Effects of Self-Management Support on Structure, Process, and Outcomes Among Vulnerable Patients With Diabetes

A three-arm practical clinical trial

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OBJECTIVE — Despite the importance of self-management support (SMS), few studies have compared SMS interventions, involved diverse populations, or entailed implementation in safety net settings. We examined the effects of two SMS strategies across outcomes corresponding to the Chronic Care Model.

RESEARCH DESIGN AND METHODS — A total of 339 outpatients with poorly controlled diabetes from county-run clinics were enrolled in a three-arm trial. Participants, more than half of whom spoke limited English, were uninsured, and/or had less than a high school education, were randomly assigned to usual care, interactive weekly automated telephone self-management support with nurse follow-up (ATSM), or monthly group medical visits with physician and health educator facilitation (GMV). We measured 1-year changes in structure (Patient Assessment of Chronic Illness Care [PACIC]), communication processes (Interpersonal Processes of Care [IPC]), and outcomes (behavioral, functional, and metabolic).

RESULTS — Compared with the usual care group, the ATSM and GMV groups showed improvements in PACIC, with effect sizes of 0.48 and 0.50, respectively ($P < 0.01$). Only the ATSM group showed improvements in IPC (effect sizes 0.40 vs. usual care and 0.25 vs. GMV, $P < 0.05$). Both SMS arms showed improvements in self-management behavior versus the usual care arm ($P < 0.05$), with gains being greater for the ATSM group than for the GMV group (effect size 0.27, $P = 0.02$). The ATSM group had fewer bed days per month than the usual care group (−1.7 days, $P = 0.05$) and the GMV group (−2.3 days, $P < 0.01$) and less interference with daily activities than the usual care group (odds ratio 0.37, $P = 0.02$). We observed no differences in A1C change.

CONCLUSIONS — Patient-centered SMS improves certain aspects of diabetes care and positively influences self-management behavior. ATSM seems to be a more effective communication vehicle than GMV in improving behavior and quality of life.

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Self-management support (SMS) is a cornerstone of chronic disease care, encompassing strategies such as individualized assessment, collaborative goal-setting, skills enhancement, access to resources, and continuity of care (1,2). Efficacy studies of disease management that include SMS have shown improved patient satisfaction, knowledge, self-efficacy, coping, and behavior but have less consistently shown improved physiological outcomes or functional status (3,4). The complex, multifaceted nature of interventions has precluded identifying effects of the SMS component. Few studies have involved ethnically diverse, socioeconomically vulnerable populations (5), have taken place in safety net settings (6,7), or have compared alternate forms of SMS or measured effects across a range of outcomes (5).

"Practical clinical trials," studies of evidence-based, reproducible interventions designed to enable rigorous evaluation with respect to both reach and effectiveness, can address these limitations (8). The Improving Diabetes Efforts Across Language and Literacy (IDEALL) project was a practical clinical trial conducted in a safety net health system that implemented two SMS strategies (automated telephone self-management support [ATSM] and group medical visits [GMV]) as adjuncts to care, and compared them with usual care. We report effectiveness results of the IDEALL project across a range of diabetes outcomes.

RESEARCH DESIGN AND METHODS

The rationale and design of the IDEALL project have been described previously (9,10). The project emanated from a strategic initiative to improve diabetes care in the Community Health Network of San Francisco, the integrated delivery system of the San Francisco Department of Public Health.

Interventions

We selected SMS strategies with different approaches to engaging patients. ATSM uses technology to provide surveillance, education, and patient activation. Efficacy studies of ATSM linked to nurse care management indicate improvements in satisfaction and functional status (11,12). GMV uses a group process to provide support, education, and patient activation. GMV has been shown to improve self-efficacy and functional status among selected patients with chronic diseases (13,14). Both strategies are rooted in self-efficacy theory, share objectives charac-

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teristic of patient-oriented SMS (1), and promote collaborative goal-setting in the form of behavioral "action plans" (1,5), wherein patients set short-term self-management goals. SMS models were delivered in English, Spanish, and Cantonese.

Detailed descriptions of interventions and related materials are available (10). Participants randomly assigned to ATSM received weekly, automated (prerecorded) telephone calls over 39 weeks (9 months). Patient responses triggered either immediate, automated health education messages and/or subsequent nurse phone follow-up (Fig. A1, available in an online appendix at http://care.diabetesjournals.org/cgi/content/full/dc08-0787/DC1). Each ATSM call takes between 6 and 10 min for patients to complete. There were no monetary incentives associated with ATSM calls. The GMV arm involved 90-min monthly sessions over 9 months, with 6–10 participants, cofacilitated by a primary care physician and health educator (Fig. A2, available in an online appendix). GMV participants received bus tokens and healthy snacks.

Medication intensification was not an explicit goal of either SMS model. All patient interactions between ATSM care managers and GMV cofacilitators, including action plans created and achieved, were documented via a standardized SMS record that also served to communicate with the patient's physician. There were no explicit expectations for either SMS model regarding comanagement with the primary care physician.

Recruitment

Details regarding recruitment and eligibility were reviewed elsewhere (9,10). Between June 2003 and December 2004, we created a registry to identify adult patients with type 2 diabetes in the Community Health Network of San Francisco, who spoke English, Spanish, or Cantonese, made ≥1 primary care visit in the prior year, and had a most recent A1C ≥8.0%. Primary care physicians excluded patients who had moved away or died, had moderate to severe dementia, or were not expected to live through the year. Research assistants approached patients for participation and to further assess for exclusions, including *1*) anticipated travel of >3 months in upcoming year, *2*) too ill or unable to travel to a GMV, *3*) no phone access, *4*) self-reported hearing impairment, and *5*) visual acuity of ≥20/100 or inability to follow instructions on a telephone keypad.

Eligible patients attended a study enrollment visit at the San Francisco General Hospital Clinical Research Center. Informed consent was obtained after a language-concordant document written at the 6th-grade level was read to potential participants. Patients were allocated using stratified (on languages) blocked randomization. Patients were encouraged to see their regular doctor as usual. Participants received $15 and $25 for the baseline and 1-year follow-up research visits, respectively. The study was approved by the institutional review board of the University of California, San Francisco.

Study variables

We developed a questionnaire in English, translated it into Spanish and Cantonese, and then back-translated in an iterative fashion to achieve concordance in meaning. The questionnaire assessed the characteristics shown in Table 1. Health literacy was measured in English and Spanish only using the short-form Test of Functional Health Literacy in Adults (15). We categorized scores of 0 to 22 as limited health literacy and of 23 to 36 as adequate health literacy.

Outcomes

Our primary outcome was 1-year change in self-management behavior. We further explored a range of outcomes corresponding to levels of the Chronic Care Model (CCM) (2). CCM is an ecological model describing factors, including self-management support, that can improve functional and clinical outcomes. We used a set of scales corresponding to *1*) structure, *2*) process, and *3*) health outcomes.

To assess patients' perspectives regarding the degree to which structure of care was aligned with the CCM, we used the Patient Assessment of Chronic Illness Care (PACIC) instrument (16) and transformed summary scores to a 100-point scale, with higher scores representing greater CCM alignment. We also explored effects on individual PACIC subscales.

To assess patients' perspectives regarding the degree to which processes of care were aligned with the CCM, we used the Diabetes Quality Improvement Program diabetes self-efficacy measure over the prior year (17) using a 0 to 100 scale. We used the Interpersonal Processes of Care for Diverse Populations (IPC) instrument (18) to capture patient reports of providers' communication over the prior year and generated a total IPC score on a 100-point scale. We also explored effects on individual IPC subscales.

We grouped health outcomes into behavioral, functional, and metabolic outcomes. To assess self-management behavior, we used a validated instrument that asks on how many of the previous 7 days the individual performed recommended activities: eating healthy foods, following a diabetic diet, exercising, self-monitoring of blood glucose, and caring for one's feet (19). Because our research with this population identified high rates of self-reported medication adherence (18), for parsimony, we did not include this item. We generated weekly self-care scores ranging from 0 to 7, with higher scores corresponding to greater number of days carrying out recommended behaviors. For exercise, participants also estimated minutes of moderate and vigorous physical activity on each of the days.

For functional status, we obtained reports of days in the prior month participants "spent most of the day in bed due to health problems" and the extent to which diabetes prevented them from carrying out normal daily activities (diabetes interference), using a 5-point Likert-type scale ranging from "not at all" to "completely" (11,12,20). We measured quality of life using the Short Form (SF)-12 instrument, transforming physical and mental health to 0–100 scales.

For metabolic outcomes, at baseline and at 1 year, we measured A1C (high-performance liquid chromatography method; Bio-Rad, Hercules, CA). Both systolic (SBP) and diastolic blood pressure (DBP) were measured using calibrated automated cuffs (Criticon Dinamap). We calculated BMI by measuring weight and height without shoes and with light clothing and an empty bladder. For the small number of participants who did not attend follow-up assessments, we obtained A1C, blood pressure, and weight by abstracting charts for values obtained within 3 months before or after the 12-month follow-up time.

Statistical analyses

We assessed success of randomization using *t* tests, χ^2 tests, and Fisher's exact test to compare baseline characteristics across study arms. We report the degree of engagement with each intervention, mea-

Table 1—*Baseline characteristics: IDEALL participants*

	All participants	ATSM	GMV	Usual care	*P* values
n	339	112	113	114	
Age (years)	56.1 ± 12.0	55.9 ± 12.7	56.5 ± 11.4	55.8 ± 11.8	0.9
Women	59.0	58.0	63.7	55.3	0.4
Ethnic group					0.5
Asian	23.3	26.8	21.2	21.9	
African American	20.6	14.3	23.9	23.7	
White/Latino	46.9	46.4	46.0	48.3	
White/non-Latino	7.7	9.8	8.0	5.3	
Other/unknown	1.5	2.7	0.9	0.9	
Language					
English	45.4	46.4	45.1	44.7	1.0
Spanish	43.1	42.0	43.4	43.9	
Cantonese	11.5	11.6	11.5	11.4	
Health literacy*					
Limited	58.8	51.0	57.1	68.0	0.1
Adequate	41.	49.0	42.9	32.0	
Education					
Up to some high school	54.3	51.8	55.8	55.3	0.6
High school graduate/GED	17.1	14.3	17.7	19.3	
≥ Some college	28.6	33.9	26.6	25.4	
Insurance					
Medicaid	19.8	20.5	22.1	16.7	0.9
Medicare	21.5	19.6	23.0	21.9	
Uninsured	50.2	50.0	46.0	54.4	
Other	8.6	9.8	8.9	7.0	
Income					
≤$5,000	28.6	26.9	31.6	27.3	0.4
$5,000–$10,000	31.8	31.5	33.7	30.3	
$10,000–$20,000	23.7	18.0	23.2	29.3	
$20,000–$30,000	9.2	14.6	6.3	7.1	
≥$30,000	6.7	9.0	5.2	6.0	
Diabetes duration (years)	9.5 ± 7.4	9.1 ± 7.3	9.2 ± 6.8	10.4 ± 8.1	0.3
Mean outpatient visits, prior year	14.1	13.3	15.3	13.7	0.3
Diabetic educator visit, prior year	53.4	58.0	49.6	53.5	0.4
Nutritionist visit, prior year	37.5	34.8	39.8	37.7	0.7
Diabetes treatment regimen					0.8†
Diet only	1.2	0.0	0.9	2.7	
Oral agents only	60.8	63.4	59.3	59.8	
Insulin only	10.1	10.7	9.7	9.8	
Insulin and oral agents	27.9	25.9	30.1	27.7	
Poor or fair health	76.4	74.1	77.0	78.1	0.8
A1C	9.5 ± 2.0	9.3 ± 1.8	9.4 ± 2.0	9.8 ± 2.0	0.2
Blood pressure					
SBP	140.0 ± 20.8	137.8 ± 21.5	143.5 ± 20.0	138.7 ± 20.7	0.1
DBP	77.3 ± 12.0	75.7 ± 12.1	78.4 ± 12.7	77.8 ± 11.2	0.2
BMI	31.5 ± 10.0	30.3 ± 6.7	31.9 ± 8.2	32.3 ± 13.5	0.3

Data are means ± SD or %. *Health literacy is based on the short version of the Test of Functional Health Literacy in Adults scale, except for Cantonese patients (n = 39), for whom scores were not obtained. †Fisher's exact test.

sured by the percentage of whoever responded to an ATSM call or attended a GMV and the mean number of behavioral action plans generated and achieved. More detailed descriptions of engagement with the interventions can be found in a companion article (10).

We measured 1-year change for each outcome in each study arm. We present mean values and 1-year changes in mean scale scores. For physical activity measures, in addition to reporting changes in minutes per week, we calculated the difference in the proportion of subjects who met minimum standards of ≥30 min of moderate or vigorous physical activity ≥3 times/week, as recommended in national guidelines. For bed days, because of the nonparametric distribution, we report median values. For diabetes interference, we measured the proportion reporting that diabetes "often" to "always" interfere with daily activities.

To test intervention effects, we compared differences in change across the three arms; analyses were conducted on an intent-to-treat basis. In tables, we present raw (unadjusted) values at baseline and 1 year and calculate differences for each intervention arm relative to usual care and for ATSM versus GMV, adjusting only for baseline values for each scale. To enable interpretation of effects that involve scales, we also calculated standardized effect sizes. For continuous variables, we used linear regression; for dichotomous variables, we used logistic regression. For bed days, we used negative binomial models to calculate log mean differences and generated incidence rate ratios.

We powered the study to detect a difference between any of the three arms of 0.5 days/week in diabetes self-management behavior, our primary outcome. We determined that 339 subjects would result in 100 subjects in each arm at the end of the study ($n = 300$), providing 80% power to detect a difference in diabetes self-care of 0.49 days/week, using two-tailed tests, α of 0.05, and Bonferroni correction for three group comparisons.

RESULTS — We approached 557 potential subjects, 70 of whom refused, 90 of whom were not eligible, and 58 of whom were potentially eligible but did not attend the study enrollment visit (Figure A3, available in an online appendix). Thus, 339 (61%) subjects enrolled and were randomly assigned to ATSM ($n = 112$), GMV ($n = 113$), or usual care ($n = 114$). Participants had a mean age of 56 years, more than half had some high school education or less, half lacked health insurance, and the majority reported incomes <$30,000 (Table 1). A roughly equal percentage spoke English or Spanish, followed by Cantonese. Among English and Spanish speakers, more than half had limited health literacy. A1C at enrollment was 9.5%, blood pressure was 140/77 mmHg, and BMI was 31.5 kg/m^2. There were no statistically significant differences in baseline characteristics across arms.

Of the subjects, 305 (90%) completed follow-up interviews at 1 year (Figure A3). Three participants died during the study period in each of the three arms. Participants lost to follow-up were younger (51.7 vs. 56.5 years, $P = 0.02$) but otherwise were no different at $P <$ 0.05. Paired values for A1C were available for 88.2% of the sample, blood pressure for 94.1%, and BMI for 92.3%.

Engagement with interventions

Of the 112 randomly assigned subjects, 105 (94%) completed ≥1 ATSM call. The mean number of ATSM calls completed among ever users was 21.9 of 39 automated calls delivered. Among ATSM users, 100 (95%) received ≥1 care manager call-back, and the mean number of call-backs was 9.2. Of these, 88 (88%) created ≥1 action plan, with a mean of 5.2. Partial or complete success was reported to care managers on a mean of 2.5 action plans.

Of the 113 randomized participants, 78 (69%) attended ≥1 GMV. The mean number of GMVs attended among ever users was 4.8 of 9 GMVs offered. Among GMV attendees, 69 (89%) created ≥1 action plan. This subgroup generated a mean of 3.2 action plans and reported partial or complete success to GMV facilitators on a mean of 1.6. Across both SMS interventions, exercise and/or diet constituted the majority of action plans.

Effects on structure and processes of care

Both ATSM and GMV participants demonstrated robust improvements relative to usual care participants in PACIC ($P < 0.0001$), with standardized effect sizes of 0.51 for ATSM versus usual care and 0.53 for GMV versus usual care (Table 2). No significant differences were observed between ATSM and GMV participants in overall PACIC change. For PACIC subscales, both ATSM and GMV participants demonstrated significant improvements relative to usual care participants in delivery system/practice design, goal setting, problem-solving, and follow-up/coordination. Only ATSM participants demonstrated significant improvements relative to usual care participants in patient activation (Table A1, available in an online appendix).

ATSM and GMV participants showed similar improvements in diabetes self-efficacy relative to usual care participants (effect size 0.41, $P < 0.01$, and 0.38, $P < 0.01$), with no significant differences between ATSM and GMV participants. In contrast, participants in ATSM reported improvements in interpersonal communication relative to both the usual care (0.50, $P < 0.001$) and GMV participants (0.31, $P = 0.03$). For the IPC subscales, ATSM yielded significant improvements relative to usual care in explanations of processes of care, explanations of self-care, and empowerment and significant improvements relative to both usual care and GMV in elicitation of patient problems and decision-making (Table A1).

Effects on behavior

Compared with usual care participants, ATSM and GMV participants showed significant increases in self-management behavior (Table 2). The increase was more robust for ATSM than for GMV participants (effect size 0.34, $P = 0.02$). For individual self-management domains (Table A1), both ATSM and GMV participants improved with respect to self-monitoring of blood glucose, but only ATSM participants improved foot care. Although ATSM and GMV participants increased relative to usual care participants for diet and exercise, only ATSM participants reported a significant increase in physical activity, with 2 more h/week relative to usual care participants (effect size 0.31, $P = 0.03$).

In a comparison of baseline and follow-up reports, a greater percentage of ATSM participants achieved weekly minimum recommendations regarding physical activity of ≥30 min three times per week (59.8 vs. 68.3%; odds ratio [OR] 1.5 [95% CI 0.9–2.4]). There was little change observed for GMV participants (60.2 vs. 59.6%, 1.0 [0.6–1.5]) and a reduction in usual care participants (58.8 vs. 53.3%; 0.8 [0.5–1.2]). The interaction between the ratio of those achieving standards of physical activity at baseline versus follow-up was significant in ATSM participants versus usual care participants ($P = 0.05$) but not in a comparison of ATSM versus GMV participants ($P = 0.50$).

Effects on functional outcomes

ATSM participants reported significant decreases in days restricted to bed compared with usual care participants (−1.7 days/month, rate ratio 0.5 [95% CI 0.3–1.0]) and with GMV participants (−2.3 days/month, rate ratio 0.4 [0.2–0.7]) (Table 2). ATSM participants were less likely to report that diabetes prevented them from carrying out daily activities: 15% reported activity restriction at baseline, compared with 6% at 1 year (OR 0.37 [95% CI 0.1–0.9]). Comparable values for GMV participants were 16 and 17% (1.0 [0.5–2.0]) and for usual care participants were 17 and 21% (1.3 [0.7–2.3]). The interaction between the proportion reporting restricted activity at

Table 2—*Comparison of baseline and 12-month outcomes*

	Baseline	12-Month follow-up	Adjusted differences (95% CI): Relative to usual care	Adjusted differences (95% CI): ATSM vs. GMV	Standardized effect size (adjusted)	*P* values
Structure of care						
Patient assessment of chronic illness care (summary scale)						
ATSM	36.8 (23.4)	58.9 (23.1)	12.2 (5.6 to 18.8)		0.51	0.0003
GMV	39.3 (26.6)	60.2 (27.2)	12.6 (6.0 to 19.2)		0.53	0.0002
Usual care	41.0 (24.2)	48.2 (26.5)				
				−0.4 (−7.0 to 6.1)	−0.02	0.9
Processes of care						
Diabetes self-efficacy						
ATSM	71.7 (17.3)	77.2 (14.6)	6.0 (2.0 to 10.1)		0.41	0.003
GMV	73.3 (16.1)	77.2 (15.0)	5.5 (1.4 to 9.6)		0.38	0.008
Usual care	73.5 (18.5)	71.7 (17.8)				
				0.5 (−3.6 to 4.6)	0.04	0.8
Interpersonal processes of care (summary scale)						
ATSM	59.2 (20.3)	72.9 (15.4)	9.0 (4.0 to 13.9)		0.50	0.0004
GMV	63.4 (21.3)	68.9 (21.3)	3.3 (−1.7 to 8.3)		0.18	0.2
Usual care	62.9 (20.6)	65.4 (21.1)				
				5.7 (0.7 to 10.7)	0.31	0.03
Behavioral outcomes						
Self-management, weekly (summary scale, in days)						
ATSM	3.7 (1.1)	4.4 (1.1)	0.6 (0.4 to 0.9)		0.62	<0.0001
GMV	3.9 (1.2)	4.1 (1.1)	0.3 (0.01 to 0.6)		0.30	0.04
Usual care	3.9 (1.2)	3.8 (1.1)				
				0.3 (0.1 to 0.6)	0.34	0.02
Moderate physical activity, weekly (min)						
ATSM	206	325.0	123.9 (14.8 to 233.0)		0.31	0.03
GMV	285	320.5	69.1 (−41.2 to 179.4)		0.17	0.2
Usual care	195	193.5				
				54.8 (−62.1 to 186.3)	0.14	0.3
Vigorous exercise, weekly (min)						
ATSM	55	54.8	32.2 (−9.8 to 74.2)		0.21	0.1
GMV	41	45.4	23.3 (−19.0 to 65.5)		0.15	0.3
Usual care	67	23.0				
				8.9 (−33.7 to 51.5)	0.06	0.7
Functional outcomes					*Rate ratio*	
Bed days, prior month						
ATSM	3.8 (8.0)	1.4 (2.7)	−1.7 (−3.3 to −0.1)		0.5 (0.3, 1.0)	0.05
GMV	3.6 (7.0)	3.6 (7.5)	0.6 (−1.0 to 2.2)		1.4 (0.7, 2.9)	0.3
Usual care	3.9 (7.6)	3.1 (7.2)				
				−2.3 (−3.9 to −0.4)	0.4 (0.2–0.7)	0.004
Restricted activity (% ≥ often/always)						
ATSM	14.9	6.0	0.4 (0.01 to 0.9)*			0.03*
GMV	16.3	16.2	1.0 (0.5 to 1.9)			0.9
Usual care	17.1	21.0	1.3 (0.7 to 2.3)			0.4
SF-12 mental health						
ATSM	57.2 (28.1)	67.0 (25.8)	3.7 (−2.0 to 9.4)		0.18	0.2
GMV	61.7 (24.0)	63.0 (24.0)	−2.9 (−8.6 to 2.9)		−0.15	0.3
Usual care	58.8 (26.7)	64.2 (27.2)				
				6.5 (0.7 to 12.4)	0.31	0.03

Table 2—*Continued*

	Baseline	12-Month follow-up	Adjusted differences (95% CI): Relative to usual care	Adjusted differences (95% CI): ATSM vs. GMV	Standardized effect size (adjusted)	P
SF-12 physical health						
ATSM	51.3 (30.0)	60.2 (29.1)	2.7 (−4.0 to 9.5)		0.11	0.4
GMV	50.9 (29.5)	57.1 (29.7)	−0.1 (−6.9 to 6.7)		−0.01	1.0
Usual care	50.0 (30.5)	56.7 (31.3)				
				2.9 (−4.0 to 9.7)	0.12	0.4
Metabolic outcomes						
A1C (%)						
ATSM (n = 101)	9.3 (1.7)	8.7 (1.9)	−0.1 (−0.5 to 0.4)		0.04	0.8
GMV (n = 96)	9.3 (1.9)	9.0 (2.0)	0.2 (−0.2 to 0.7)		−0.14	0.3
Usual care (n = 103)	9.8 (2.1)	9.0 (2.2)				
				−0.3 (−0.8 to 0.2)	0.18	0.2
SBP (mmHg)						
ATSM (n = 107)	136.9 (21.4)	136.9 (20.4)	−3.2 (−8.3 to 1.9)		0.19	0.2
GMV (n = 104)	142.4 (19.8)	138.9 (20.3)	−3.9 (−9.0 to 1.2)		0.23	0.1
Usual care (n = 108)	139.6 (20.8)	141.5 (23.9)				
				0.7 (−4.5 to 5.9)	−0.04	0.8
DBP (mmHg)						
ATSM (n = 107)	75.0 (11.8)	75.4 (12.3)	−1.6 (−5.1 to 2.0)		0.14	0.4
GMV (n = 104)	78.1 (12.7)	75.5 (11.3)	−3.1 (−6.6 to 0.4)		0.26	0.08
Usual care (n = 108)	78.1 (10.9)	78.5 (18.5)				
				1.5 (−2.0 to 5.1)	−0.13	0.4
BMI (kg/m^2)						
ATSM (n = 104)	30.3 (6.8)	30.7 (6.9)	0.1 (−0.4 to 0.5)		−0.06	0.8
GMV (n = 104)	32.1 (8.2)	32.4 (8.4)	0.02 (−0.5 to 0.5)		−0.01	0.9
Usual care (n = 105)	31.2 (8.7)	31.4 (8.5)				
				0.1 (−0.4 to 0.5)	−0.06	0.8

Baseline and 12-month follow-up data are on a 0–100 scale unless otherwise indicated. For ATSM, n = 101; for GMV, n = 99, and for usual care, n = 105, unless otherwise specified. *Data are ORs for change within ATSM that is significantly different from change within usual care (OR 0.4 vs. 1.3, P = 0.02); GMV is not significantly different from usual care or ATSM (P > 0.20).

baseline versus follow-up was not significant for ATSM versus GMV participants (P = 0.6) but was for ATSM versus usual care participants (P = 0.04). Although SF-12 physical health increased across all three groups, there were no statistically significant differences between ATSM, GMV, and usual care participants. SF-12 mental health differentially improved for ATSM relative to GMV (effect size 0.31, P = 0.03) and usual care (effect size 0.18, P = 0.2) participants.

Effects on metabolic outcomes

Glycemic control improved across all three arms, but there were no statistically significant differences in A1C change between ATSM, GMV, and usual care participants. Although SBP and DBP fell in both the ATSM and GMV arms relative to the usual care arm, these values did not reach statistical significance. Changes in BMI were not different across the three arms.

Post hoc analyses

To better understand our findings regarding the relative superiority of ATSM over GMV, we carried out two post hoc analyses. To test whether the different engagement rates might explain observed differences in behavioral and functional outcomes, we created a standardized, three-level variable that categorized participant engagement into low, medium, and high. Whereas greater engagement was associated with improvements in self-management behavior and functional status in both SMS arms, including this variable as a covariate in our models did not alter the size of the effect of ATSM relative to that of GMV for either outcome. To explore whether disproportionate improvements in IPC observed in ATSM versus GMV mediated differences in behavioral and functional outcomes, we reran self-management and bed-day models, including IPC scores as an additional covariate. Inclusion of IPC scores reduced the effect of ATSM versus GMV for self-management behavior from 0.33 days/week (P = 0.02) to 0.25 days/week (P = 0.07) and reduced the rate ratio in bed days from 0.35 (P < 0.01) to 0.45 (P = 0.03).

CONCLUSIONS

— We performed an effectiveness study of SMS using a three-arm practical clinical trial design among linguistically and ethnically diverse, low-income diabetic patients in a safety net system. To our knowledge, this represents the first study to compare different forms of diabetes SMS with usual care. We found that providing tailored SMS using patient-generated behavioral action plans resulted in improvements in patients' experiences with chronic illness care, self-efficacy, and self-management behaviors. The ATSM model yielded more robust and consistent improvements across many levels of the CCM and was uniquely associated with improvements in interpersonal processes of care, physical activity, and functional status, suggesting that this form of SMS is particularly effective for vulnerable populations. That the differences between ATSM and GMV participants with respect to behavior and functional status were reduced when we included interpersonal processes of care as a mediator suggests that communication characteristics inherent to the ATSM model, such as its proactive nature or hierarchical logic (capacity to trigger telephonic information or nurse call-backs contingent on patient responses) may have preferentially activated those with greater SMS needs.

Our findings are consistent with research in other settings and support the versatility of ATSM methodology. Efficacy studies of ATSM linked to nurse care management demonstrated improvements in self-efficacy and functional status (11) but did not show effects on diet or physical activity. As with our study, there was little effect of ATSM with respect to glycemic control, although positive effects on glycemic control for a subgroup with poor control were reported.

Our mixed results regarding the GMV model are also noteworthy. Prior studies of GMVs have not been population-based, with enrollment of only those reporting a very high level of interest in attending GMVs (21), or reported outcomes among subjects who attended groups and compared them with wait-list control subjects irrespective of ultimate attendance (14). As the GMV model has begun to diffuse into practice, there is evidence that it improves processes of care but has little effect on metabolic outcomes. Only one-half to two-thirds of patients report any interest in attending GMVs (22). We used a population-based strategy to identify and enroll all eligible, consenting participants, regardless of the extent of their reported willingness to attend GMVs or respond to ATSM calls. Although we have previously reported a lower rate of participation for GMVs compared with ATSM (10), our post hoc analysis suggests that differences in participation do not explain the disproportionate improvements observed for ATSM participants.

There are a number of possible explanations for the lack of effect on metabolic outcomes. First, because we only enrolled participants who had A1C of ≥8.0%, all three arms were subject to regression to the mean. Second, the sample size was too small to detect modest changes in glycemic control. Recent controlled studies of telephone-based counseling and other forms of SMS suggest that A1C tends to fall by only 0.3% (5,23,24). Third, observed improvements in self-management behavior may not, in isolation, lead to rapid and clinically significant improvements in glycemic control. In addition, we found no evidence that participants were more likely to be taking insulin or other hypoglycemic medications as a result of exposure to either SMS arm (data not shown). Interventions that provide decision support to patients and clinicians regarding medication intensification may be required to improve clinical metrics.

Although the lack of effect on metabolic indicators in response to SMS exposure is noteworthy, the beneficial effects on patient-reported diabetes behavior and functional outcomes in ATSM are both clinically relevant and meaningful from the patients' perspective. Increases in physical activity, for example, can yield improvements in cardiovascular fitness and functional status, independent of associated weight loss, glycemic control, or reductions in blood pressure. Similarly, because diabetes is strongly associated with functional decline and progression to disability, the reduction in number of days spent bed-bound in ATSM participants represents an important short-term benefit for a sample of whom more than three-fourths reported fair or poor health. Measures of restricted activity, such as bed days, are robust predictors of functional decline among community-dwelling individuals with chronic disease (20).

Study strengths include a randomized design, population-based recruitment, a safety net setting, a multilingual population with a range of literacy skills, the implementation of linguistically tailored SMS embedded in, rather than "carved out" of, primary care (5), high rates of participant follow-up, and use of validated outcome measures. There are a number of limitations to this study. First, although the practical clinical trial design increased external validity (9), interventions took place in one safety net health system. Second, many study end points were captured by patient report. Because the study was not blinded and because the usual care group did not receive any additional SMS intervention, systematic inaccuracies in patient-reported outcomes may have occurred due to recall bias or social desirability. The measures of self-management behavior and functional status used have been shown to be reliable and valid indicators of objective health measures, the research assistants were masked to participants' group assignment, and the randomized design reduced the likelihood of an intervention-specific bias, particularly given the differential changes in outcomes observed between interventions. Third, we cannot determine whether differences between the ATSM and GMV models resulted from their different structures, program logic, periodicity, or levels of intensity. Fourth, the study was not adequately powered to provide definitive answers regarding relative impacts across subgroups, such as those with limited English proficiency and limited literacy. Finally, although start-up and implementation costs of the ATSM and GMV programs were similar, a formal cost-effectiveness analysis was beyond the scope of this report but is the subject of a companion article (25).

In summary, traditional SMS approaches often do not reach significant segments of the population with chronic disease, such as individuals who are uninsured or publicly insured or those with communication barriers, such as limited literacy or limited English proficiency (26). This represents a significant limitation with respect to realizing the public health benefits of SMS. Although implementing elements of the CCM in community health centers can improve quality indicators (7), there is little translational research as to how to improve patient-reported outcomes in safety net settings (5). Providing tailored SMS for linguistically and ethnically diverse diabetic patients in a safety net system resulted in improvements in patients' experiences with chronic illness care, self-efficacy, and self-management behaviors. The ATSM model, which combines accessible technology with targeted interpersonal support, yielded more robust and consistent improvements across many levels of the CCM, including functional status. For health system planners, our study suggests that ATSM is a more effective communication vehicle than GMV to deliver population-based SMS and improve health-promoting behavior and quality of life. For SMS programs to also translate into improvements in metabolic indicators, they may need to be combined with additional features of the CCM, such as decision support regarding medication intensification.

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