

Title: Diabetes Health Information Technology Innovation to Improve Quality of Life for Health Plan Members in Urban Safety Net

Abstract: 99 words

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Abstract

Safety net systems need innovative diabetes self-management programs for linguistically diverse patients. A low-income government-sponsored managed care plan implemented a 27-week automated telephone self-management support (ATSM) / health coaching intervention for English, Spanish-, and Cantonese-speaking members from four publicly-funded clinics in a practice-based research network. Compared to waitlist, immediate intervention participants had greater 6-month improvements in overall diabetes self-care behaviors (standardized effect size [ES] 0.29, $p < 0.01$) and SF-12 physical scores (ES 0.25, $p = 0.03$); changes in patient-centered processes of care and cardiometabolic outcomes did not differ. ATSM is a strategy for improving patient-reported self-management and may also improve some outcomes.

Trial Registration: NCT00683020

Key words: self care; diabetes; health information technology; health literacy; limited English proficiency; chronic disease; healthcare disparities; practice-based research network

Introduction

Patient-centered, culturally concordant care is a cornerstone of chronic disease care (Institute of Medicine, 2001). Patients with limited health literacy (LHL) and limited English proficiency (LEP) face barriers to communication and access leading to suboptimal care and poor health outcomes (Davis et al., 2006; Fernandez et al., 2011; Sarkar et al., 2010; Schillinger, Bindman, Wang, Stewart, & Piette, 2004; Schillinger, Barton, Karter, Wang, & Adler, 2006; Agency for Healthcare Research and Quality, 2010).

With health care reform, Medicaid will expand coverage among low-income adults with chronic medical conditions, particularly for LHL and LEP patients (Martin & Parker, 2011; Maxwell, Cortes, Schneider, Graves, & Rosman, 2011; Pande, Ross-Degnan, Zaslavsky, & Salomon, 2011; Sentell, 2012; Sommers, Tomasi, Swartz, & Epstein, 2012). Medicaid managed care administrators report a need for innovative strategies to promote diabetes self-management among these populations (Goldman, Handley, Rundall, & Schillinger, 2007; Rittenhouse & Robinson, 2006). Health-related quality of life (HRQOL) is an increasingly important patient-centered care goal that also predicts utilization (DeSalvo et al., 2009; Dorr et al., 2006; Fleishman, Cohen, Manning, & Kosinski, 2006; Magid, Houry, Ellis, Lyons, & Rumsfeld, 2004; Montori & Fernandez-Balsells, 2009; Norris, Engelgau, & Narayan, 2001; Rubin & Peyrot, 1999; Selby, Beal, & Frank, 2012; Singh, Nelson, Fink, & Nichol, 2005).

The U.S. Department of Health and Human Services highlighted automated telephone self-management (ATSM) as an exemplary strategy to enhance outcomes for LHL populations (Institute of Medicine, 2010). A randomized controlled trial among safety net patients with poorly controlled diabetes was associated with improvements in self-management behaviors, self-reported days in bed, and interference in daily activities, with a cost utility for functional

outcomes comparable to other diabetes interventions (Handley, Shumway, & Schillinger, 2008; Schillinger, Handley, Wang, & Hammer, 2009).

To translate research into practice, a low-income government-sponsored managed care plan implemented language-concordant ATSM with health coaching for members with diabetes at 4 clinics within an urban practice-based research network (PBRN). The Self-Management Automated and Real-Time Telephonic Support Study (SMARTSteps / Pasos Positivos / 明智進步計劃) is a controlled quasi-experimental evaluation of the program's impact on health-related quality of life, diabetes self-management, patient-centered processes of care, and cardiometabolic outcomes.

Methods

San Francisco Health Plan (SFHP) is a non-profit government-sponsored managed care plan created to provide high quality medical care to the largest number of low-income San Francisco residents possible. Community Health Network of San Francisco (CHNSF) – the public health department's integrated healthcare delivery system – is part of the San Francisco Bay Area Collaborative Research Network (<http://accelerate.ucsf.edu/community/sfbaycrn>), UCSF's primary care practice-based research network that supports the development and dissemination of practice-based evidence that improve in primary care practices and health outcomes in diverse communities.

The quasi-experimental evaluation used a waitlist variant of a stepped wedge design, in which SFHP randomized participants to waitlist or immediate intervention during four recruitment waves (April 2009 – March 2011) and waitlist participant crossed over to

intervention after 6 months (Handley, Schillinger, & Shiboski, 2011; Ratanawongsa et al., 2012). This design permitted controlled evaluation, but with less intensive implementation staffing, and allowed all participants to participate in the intervention.

Eligible members were English-, Cantonese-, or Spanish-speaking adults (age ≥ 18) with diabetes type 1 or 2 and ≥ 1 primary care visit in the preceding 24 months to one of four CHNSF clinics. Members who were pregnant, lacked a touch-tone phone, leaving the region, or unable to provide verbal consent were ineligible. We retained in this evaluation those who disenrolled from SFHP membership during the study. We assessed diabetes diagnoses through the CHNSF diabetes registry or a combination of SFHP claims with confirmation clinician-documented diagnosis of diabetes, fasting glucose ≥ 126 mg/dl, or HbA1c $\geq 7\%$ (American Diabetes Association, 2009).

SFHP conducted recruitment through mailed post cards and scripted outreach calls. Enrollment workers confirmed eligibility by phone, offered \$25 gift card incentives, and assessed willingness to complete evaluation interviews administered by UCSF bilingual research assistants, who later obtained verbal consent by telephone. The Committee on Human Research at the University of California, San Francisco, approved the evaluation.

Interventions

SFHP assigned program participants through language-stratified randomization to 2 immediate intervention arms and 2 waitlist control arms. Tailored for literacy, language, and culture with extensive patient input (Schillinger et al., 2008), the ATSM system provided 27 weeks of 8-12 minute weekly calls in English, Cantonese, or Spanish. Calls offered rotating sets of queries about self-care, psychosocial issues, and access to preventive services. Patients

received health education messages using narratives based on their touchtone responses. A series of cognitive interviews with English-, Spanish-, and Cantonese-speaking patients were used to develop and refine both the queries and health education messages, as well as the response protocols (Schillinger et al., 2008). “Out-of-range” responses triggered callbacks within 3 days from a language-concordant SFHP lay health coaches, who engaged in collaborative goal-setting to form patient-centered action plans (Bodenheimer & Handley, 2009; Fisher, Brownson, O'Toole, Shetty, Anwuri, & Glasgow, 2005; Lorig, 2006). Health coaches – supervised by an SFHP registered nurse care manager – documented in the SFHP care management database system, but contacted primary care clinics by email, fax, and phone for actionable concerns.

One of the two intervention arms received the ATSM intervention as well as medication activation and intensification coaching, triggered by self-reported non-adherence on ATSM responses, refill non-adherence by pharmacy claims, or suboptimal cardiometabolic measures (Ratanawongsa et al., 2012). This evaluation paper focuses on the comparison between the combined ATSM intervention groups and the waitlist control.

Waitlist participants received usual clinical care and existing SFHP benefits (reminders and incentives for receipt of recommended health services). After the 6-month waitlist period, participants crossed over to begin one of the 2 interventions.

Measures

Structured computer-assisted telephone interviews occurred within 2 weeks of randomization and at 6-month follow-up (after the conclusion of ATSM for immediate intervention participants or prior to crossover for waitlist participants). Spanish and Cantonese

questionnaires were translated and back-translated into English. Participants received a \$50 gift card for each interview.

Self-reported socio-demographic variables included age, gender, race/ethnicity, language, English proficiency (Wilson, Chen, Grumbach, Wang, & Fernandez, 2005), years since immigration to the U.S., marital status, educational attainment, employment status, annual household income, self-reported health literacy (Chew et al., 2008; Sarkar, Schillinger, Lopez, & Sudore, 2011), and duration of diabetes.

HRQOL was captured by SF-12 physical and mental component scores, calculated and transformed to a 100-point scale (Ware, Kosinski, & Keller, 1996). Secondary outcomes included:

- Self-reported days spent mostly in bed due to health problems, in the prior 30 days (Schillinger et al., 2009)
- Diabetes “often” or “always” interfering with normal daily activities (Gill, Allore, & Guo, 2003; Piette, Weinberger, & McPhee, 2000; Schillinger et al., 2009)
- Diabetes self-care in the preceding 7 days (0 to 7 overall and for each subscale) (Fleming et al., 2001; Toobert, Hampson, & Glasgow, 2000)
- Diabetes self-efficacy (“how difficult has it been for you to do the following things for your diabetes exactly as members of your diabetes health care team recommended”) over the prior 6 months (0 to 100 scale) (Heisler, Bouknight, Hayward, Smith, & Kerr, 2002)
- Patient Assessment of Care for Chronic Conditions (PACIC) over the prior 6 months (100-point scale) (Glasgow, Whitesides, Nelson, & King, 2005)
- Interpersonal Processes of Care (IPC) over the prior 6 months (100-point scale) (Schillinger et al., 2009; Stewart, Napoles-Springer, Gregorich, & Santoyo-Olsson, 2007)

For all program participants, regardless of interview participation, we abstracted cardiometabolic measures obtained through routine care – hemoglobin A1c (HbA1c), low-density lipoprotein (LDL), and blood pressure (BP) – from the CHNSF electronic health record, clinical registry, and paper charts 45 days before or 45 days after target dates (baseline, 6 months, and 12 months). If multiple measures were available, we used values closest to the target date.

Analyses

We assessed for differences in baseline characteristics between waitlist and immediate intervention participants using chi-square tests, Fisher’s exact tests, t-tests, and Wilcoxon tests. We compared 6-month changes for each outcome for the waitlist control and immediate intervention groups, on an intent-to-treat basis, using linear and logistic regression adjusting for baseline values. We calculated standardized effect sizes for scales. For self-reported days in bed, we used negative binomial models to calculate log mean differences and generated incidence rate ratios.

Estimating 500 eligible SFHP members, we anticipated recruitment of 260 participants, with 10% drop-out or loss to follow-up at 6 months. We calculated that we would have 80% power to detect a standardized effect size (SE) of 0.35 in the primary outcome of SF-12 scores. We estimated 20% of participants would have missing cardiometabolic data, yielding 80% power to detect a difference in HbA1c of 0.51% (SE 0.28).

Results

The Figure depicts the CONSORT flow diagram. Among those randomized, 252 participants (70%) completed both a baseline and 6-month follow-up interviews. Table 1 describes sociodemographic and medical characteristics of both groups, which had no observable differences. Among the 151 intervention participants who received all 27 weeks of calls, 85% completed at least one call. Immediate intervention participants completed a median of 20 calls (interquartile range 5-25).

Table 2 shows all outcomes comparing intervention to waitlist control participants. Intervention participants reported better changes in overall diabetes self-care behaviors with standardized effect sizes (ES 0.29, $p < 0.01$), as well as subscale improvements in glucose monitoring (ES 0.30, $p < 0.01$) and foot checks (ES 0.32, $p < 0.01$). However, changes in self-efficacy, physical activity and exercise time, PACIC scores, and IPC scores did not differ between immediate intervention and waitlist control participants. We also observed a possible 6-month improvement in the primary outcome measure, the SF-12 physical component scores (standardized effect size [ES] 0.25, $p = 0.03$), without concomitant improvements in SF-12 mental component scores, self-reported days in bed, or diabetes interference.

Using baseline and 6-month follow-up values for 106 participants for HbA1c, 167 participants for BP, and 39 participants for LDL, we found no differences between waitlist and intervention groups in cardiometabolic outcomes.

Discussion

This study waitlist-controlled study of automated self management (ATSM) support in diabetic patients confirms some benefits documented in prior randomized controlled trials

(Handley, Shumway, & Schillinger, 2008; Schillinger, Handley, Wang, & Hammer, 2009) .In particular, our ATSM documented improvement in patients' self-management behaviors and possible improvement in physical function. The study is also important because it demonstrates the potential value of waitlist-controlled method in buy practice setting where randomization would not be possible.

This PBRN study harnessed partnerships among a government-sponsored health plan, a safety net integrated health care system, and practice-based implementation researchers to translate a self-management support intervention from a randomized controlled trial into a practical implementation for a vulnerable population (Beach et al., 2006; Bonell et al., 2011; Chin et al., 2001; Cooper, Hill, & Powe, 2002; Glasgow, Davis, Funnell, & Beck, 2003; Green, 2008; Tunis, Stryer, & Clancy, 2003). Patients with LHL and LEP lack access to traditional self-management support, a critical component of chronic disease care delivery (Fisher, Brownson, O'Toole, Shetty, Anwuri, & Glasgow, 2005; Institute of Medicine, 2001; Institute of Medicine, 2004; Agency for Healthcare Research and Quality, 2010). Safety net implementation of self-management programs requires staff re-training, organizational change, investments in information technology, and tailoring for diverse populations (Eakin, Bull, Glasgow, & Mason, 2002; Fiscella & Geiger, 2006; Regenstein et al., 2005; Sarkar et al., 2008; Wagner, Austin, & Von Korff, 1996). ATSM with health coaching may represent a more scalable strategy for health plans and health systems aiming to enhance chronic disease outcomes at a population-level (Bennett, Coleman, Parry, Bodenheimer, & Chen, 2010; Margolius et al., 2012; Wolever & Eisenberg, 2011).

Our findings showed differences in some outcomes measured over shorter timeframes (diabetes self-management over 1 week and SF-12 physical component score for last 30 days)

but not longer-term outcomes (IPC, PACIC, and cardiometabolic outcomes over 6 months). This may be due to the fact that the intervention lasted 6 months and behavior change occurs slowly over time; because of the crossover design, we were not able to measure how differences may have been sustained or changed over 12 months. The 6-month timeframe may partly explain why self-efficacy scores were not significantly different, but this measure also depends on patient perceptions of the patient-centeredness of the health care team's recommendations and communication styles. Thus, this measure may correlate more with the PACIC and IPC measures.

The lack of improvements in patient-centered processes (PACIC and IPC) or cardiometabolic outcomes may be due to SFHP health coach inability to document within the electronic health record, SFHP lack of prescribing authority, and the population's good baseline control. However, cardiometabolic targets may not correlate with quality of life and must be adjusted based on individuals' medical and social comorbidities, values, and preferences (American Diabetes Association, 2009; Montori & Fernandez-Balsells, 2009; Sundaram et al., 2007). Future interventions should consider health IT-facilitated strategies to integrate health plan interventions with patient-centered medical homes.

The evaluation had limitations. The change in HRQOL was small. Phone-based population recruitment may have resulted in selection bias. SFHP health coach turnover may have caused variation in the fidelity of health coach counseling and documentation. Health coaches were linguistically but not necessarily culturally-concordant with patients. The results may not be generalizable to other Medicaid managed care populations. Recruitment and cardiometabolic data availability did not reach target goals for evaluating cardiometabolic outcomes. Finally, additional patient stakeholder engagement in defining the content and

approaches to the health coaching component may have improved the effectiveness of this intervention. For example, in recently funded work adapting SMARTSteps for diabetes prevention among women with recent gestational diabetes, the research team is partnering with local Women, Infant, and Children (WIC) programs and conducting focus groups to elicit postpartum women's perspectives about their health concerns, barriers to care, and desires for prevention support. This effort will help tailor the relevance of health messages, coaching narratives, and protocols for this population's specific goals and preferences, in addition to language and literacy (Handley, 2013).

In summary, this PRBN study demonstrated that a health IT self-management innovation for diverse low-income beneficiaries with diabetes was associated with high rates of engagement, enhanced self-care, and a modest improvements in one measure of HRQOL. Medicaid plans may benefit from efficient implementation of similar HIT-facilitated interventions to improve self-management and HRQOL in their populations. Moreover, this waitlist-controlled study of ATSM confirms the result of a previous RCT. This finding alone is important for those who need to conduct research in busy practice settings where randomization is not possible.

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Table 1: Baseline sociodemographic and medical characteristics in a quasi-experimental evaluation study of a language-concordant automated telephone self-management / health coaching diabetes intervention by a low-income government-sponsored health care plan (N=252)

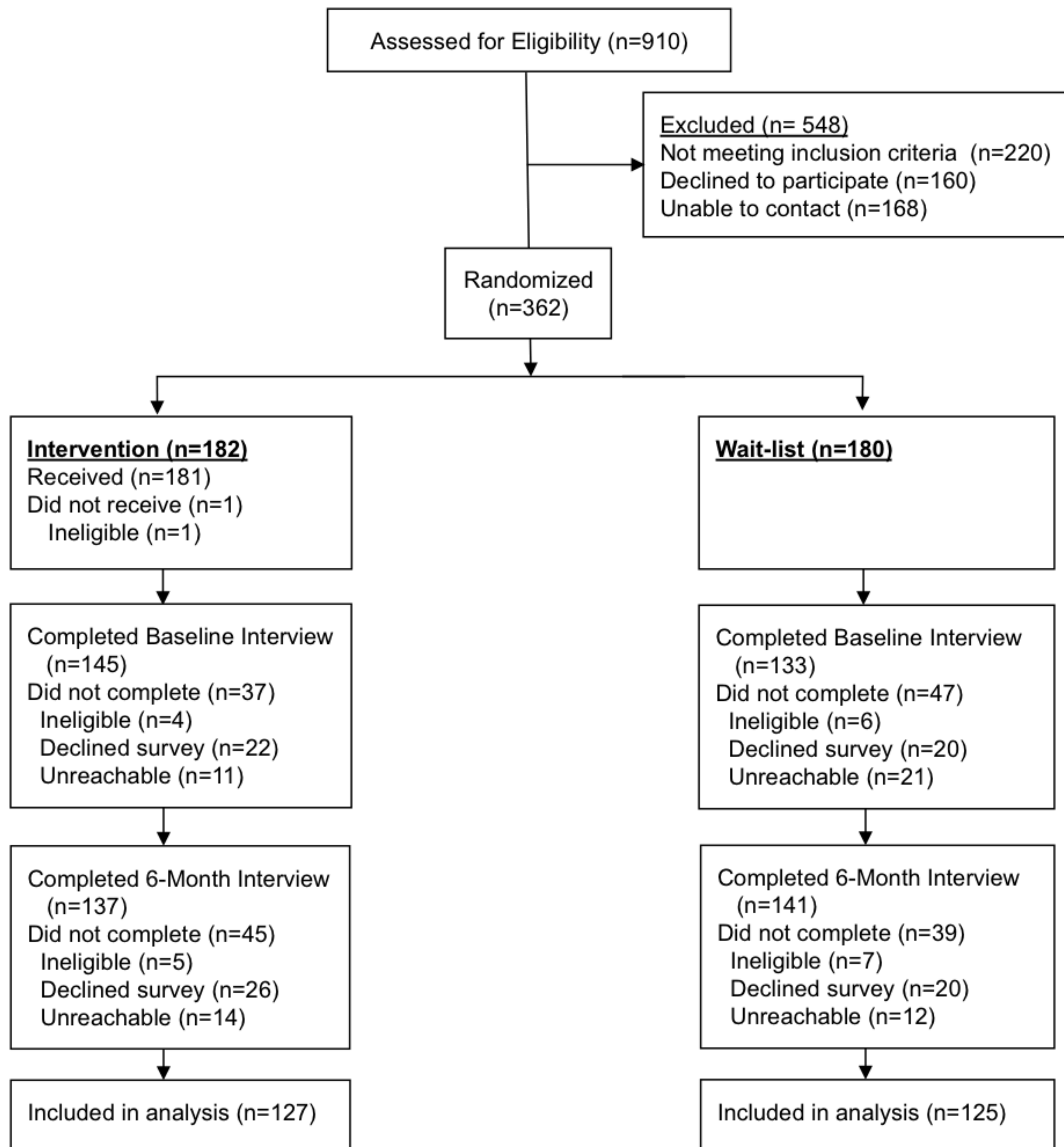
Table 2: Outcomes for intervention and waitlist controls in a quasi-experimental evaluation study of a language-concordant automated telephone self-management / health coaching diabetes intervention by a low-income government-sponsored health care plan (n=252)

Figure: Patient recruitment and randomization flowchart for a quasi-experimental evaluation study of a language-concordant automated telephone self-management / health coaching diabetes intervention by a low-income government-sponsored health care plan

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Table 1: Baseline sociodemographic and medical characteristics in a quasi-experimental evaluation study of a language-concordant automated telephone self-management / health coaching diabetes intervention by a low-income government-sponsored health care plan (N=252)

Characteristic	Intervention (n=127)	Waitlist (n=125)	p- value*
Age in years, mean (SD)	56.5 (7.9)	55.0 (8.6)	0.21
Women, n (%)	98 (77.2)	89 (71.2)	0.28
Race / ethnicity, n (%)			0.40+
Latino	32 (25.2)	25 (20.0)	
Black / African-American	7 (5.5)	12 (9.6)	
Asian / Pacific Islander	77 (60.6)	78 (62.4)	
White / Caucasian	7 (5.5)	9 (7.2)	
Multi-Ethnic / Other	4 (3.2)	1 (0.8)	
Born outside the U.S., n (%)	110 (86.6)	106 (84.8)	0.68
Language, n (%)			0.97
Cantonese-speaking	69 (54.3)	69 (55.2)	
Spanish-speaking	25 (19.7)	23 (18.4)	
Language-concordant primary care provider	33 (36.7)	26 (29.5)	0.31
Educational attainment, n (%)			0.41
8 th grade education or less	50 (39.4)	58 (46.4)	
Some high school	13 (10.2)	12 (9.6)	
High school graduate or GED	33 (26.0)	22 (17.6)	
College graduate or above	31 (24.4)	33 (26.4)	
Limited health literacy, n (%)	58 (46.0)	50 (40.0)	0.33
Employment status, n (%)			0.57
Employed full-time	28 (22.0)	26 (20.8)	
Part-time	63 (49.6)	58 (46.4)	
Unemployed	12 (9.4)	15 (12.0)	
Disabled	7 (5.0)	13 (10.4)	
Homemaker / Retired / Other	17 (13.4)	13 (10.4)	
Annual household income, n (%)			0.99
≤ \$20,000	73 (63.6)	75 (63.0)	
\$20,001 – 30,000	24 (20.3)	25 (21.0)	
>\$30,000	19 (16.1)	19 (16.0)	
Financial Class - Insurance type, n (%)			0.61‡
Medicaid	28 (22.2)	22 (17.6)	
Medicare	4 (3.2)	7 (5.6)	
Uninsured/Commercial	1 (0.8)	2 (1.6)	
Healthy Worker/Healthy San Francisco	93 (73.8)	94 (75.2)	
Diabetes years, mean (SD)	6.9 (5.9)	7.2 (5.4)	0.36
Insulin treatment, n (%)	25 (19.7)	18 (14.4)	0.26
Hemoglobin A1c >8.0%, n (%)	37 (29.8)	29 (24.4)	0.34
Hemoglobin A1c, mean (SD)	7.8 (1.6)	7.5 (1.3)	0.13
Systolic blood pressure, mean mm Hg (SD)	127.3 (17.3)	128.1 (18.2)	0.60
Low-density lipoprotein, mean mg/dL (SD)	92.7 (30.3)	93.5 (31.5)	0.84

* P-values derived from chi-square tests for categorical variables if appropriate and Fisher's exact tests if needed, t-tests for interval variables if normally distributed and Wilcoxon tests if interval variables not normally distributed (age, diabetes duration and cardiometabolic indicators).

† P-values calculated based on categories of Asian / Pacific Islander, Black / African-American, Hispanic / Latino, Multiethnic / Other, and White / Caucasian

‡ P-values calculated based on categories of Healthy Worker / Healthy San Francisco, Medicaid (Community Alternatives Program or Fee-For-Service), Medicare, and Commercial / Uninsured.

Table 2: Outcomes for intervention and waitlist controls in a quasi-experimental evaluation study of a language-concordant automated telephone self-management / health coaching diabetes intervention by a low-income government-sponsored health care plan (n=252)

Outcome	Intervention (n=127)		Waitlist (n=125)				
	Baseline	6 Months	Baseline	6 Months			
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Difference* (95% CI)	Standardized Effect Size*	p-value
Physical SF-12	46.1 (9.0)	47.4 (8.8)	46.5 (9.5)	45.5 (10.1)	2.0 (0.1,3.9)	0.25	0.03
Mental SF-12	48.7 (10.7)	50.4 (11.1)	49.9 (10.4)	49.4 (11.0)	1.4 (-0.9,3.6)	0.14	0.23
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Difference* (95% CI)	Rate Ratio* (95% CI)	p-value
Self-reported days in bed in prior month	1.4 (4.5)	1.0 (3.3)	1.0 (3.2)	1.6 (5.1)	-0.5 (-1.3, 0.13)	0.6 (0.3, 1.4)	0.25
	Proportion	Proportion	Proportion	Proportion		Odds Ratio* (95% CI)	p-value
Diabetes interference†	6.3%	3.9%	8.9%	8.8%		0.5 (0.2, 1.4)	0.18
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Difference* (95% CI)	Standardized Effect Size*	p-value
Overall Diabetes Self-Care	4.5 (1.0)	5.1 (0.9)	4.4 (1.0)	4.8 (1.1)	0.3 (0.1, 0.5)	0.29	<0.01
Medication adherence	6.5 (0.8)	6.7 (0.7)	6.3 (1.5)	6.5 (1.1)	0.0 (-0.2, 0.2)	0.01	0.87
Self-efficacy	76.7 (13.7)	82.6 (12.6)	73.5 (17.7)	80.1 (16.0)	1.1 (-2.1, 4.2)	0.07	0.49
Patient assessment of chronic illness care	44.0 (23.9)	55.5 (24.1)	45.2 (23.0)	54.9 (23.3)	1.3 (-3.0, 5.6)	0.07	0.54
Interpersonal processes of care	58.4 (11.7)	56.5 (11.1)	58.3 (11.3)	54.5 (11.3)	2.0 (-0.4, 4.4)	0.17	0.11
Hemoglobin A1c	8.0 (1.7)	7.5 (1.1)	7.9 (1.5)	7.7 (1.2)	-0.3 (-0.6, 0.1)	-0.22	0.13

Systolic blood pressure	129 (20.2)	129 (16.9)	128 (19.2)	128 (16.2)	0.6 (-3.8, 5.1)	0.03	0.78
Diastolic blood pressure	74.1 (12.4)	75.8 (11.6)	76.0 (12.6)	74.6 (9.9)	2.1 (-0.6, 4.9)	0.19	0.13
Low-density lipoprotein	121.0 (42.4)	106.0 (33.0)	98.9 (29.1)	90.8 (25.4)	11.0 (-6.5, 28.4)	0.28	0.22

* Regression adjusted for baseline values.

† Proportion of participants choosing responses of “often” or “always.”