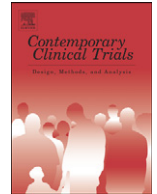




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The Mexican-American Trial of Community Health workers (MATCH): Design and baseline characteristics of a randomized controlled trial testing a culturally tailored community diabetes self-management intervention

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ABSTRACT

Objectives: Community Health Workers (CHWs) have been recommended to reduce diabetes disparities, but few robust trials of this approach have been conducted. Limitations of prior studies include: unspecified *a priori* outcomes; lack of blinded outcome assessments; high participant attrition rates; and lack of attention to intervention fidelity. These limitations reflect challenges in balancing methodologic rigor with the needs of vulnerable populations. The Mexican-American Trial of Community Health workers (MATCH) was a blinded randomized controlled trial testing CHW efficacy in improving physiologic outcomes and self-management behaviors among Mexican-Americans with type 2 diabetes. This paper describes methods used to overcome limitations of prior studies.

Research design and methods: The primary aim was to determine if a CHW intervention would result in significant reductions in Hemoglobin A1c and rates of uncontrolled blood pressure. 144 Mexican-Americans with diabetes were randomized. The intervention consisted of self-management training delivered by CHWs over a 24-month period; the comparison population received identical information via bilingual newsletter. Blinded research assistants completed assessments at baseline, 12 months, and 24 months post-randomization.

Results: The MATCH cohort was characterized by low acculturation and socioeconomic status. Study participants had low rates of medication adherence and glucose monitoring. 70% had poor glycemic control with A1c levels over 7.0, and 57.3% had blood pressures worse than ADA target levels (<130/80).

Conclusions: MATCH preserved community sensitivity and methodologic rigor. The study's attention to intervention fidelity, behavioral attention control, blinded outcomes assessment, and strategies to enhance participant retention can be replicated by researchers testing culturally-tailored CHW interventions.

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1. Introduction

The past decade has seen a significant rise in the prevalence of diagnosed diabetes mellitus among adults in the US, with adverse impact particularly felt by ethnic minorities and low income populations. Compared to a 6.6% rate among

non-Hispanic whites today, the age-adjusted prevalence of diabetes is 11.8% among non-Hispanic blacks, 11.9% among Mexican Americans, and 12.6% among Puerto Ricans [1]. Persistent health disparities in diabetes incidence and complications have led to calls for the development of effective interventions for underserved at-risk groups [2,3]. Glazier's review of interventions to improve diabetes care in socially disadvantaged populations concluded that the most effective interventions were characterized by cultural tailoring, use of lay community educators, individualized treatments, the incorporation of treatment algorithms, a focus on behavior-related tasks, provision of feedback, and a high number of contacts over more than 6 months [4].

The Community Health Worker (CHW) model has garnered great interest in recent years as one such culturally tailored approach towards improving diabetes outcomes. For several decades, CHW programs in the US have hired and trained lay people who live in target communities to provide outreach and health education [5,6]. Although trained and supervised by health professionals, the value of CHWs is believed to lie in the shared experience, language, and/or culture with the communities they serve [7].

Despite their potential to reduce diabetes disparities, CHW interventions have to date had only modest adoption by public and private payers. One barrier to adoption is the paucity of well-designed clinical trials, leading to calls for greater methodologic rigor in the field [6,8–10]. Methodologic limitations may reflect practical challenges in working with vulnerable and underserved communities, in which research processes and external observers may be viewed with suspicion.

This paper describes the design and implementation of the Mexican American Trial of Community Health workers (MATCH), a blinded, behavioral randomized controlled trial to test the efficacy of a CHW intervention in improving diabetes self care and outcomes in a vulnerable minority population. Study design reflected the MATCH investigators' belief that, despite challenges associated with implementing research in underserved communities, a rigorous study design could be used and cultural sensitivity preserved.

MATCH was developed to test the hypothesis that indigenous CHWs, trained to teach culturally appropriate diabetes self-management skills, could reduce mean levels of Hemoglobin A1c levels, and increase the percent of study participants who achieved target blood pressure at the end of 1 year, and sustain these improvements at the end of 2 years. Improvements in three specific self-management behaviors were also assessed: daily self-monitoring of blood glucose, daily medication-taking, and adherence to diet and physical activity recommendations.

2. Research design and methods

2.1. Recruitment

MATCH was designed as a single site behavioral randomized efficacy trial based at Rush University Medical Center, with recruitment from several contiguous Mexican-American neighborhoods in Chicago and adjoining suburbs. Recruitment strategies have been previously described [11]. 144 persons with type 2 diabetes mellitus were randomized to intervention

and attention control conditions. Eligible participants had to be Mexican-American, defined as either having been born in Mexico, or having at least one parent or two grandparents born in Mexico. Because adherence to medications was a major study outcome, assessed using an electronic pill cap device, participants were required to be using at least one oral medication to control their diabetes. To ensure that lack of access to health care services did not pose an insurmountable barrier to diabetes self-management, participants were required to have health insurance or to be enrolled as a patient at a free clinic or public facility at the time of randomization. Exclusions for participation included: active treatment for schizophrenia; inability to provide informed consent; any prior major end-organ complications of diabetes such as end-stage renal disease or stroke; another household member already participating in MATCH; or plans to spend more than 4 months in Mexico in the next year.

Enrollment for the study was completed over a 35 month period. Patient flow from screening to enrollment is shown in Fig. 1. The study had a screening to enrollment ratio of 42%, comparable to other published trials involving Hispanics. In order to test the CHW intervention under real world conditions, no financial or other incentives were offered in exchange for study participation. Recruitment materials, consent documents, and the study protocol were reviewed and approved by the Rush University Institutional Review Board.

2.2. Study design

After giving informed consent, participants underwent baseline evaluations in two separate home visits; twelve participants elected to have these visits conducted in either a community setting or at the Medical Center. During the first visit, the following assessments were completed: demographics, co-morbidities, acculturation [12], health care utilization, the Personal Resource Questionnaire of social support [13], Perceived Discrimination [14], Perceived Stress [15], Spielberger Trait Anxiety [16], Diabetes Empowerment Scale [17], the Summary of Diabetes Self-care Activities [18], the four-item Morisky Medication Adherence Scale [19], the PHQ2 depression screen [20], and the Beck Depression Inventory. Interviews were conducted in the participant's preferred language, using validated Spanish translations of instruments. Clinical assessments included: height, weight, blood pressure, waist circumference and a blood specimen collected for Hemoglobin A1c.

At the conclusion of the evaluation, a medication bottle with a MEMS electronic monitoring pill cap was given to the participants to use with one of their oral diabetes medications to document daily medication adherence (MEMS 6 Track Cap, AARDEX, Ltd, Switzerland). Thirty days later, a brief second visit was conducted to collect the pill cap; at that visit, the participant's glucose meter was also examined to determine the number of days in the preceding month on which glucose had been checked at least once.

Upon return of the electronic pill caps to the Data Management Center (DMC), participants were randomized and informed of their group assignment. Participants could not be blinded to which treatment they were receiving, either educational visits by a community health worker or diabetes education via a bilingual newsletter mailed to their home. In

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