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Improving the quality of depression and pain care in multiple sclerosis using collaborative care: The MS-care trial protocol☆

Dawn M. Ehde[a,*], Kevin N. Alschuler[a,b], Mark D. Sullivan[c], Ivan P. Molton[a], Marcia A. Ciol[a], Charles H. Bombardier[a], Mary C. Curran[a], Kevin J. Gertz[a], Annette Wundes[a,b], Jesse R. Fann[a,c]

[a] Department of Rehabilitation Medicine, School of Medicine, University of Washington, 325 9th Ave, Box 359612, Seattle, WA 98104, USA
[b] Department of Neurology, School of Medicine, University of Washington, UW Multiple Sclerosis Center, 1536 N 115th St, McMurray Building Suite 130, Seattle, WA 98133, USA
[c] Department of Psychiatry and Behavioral Sciences, School of Medicine, University of Washington, 1959 NE Pacific Street, Box 356560, Seattle, WA 98195, USA

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ABSTRACT

Background and objectives: Evidence-based pharmacological and behavioral interventions are often underutilized or inaccessible to persons with multiple sclerosis (MS) who have chronic pain and/or depression. Collaborative care is an evidence-based patient-centered, integrated, system-level approach to improving the quality and outcomes of depression care. We describe the development of and randomized controlled trial testing a novel intervention, *MS Care*, which uses a collaborative care model to improve the care of depression and chronic pain in a MS specialty care setting.

Methods: We describe a 16-week randomized controlled trial comparing the MS Care collaborative care intervention to usual care in an outpatient MS specialty center. Eligible participants with chronic pain of at least moderate intensity ($\geq 3/10$) and/or major depressive disorder are randomly assigned to MS Care or usual care. MS Care utilizes a care manager to implement and coordinate guideline-based medical and behavioral treatments with the patient, clinic providers, and pain/depression treatment experts. We will compare outcomes at post-treatment and 6-month follow up.

Projected patient outcomes: We hypothesize that participants randomly assigned to MS Care will demonstrate significantly greater control of both pain and depression at post-treatment (primary endpoint) relative to those assigned to usual care. Secondary analyses will examine quality of care, patient satisfaction, adherence to MS care, and quality of life. Study findings will aid patients, clinicians, healthcare system leaders, and policy makers in making decisions about effective care for pain and depression in MS healthcare systems. (PCORI- IH-1304-6379; clinicaltrials.gov: NCT02137044).

This trial is registered at ClinicalTrials.gov, protocol NCT02137044.

1. Introduction

Multiple sclerosis (MS) is the most common cause of acquired neurologic disability in young adults [1]. Because MS is typically diagnosed between the ages of 20 and 50, people live many years managing the physical, cognitive, and psychological aspects of the disease [1]. Chronic pain and major depressive disorder (MDD) are two of the most prevalent problems experienced by MS patients. Nearly 25% of adults with MS have MDD [2] and over 50% experience moderate or severe chronic pain [3–5]. Approximately 20% to 25% of people with MS have both depression and chronic pain [6]. Both are associated with poorer MS outcomes, functioning and health-related quality of life, and greater healthcare utilization [4,7–9].

Depression and chronic pain are often under-treated in MS patients [10], despite the availability of effective treatments [4,5,11,12]. An estimated 50–66% of people with MS and MDD are under-treated [13–16]. Systematic screening alone has not consistently led to adequate treatment [12]. Pain treatments that patients prefer and evidence-based non-pharmacological pain management strategies are seldom used [17]. There is an urgent need to identify ways to improve

Abbreviations: BPI, Brief Pain Inventory; HSCL-20vB, Hopkins Symptom Checklist-20 Version B; MS, Multiple Sclerosis; PHQ-9, Patient Health Questionnaire 9; MS Care, MS Care collaborative care intervention

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* Corresponding author at: University of Washington, Department of Rehabilitation Medicine, Box 359612, Seattle, WA 98104, USA.
E-mail address: ehde@uw.edu (D.M. Ehde).

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access to effective pain and depression care.

Successful healthcare delivery models developed in other patient populations provide a template for improving pain and depression care in MS. One highly successful model is collaborative care, a systematic, population-based approach to integrated care [18]. Core components of collaborative care include: [1] care managers who deliver brief evidence-based treatments and coordinate patients, providers, experts, and community resources; [2] registries to facilitate and track information, including outcomes; [3] measurement based treatment to target; and [4] stepped-care in which treatments are intensified as need [19]. Collaborative care has been used to improve healthcare for depression, and more recently, pain, within primary and specialty care settings [20–24]. Collaborative care is a cost-effective method for improving adherence and response to treatment, quality of life, and satisfaction with care for depression, pain, and other chronic conditions such as diabetes [23–27].

Only one small ($N = 83$), non-randomized trial using a collaborative care approach for depression care has been published in MS [28]. The trial emphasized depression screening, referral to a psychiatric nurse care manager, choice of guideline-based antidepressant or problem-solving therapies, outcomes monitoring, and relapse prevention. About a third ($n = 28$) of the subjects participated in the depression management intervention for a median of seven sessions with the care manager. The authors found that the frequency of major depression at 6-months was lower in the intervention group relative to usual care, suggesting that it is worthwhile to conduct more investigation of this approach. Thus far, no studies have evaluated collaborative care focusing on pain in patients with MS.

We sought to develop and test a new intervention, *MS Care*, which utilized collaborative care principles to improve depression and chronic pain care in MS. The purpose of this paper is to describe: [1] the development and structure of the MS Care intervention for improving chronic pain and depression outcomes in patients with MS, and [2] the methodology of the MS Care study, a randomized controlled trial testing the effectiveness of the intervention in outpatients at a specialty MS clinic.

2. Methods

2.1. Stakeholder engagement during study design and implementation

The MS Care study is funded by the Patient-Centered Outcomes Research Institute (PCORI), which encourages active participation of stakeholders throughout all phases of the research enterprise, from study design through dissemination [29]. In the present study, stakeholders include individuals with MS, partners/family members of individuals with MS, MS clinic providers/staff, and representatives from community advocacy groups, including the National MS Society. Stakeholders are involved in all facets of the study, including shaping the study design and intervention to meet the needs of individuals with MS and the MS treatment environment, identifying outcomes of interest to stakeholders, trouble-shooting problems that come up during study implementation, monitoring study progress, and participating in the dissemination of study results.

2.2. Study aims, hypotheses, and design

The study is a single-center two-group randomized (1:1) effectiveness trial comparing two alternative approaches to pain and depression care in which outcome assessors are unaware of intervention allocation. The specific aims and related hypotheses are:

Aim 1. To test the effectiveness of MS Care, a patient-centered collaborative care approach to treating depression and pain in individuals with MS, relative to usual care, in reducing pain and depression at post-treatment (primary endpoint) and at 6-month follow-up.

Hypothesis 1. Compared to those in usual care, patients randomly assigned to MS Care will demonstrate significantly greater control of both pain and depression at post-treatment (primary endpoint) and at 6-month follow-up.

Aim 2. To examine the impact of MS Care on secondary outcomes including quality of depression and pain care, disability, patient satisfaction, adherence to MS care, and quality of life at post-treatment (primary endpoint) and at 6-month follow-up.

Hypothesis 2. Patients randomly assigned to MS Care will show significantly better quality of life, disability, fatigue, adherence to MS Care, patient satisfaction, and quality of care at post-treatment and 6-month follow-up.

We specifically selected a randomized controlled study design to provide Level I evidence per American Academy of Neurology's Evidence Classification Criteria [30]. Furthermore, as there is clinical equipoise, a randomized study is ethically acceptable. As collaborative care is traditionally offered as an enhancement to care, the question of critical importance is whether MS Care improves outcomes above and beyond that which can be achieved with the current model of usual care.

We will report the participant flow and study procedures following the Consolidated Standards of Reporting Trials (CONSORT) guidelines [31]. The trial was registered on ClinicalTrials.gov on April 22, 2014.

2.3. Study setting

A sample of 190–200 participants (to achieve the goal of 160 completers) is being recruited from the UW Medicine Multiple Sclerosis Center at the University of Washington, Seattle, WA. The UW Medicine MS Center is a multidisciplinary center with in-house neurology, rehabilitation medicine, rehabilitation psychology, rehabilitation counseling, infusion, and nursing services, as well as co-located physical therapy, occupational therapy, and speech therapy services.

2.4. Participant eligibility and recruitment procedures

Inclusion and exclusion criteria were selected to maximize the generalizability of the study findings to the population of patients obtaining care at MS specialty centers. *Inclusion criteria* are: patient [1] has definitive diagnosis of MS confirmed by patient's MS physician in the MS Center using McDonald 2010 criteria;[32][2] plans to continue to receive care at the UW Medicine MS Center during the enrollment period to ensure integration of services; [3] has access to and is able to communicate over the telephone to facilitate the telehealth components of the intervention and outcome assessments; [4] reads, speaks and understands English; [5] is 18 years or older; and [6] reports a clinically significant problem in pain or depression, specifically: (a) chronic pain: average pain intensity in the past week of at least moderate severity (defined as a 3 or greater on 0–10 numeric rating scale)[33] and pain of at least six months duration, with pain reportedly present greater than or equal to half of the days in the past six months; or (b) depression: depressive symptoms over the past two weeks in the range of probable major depression on Patient Health Questionnaire-9 (PHQ-9: total score 10 or higher)[34] and endorsement of depressed mood and/or anhedonia (i.e., one of the cardinal symptoms of depression) present more than half the days in the past two weeks.

Exclusion criteria are: [1] presence of a severe psychiatric disorder as evidenced by (a) high suicide risk (i.e., current intent or plan, or thoughts of suicide in the past month with at least one suicide attempt in the past), (b) diagnosis of bipolar disorder with current psychotic features, or (c) symptoms of a current psychotic disorder [35] at the time of screening; [2] severe cognitive impairment, resulting in inability to provide informed consent, defined as two or more errors on