excerpt #4, a Chinese pain counselor was describing the conversation with a Chinese patient. In Excerpt #5, a Latinx pain counselor described culturally specific adaptations to develop trust with Spanish-speaking patients. Trying to establish some level of connection helped interventionists develop a quick bond. Spanish-speaking patients relax and be more open to study participation.

Building trust in a single treatment session. Most study acupuncturists typically worked in outpatient settings where they reported that establishing an ongoing relationship between the clinician and patient is an important aspect of the care (Table 2, Theme 1.2.1). As a result, acupuncturists were particularly keyed into the difference between developing a long-term relationship in outpatient care versus the short-term inpatient setting. Because of the staffing schedule, an acupuncturist would often only meet a patient once, with other colleagues providing the patient's subsequent treatments. Acupuncturists spoke about this challenge but they differed on how best to handle only meeting a patient for a single treatment. In Excerpt #6, the acupuncturist reported using the first few minutes of the treatment to relate and measure the success of that relationship building by whether the patient fell asleep during treatment. On the contrary (Excerpt #7), another acupuncturist explained how relationship building in a single session is not really possible. Therefore, other aspects of care, such as minimizing

TABLE 2. EXEMPLARY QUOTES OF PATIENT-CENTERED ADAPTATIONS

Interviewee/Excerpt#	Quote		
Theme 1.1: Language, Cultu			
Excerpt #1 Pain Counselor-CRC#4	Medicina integral [integrative medicine] or medicina natural [natural medicine], yeah, and I'll mention it. I think in both cases I'll mention examples. Because even English speakers will say "Wait, what are you talking about?" When you say that's what that is No, so I'll say things like massage, acupuncture, acupressure, herbal medicine, and vitamins. And they are like "Oh, okay. I get what you're saying."		
Excerpt #2 Pain Counselor-CRC#3	If they ask me like, "Oh, I've seen that it's needles", if they're nervous about it. I say, "I don't like to call them needles. I like to call them wires because they're really, really small and they're as thick as a strand of hair." And I have the little chart that we printed out with a match and then a needle just to compare sizes. And then I say, "As far as pain goes, most of the insertion sites, you won't feel anything. From personal experience, I mostly don't feel anything but when I do, I'll feel like someone's tugging on a hair on my arm. So it's just very slight and momentary and then it goes away."		
Excerpt #3 Pain Counselor-CRC#4	 #4: And they actually felt uncomfortable with some of the—which I think we went over afterward—because he's homeless, and so he doesn't necessarily have a safe place. So it was hard to imagine a safe place. Interviewer: Right. Was that before we switched the language? #4: Yeah, that was before. 		
Theme 1.2: Developing Trus			
Excerpt #4 Pain Counselor-CRC#2	I think some of them might get surprised [that study acupuncturists are not Chinese]. I think I remember one patient were asking me, "Oh, so they don't speak Chinese? Then how do they study Chinese medicine?" So I told them, "Oh, there's schools that you can learn about it in English." I don't know if it's because I'm introducing the acupuncturist all the time, and it's reassuring to have someone that looks like them to tell them that this person's legit It's a trust issue.		
Excerpt #5 Pain Counselor-CRC#4	I try to connect with them on that cultural level. So I came in, I talk about the same things, that I'm from the Osher Center we focus on natural medicine, but my form of delivery is different. I try to be a little more warm. And then they asked me where I'm from, that's a common thing for people who come from other countries I would say, or at least from Latin America and Central America in my experience. And so they'll ask where I'm from, and I mention I'm born here but that my mom is from [Latin American location], and my dad is from [Latin American location]. And then we'll talk a little bit about that. Maybe they're familiar or maybe they're from there. And so one of them, his wife actually has the same last name as me so we connected on that.		
Theme 1.2.1: Building Trust			
Excerpt #6 Acupuncturist #3	Learning how to choreograph our relationship ahead of time as much as possible is not really something that you can do in-patient. And so, creating that, I think that a big indicator of the success of that creation in the first 5 to 10 minutes is how many people literally just fall asleep. And if they were feeling anxious, they would not fall asleep. If they were feeling tremendous pain, they would not be able to sleep.		
Excerpt #7 Acupuncturist #7	Like, I think it's not developing the relationship just because we don't have enough time. I mean, we're only seeing them once I think the minimizing interruptions and then the quiet time does seem to be a big piece of it. Although that's also separate from the intervention is just like a nice additive effect potentially.		
Theme 1.3: Agency to Declin			
Excerpt #8 Pain Counselor-CRC#3	I kind of stressed the fact that it is voluntary because I feel like just coming from a Latino background, it's easy to think, "Oh, someone's coming in. They know what's best for me. Or I should listen to what" I just don't want them to I know that feeling like in my grandparents for example. And so I always try to remind them, "This is voluntary." Especially if they just don't want to say no because they don't want to be rude. But you can tell that they're just like, they don't want to do this. So then I just try to remind them, which I think that some of the English speaking patients, they're more willing to kind of stand up for themselves and be like, "No. I don't want to do this." So that's kind of a difference, because I think that kind of happened with the second patient. He had just had different people, care providers, come in. And so by the time I came in, he's like, "I'm just so tired. I'm so I just had like three meetings." And I'm like, "That's fine. You don't have to talk to me." You know?		
Excerpt #9 Acupuncturist #1	They just change their mind, or they're not ready, or it's too much. There's just too much going on. So I'm like, "It's totally okay. You have every right to decline this." So I just reinforce that it's fine to have autonomy in that. Because how many things here can they really say no to?		

interruptions and increasing quiet, offer more relevant patient-centered care. Both of these examples demonstrated how study staff made conscious adaptations to intervention delivery that might never appear in the study protocol.

Agency to decline treatment. While all studies have challenges to participant recruitment, one factor that was not anticipated was how much work would be needed to schedule and reschedule inpatient treatments. Although acupuncture and pain counseling treatments were typically scheduled only a few hours in advance, when interventionists arrived, patients were sometimes unavailable or uninterested in receiving the treatment (Table 2, Theme 1.3). As interventionists described, patients sometimes did not want another interruption to have time for sleep or with visitors. Interventionists repeatedly stated the importance of allowing patients the ability to decline treatment in the moment. In Excerpt #8, a pain counselor described how the voluntary nature of accepting treatment was negotiated with Spanish-speaking patients.

The lack of pressure to accept all treatments while hospitalized was applicable to all patients. In Excerpt #9, an acupuncturist also spoke about how in the hospital, the right to decline was something that they could offer. Because inpatients have limited control over the treatments they are given, it was important that study interventions were not yet another treatment to endure. As the acupuncturist described, if patients declined a treatment, study staff would provide alternatives, such as rescheduling for later in the day or the next day. Although this made daily study logistics more complicated, study staff concluded that it was better for the patients.

Hospital-centered adaptations

Designed as a pragmatic trial, interventions delivered in each hospital setting had to balance between standardization and meeting the local context. Sites differed in anticipated ways (hospital type and patient population) and in unanticipated ways (how interventionists worked with other staff and decision-makers, physical building and layout of wards). The next sections and Table 3 present the range of site-specific adaptations.

Establishing trust with hospital staff. Interventionists discussed efforts to help create smooth working relationships with other providers in the hospital. Sometimes this had to do with understanding clinical responsibilities within the hospital system, such as contacting an attending physician rather than a resident physician (Excerpt #10). Acupuncturists described adjusting their language to fit the biomedical setting while still maintaining their identities and areas of expertise (Excerpt #11). As the acupuncturist stated, the successful role of the acupuncturist is not only to know about qi and blood, but also to translate those concepts to biomedical clinicians, which was described as "speak[ing] in a language that they understand."

Bridge-building was an important practice that interventionists described through their work to create and sustain relationships with individual hospital staff, primarily nurses. Because of the nature and logistics of the pragmatic trial, acupuncturists sometimes had extra time between delivering interventions. Filling these "down-times" by offering acupuncture to staff (primarily nurses and patient care assistants) led to numerous benefits for the study, for staff, and for the acupuncturists themselves (Excerpt #12). Giving nurses and other staff an opportunity to experience acupuncture had side benefits for reducing staff stress levels, and also benefited the study as it increased the likelihood that staff worked more smoothly with, as one acupuncturist self-described, "potentially irritating" interventionists. Some staff began receiving acupuncture regularly during their breaks while in the hospital.

Patients who were not eligible for the study were also beneficiaries of these "extra" acupuncture treatments. Again, although this practice was not directly helpful for the RCT findings, these treatments provided a way for interventionists to support hospital staff and patients more broadly and situated themselves as important members of the hospital team. For example, a pain counselor/CRC described a patient's positive experience with acupuncture that she witnessed that also helped the staff (Excerpt #13). Although there were many positive outcomes of the extra acupuncture, the practice was not universally well-regarded. After several months of offering staff members acupuncture on their breaks, one of the locations stopped allowing it because of concerns about equity regarding which staff members were receiving acupuncture. At the other site, staff acupuncture continued to be offered when the acupuncturists' schedules were not filled with study participants (Excerpt #14). It was clear that acupuncture was seen as a benefit beyond the RCT and helped promote institutional support through the individuals who enjoy it. However, sometimes this led to institutional barriers around scheduling and practicalities of delivery.

Interventionists within the medical hierarchy. Acupuncturists discussed where they fit within the hospital and clinician contexts. Most described themselves as hospital guests or as providing adjuvant care, and acknowledged both the importance of their work and the medical hierarchy. As acupuncturist #6 explained, because hospital staff may not have had prior exposure to acupuncture, they had to be "good ambassadors" or as acupuncturist #2 explained, not step on toes or get in the way. This is further explained in Excerpt #15. Acupuncturists wore badges and laboratory coats to convey their roles as hospital clinicians.

Pain counselors also described themselves as important members of the care team by providing tangible benefits to patients (Excerpt #16). As the quote continued, because the patients at the public hospital are interrupted more, sleepier, and less focused, the pain counseling offered an important service especially for this population.

By providing this service, many of the pain counselors compared their roles with chaplains, social workers, or even physical therapists. As a pain counselor explained, there is great value in the chaplains who "just sit with [patients], they pray, they offer something that nobody else is able to offer," and social workers who have a better sense of "the conditions that patients, like what the patient themself is going through, what their family dynamics are." For relieving pain, sometimes when they were sitting in the room waiting and the patient was speaking to the social worker, they heard additional insights that they used in their pain counseling sessions.

Interviewee/Excerpt #	Quote
Theme 2.1: Establishing	Trust with Hospital Staff
Excerpt #10 Pain Counselor-CRC#2	Residents [physicians] are not as familiar with what we're doing. And I don't know if they're more cautious about who approaches the patients and their attendings, so it's usually easier to talk to attendings then residents We would bump into attendings and they're very excited about [our] service. And then when we call their team pager it's usually the resident that picks up and some of them will say, "Oh, I don't know about that. What's the risk?" And then you say, "Ohyour attending that recommends him to us" oh then, "Okay. Nevermind."
Excerpt #11	We're in the midst of hiring another full-time acupuncturist now, and one of our big questions
Acupuncturist #3	is, you're in the hospital, you're in the elevator. A doctor stops you and says, "Hey, how does this work? How do you explain that to them?" You can't say words like <i>qi</i> and blood. They glaze over immediately. So I think having really good [acupuncturist] representatives just talk to the [medical] team, do presentations to the team about what we do in ways that both validates our medicine and speaks in a language that they understandI'm not trying to be an MD in here. I do need to have complete knowledge of their records. Patients really appreciate me coming in and knowing when their surgery was, knowing when their last bowel movement was, and being able to have an understanding of their medical situation. And I often include that when I meet them, or when I see them again, and go, "Oh look, you got your tube out." So I'm familiar with their case from a Western medicine perspective, but I'm not trying to be their MD.
Excerpt #12 Acupuncturist #5	I do think it's really important that the nurses understand how acupuncture works. I mean, I think a lot of people haven't had it or they haven't had it for a while or whatever. And so I think when we give the nurses acupuncture, it does give them a kind of experiential appreciation for the practice itselfBut more than that, it creates bridges. It creates a certain friendliness. And yeah, I think it's really important because the hospital context, a lot of the people working in this context are very time-driven, can be really stressed out. They're dealing with really significant health crises that the people they're caring for are undergoing. And so, yeah. So there's a huge potential for us to be an irritant. There was a little bit of iciness I think when I first was working here because no one knew who I was and they were kind of like not sure what to make of me or whatever.
Excerpt #13 Pain Counselor-CRC#1	There's a way we can be a real helpful presence. There's a patient that I mentioned that has schizophrenia who's been in the hospital for six months because they don't have a good place for her to goshe gets into a loop. She's like "Can I go home?" And that's what she asks everybody. "Can I go home?" And the nurses sometimes are just sick of hearing that questionSo I'll say, is it okay if I offer acupunctureYou know, we had like 15 conversations where I finally explained it to her, and at first she wasn't sureShe thought about it, she tried it and loved it, and it relaxed her. So what the nurses said was "Oh it's so great because she just kind of relaxes, and it's so much easier to be here for the few hours after the acupuncture. She gets really restful sleep, then she's not as agitated. It gives her something to do." Because she's really boredso yeah, there's like a way where we can fill a lot of different types of needs and just be like a positive presence, you know.
Excerpt #14 Pain Counselor-CRC#1	I just make it a point to offer everybody. Like I offer the people that are cleaning, they know, some of them have my cellphone and can reach out if they can get it. And I think that's actually beneficial long term if we were to be able to implement those as a service, we've already got all these people institutionally kind of supporting or at least understanding what it is.
	ists Within the Medical Hierarchy
Excerpt #15 Acupuncturist #1	I really want to make sure I'm never halting what the doctors need to do, what the nurses need to do, and getting in the way. I think the thing I'm always trying to do is see to the patient's need but never hindering or being a barrier to other care. So if I see that they need to do something, I'm like "Okay we'll come back and we'll do this later," or "We'll see if we can reschedule this." I think part of being collaborative, in my mind, is that I do see us as adjuvant. We are a wonderful addition to the care. We are a wonderful addition to the care, but we are not the primary care. And I want to never, again, be in the way. And it's not to say that we don't deserve to be there, it's more just about recognizing what is primary and what is secondary.
Excerpt #16 Pain Counselor-CRC#1	They thank me for listening. I remember one of the first folks there, he just started crying in the middle of it. He said, you know, he was a writer and we started talking about books or something, he just started crying, all of the sudden he said "You know, with this whole dying thing it takes a lot of energy and people are really tired of your pain." And he said "I haven't had a conversation like this that wasn't about medications or what to do with my body in some way or other, just about like books and literature." He was crying telling me "Thank you so much for just talking with me."

TABLE 3. (CONTINUED)

Interviewee/Excerpt #	Quote		
Theme 2.3: Site-Specific	Differences		
Excerpt #17	The first one I did was with a man in his end of life, I think. It was in a double room, so the		
Pain Counselor-CRC#2	environment isn't ideal. The patient is sleeping, next to him is flushing the toilet and it's kind of awkward for me to do the imagery session. Like, "Oh, think about beach", and then there's toilet flush, and then there are people yelling outside, and there's TV sound.		
	But all of them fall asleep at the end of the session with the imagery.		
Excerpt #18 Pain Counselor-CRC#1	We work on, as far as implementing the study, we work on four floors at [public hospital], a total of 11 wards. At [academic hospital] we work on two wards which are split one on each floor. There's a lot more time that we spend sort of just walking and going in and out of doors, and up and down elevators, and waiting for elevators, and waiting for nurses. A lot of the mechanics of how we do the screening, or how we look up a patient, to then call their primary team, and then do X, Y, and Z, takes longerSo for us to actually log onto a computer, sometimes means going to another floor, to another ward, across the hospital to another wardThe patient population is pretty different. At [academic hospital], they tend to be predominantly white, affluent, English speaking folks, or like		
	middle class to higher and even rich people At [public hospital] there's a lot more folks who have been homeless, have mental health issues, treated and untreated. A lot, a lot of meth use and crack and other drugs that they're either and a lot of alcohol use, that they're either withdrawing from or have been in treatment, were already in a methadone program and then came to [public hospital]. But there tends to be a lot more complex cases per patient. Patients who didn't get the cancer diagnosis until way late, and so their cancer is way more advanced. People who were in there for a gunshot wound and then got diagnosed with cancer. There's just a lot, people going through a lot.		
Excerpt #19 Pain Counselor-CRC#1	They're like oh yeah I already do my own. I do yoga, I do meditation. Whereas that's not so much true at [public hospital], I feel like they're a little bit more receptive. There's also folks at [public hospital] who are like you know what do I have to lose? Let me try it, it's free, maybe it will help me feel better.		

Site-specific differences. The physical environments at both hospitals were quite different; subsequently, the interventions and care patients received were different. For example, a pain counselor described the first session conducted at the public hospital (Excerpt #17). Despite the challenges of the double-room with a roommate, and various other noises and distractions, the patient still participated in guided imagery and was able to fall asleep.

Compare this description with the academic medical center hospital that was only a few years old, offered large single rooms with a wall of windows, TV channel devoted to calm music, an indoor/outdoor healing space, and the ability to choose all food with organic options. As an acupuncturist said, these weren't just rooms, but a "healing environment."

Not only did the physical environment affect intervention delivery, but interventionists also adapted their work when navigating the hospitals. As a CRC/pain counselor explained, one challenge at the public hospital was that crowded wards and floors led to "bumping into people" or being "in their hair a lot more" than at the academic hospital (Excerpt #18). They explained further that because patients at the public hospital had greater challenges, it also meant having to screen more people to find eligible patients who could consent. Unexpectedly, interventionists also reported (Excerpt #19) that although more affluent, Englishspeaking patients were more familiar with coping skills used in pain counseling, they were also less likely to want to participate in pain counseling because elements of it were familiar. Unlike acupuncture, which is a treatment that needs to be practitioner delivered, pain counseling is something that once learned can be done as self-care by the patient.

Discussion

This study builds on prior literature that examines implementing integrative medicine in the context of operational and cultural dynamics of hospital settings^{18,23} by including interventionist voices.¹⁹ These findings are consistent with previous research on the added value of CIH as part of inpatient care while contributing unique insights on implementation in a public hospital and adapting interventions to diverse patient populations.

Study interventionists provided an important voice in the ongoing evaluation of a pragmatic RCT to test CIH therapies for pain management among inpatients with cancer. Many study staff were bicultural, and interventionists spoke about their successes of meeting patients where they were in a spirit of cultural humility.²⁴ Notably, the study was not explicitly designed with a cultural humility framework, but by adopting an attitude of self-reflection and ongoing learning, interventionists discussed how they provided patient-centered study enrollment and treatment. In addition, acupuncturists adapted their language and clinical practice to the dominant culture of biomedicine, viewing themselves as both colleagues and guests. Findings from this process evaluation facilitated day-to-day conduct of the pragmatic trial by improving recruitment processes and intervention delivery. Moreover, adaptations have helped ensure that the study interventions are indeed pragmatic and consistent with clinical service delivery. This has long-term implications for implementation and sustainability of the interventions if study findings are positive.

While interventionists made numerous small adaptations to tailor interventions to patients' language and cultural beliefs and practices, as previous inpatient CIH research has found, they also made real-time adaptations to build trust and allow for patient agency¹⁴ in an environment where few decisions are made by patients.²⁵ Some of these changes became part of the intervention protocol and indicate the benefits of centering at the margins when working in public health settings and with diverse communities.²⁶ For example, by asking people to picture a place where they feel calm, the intervention can be used across populations.

This study has a variety of limitations. As a qualitative study of small sample size in only two hospital sites in an area known to be very open to CIH, it is unclear if findings can be generalized beyond this particular study. However, as a first step in collecting CIH practitioner experiences with delivering standardized RCT interventions, these voices are an important foundation upon which future research can build. Future research should closely examine RCT adaptations to understand the use of patient-centered tailoring. In addition, future studies should examine how ancillary practices such as offering acupuncture to hospital staff and patients not in the study may add to the overall ability to smoothly run a pragmatic trial.

Conclusion

Intervention design tailored for the local context has the opportunity to make CIH treatments more readily available and accessible to a wider patient population. Interventionists described these inclusive adaptations as necessary for a patient-centered approach. Adaptation to the institutional context and individual patient needs can be done in an RCT without compromising intervention fidelity and that intervention design should center at the margins to help CIH become accessible to all.

Authors' Contributions

This is a list detailing each listed author's contributions to and responsibilities for the article. E.Y.H.: data analysis, writing, and reviewing/approval of the article. A.T.-L.: data collection, data analysis, writing, and reviewing/approval of the article. R.L.: data collection, data analysis, writing, and reviewing/approval of the article. X.Z.: data analysis, writing, and reviewing/approval of the article. N.T.: project management, data collection, writing, and reviewing/approval of the article. M.T.C.: project conceptualization, data analysis, writing, and reviewing/approval of the article. All coauthors have reviewed and approved of the article before submission.

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Disclaimer

The views in this publication are solely the responsibility of the authors and do not necessarily represent the views of the Patient-Centered Outcomes Research Institute, its Board of Governors, or Methodology Committee, or any of the funders.

Author Disclosure Statement

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