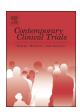
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journal homepage: www.elsevier.com/locate/conclintrial



The macular degeneration and aging study: Design and research protocol of a randomized trial for a psychosocial intervention with macular degeneration patients



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ARTICLE INFO

Article history: Received 4 November 2014 Received in revised form 15 March 2015 Accepted 17 March 2015 Available online 24 March 2015

Keywords:
Randomized controlled trial
Aging
Macular degeneration
Future planning
Preventive problem-solving

ABSTRACT

Background: Age-related Macular Degeneration (AMD) is the leading cause of irreversible and predictable blindness among older adults with serious physical and mental health consequences. Visual impairment is associated with negative future outlook and depression and has serious consequences for older adults' quality of life and, by way of depression, on long-term survival. Psychosocial interventions have the potential to alleviate and prevent depression symptoms among older AMD patients.

Methods: We describe the protocol of the Macular Degeneration and Aging Study, a randomized clinical trial of a psychosocial Preventive Problem-Solving Intervention. The intervention is aimed at enhancing well-being and future planning among older adults with macular degeneration by increasing preparation for future care.

Results: Adequate randomization and therapeutic fidelity were achieved. Current retention rates were acceptable, given the vulnerability of the population. Acceptability (adherence and satisfaction) was high.

Conclusion: Given the high public health significance and impact on quality of life among older adults with vision loss, this protocol contributes a valid test of a promising intervention for maintaining mental and physical health in this population.

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1. Introduction

Age-related Macular Degeneration (AMD) is the leading cause of irreversible and predictable blindness among older

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adults. About 5% of individuals aged 60–64 have early stages of the disease [1]; rates of severe AMD double with each decade after age 60 [2]. AMD is associated with blurring or distortion of central vision, a central blind spot, and loss of detail-, contrast-, and color-vision [3]. Common consequences are an inability to drive, read, watch television, recognize people, and engage in other valued, discretionary activities [4], especially those outside the home, which are central to well-being [5]. Visual impairment often leads to a negative future outlook [6,7] and 33% of patients meet diagnostic criteria for depression [8]. Thus, AMD has serious consequences for older adults' quality of life [8–12]. Furthermore, Medicare beneficiaries with vision loss incur

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significantly higher costs than those with normal vision, and approximately 90% of these costs are non-eye related medical costs [13], suggesting a growing public health concern for this vulnerable population.

1.1. AMD and preparation for future care

In addition to the potential for negative mental health outcomes, the depression symptoms often associated with AMD can lead to difficulty with problem-solving and planning for the future [7,14] and older adults with AMD have lower rates of preparation for future care than their non-vision-impaired peers [15]. The progressive and sometimes sudden vision loss that occurs with AMD places older adults with the disease at increased risk for requiring care and/or change of residence. Because of this risk, preparation for future care activities, such as being aware of possible care needs, gathering information and making choices about preferred types of care, and sharing care plans with caregivers, become especially important in creating a future scenario that meets the individual's needs and preferences. Consistent with theories of active life management [16], and proactive coping [17,18], preparation for future care (PFC), such as discussing preferences and options for long-term care with family members or health care providers, is an adaptive response that improves the management of expected agerelated losses for most older adults. Indeed, a study of primary care patients showed that those with more concrete planning exhibited fewer depression and anxiety symptoms after a twoyear period than those who did not plan [19]. In contrast, lack of future care planning may lead to distress during care decisions, poor everyday functioning, and stress to caregivers [20,21]. Lack of planning for vision loss and age-related health decline may increase the risk of inappropriate residential or care arrangements [22,23] that are not tailored to the patient's values and preferences. Unnecessary health consequences, such as falls and emergency room visits [24-27] may also be viewed as a consequence of poor planning.

1.2. Aims

Because of the negative emotional/mental health effects of Macular Degeneration, several interventions with older AMD patients have been developed in the last decade. These focus on vision rehabilitation [28], adaptive skills training [29], cognitive restructuring or reframing [30], disease knowledge, self-efficacy in using assistive devices and maintaining activities [31,32], problem-solving therapy and behavioral activation to prevent depression [33,34]. Although these studies show that both group interventions and individual home-based problem-solving training can significantly improve functioning and mood in patients with AMD, the beneficial effects rarely exceed 6 months and some have been tested only up to 4 months. We postulate that an AMD intervention with an added focus on future care needs will show longer lasting effects on well-being. The aims of this paper are (1) to present a new intervention that includes preparation for future losses due to vision and aging, (2) to describe an efficacy trial of this intervention, (3) to present evidence for effective randomization in the trial; and (4) to compare this intervention to an enhanced control condition with regard to retention rates, compliance, and satisfaction.

2. Methods

The Macular Degeneration and Aging Study (MADAS) is a randomized clinical trial of older adults with AMD in which Preventive Problem-Solving Intervention (PREPSI) is tested against an Enhanced Attention Control (EAC) condition to examine the effectiveness in improving psychological wellbeing, mood, and preparation for future care. PREPSI addresses PFC by teaching basic problem-solving and then applying these principles to potential future problems. The intervention has two stages. In stage one all participants receive Vision Education (VE) classes to equalize knowledge across groups. In stage two they are randomized to the intervention or control conditions, which are delivered in-home.

2.1. Ethics approval

The study was approved by the Institutional Review Board of the University of Rochester and is registered with ClinicalTrials.gov (NCT02224963). Recruitment has ended, but follow-up is ongoing.

2.2. Recruitment of subjects

Adults aged 60+ who have received a diagnosis of AMD were invited to participate: 631 contacted us by phone in response to advertisements, or were referred to us, with permission for us to call them, by the Association for the Blind and Visually Impaired or area clinicians. Of these, 67 were not eligible, 42 could not be reached, and 248 declined participation for reasons of timing, general lack of interest, or desire for a medical study. A total of 274 agreed to participate; 50 were unable to start at the time they were asked, had family or health issues, or changed their mind. We consented and completed the baseline interview with 224 participants; 207 attended the VE classes. Subject flow is shown in Fig. 1. Recruitment into the trial began in September of 2009 and ended in February of 2014.

2.2.1. Inclusion/exclusion criteria

Inclusion criteria were (1) diagnosis of AMD (2) 60 years and older; (3) able to communicate in English.

After Interview 1, subjects were excluded if they: (1) had significant cognitive impairment at baseline (total score on MMSE(Blind)) <18 [35] (n=5), equivalent to <21 used in other aging studies [36]; (2) resided in a nursing home (assisted living facilities were acceptable) (n=0); (3) were acutely suicidal, psychotic (PI and the clinical psychologist/psychiatrist were paged immediately, n=0), or if their homes were deemed unsafe for staff (n=2). Patients were also excluded if they had a terminal illness preventing completion of the intervention (n=6). Four were lost to follow-up after Interview 1.

2.2.2. Primary recruitment sites and strategies

Participants were recruited from a number of sites: The Association for the Blind and Visually Impaired (ABVI, 30%), the University of Rochester's Flaum Eye Institute (FEI, 9%) and local retinal practices (2%). We also used local media (29% of recruited participants), including newspaper advertisements, television appearances. Finally, we reached 30% of participants

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