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The Indiana Cancer Pain and Depression (INCPAD) trial Design of a telecare management intervention for cancer-related symptoms and baseline characteristics of study participants

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Abstract

Objective: Pain and depression are two of the most prevalent and treatable cancer-related symptoms, each present in at least 20–30% of oncology patients. Both symptoms are frequently either unrecognized or undertreated, however. This article describes a telecare management intervention delivered by a nurse–psychiatrist team that is designed to improve recognition and treatment of pain and depression. The enrolled sample is also described.

Methods: The Indiana Cancer Pain and Depression study is a National Cancer Institute-sponsored randomized clinical trial. Four hundred five patients with cancer-related pain and/or clinically significant depression from 16 urban or rural oncology practices throughout Indiana have been enrolled and randomized to either the intervention group or to a usual-care control group. Intervention patients receive centralized telecare management coupled with automated home-based symptom monitoring. Outcomes will be assessed at 1, 3, 6 and 12 months by research assistants blinded to treatment arms.

Results: Of 4465 patients screened, 2185 (49%) endorsed symptoms of pain or depression. Of screen-positive patients, about one-third were ineligible (most commonly due to pain or depression not meeting severity thresholds or to pain that is not related to cancer). Of the 405 patients enrolled, 32% have depression only, 24% have pain only and 44% have both depression and pain. At baseline, participants reported an average of 16.8 days out of the past 4 weeks during which they were confined to bed or had to reduce their usual activities by ≥50% due to pain or depression. Also, 176 (44%) reported being unable to work due to health reasons.

Conclusions: When completed, the Indiana Cancer Pain and Depression trial will test whether centralized telecare management coupled with automated home-based symptom monitoring improves outcomes in cancer patients with depression and/or pain. Findings will be important for both oncologists and mental health clinicians confronted with oncology patients' depression or pain.

Keywords: Cancer; Pain; Depression; Antidepressants; Analgesics; Telemedicine; Care management

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1. Introduction

1.1. Pain and depression in cancer

Pain and depression are two of the most common treatable symptoms in cancer patients yet often remain undetected and/or inadequately treated. Pain is present in 14–100% of cancer patients, depending on the setting, and the prevalence of major depressive disorder is 10–25%, with a similar range for clinically depressive symptoms [1–4]. The impact of these symptoms on functional status and quality of life is considerable [5–10]. Depression is frequently underdiagnosed in cancer patients [11–13], and up to half of cancer patients depressed at baseline remain depressed at the 1-year follow-up [1]. Likewise, cancer pain often is undertreated [1,14,15].

1.2. Barriers to optimal management

Four common barriers to effective treatment of symptoms in both primary and specialty care are underdetection of bothersome symptoms, inadequate initial treatment, failure to monitor adherence and response and failure to adjust therapy in nonresponding patients [16]. These are well established for depression as well as pain and other symptoms [17–25]. These four barriers are also among the most common and "action-able" in oncology [26–30]. In primary care, much has been written about the concept of "competing demands" in time-limited visits [31,32]. Clearly, this pertains to oncology practice as well, in which the time required for evaluation and treatment of the primary cancer competes with time left over for such associated symptoms as pain and depression. Understandably, the nuances of antidepressants and various pain regimens as well as subsequent symptom monitoring may be outweighed by the requisite attention to chemotherapy, tumor response, hematological nadirs and other complexities of cancer treatment.

1.3. Potential benefits of care management

Multicomponent-system interventions consistently improve depression outcomes, whereas single-component interventions, such as depression screening and provider education, are insufficient by themselves [17,18,33,34]. Indeed, the U.S. Preventive Services Task Force recommends depression screening only if there are adequate systems in place to support depression treatment and monitoring [35]. A review of 28 randomized multicomponent effectiveness trials for treatment of depression in primary care demonstrated a median absolute increase of 18.4% in the proportion of patients achieving a 50% improvement [36]. Disease management programs have also been proven to be beneficial for diabetes, heart failure, asthma and other chronic medical disorders [37]. However, the effectiveness of collaborative care and/or disease management programs for pain has not been established, and the generalizability of studies largely conducted in primary care to the more specialized setting of oncology practices is not known.

1.4. Role of telemedicine

Numerous clinical trials have established the effectiveness of telephone care management and telepsychiatry for depression treatment in primary care patients across a variety of settings, ranging from large organized health care systems to more rural settings [38–42]. Indeed, their benefits compared with usual care may even be greater in rural settings [43]. Preliminary data in cancer trials also suggest the potential effectiveness of telemedicine for pain management [44].

Although simple telephone-based screening for depression in oncology practices has been proven to be acceptable [45], telecare management of depressed cancer patients has not been studied. The promising studies in cancer patients with depression, pain and/or fatigue by Given et al. [44,46,47] differ from our trial in that (a) their interventions were psychoeducational rather than pharmacological (which affects generalizability since medications are more commonly the initial approach for pain and depression in oncology practices); (b) the number of required nursing contacts (9–10) was higher, and half were in-person visits; and (c) some of the outcomes were of marginal significance due to a much smaller sample size.

1.5. Conceptual model in the Indiana Cancer Pain and Depression trial: three-component model

Fig. 1 illustrates the three-component model (TCM) developed for the treatment of depression in medical settings [48] and empirically validated in a dissemination depression trial involving 60 primary care practices [49,50]. TCM is based on relationships between three types of providers collaborating through complementary roles in overcoming barriers to optimal disease management. The three providers are the patient's primary provider, a nurse care manager and a specialty consultant. The Indiana Cancer Pain and Depression (INCPAD) trial comprises an oncology practice (often consisting of an intrapractice oncologist–nurse partnership), a depression–pain care manager (DPCM) and

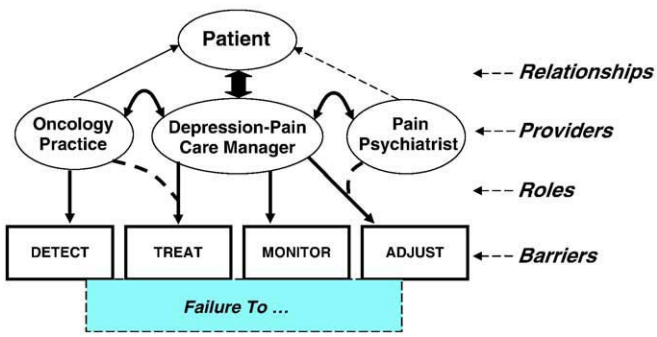

Fig. 1. Conceptual model underlying the INCPAD trial.