



## Care transitions among Latino diabetics: barriers to study enrollment and transition care

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### ABSTRACT

**Objective:** Latinos are disproportionately affected by diabetes and people with diabetes experience frequent hospital admissions and readmissions. Care transition interventions can help reduce rates of readmission; however, there are many barriers to recruiting Latinos for participation in intervention research. Exploring reasons for study refusal furthers understanding of low research participation rates to help researchers address barriers.

**Design:** This study presents a cross-sectional, descriptive analysis of reasons for study refusal and attrition drawing from data collected as part of a randomized controlled trial conducted to test the effectiveness of a transitions intervention for diabetic Latino discharged from the hospital to home. Reasons for refusal were elicited from participants, transcribed, and coded. Descriptive statistics and bivariate analyses were used to compare those who completed the study and those who did not complete the study.

**Results:** Reasons for study enrollment refusal and loss to follow-up ranged from difficulty locating the patient to homelessness to patient reluctance to having providers in the home. Study completers were more likely than non-completers to reside with family members ( $p = .03$ ) and have a spouse as a primary caregiver ( $p = .08$ ).

**Conclusions:** Inner city, monolingual Latinos may be difficult to enroll and engage in home-based interventions. Although not representative of all Latino populations, barriers encountered highlight the need for targeted research to improve transitional care among Latinos. Researchers and clinicians should take into consideration the unique barriers that Latinos face in participating in research and intervention studies.

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## 1. Introduction

Diabetes is a chronic condition that affects more than 25 million people in the United States (NCCDP 2014). Latinos have a 66% higher risk of developing diabetes than non-Latinos. More than 13% of Latinos have diabetes (Schiller et al. 2010), and compared to

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Caucasians, Latino diabetics experience increased disease-related complications and have greater diabetes-related mortality rates (Kochanek et al. 2011). For all hospital admission, diabetes-related complications account for 20% of admissions (Fraze, Jiang, and Burgess 2010) and the 30-day and 12-month hospital readmission rates for diabetes are 21% and 45%, respectively (Kanel, Elster, and Verbin 2010). Latinos have a significantly higher six-month readmission rate compared to Caucasians and African Americans, with the greatest risk found among lower-income Latinos (Jiang et al. 2005). Given the increased scrutiny on 30-day readmissions brought on by the Affordable Care Act's (ACA) Readmissions Reduction Program and expanding financial penalties for hospitals with high rates of readmissions, there is extreme interest in identifying successful interventions to mitigate these readmission rates among high-risk populations. In fact, the Center for Medicare and Medicaid Innovation has allocated \$500 million over five years in grant funding to support implementation of evidence-based models for care transitions. Thus with tremendous resources at stake, it is important to understand care setting transition experiences among diverse, high-risk subpopulations.

Although Latinos with diabetes are at higher risk for hospital readmission, few studies have specifically targeted this high-risk group for intervention. Numerous studies have documented challenges in recruiting minorities for intervention research (Schmotzer 2012), with low-income, immigrant Latinos cited as a particularly difficult population to recruit (Ford et al. 2008). In a meta-analysis of 22 studies investigating barriers and facilitators among women and minorities in clinical trials, barriers to participation included fear, mistrust of the healthcare system, and perceived burden associated with study activities (Schmotzer 2012). In a diabetes trial targeting Mexican Americans (Martin et al. 2011), researchers found that despite the use of community outreach workers, recruitment remained a challenge. Barriers to recruitment were similar to those identified in the meta-analysis and included perceived burden of the study, lack of financial incentives, and distrust of the study objectives. Latinos are underrepresented in intervention research and as a result, programs that are designed based on evidence found in the literature are limited and may not be relevant or generalizable to the experiences of Latinos. Thus, there is a critical need to understand and address barriers to recruiting and retaining underserved populations, particularly Latinos with diabetes, in intervention research. Further, given the penalties hospitals are incurring for 30-day readmissions, understanding challenges in providing care during transition from hospital to community is critical.

The purpose of this study is to describe barriers to study enrollment, retention, and provision of a care transition intervention among an inner city, largely immigrant, Latino patient population with diabetes. Understanding these barriers will help researchers to improve the participation rates of Latinos in intervention studies in order to increase the representation of this underserved population in the scientific literature. Additionally, it will inform clinicians of the multifaceted challenges in providing care setting transition support.

## 2. Methods

We first present the methods for the intervention study to provide contextual information for the study. Then, we present the methods from the qualitative analyses used to describe the barriers to study enrollment, retention, and provision of the intervention. The intervention was a randomized trial designed to test the effectiveness of a care setting

transitions intervention for Latinos with diabetes discharged from the hospital to home. This study was conducted at two community hospitals in Los Angeles, both of which serve a predominantly Latino population. During the recruitment phase, a recruitment log was created to track the rate of and reasons for refusal to participate. A similar log was created to track the rate of and reasons for drop out after participants enrolled in the study. The study was reviewed and approved by the Institutional Review Board (IRB) of the research university.

### **2.1. The intervention**

The purpose of the transition intervention was to address commonly experienced problems that arise for patients transitioning from hospital to home. Common problems include medication error, difficulty with access to new medication and follow-up medical appointments, lack of linkages to needed community-based services, and lack of understanding of how to better self-manage diabetes. The transition intervention was provided by trained bilingual, bicultural, health educators and consisted of up to three in-home patient visits plus telephone follow-up over a 10-day period. The initial home visit occurred within 48–72 hours of discharge. Subsequent home visits and calls were conducted based on the assessed patient need. Intervention activities included (1) review of discharge plans, medications, and follow-up instructions, (2) assessment of depression, diabetes knowledge, and self-management skills, (3) development of a care plan, and (4) provision of linkages to community and health care services. Given the Latino concept of *familism* which emphasizes the importance of the family unit as a decision-making body (Galanti 2003), family members were invited to participate in the intervention and care plan development. The problems identified in the care plan were mutually agreed upon by the patient, family member(s), and transition coach. Subsequent follow-up contact by the health educator focused on implementation activities related to the care plan developed on the first visit.

### **2.2. Eligibility criteria for the study**

Latinos ages 40 and older with diabetes and admitted to the hospital for a diabetes-related condition (e.g. congestive heart failure, peripheral arterial disease, coronary artery disease or atherosclerosis, eye problems, and amputations) were eligible for study participation. Participants had to be cognitively intact, reside in the community, and able to provide study consent. Exclusion criteria included diagnosis of end-stage renal disease, planned discharge to a nursing facility, or under the care of hospice.

### **2.3. Recruitment and consenting processes**

Trained bilingual research assistants identified patients with diabetes and cause for hospitalization by reviewing hospital admission records. Hospitalized diabetic patients were approached by the research assistant, screened for eligibility, and provided with study information. Initially, participants were asked to sign an informed consent form written in Spanish. However, many patients encountered difficulty with reading the Spanish forms due to low Spanish literacy levels so a protocol change was requested and the IRB approved a verbal consent process. Reasons for refusal were tracked on the recruitment log.

After consenting to participate in the study, each patient was randomly assigned to either the intervention group or usual care. Specific effort was made to utilize evidence-based, effective recruitment and retention methods including (1) employing bilingual research staff, (2) preparing program materials in Spanish, (3) utilizing bicultural health educators, and (4) delivering the intervention in-person (Gallagher-Thompson et al. 2004; Mann, Hoke, and Williams 2005; Yancey, Ortega, and Kumanyika 2006).

## **2.4. Measures**

### **2.4.1. Reasons for refusal to participate in the study and loss to follow-up**

During the recruitment step, eligible patients who refused to participate in the study were asked by the research assistant why they elected not to participate. This information was recorded verbatim. Reasons why study participants refused baseline or subsequent follow-up surveys and interventions were also recorded verbatim by the research assistant and/or health educator conducting the intervention.

### **2.4.2. Demographic data**

Participant characteristics for those who participated in the study were collected using a demographic data collection sheet, administered by the research assistant. These data were initially collected at the initial home visit following hospital discharge, but due to difficulty with contacting participants post discharge, demographic data collection was subsequently collected at the time of study consent, at hospital bedside. Among patients who did not consent to participate in the study, demographic information was not collected, as designated by the IRB.

## **2.5. Analyses**

Descriptive statistics were used to describe the sample. Bivariate analyses were used to compare the characteristics of those lost to follow-up to those who completed the study. Qualitative information about study refusal and lack of receipt of the intervention were extracted from the recruitment logs. Then, two coders read through the data and independently coded each entry line-by-line using a data-driven framework (Hsieh and Shannon 2005; Morse and Field 1995; Patton 2002). This allows codes to emerge from the data as opposed to developing an a priori codebook. Coding results were compared to ensure accuracy and coder discussed any discrepancies. All identified codes were then grouped by similarity and categorized into descriptive themes.

## **3. Results**

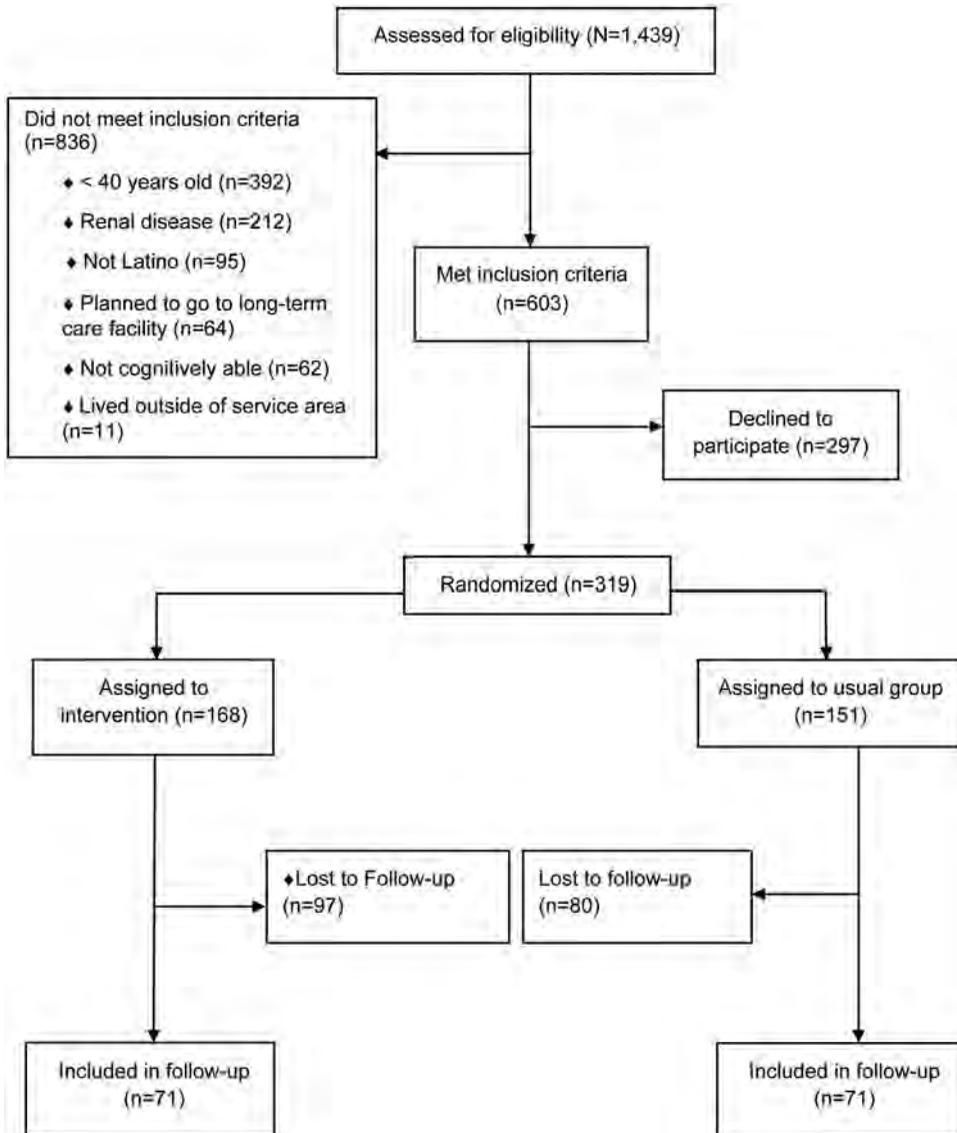
### **3.1. Sample description**

A total of 1439 patients were screened for study eligibility, most of whom (58.1%) did not meet eligibility criteria. Among those who were eligible ( $n = 603$ ), 297 refused participation in the study, with a final sample of 319 randomized into study groups (see Figure 1). Of these, 58 people did not complete the baseline demographics. For those completing the baseline survey, the mean age was 60.3 (SD = 12.6) years; 50.2% were female.

The majority were Mexican (67.7%), born outside the United States (71.5%), did not speak English (92.8%), had high school or less education (64.9%), and had income less than \$20,000 (68.9%). Complete sample descriptions are summarized in [Table 1](#).

### 3.2. Reasons for study enrollment refusal and loss to follow-up

[Table 2](#) presents detailed reasons for study refusal and for loss to follow-up among eligible participants. Of the 297 people who were eligible for participation but refused enrollment, 26.9% did not provide a reason for refusing enrollment. Among those who gave reasons



**Figure 1.** CONSORT diagram of Latino diabetes transitions project.

(73%), 22.9% indicated that they wanted to think about it, but were discharged before signing the consent form, 12.8% believed that they did not need help or were already participating in a similar program, 7.4% were not interested in participating, 4.7% indicated that they were homeless, 4.4% had plans to move to Mexico post discharge, 3.4% refused because family members did not want the patient to participate in the study, 2.7% stated that they were too ill, 2.7% indicated that their diabetes was under control, 2.4% denied having diabetes, 2.4% did not want home visits, and 2.4% did not trust the intervention.

Among the 319 patients enrolled in the study, more than half (55.5%) were lost to follow-up. Of these who were not reachable by phone or a visit, 25.2% did not answer (e.g. the phone would ring with no answer or messages left on answering service were not returned) or were not at home when a research assistant attempting to follow-up in person, and another 25.5% had phone numbers disconnected within 30 days of hospital discharge. An additional 10.2% provided the researchers with a telephone number and/or address that was confirmed to be incorrect. Several participants relocated: 5.1% moved to Mexico, 3.4% moved to a nursing facility, and 2.8% moved out of the area. Additionally, 17.1% were no longer interested, 2.8% did not want home visits, 2.3% indicated that they were too busy to participate, 2.3% had family members refuse, and 5.7% died before the intervention was provided. A full list of reasons for study attrition is located in [Table 2](#).

### **3.3. Study completers versus those lost to follow-up**

Bivariate analysis revealed very little differences between those completing the study and those lost to follow-up. One area of difference was in the patient's living situation. Individuals residing with people other than a spouse or child were more likely to be lost to follow-up ( $p = .03$ ). Similarly, there was a trend toward significance for primary caregivers, with those completing more likely to have a spouse as a primary caregiver as compared with a child or paid caregiver ( $p = .08$ ) (see [Table 1](#)).

## **4. Discussion**

We identified a variety of barriers to study enrollment and completion among a low-income, low literacy, largely immigrant, sample of Latino patients with diabetes. These barriers included potential distrust in participating in the study (evidenced by family member refusal and provision of incorrect telephone numbers) unstable living situations and contact mechanisms, and lack of interest or perceived need for support. Interestingly, a small portion of eligible participants denied having a diagnosis of diabetes despite medical record documentation of the condition.

These findings highlight several areas of significance. First, the potential distrust of research presents a clear barrier to recruitment among minority and underserved communities for participation in studies. The resulting underrepresentation of minority groups in research studies may skew results and limit the generalizability of findings to all populations. Researchers need to continue to explore innovative ways to overcome barriers and build trust within all communities to increase the rate of research participation. Other studies with Latino immigrants have also found trust to be a barrier to research (De La Rosa et al. 2012). In a study of substance abuse and HIV, researchers found that

**Table 1.** Sample characteristics of those who enrolled in the study.

	Total sample <i>n</i> = 319	Completed study <i>n</i> = 142	Lost to follow-up <i>n</i> = 177	<i>p</i> -Value
<i>Age (Mean, standard deviation)</i>	60.3 (12.6)	59.65 (11.8)	60.94 (13.4)	.412
Gender				.899
Male	33.5%	39.4%	28.8%	
Female	50.2%	59.9%	42.4%	
Missing	16.3%	0.7%	28.8%	
Ethnic background				.393
Mexican	67.7%	81.7%	56.5%	
Central/South American	12.0%	13.4%	10.7%	
Puerto Rican	1.6%	1.4%	1.7%	
Other	2.2%	2.1%	2.3%	
Missing	16.6%	1.4%	28.8%	
Born in the United States				.340
No	71.5%	87.3%	58.8%	
Yes	11.6%	12.0%	11.3%	
Missing	16.9%	0.7%	29.9%	
Highest education				.25
Less than high school	64.9%	80.3%	52.5%	
High school graduate or higher	16.9%	17.6%	16.4%	
Did not specify	N/A	N/A	N/A	
Missing	18.20%	2.10%	31.10%	
Marital status				.212
Married	40.1%	51.4%	31.1%	
Single	21.3%	22.5%	20.3%	
Widowed	13.5%	18.3%	9.6%	
Divorced/separated	7.8%	6.3%	9.1%	
Did not specify	N/A	N/A	N/A	
Missing	17.20%	1.40%	29.90%	
Annual income				.283
Under \$10,000	56.7%	69.7%	46.3%	
\$10,000–\$19,000	12.2%	14.8%	10.2%	
\$20,000–\$29,999	3.8%	3.5%	4.0%	
\$30,000–\$45,000	1.6%	2.8%	0.6%	
Don't know/refused	7.5%	6.3%	8.5%	
Missing	18.2%	2.8%	30.5%	
Living arrangement				.966
Own home/apartment	81.6%	81.0%	58.2%	
Family member's house	12.7%	12.7%	9.0%	
Senior living	1.1%	1.4%	0.6%	
Other	4.5%	4.2%	3.4%	
Missing	16.3%	0.7%	28.8%	
Lives with				<b>.025</b>
Alone	10.7%	12.0%	9.6%	
Spouse	33.2%	47.2%	22.0%	
Child	29.2%	32.4%	26.6%	
Paid caregiver	0.6%	0.7%	0.6%	
Other	10.0%	7.0%	12.4%	
Missing	16.3%	0.7%	28.8%	
Type of insurance				.441
Private insurance	6.0%	6.3%	5.6%	
Medicare	16.6%	14.1%	18.6%	
MediCal	30.4%	32.4%	28.8%	
None/self-pay	7.5%	9.9%	5.6%	
Other	3.1%	4.2%	2.3%	
Missing	36.4%	33.1%	39.0%	
Primary caregiver				.083
Spouse/significant other	12.5%	20.4%	6.2%	
Child	12.2%	12.0%	12.4%	
None	47.6%	54.9%	41.8%	
Paid caregiver	0.3%	5.6%	5.6%	
Other	5.6%	6.3%	5.1%	
Missing	16.3%	0.7%	28.8%	

Notes: Chi-square test and t-test excluded missing responses. Bold indicates  $p < .05$ .

**Table 2.** Detailed reasons for study refusal and for loss to follow-up.

Reasons	Refused study enrollment (n = 297)	Enrolled, but lost to follow-up (n = 177)
Undetermined/no reason	26.9%	0
Discharged without signing consent	22.9%	N/A
Believe help not needed/participating in a similar program	12.8%	0
Not/no longer interested in participating	7.4%	17.1%
Homeless	4.7%	0
Going/moved to Mexico	4.4%	5.1%
Moved to nursing facility	N/A	3.4%
Moved out of area	N/A	2.8%
Family members did not want the patient to participate	3.4%	2.3%
Wrong telephone/address given	N/A	10.2%
Telephone disconnected/unable to reach	N/A	50.7%
Physical/mental illness	2.7%	0
Diabetes under control	2.7%	0
Doesn't have diabetes	2.4%	0.9
Doesn't want in-home visits	2.4%	2.8%
Distrusts study/intervention/reluctance	2.4%	0
Too busy/no time	2.0%	2.3%
Listening to his own doctor only	1.7%	0
Died	0	5.7%
Other	1.3%	2.7%

although participants provided correct contact information, many did not answer phone calls and researchers struggled to get participants to return their messages (De La Rosa et al. 2012). In a recent review of barriers to research participation among African Americans, Latinos, Asian Americans, and Pacific Islanders, George et al. (2014) found that mistrust was a shared barrier across these four groups. Competing demands, language barriers, and fear of unintended outcomes were also reported in multiple groups. Language barriers were not found in the current study because of the use of bilingual research assistants. Although fear of unintended outcomes was not reported by participants, it is possible that this sentiment is reflected in the reported lack of perceived need for support.

Second, the discrepancy between the documentation of diabetes on a patient's medical record and their verbal denial of the condition may represent a miscommunication of the diagnosis. For patients who may be monolingual, the use of appropriate interpreters is important to ensure that the patient and provider are communicating effectively. The discrepancy may also represent the patient's refusal to acknowledge their condition to others which has the potential to prevent them from accessing resources and services that may be of benefit. These findings highlight the importance of building trust and improving communication within minority and underserved communities.

Rates of refusal for this study do not differ widely from those of a similar care setting transitions study conducted among a largely Caucasian sample within the same county. Researchers documented a 26.5% refusal rate, with the most common reasons for refusal being lack of need for transition care support, having sufficient caregiving support in the home, and unwillingness to have someone come to their home (Coulourides et al. 2014). Similarly to this study, the researchers reported that half of eligible patients were lost to hospital discharge prior to signing a consent form. However, attrition rates among the largely Caucasian, higher income participants were significantly lower; 37.0% were lost to follow-up as compared with 55.5% of our study of largely low-income, immigrant, Latinos. Reasons for participant drop out also differed between

samples. None of the largely Caucasian sample provided researchers with an incorrect telephone number and 10.4% of the Caucasian sample had a disconnected telephone at three months post discharge as compared with 25.5% of the Latino sample (Coulourides, Navarro, and Enguidanos 2013).

We found a few differences between those who completed our study and those who were lost to follow up. This finding provides some insight for researchers and health care providers in trying to identify participants or patients who are higher risk for attrition and lack of medical follow-up. One area of significance was in living situation. Patients living in non-family arrangements were more likely to drop out than patients living with family members. This may speak to the instability of living situations when people reside with individuals other than family members.

#### **4.1. Clinical implications**

Transition programs for low-income, monolingual Latino populations may want to consider implementing models that provide an intervention based largely in the hospital rather than the home or community (Dedhia et al. 2009; Jack et al. 2009; Williams and Coleman 2009). For example, the BOOST program (Williams and Coleman 2009) focuses on risk screening, medications management, and disease and medication education and training during the hospital with post-discharge telephone support. This type of approach may overcome many of the barriers identified in the current study, such as lack of stable living situation and contact mechanisms. However, these interventions must rely heavily on training during the hospital stay. Through initiation of transition coaching during hospitalization, potential barriers arising from mistrust may be overcome, enabling improved success in provision of follow-up services and support.

Many barriers identified in this study may impact not only participation in a research study but also access to medical services. Distrust or discomfort, which may be reflected in the wrong phone numbers provided and refusal of home visits, may preclude Latinos with diabetes from allowing medical professionals such as social workers and nurses into their home. Thus, in home-based interventions and medical programs, such as home health and hospice, may be declined by this population. Similarly, health literacy issues, language barriers, and lack of a stable living situation may prevent Latinos from following up with specialty care referrals and following through with other discharge recommendations.

The study has several limitations. This study was conducted within one city and may not be representative of all Latino populations. Reasons for refusal and study attrition were gathered through patient report and may not be reflective of actual reasons for refusal. Additionally, about 25% of our sample did not provide a reason for refusal.

Barriers encountered in this study illustrate challenges encountered in enrolling low-income, immigrant Latino groups in research studies and the provision of medical care continuity among Latinos with diabetes. This study also highlights the need for further research to improve transitional care among Latinos. Additionally, care transition interventions targeting monolingual Latino populations may need to reevaluate their approach to this care.

#### **Disclosure statement**

No potential conflict of interest was reported by the authors.

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## Key messages

- (1) Numerous barriers exist to engaging inner city Latinos in longitudinal research.
- (2) Study and intervention designs, particularly for hospitalized Latinos, must consider strategies to overcome reluctance to participate in research and barriers to longitudinal follow-up.

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