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Active Care Management Supported by Home Telemonitoring in Veterans with Type 2 Diabetes: (The DiaTel Randomized Controlled Trial)

Running Title: Diabetes Telemonitoring (DiaTel) Study

Roslyn A. Stone, PhD,[1,2] R. Harsha Rao, MD,[3,4] Mary Ann Sevick, ScD,[2,4,5,6] Chunrong Cheng, PhD,[1,2] Linda J. Hough, MPH,[7] David S. Macpherson, MD,[4,8] Carol M. Franko, CRNP,[5] Rebecca A. Anglin, RN,[3] D. Scott Obrosky, MS,[4] Frederick R. DeRubertis, MD[3,4]

From the [1]Department of Biostatistics, Graduate School of Public Health, University of Pittsburgh, Pittsburgh, Pennsylvania; [2]Center for Health Equity Research and Promotion, VA Pittsburgh Healthcare System, Pittsburgh, Pennsylvania; [3]Medical Specialty Service Line, VA Pittsburgh Healthcare System, Pittsburgh, Pennsylvania; [4]Department of Medicine, School of Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania; [5]Geriatric Research Education and Clinical Center, VA Pittsburgh Healthcare System, Pittsburgh, Pennsylvania; [6]Department of Behavioral and Community Health Sciences, Graduate School of Public Health, University of Pittsburgh, Pittsburgh, Pennsylvania, [7]Veterans Research Foundation of Pittsburgh, Pittsburgh, Pennsylvania, [8]VISN 4 Healthcare Network, Pittsburgh, Pennsylvania

Address Correspondence to:
Frederick R. DeRubertis, MD
Email: Frederick.DeRubertis@va.gov

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Objective: We compared the short-term efficacy of home telemonitoring (HT) coupled with active medication management by a nurse practitioner (NP) to a monthly care coordination telephone call (CC) on glycemic control in Veterans with type 2 diabetes and entry HbA1c≥7.5%.

Research design and methods: Veterans who received primary care at the VA Pittsburgh Healthcare System June 2004-December 2005, were on oral hypoglycemic agents and/or insulin for one year or more, with HbA1c≥7.5% at enrollment were randomized to either active care management with HT (ACM+HT, n=73) or CC (n=77). Both groups received monthly calls for diabetes education and self-management review. ACM+HT participants transmitted blood glucose, blood pressure (BP) and weight to a NP using the Viterion 100 TeleHealth Monitor; the NP adjusted medications for glucose, BP and lipid control based on established ADA targets. Measures were obtained at baseline, 3 and 6 month visits.

Results: Baseline characteristics were similar in both groups, with mean HbA1c of 9.4% (CC) and 9.6% (ACM+HT). Compared to CC, ACM+HT demonstrated significantly larger decreases in HbA1c at 3 months (1.7% vs. 0.7%) and 6 months (1.7% vs. 0.8%; P<0.001 for each), with most improvement occurring by 3 months.

Conclusions: Compared to CC, ACM+HT demonstrated significantly greater reductions in HbA1c by 3 and 6 months. However, both interventions improved glycemic control in primary care patients with previously inadequate control.

Within the Veterans Health Administration (VHA), approximately 500,000 Veterans receive care for diabetes annually; diabetes is a leading cause of morbidity and mortality, and a major contributor to healthcare cost (1,2). Sampling data from 2009 indicate that approximately 28% of Veterans nationally have suboptimal glycemic control with HbA1c ≥8% (3). Increases in HbA1c levels above the normal range in patients with diabetes are associated with progressive increases in morbidity and mortality due to micro- and macrovascular disease (4). Intensive glycemic control can reduce microvascular complications in both type 1 and type 2 diabetes (5,6). However, recent studies have not demonstrated that intensive glycemic control for 3 to 6 years with achieved HbA1c targets from 6.4% to 6.9% reduces macrovascular complications in patients with long-standing type 2 diabetes (7-9). By contrast, intensive glycemic control initiated early in the course of either type 1 or type 2 diabetes appears to reduce risk of subsequent macrovascular complications significantly even when glycemic control later deteriorates (10,11).

Home-based telemedicine (HT) has been examined as a tool for chronic disease management (12), including diabetes (13-19). This approach can obviate geographic barriers, provide automated education, feedback, data transmission and facilitate provider-to-patient communication (12). However, outcomes with HT in diabetes and other chronic diseases have been variable (12). In several randomized controlled trials (RCTs) using HT in diabetes care (13-19) only two have reported significant improvement in HbA1c (17,18). Neither of these trials included active medication management by a provider in response to real-time transmission of self-monitored blood glucose (SMBG) data or have specifically targeted patients not meeting glycemic control goals in response to pharmacologic therapy under conditions of usual care.

The present study compared the efficacy of HT coupled with active medication management (ACM) by a nurse practitioner (NP), ACM+HT intervention, to a lower intensity care coordination intervention (CC) consisting of monthly telephone contact with a diabetes nurse educator (DE). Our study specifically targeted Veterans with HbA1c levels ≥ 8% after 1 year or more on pharmacologic therapy under conditions of usual care.

RESEARCH DESIGN AND METHODS

The DiaTel Study was a RCT of Veterans with type 2 diabetes receiving their primary care at the VA Pittsburgh Healthcare System (VAPHS) at one of the three main Pittsburgh campuses or five outlying community-based clinics. The study was approved by the VAPHS Institutional Review Board and conducted according to the principles in the Declaration of Helsinki. All participants provided signed informed consent.

Under a separate VAPHS-approved protocol, a sampling frame of potentially-eligible Veterans was developed from VAPHS electronic medical and pharmacy records using the following criteria: had at least one outpatient visit in a primary care clinic between 1 June 2004 and 31 December 2005; were aged < 80 years; received pharmacologic treatment for diabetes for 12 or more months; had no referrals to the VAPHS Diabetes Clinic in the preceding 18 months; and had a most recent HbA1c≥8.0%. Approximately 20% of Veterans with diabetes in our sampling frame met that HbA1c criterion.

After review and approval by their primary care providers (PCPs), potentially eligible Veterans were invited by letter to

participate. Non-respondents were contacted by primary care clinic staff to solicit their participation. The study was described to interested Veterans by research staff who obtained signed consent. Eligibility was further verified by a point-of-care capillary HbA1c $\geq$7.5% at enrollment using the Bayer DCA 2000 (Bayer Healthcare). Veterans were excluded who had a life expectancy of less than 6 months; were participating in another study; resided in an institutional setting; or did not have a land-based, analog home-telephone line as required for the HT device used.

Participants were randomized to ACM+HT or CC. Randomization was stratified by quartile of capillary HbA1c within each site, and blocked on time. The project statistician generated the random sequences; the study nurses enrolled the participants; the study coordinator informed the nurses of the intervention assignment after each participant was enrolled. After an initial education session, participants were informed of their intervention assignments. Due to the nature of the intervention, neither participants nor study nurses could be blinded. However, primary outcomes were ascertained by personnel unconnected to this study who were unaware of intervention assignments. Recruitment started October 1, 2005; the final 6-month follow-up was January 11, 2007.

Interventions: Participants in both groups attended an initial 2-hour educational session for diabetes self-management and nutrition. Participants randomized to ACM+HT received a 6-month diabetes management support intervention using the Viterion 100 Monitor home-telemonitoring device. The device permits: continuous home messaging with reminders and education; ongoing monitoring of SMBG, blood pressure (BP) and weight; daily transmission of these data to study providers via a secure network (20). Participants were instructed to transmit uploaded measurements from Viterion-compatible peripheral devices to the study NP daily. Monday through Friday, the NP reviewed SMBG, BP, weight, and risk stratification reports generated by the Viterion and contacted participants as necessary. The NP provided timely telephone follow-up, including further self-management education for participants who generated "high-risk" reports based on unacceptably high or low SMBG or BP pressure readings. Medications for glycemic, BP and lipid control were adjusted by the NP supervised by the study Endocrinologist without prior approval of the PCP who was informed retrospectively of all changes. The NP maintained records of all medication changes made in the ACM+HT group. The NP also called ACM+HT participants monthly to provide individualized self-management counseling tailored to specific issues, based on the status of glucose and BP control from the transmitted data.

Participants randomized to CC received monthly telephone calls from the study DE regarding general health conditions, status of glycemic control, BP, and weight from daily logs maintained by the participants, and compliance with the prescribed diabetic regimen. Issues requiring active intervention were referred to their PCP. Participants also could initiate contact with the study DE to discuss concerns related to diabetes management.

Outcomes: At baseline, 3 and 6 months, participants presented to VAPHS for measurement of HbA1c, BP, weight, and a fasting lipid panel. Baseline medication regimen (dose) and changes in the regimen (dose and date) for oral hypoglycemic agents, insulin, antihypertensive medications, and lipid-lowering medications were abstracted from the electronic pharmacy records and verified by participant interview.

Statistical Methods: This study was designed to detect a 1% difference in HbA1c with 80% power using a 0.05-level 2-sided test. Improvement was defined in terms of

mean differences at 3 and 6 months as well as differential change over time. The primary outcome, HbA1c, was specified a priori. P-values <0.05 were considered to be statistically significant, with no adjustment for multiple comparisons.

Our intent-to-treat approach included all randomized participants to the extent possible. Data features that mandated special methods were the laboratory reporting of a small number of HbA1c values exceeding some cutpoint (truncated values, i.e., reported as >11.5%, >11.8% or >12.3%) and a few missing HbA1c values. A modified multiple-imputation approach was used to obtain unbiased estimates, appropriate variances and valid tests, based on a chained-equations algorithm (21) implemented in Stata SE 9.2 (22).

Mean HbA1c, weight, BP, and lipid values were compared for the ACM+HT and CC groups at baseline, 3 and 6 months. The proportions of participants in each group who reached defined clinical target values at each timepoint were compared using Fisher Exact tests.

For each continuous outcome, difference scores were computed between each pair of timepoints (baseline-3 months, baseline-6 months, and 3 months-6 months). Between-group comparisons of difference scores were obtained by regressing the difference scores for each pair of timepoints on a dummy variable for treatment group (if necessary to accommodate multiple imputation) or using a t-test. Within-group difference scores were compared to zero using linear regression including only an intercept, or a t-test (as appropriate). The interaction of treatment group and insulin status at baseline was assessed. In the ACM+HT group, Pearson correlations summarized associations between HbA1c at 6 months and the frequencies of SMBG and adjustments of insulin.

RESULTS

Of the 1,055 Veterans in the initial sampling frame deemed appropriate for the study, 658 (62.4%) responded to letters of invitation to participate and 381 (57%) agreed to be contacted. Of these, 211 presented to VAPHS for signed informed consent, additional screening, and baseline measurements. The 150 consenting Veterans who had a capillary HbA1c≥7.5% at the baseline were randomized to ACM+HT (n=73) or CC (n=77). Of these, 3ACM+HT and 2 CC participants were excluded because they were subsequently found to meet baseline exclusion criteria; 2 CC participants withdrew prior to the initial education session and 6 ACM+HT participants withdrew afterwards. This analysis includes the remaining 64 ACM+HT and 73 CC participants.

All participants completed the baseline assessment; 6 ACM+HT and 4 CC participants missed the 3-month assessment and 8 ACM+HT and 7 CC participants missed the 6-month assessment. A total of 8 HbA1c values in the ACM+HT group and 9 HbA1c values in the CC group were missing, and 10 HbA1c values were truncated.

Baseline Patient Characteristics: There were no significant differences by treatment group for age, gender, race, or any of the other baseline characteristics shown in the online appendix Table A1 (which is available at http://care.diabetesjournals.org). About one-third of the participants in both groups were aged 65 or older; the vast majority was male and non-Hispanic white. The predominant comorbidities were coronary artery disease and congestive heart failure.

Medication Management: Most participants in each group were on oral hypoglycemic agents (predominantly glyburide and metformin), antihypertensive and lipid-lowering medications at baseline, 3 and 6 months; more than 50% were on insulin (online appendix Table A2). There were no

significant differences by medication class at any time point (P>0.14 for each). By 6 months, ACM+HT participants had significantly more medication or dose changes on average involving antihypertensive agents (3.1 for ACM+HT vs. 1.9 for CC; P=0.02), but not lipid-lowering agents (1.4 for ACM+HT vs. 1.1 for CC; P=0.29) or oral hypoglycemic agents (1.8 for ACM+HT vs. 1.8 for CC; P=0.91).

At baseline, 39 ACM+HT and 40 CC participants were on insulin. By 6 months, 1 ACM+HT and 1 CC participant had discontinued insulin, while 5 ACM+HT and 3 CC participants had begun insulin. Although the average daily insulin dose was similar in both groups at baseline, the average daily dose for ACM+HT participants was approximately 18 IUs higher than for CC at 3 and 6 months (P=0.02 and P=0.048, respectively). The average number of adjustments in insulin was also higher in ACM+HT (6.6) than in CC (2.8); P<0.001. However, no significant correlation was found between the frequency of insulin adjustment and HbA1c at 6 months in either ACM+HT (r=0.12; P=0.43) or in CC (r=0.14; P=038).

Primary Outcomes: Dotplots of individual values for HbA1c, weight, BP, and lipids are shown by treatment group for each timepoint in Figure 1. Baseline values were similar for both groups (P>0.45 for each; Table 1). HbA1c was significantly lower for ACM+HT than for CC participants at both 3 and 6 months (0.7% lower at each time point; P<0.001 for each). Significantly greater decreases in HbA1c were observed in the ACM+HT group relative to CC at 3 months (1.7% vs. 0.7%) and 6 months (1.7% vs. 0.8%), corresponding to differential decreases of approximately 0.9% (P<0.001 for each; online appendix Table A3). There was no significant interaction between baseline insulin usage and treatment response at any time point (P>0.39 for each; online appendix Figure 1).

None of the other primary outcomes differed significantly by treatment group at either 3 or 6 months (Table 1). However, except for weight and HDL cholesterol levels, the direction of the differences favored the ACM+HT group. Within both treatment groups, HbA1c, BP, cholesterol, and LDL improved significantly at 3 and 6 months relative to baseline while HDL decreased (online appendix Table A3). Triglycerides declined significantly from baseline only in the ACM+HT group. A four-pound mean weight increase in the ACM+HT group was the only significant within-group change between 3 and 6 months.

Similar proportions of ACM+HT and CC participants had HbA1c levels <8% or <9% at baseline (Table 2). However, at 6 months, 20.3% of ACM+HT and 5.5% of CC participants achieved HbA1c<7% (P=0.01). Significantly more ACM+HT than CC participants also reached HbA1c levels of <8% and <9% at both 3 and 6 months (P≤0.03 for each). Less than half of participants had systolic BP≤130 at any time point, while a majority met the targets for diastolic BP, LDL and triglycerides. A higher percentage of ACM+HT than CC participants met the LDL treatment target of <100 mg/dl at 6 months (79.7% vs. 59.4%, respectively; P=0.02).

SMBG Among ACM+HT Participants: Seven ACM+HT participants (10.9%) never transmitted any SMBG data after initial training. Another 9 participants (14.1%) performed SMBG on average less than once per day, while 75.0% performed SMBG between one and four times per day (average 2.3 times daily) during the period in which they transmitted measurements. Among the 57 participants who transmitted measurements, 35 (61.4%) transmitted SMBG <50 mg/dL on at least one day (median 1 day) and 16 (28.1%) transmitted SMBG between 50 and 70 mg/dL (median 10 days). Within

the ACM+HT group the frequency of SMBG did not correlate significantly with reduction in HbA1c (r=-0.11; P=0.39).

Nurse-to-participant telephone contact time was substantially greater in ACM+HT than CC (approximately 1.3 vs.0.3 hrs/participant/month, respectively). In the ACM+HT group, telephone contact was triggered by transmitted suboptimal SMBG or BP levels. Thus, contact time was disproportionately high in this subgroup of ACM+HT participants.

One participant in the ACM+HT group died at home suddenly 7 months after entry into the study. No post-mortem was obtained. The participant had diabetic neuropathy, stage IV renal insufficiency and congestive heart failure for which he had been hospitalized recently. He was treated with insulin alone, and thus was on no oral hypoglycemics that may have complicated his heart failure. His HbA1c levels fell from 11.8% at baseline to 6.5% at 3 months. Of his 468 transmitted SMBG values, 4 (0.85%) were < 50 mg/dl, a frequency similar to that of ACM+HT participants overall (0.66%) and that (0.59%) of 7 other ACM+HT participants on insulin with rapid declines in HbA1c (≥ 3%) over 3 months. No SMBG <50 mg/dl occurred during the month prior to his death. The relationships, if any, between the rapid decline in HbA1c, hypoglycemia and sudden death in this patient are uncertain.

CONCLUSIONS

Participants in this study had suboptimal glycemic control after at least a year of pharmacologic therapy directed by a PCP. Each of the interventions employed in the study resulted in short-term improvements in HbA1c. However, the latter were significantly greater in ACM+HT compared to CC. The relative contributions of the automated messaging and monitoring capacity provided by the HT device, the nearly 4-fold greater nurse-to-participant telephone contact time, and the greater intensification of insulin therapy in the ACM+HT vs. CC group to the HbA1c outcomes cannot be determined from, and is a limitation of, our study design. Self-management education was an intrinsic component of the more frequent nurse-to-participant phone communications in the ACM+HT group, and was additive to the educational messaging provided via the HT device. A meta-analysis of 31 RCTs indicated an association between increased patient contact time with a DE and lower HbA1c levels, with an estimated decrease in HbA1c of 1% for every additional 23.6 hrs of contact (23). This effect may have contributed significantly to the more marked reduction in HbA1c in the ACM+HT vs. CC group. Greater intensification of insulin therapy in the ACM+HT group likely also contributed to the more marked declining HbA1c compared to that of CC. However no significant correlations were found between the frequency of insulin adjustments and HbA1c outcomes at 6 months in either group.

A majority (75%) of ACM+HT performed SMBG at least daily, with a mean of 2.3 SMBG/day. This is much more frequent than observed by NHANES (25) where 29% of patients with diabetes on insulin, 65% on oral agents, and 80% who managed their disease with diet alone performed SMBG less than once per month (25). Consistent with NHANES data which showed no correlation between the frequency of SMBG and HbA1c (25), we did not find a significant association between frequency of SMBG and magnitude of decline in HbA1c within the ACM+HT group. Lack of SMBG data for the control group is a limitation of our study which precluded ascertainment of the relative frequency of monitoring in CC vs. ACM + HT, the relationship of SMBG to the respective HbA1c outcomes, and the relative frequency of hypoglycemia in the two groups. However, multiple prior reports have

indicated that the relationship between the frequency of SMBG and glycemic control is complex and inconsistent, and may depend on coupling SMBG with a structured plan for treating glucose elevations (24,25). Full realization of the benefits of real-time transmission of SMBG indices, whatever their frequency, likely depends on the prescriptive response of the provider receiving the data (24).

It is uncertain whether the improved glycemic control observed in ACM+HT can be sustained beyond 6 months with or without continued ACM+HT, and if sustained, will translate into improved clinical outcomes. Recent studies have failed to demonstrate improved macrovascular outcomes with intensive glycemic control among patients with type 2 diabetes (7-9). The ACCORD trial (7) reported increased mortality in a subgroup of type 2 diabetes patients subject to intensive glycemic control. The VA Diabetes Trial (9) suggested improved cardiovascular outcomes occurred only in younger patients with a shorter duration of diabetes, and also raised concern about an association between hypoglycemia and cardiovascular events (9). Consistent with the VA Diabetes Trial, 10-year follow-up results from the United Kingdom Prospective Diabetes Study (10) indicated that intensive glycemic control established earlier in the course of type 2 diabetes does reduce subsequent cardiovascular events, even though the differential in HbA1c among patients initially treated intensively dissipated within a year.

By design, our study focused on patients with diabetes and suboptimal glucose control. Many of these patients did not have concurrent issues related to their BP or lipid levels. Perhaps for this reason and the short duration of the trial, we did not observe large differences in these outcomes, despite continuous active medication management and self-management education for BP and lipids in ACM+HT participants. A significantly higher proportion of ACM+HT (79.7%) versus CC participants (59.4%) achieved the LDL cholesterol target of <100 mg/dl at 6 months. A longer trial employing HT in a different patient population might provide a better assessment of the value of this intervention in improving management of BP and lipids, as suggested by the five-year IDEATel trial (18).

While the present study was conducted in participants receiving care within the VA system, our findings are relevant to other patient populations. The IDEATel study, a RCT of 1665 underserved diabetic Medicare recipients whose age, educational and socioeconomic status was similar to participants in the present study, compared the use of HT combined with nurse case management under the supervision of an Endocrinologist to usual care in community settings (18). Small but significant reductions in HbA1c, BP and LDL-C favoring the intervention group were found at 5 years (18). Although IDEATel did not combine active medication management by an NP with HT, the latter is now accepted practice in many healthcare organizations outside the VA. Use of only one provider in the present study may limit the ability to generalize our findings to similar interventions conducted by multiple providers. However, employment of a standardized treatment protocol supports the relevance of our results to other clinical settings. Additional research is needed to examine this question, whether ACM+HT is a cost-effective approach for management of patients who have not achieved adequate glycemic control with usual care, and whether the short-term improvements in glycemic control observed with ACM+HT can be sustained with less resource utilization.

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Figure Legend

Figure 1. Dotplots of the primary outcome measures (HbA1c, weight, systolic BP, diastolic BP, cholesterol, HDL, LDL, and triglycerides) at baseline, 3 and 6 months by treatment group. Black circles denote the ACM+HT group and open circles denote the CC group. Time-specific mean values are connected by solid black lines for the ACM+HT group and dotted lines for the CC group.

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Table 1. Time-specific means and standard deviations of primary outcomes by treatment group. Mean differences (CC-ACM+HT), 95% confidence intervals (95% CIs) for these differences, and corresponding P-values are shown at each time point. A positive difference ($Diff_{CC-ACM}$) indicates that the mean for that outcome at that timepoint is lower in the ACM+HT group than in the CC group.

		CC (N=73)		ACM+HT (N=64)		$Diff_{CC-ACM}$			
Primary outcome	**Time**	**Mean**	**SD**	**Mean**	**SD**	**Mean†**	**95%CI**		***P-value***
HbA1c (%)	Base	9.4	1.4	9.6	1.6	-0.2	-0.7	0.3	*0.53*
	3m	8.7	1.2	7.9	1.2	0.7	0.3	1.2	*<0.001*
	6m	8.6	1.3	7.9	1.2	0.7	0.3	1.2	*<0.001*
Weight (lbs)	Base	223.5	47.9	226.6	45.4	-3.1	-18.9	12.7	*0.70*
	3m	222.0	49.6	225.5	44.5	-3.5	-19.5	12.5	*0.67*
	6m	223.9	48.6	229.5	47.6	-5.7	-21.9	10.6	*0.49*
Systolic BP (mmHg)	Base	142.3	19.0	144.8	21.7	-2.6	-9.5	4.3	*0.46*
	3m	137.1	21.4	135.9	23.3	1.2	-6.2	8.7	*0.74*
	6m	133.0	19.0	132.0	24.3	1.0	-6.2	8.2	*0.79*
Diastolic BP (mmHg)	Base	80.5	10.1	79.9	13.3	0.6	-3.4	4.5	*0.78*
	3m	76.6	12.9	75.4	12.0	1.3	-2.9	5.4	*0.55*
	6m	75.9	13.2	72.4	14.6	3.5	-1.1	8.2	*0.13*
Cholesterol (mg/dl)	Base	175.6	43.5	177.3	54.2	-1.7	-18.2	14.8	*0.84*
	3m	160.8	37.5	149.8	37.2	11.0	-1.7	23.6	*0.09*
	6m	159.1	37.2	148.2	40.2	11.0	-2.0	24.0	*0.10*
HDL (mg/dl)	Base	38.4	13.0	38.4	13.5	0.0	-4.5	4.5	*0.99*
	3m	36.2	11.0	35.0	10.7	1.3	-2.4	4.9	*0.50*
	6m	36.4	13.6	35.1	11.3	1.3	-3.0	5.5	*0.55*
LDL†† (mg/dl)	Base	101.8	32.0	98.8	36.3	3.0	-8.9	15.0	*0.62*
	3m	92.3	32.2	86.3	27.7	6.0	-4.6	16.6	*0.27*
	6m	91.2	30.6	82.3	27.9	8.9	-1.6	19.3	*0.10*
Triglycerides (mg/dl)	Base	194.1	160.4	191.3	133.3	2.7	-47.5	53.0	*0.92*
	3m	170.0	133.6	149.9	114.1	20.1	-22.3	62.5	*0.35*
	6m	170.7	115.9	152.4	99.7	18.3	-18.0	54.6	*0.32*

† Because measurements are rounded to one decimal place for reporting purposes, the rounded difference scores may differ slightly from the differences of the rounded means.

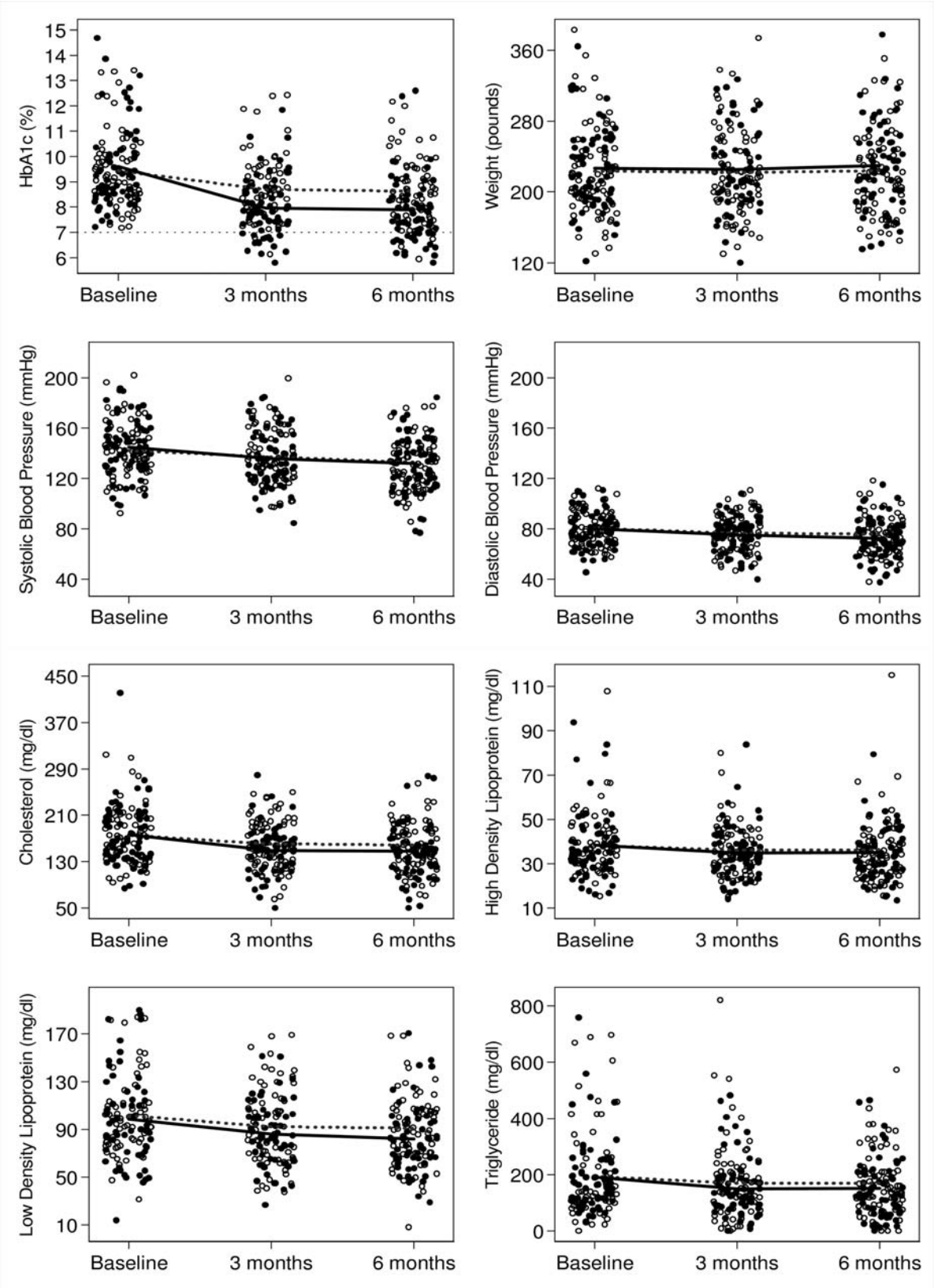
†† CC: N=69; ACM+HT: N=59

Table 2. Number of participants achieving each identified clinical target at baseline, 3 and 6 months, by treatment group.

	CC N=73		ACM+HT N=64		
	n	**%**	**n**	**%**	***P-value***
HbA1c < 7%					
Baseline	0	-	0	-	-
3 months	4	5.5	9	14.1	*0.14*
6 months	4	5.5	13	20.3	*0.01*
HbA1c < 8%					
Baseline	6	8.2	7	10.9	*0.77*
3 months	17	23.3	34	53.1	*<0.001*
6 months	25	34.2	37	57.8	*<0.01*
HbA1c < 9%					
Baseline	29	39.7	25	39.1	*>0.99*
3 months	47	64.4	54	84.4	*0.01*
6 months	49	67.1	54	84.4	*0.03*
Systolic BP ≤ 130 mm Hg					
Baseline	19	26.0	18	28.1	*0.85*
3 months	28	39.7	29	45.3	*0.49*
6 months	34	46.6	30	46.9	*>0.99*
Diastolic BP ≤ 80 mm Hg					
Baseline	42	57.5	39	60.9	*0.73*
3 months	46	63.0	43	71.9	*0.72*
6 months	53	72.6	50	78.1	*0.55*
LDL cholesterol† < 100 mg/dl					
Baseline	36	52.2	31	52.5	*>0.99*
3 months	44	63.8	43	72.9	*0.34*
6 months	41	59.4	47	79.7	*0.02*
Triglyceride ≤ 150 mg/dl					
Baseline	43	58.9	33	51.6	*0.39*
3 months	39	53.4	42	65.6	*>0.17*
6 months	42	57.5	40	62.5	*>0.60*

†For LDL cholesterol, denominators are 69 CC and 59 ACM+HT

Figure.


HbA1c (%)
15
14
13
12
11
10
9
8
7
6
Baseline
3 months
6 months
Weight (pounds)
360
280
200
120
Systolic Blood Pressure (mmHg)
200
160
120
80
40
Diastolic Blood Pressure (mmHg)
Cholesterol (mg/dl)
450
370
290
210
130
50
High Density Lipoprotein (mg/dl)
110
90
70
50
30
10
Low Density Lipoprotein (mg/dl)
170
130
90
50
10
Triglyceride (mg/dl)
800
600
400
200
0