Design and rationale for a randomized controlled trial to reduce readmissions among patients with depressive symptoms

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A B S T R A C T

Background: The Re-Engineered Discharge (Project RED) reduces 30-day readmission rates by 30%. However, our data indicates that for patients displaying depressive symptoms during hospitalization, Project RED is less effective in preventing unplanned readmission. We aim to examine the effectiveness of RED-D, a modified brief Cognitive behavioral therapy (CBT) protocol delivered as a post-discharge extension of the Re-Engineered Discharge, in reducing 30-day readmissions rates and emergency department (ED) use as well as depressive symptoms for medical patients with comorbid depressive symptoms.
Methods: This paper details the study design and implementation of an ongoing, federally funded randomized controlled trial of our post-discharge mental health intervention, RED-D, compared to the RED plus usual care. This research has two primary objectives: (1) to determine whether RED-D delivered telephonically by a mental health professional immediately following discharge is effective in reducing hospital readmission and emergency department use for patients displaying depressive symptoms during their inpatient stay, and (2) to examine whether this approach yields a clinically significant reduction in depressive symptoms. We intend to recruit 1200 participants randomized to our intervention, RED-D (n = 600), and to RED plus usual care (n = 600).
Conclusions: Hospitalized patients with depressive symptoms are at increased risk for 30-day readmission. We aim to conduct a randomized clinical trial to evaluate the comparative effectiveness of RED-D, our post-discharge modified brief CBT intervention compared to RED alone in reducing readmissions and depressive symptoms for this at-risk population.

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1. Introduction

Recent efforts to streamline hospital discharge processes and bridge gaps in care transitions have improved patient safety and significantly reduced 30-day readmissions rates. Evidence from the randomized controlled trial of the Re-Engineered Discharge (Project RED), indicates that a systematic approach to the discharge process can reduce the risk of 30-day readmission for general medical patients by 30% [1]. Despite receiving RED, general medical patients who display comorbid depressive symptoms during an acute hospitalization remain at increased risk for readmission [2], and require care transition support that targets depressive symptoms and limits the impact of psychosocial sequelae of depressive episodes. See Fig. 1

Depression is linked to readmission in certain patient populations including the elderly [3–4], and those with specific diagnoses (e.g. Congestive Heart Failure (CHF), Chronic Obstructive Pulmonary Disease (COPD), Myocardial Infarction (MI)) [5–12]. Functional decline associated with

chronic medical illness is often accompanied by depressive symptoms, which arise in 20% to 50% of chronically ill persons [13–16]. Depressive symptoms can reduce a patients' ability to cope with physical symptoms and adhere to medical treatment, causing increased health care utilization and cost [17–23]. Project RED clinical trial data demonstrate a striking association between the presence of depressive symptoms and rates of 30-day rehospitalization [2], specifically, we found that for hospitalized patients with mild or moderate to severe depressive symptoms, the incidence rate ratio (IRR) for readmission was 1.49 (95% confidence interval [CI]: 1.11–2.00), and 1.96 (95% CI:1.51–2.49) respectively, when compared with hospitalized patients with no depressive symptoms [2]. This finding prompted the authors to hypothesize that even a small improvement in depressive symptoms may reduce a patient's risk of readmission.

Medical patients with comorbid depression often present with physical health concerns and fewer chronic mental health difficulties than patients with a primary mental health diagnosis. Although traditional psychotherapy approaches such as CBT, which aims to address the thoughts, emotions, and behaviors that contribute to and reinforce depressive symptoms, and interpersonal therapy are effective for treating depression [24], they do not typically address physical concerns of

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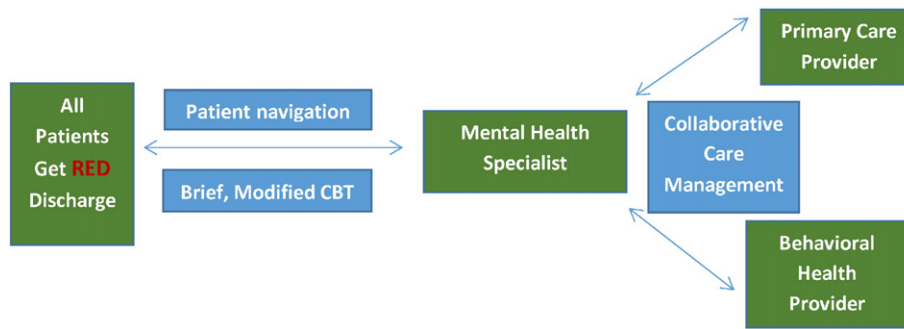E-mail address: suzanne.mitchell@bmc.org (S.E. Mitchell).

Fig. 1. An overview of the RED-D Intervention.

medically ill patients with comorbid depression. By contrast, interventions for chronic disease self-management do address physical and emotional concerns of patients with medical illness however [25], such models do not typically offer the level of psychological support for medically ill patients with major depressive symptom burdens. A modified mental health intervention focused on the physical and emotional health needs of medical patients with comorbid depressive symptoms is therefore required.

We aim to conduct a randomized controlled trial to examine the effect of the Re-Engineered Discharge for hospitalized patients with Depressive Symptoms (RED-D), a 12-week mental health intervention, compared to RED plus usual care on rates of 30-day readmission and emergency department (ED) visits, and on comorbid depressive symptom burden of hospitalized general medical patients. RED-D involves a modified brief CBT approach with elements of self-management education, patient navigation, and the collaborative care model, delivered telephonically by a mental health professional. Herein, we describe the design and methods protocol for our five-year study now underway.

2. Methods

The Re-Engineered Discharge for patients with Depression (RED-D) study was developed to examine the clinical efficacy of an evidence-based mental health intervention delivered as an extension of the Re-Engineered Discharge (RED) following discharge for general medical patients displaying depressive symptoms during an acute hospitalization. The RED-D intervention is initiated post-discharge with patient navigation support to promote adherence to the discharge plan and minimize the psychosocial and clinical sequelae resulting from depressive symptom burden, which impairs self-management capabilities. Simultaneously and subsequently, RED-D addresses the patient's need for treatment of comorbid depression that results from living with chronic progressive functional decline and illness using a modified brief CBT approach with components of self-management and mindfulness education in a collaborative care model. RED-D's collaborative care component enhances communication between the RED-D mental health professional and the patient's primary care health providers (PCP).

The study is being conducted at an urban safety-net hospital, Boston Medical Center (BMC), and includes patients admitted to the general medical service, observation unit, or surgical unit. Over a five-year period we seek to recruit a total of 1200 patients who have been admitted to BMC and display moderate to severe depressive symptoms during an acute hospitalization. Of these, 600 are randomized to the control arm, which involves the Re-Engineered Discharge process delivered by a nurse, followed by usual care. The remaining 600 patients are randomized to the intervention arm, and in addition to the RED discharge, receive the telephone-based RED-D protocol for 12 weeks following hospital discharge. Prior to the start of the study, a statistician used SAS [26] to generate a blocked randomization schedule and prepared and numbered two sets of sealed study allocation envelopes in accordance with this schedule. Once a patient is enrolled, the research assistant opens the next envelope and the patient is assigned to either the control or intervention condition. The Institutional Review Board (IRB) of Boston University School of Medicine approved the RED-D study.

Potential study participants are identified each day through unit registries of patients admitted during the previous 24 h. Research assistants approach potentially eligible patients during the index hospitalization. Interested participants complete the Patient Health Questionnaire-9 (PHQ-9) screen for depressive symptoms [27]. If patients receive a score of 10 or higher on the PHQ-9, they are required to provide informed consent to participate in further screening to determine their eligibility. If patients meet all of the eligibility criteria, including a PHQ-9 score ≥ 10, and are not subject to any exclusion criteria, they are enrolled in the study. Participants are excluded if they are scheduled to be discharged to another care facility, are planning to leave the greater Boston area within six months, are unable to communicate in English, are undergoing active cancer therapy or dialysis, or have cognitive, bipolar, psychotic, or active substance use disorders. At the time of submission, 356 patients have been recruited and enrolled to date.

2.1. Intervention and control conditions

2.1.1. Rationale for the RED-D Intervention

RED-D is a manualized, patient-centered mental health intervention which consists of patient navigation, self-management education, and a modified brief CBT protocol delivered using a collaborative care model that is initiated following hospital discharge for the treatment of comorbid depressive symptoms in hospitalized patients. RED-D is delivered telephonically for 12 weeks by a midlevel mental health professional in weekly sessions of up to 1 h in duration. We designed a telephone-based protocol to increase patient engagement and adherence to the intervention. The weekly sessions comprise of patient navigation support and six modules of modified brief CBT for depression. The dose and duration of navigation and brief CBT is determined by the patient's symptom burden, navigation needs, and readiness for engagement in depression treatment consistent with traditional psychotherapy treatment. This approach ensures the maximum impact of the CBT component which, if initiated too soon following discharge, has been associated with a high drop-out rate [28]. To ensure the fidelity of the RED-D intervention, we supply the mental health professional with a comprehensive and structured 12-week protocol manual. We will randomly digitally record weekly phone sessions between the mental health specialist and the study participant for quality improvement and to ensure intervention fidelity. The study psychiatrist and family medicine physicians will review these recordings to evaluate the degree of congruence with the protocol manual. In addition, the RED-D mental health specialist will track the occurrence of each component of the intervention for each telephone contact to support the assessment of the extent to which each of the components is emphasized during each call and at what specific times during the post-discharge period these components are most useful.