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Rationale and design of a pilot study examining Acceptance and Commitment Therapy for persistent pain in an integrated primary care clinic

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ABSTRACT

Most of the 100 million Americans with persistent pain are treated in primary care clinics, but evidence-based psychosocial approaches targeting pain-related disability are not usually provided in these settings. This manuscript describes the rationale and methods for a protocol to pilot test the feasibility and effectiveness of Acceptance and Commitment Therapy (ACT), an evidence-based psychological treatment for persistent pain, delivered by a Behavioral Health Consultant in primary care. Eligible patients are identified through electronic health record registries and invited to participate via secure messaging, letters and a follow-up phone call. Participants are also recruited with advertising and clinician referral. Patients agreeing to participate are consented and complete initial assessments, with a target of 60 participants. Randomization is stratified based on pain severity with participants assigned to either ACT or Enhanced Treatment as Usual (E-TAU). ACT participants receive one standardized Behavioral Health Consultation visit followed by three ACT-based group visits and one group booster visit. All patients attend six assessment visits, during which the E-TAU patients are provided with educational pain management handouts based on standard cognitive behavioral treatment of pain. The study aims to determine feasibility and effectiveness of brief ACT for persistent pain delivered by an integrated behavioral health clinician in primary care from pre- to post-treatment, and to examine mechanisms of change in ACT participants. This study, in a "real-world" setting, will lay groundwork for a larger trial. If effective, it could improve treatment methods and quality of life for patients with persistent pain using a scalable approach.

1. Introduction

Over 100 million Americans suffer from persistent ("chronic") pain [1], and worldwide, persistent pain causes more disability than any other condition [2]. Most patients with persistent pain seek treatment from their primary care clinicians (PCCs) [3,4]. PCCs find patients with persistent pain to be stressful [5] due to factors such as limited training in managing pain [5,6], risk for opioid use disorder and diversion [7], complex presentation [8], and co-morbid psychological problems [5].

Despite significant safety and efficacy concerns [9–11], and even with declining prescription rates [12], opioids continue to be a frequently used pain treatment [12,13]. Opioid analgesics have significant negative side effects [10] and long-term efficacy is dubious [11], as opioids do not always lead to better pain control or improved functioning [9,14]. Even when indicated, opioids address the physical aspect of pain, failing to attend to well-established psychosocial factors that worsen pain-related disability (e.g., beliefs, pain-related coping, emotional responses to pain) [15].

Persistent pain is a complex phenomenon characterized by interacting biological, emotional, cognitive, behavioral, and social mechanisms [16]. The Centers for Disease Control recommends use of nonpharmacologic therapies such as cognitive behavioral therapy

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(CBT) [9] to treat persistent pain. Although there are a variety of effective CBT treatments available for chronic pain [18], traditional CBT approaches aim to reduce disability largely through focusing on management of pain and associated thoughts and feelings [17,18], and not all patients respond to CBT [18,19]. Although a CBT approach can be helpful for coping with chronic pain, it may miss important mediating factors associated with long-term functional improvement, most notably: attainment of personally meaningful goals and improved psychological flexibility when managing pain [20,21].

An alternative to traditional CBT is Acceptance and Commitment Therapy (ACT) [22,23], which instead helps increase flexibility in responding (i.e., coping) through enhancing acceptance of the pain experience, including thoughts/feelings (e.g., with mindfulness exercises), ultimately helping patients live in a more functional and personally meaningful way [17,20,24]. ACT is a transdiagnostic, evidence-based treatment [25,26], and is associated with improvements in physical functioning, improved pain-related disability and decreases in emotional distress for patients with persistent pain regardless of changes in perceived pain intensity [27,28]. ACT has also demonstrated sustained medium-large effect sizes on social functioning, as well as physical functioning [27,29].

Most patients with persistent pain seek treatment in primary care settings [3], but ACT is usually delivered in specialty clinics. One pilot study examined a 16-hour program of ACT delivered by an external therapist in a primary care clinic [30]. The outcomes were promising, but a more sustainable and interdisciplinary approach to providing ACT in primary care may be delivery by primary care behavioral health clinicians (e.g., clinical or health psychologists) who are embedded in the primary care setting. These integrated Behavioral Health Clinicians, sometimes called “Consultants,” (BHCs) [31–33] work side by side with PCPs and deliver brief, evidence-based assessments and interventions individually, with family members or in groups [32–34]. BHCs help effectively address many presenting complaints, including pain and mood, resulting in significant improvements in functioning after one to four 15–30 min visits [35–38]. Gains made can be sustained an average of two years [39].

To date, BHC studies are few, not rigorous in design, and none have examined ACT or impact on the persistent pain population, thus limiting implementation of this promising treatment delivery model. This paper describes the design of a study examining if brief ACT, delivered by an integrated BHC in primary care, is feasible and effective in reducing disability for patients with persistent pain.

2. Methods

This study is approved by the University of Texas Health Science Center's Institutional Review Board, Clinical Trials Office, and Compliance Office.

2.1. Study design

This study is a single-site randomized control trial that plans to enroll and randomize a sample of 60 men and women, 18 + years of age, diagnosed and under treatment for any persistent non-cancer pain condition that meets inclusion and exclusion criteria to either the ACT treatment program or control group (Enhanced Treatment as Usual; E-TAU). The study is being conducted in a primary care clinic with an established integrated BHC service. Participants in the ACT arm receive one 30-minute individual visit, followed by three weekly hour-long classes. They also attend a “booster” visit two months following completion of the last class. We chose to deliver the majority of the intervention in a class (group) format as this is more appropriate for a primary care setting, given a high prevalence of persistent pain, and allows for greater accessibility to services and optimal use of a BHC's time. Social connectivity and support is also important for patients with persistent pain [15,40,41] and group treatment delivery format may help facilitate this support, as well as provide reinforcement of behavior change and commitment to action. Group-based formats significantly reduce wait times for pain management services [42] and pain management groups allow a provider to harness effective treatment resources that are not available in individual care formats (e.g., peer support and modeling [43]); including an initial individual visit helps to ensure an understanding of the patient's history, functioning, values and personalization of the treatment plan. Participants in the E-TAU arm receive educational handouts on pain management based on cognitive behavioral science during the same time frame in which the ACT participants receive their class interventions (see Fig. 1 for study recruitment and Fig. 2 for study intervention).

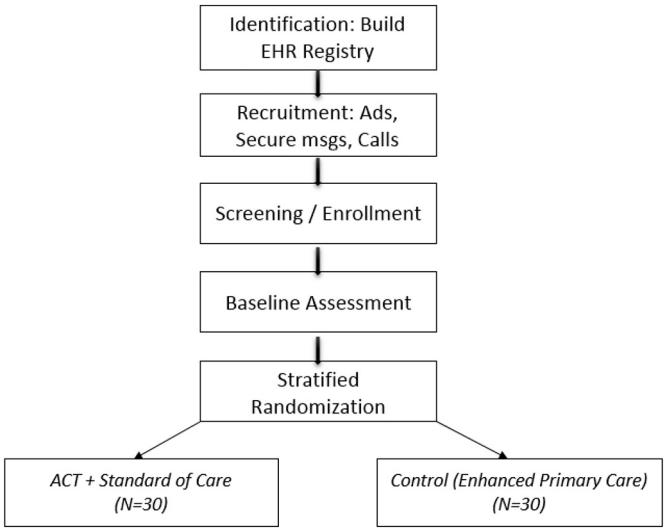

Fig. 1. Study recruitment flow.

2.2. Study aims

The specific aims and hypotheses for this study are:

1. The first aim is to determine the feasibility and effectiveness of a

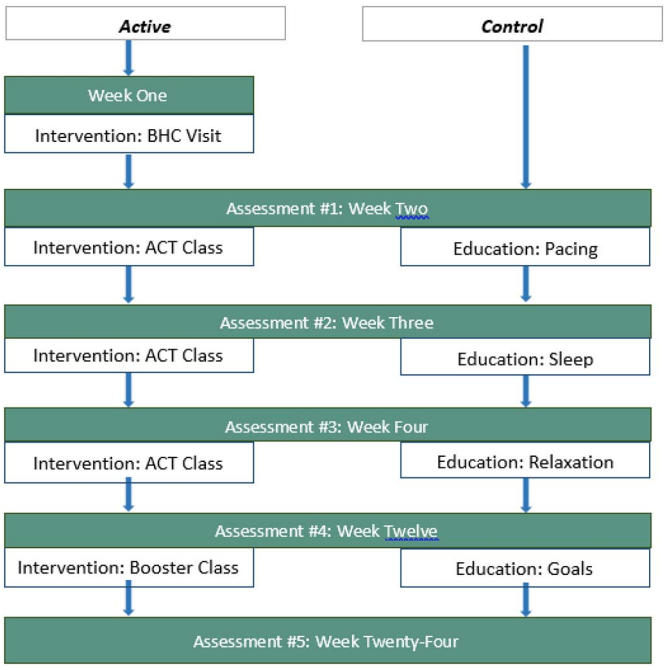

Fig. 2. Study intervention & assessment flow.