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# Randomized control trial to test a computerized psychosocial cancer assessment and referral program: Methods and research design

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ABSTRACT

The National Cancer Coalition Network, National Cancer Institute, and American College of Surgeons all emphasize the need for oncology providers to identify, address, and monitor psychosocial needs of their patients. The Mental Health Assessment and Dynamic Referral for Oncology (MHADRO) is a patient-driven, computerized, psychosocial assessment that identifies, addresses, and monitors physical, psychological, and social issues faced by oncology patients. This paper presents the methodology of a randomized controlled trial (RCT) that tested the impact of the MHADRO on patient outcomes at 2, 6, and 12 months. Patient outcomes including overall psychological distress, depression, anxiety, functional disability, and use of psychosocial resources will be presented in future publications after all follow-up data is gathered. Eight hundred and thirty six cancer patients with heterogeneous diagnoses, across three comprehensive cancer centers in different parts of the United States, were randomized to the MHADRO (intervention) or an assessment-only control group. Patients in the intervention group were provided detailed, personalized reports and, when needed, referrals to mental health services; their oncology provider received detailed reports designed to foster clinical decision making. Those patients who demonstrated high levels of psychosocial problems were given the option to authorize that a copy of their report be sent electronically to a "best match" mental health professional. Demographic and patient cancer-related data as well as comparisons between patients who were enrolled and those who declined enrollment are presented. Challenges encountered during the RCT and strategies used to address them are discussed.

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## 1. Introduction

Changes in quality of life, anxiety, and depression are all psychosocial consequences related to cancer [1]. Researchers have studied interventions that reduce such negative effects [2–4], with recent studies focusing on telephone [5–7] and computer-based interventions [8–10]. For example, Loiselle and colleagues tested the impact of unlimited access to an eight week, computer-based, psychosocial program [11]. They found improvement in female cancer patients' quality of life when compared to the treatment as usual control condition. They note that they were able to successfully incorporate their program into the clinical care for newly diagnosed patients at four ambulatory oncology clinics. They

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argue that their findings, as well as others like them [12,13], support the use of technological interventions in oncology settings. Similarly, Erharter and colleagues [14] had over one hundred patients with brain cancer complete a computerized assessment that evaluated overall quality of life; physical, social, role, emotional, cognitive, and global functioning; and common physical and neurological symptoms of brain cancer and brain cancer treatment. The assessments were done while awaiting neuro examinations at three outpatient oncology clinics. Patients completed an average of 4.74 assessments over the course of the approximately three year study. Results further supported the feasibility of integrating the monitoring program into the routine clinical care flow of their centers, and it proved to be effective in identifying psychosocial symptoms in patients attending the clinic.

The Mental Health Assessment and Dynamic Referral for Oncology (MHADRO) is a computerized psychosocial assessment program that assists oncology providers in identifying, monitoring, and managing psychosocial issues in individuals with cancer [15]. The MHADRO provides reports for the oncology provider, the patient, and, when appropriate, a mental health provider to which the patient is referred. In addition to the reports, which are described in detail in Section 2.5.1.2 below, the MHADRO has the unique capability to provide patients with a *dynamic referral* to a mental health provider if they are experiencing high levels of distress or sexual dysfunction and are interested in receiving professional help. Unlike a standard mental health referral, which typically consists of either a general recommendation to see a clinician or a pre-printed list of mental health providers, a dynamic referral matches the patient's zip code and insurance carrier to a mental health specialist in his or her area and the referral is sent electronically to the mental health provider, who then reaches out proactively to contact the patient, perform a brief telephone screening, and set up an initial appointment, if appropriate. The MHADRO's referral capabilities are described in greater detail in Section 2.5.1.3. The MHADRO can be completed during outpatient appointments and during chemotherapy infusions in facilities that can provide for patient-facing computing. A prototype was well accepted by oncology providers and patients alike during a field test [15]. This paper presents the methodology of the randomized controlled trial (RCT) designed to test the impact of the MHADRO on patients' psychosocial and medical outcomes.

## 2. Method

### 2.1. Hypotheses

Our primary hypothesis for the clinical trial is that, compared to assessment only, the MHADRO will result in greater reductions in psychological distress among cancer patients at 2, 6, and 12 months after the initial assessment (Fig. 1). The hypothesized mechanisms of action include the initiation of mental health counseling, psychotropic medications, and psychosocial support group participation. We anticipate that these actions will be promoted both directly through the patient reports and dynamic referral functions, as well as indirectly through prompting clinical action by the individual's oncology provider. Secondary objectives include evaluating the MHADRO's effect on the patient–provider partnership, medical regimen and lifestyle change, and health-related outcomes. We completed baseline enrollment in February 2012 and are currently completing the follow-up assessments. Final results will be published after all of the follow-up data is complete in another publication.

Although there are no hypotheses for the present study, we aim to present a detailed analysis of this large, multi-site RCT with emphasis on challenges encountered and overcome during the course of the three year study. We will present demographic and cancer related descriptive data of all patients enrolled as well as differences in demographic and cancer related variables across patients who accepted and declined enrollment.

### 2.2. Study design

The study design is a parallel group, 1:1 allocation, randomized, single-blind clinical trial. The baseline assessment was completed by participants during their oncology outpatient visit. They were re-assessed at 2, 6, and 12 months by a centralized, blinded research assistant by telephone. Participants who preferred to complete their assessments on-line rather than by phone where provided an encrypted link to a secure website. The website only contained the questions to the assessment, not any personal information or previous assessment data. The study was approved by the Institutional Review Boards of all three institutions.

### 2.3. Participants and research sites

Participants consisted of 836 cancer patients recruited from three comprehensive cancer centers: the University of Massachusetts Medical School Cancer Center (n = 581; 70%), the Cancer Institute of New Jersey at Cooper Hospital (n = 126; 15%), and the University of Texas MD Anderson Cancer Center (n = 129; 15%). Because the program is designed to operate across all cancers in a general oncology setting, inclusion criteria were kept deliberately broad. Any patient with a past or current cancer diagnosis who was 18 years old or older was considered for enrollment. Patients were excluded if they had any of the following: altered mental status (e.g., psychosis, delirium, and disorientation), hostile or agitated behavior, severe illness that would preclude conversation or computer use (e.g., persistent vomiting, severe pain), or factors precluding follow-up (e.g., transient residence or lack of a telephone). Patients were recruited regardless of type, duration of illness, stage of cancer or phase of treatment.

### 2.4. Study procedures

Participants arriving for routine oncology (treatment or follow up) appointments or chemotherapy infusions were approached in an exam room or an infusion chair after their treating oncology provider's permission to approach the individual was obtained. Each patient was given information about the study's purpose and participant requirements. They were informed that their participation would not delay their care, and that they could interrupt or discontinue the assessment at any time. Individuals with transient symptoms that precluded enrollment during a given appointment, such