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A Telecommunications System for Monitoring and Counseling Patients With Hypertension

Impact on Medication Adherence and Blood Pressure Control

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This study was conducted to evaluate the effect of automated telephone patient monitoring and counseling on patient adherence to antihypertensive medications and on blood pressure control. A randomized controlled trial was conducted in 29 greater Boston communities. The study subjects were 267 patients recruited from community sites who were ≥ 60 years of age, on antihypertensive medication, with a systolic blood pressure (SBP) of ≥ 160 mm Hg and/or a diastolic blood pressure (DBP) of ≥ 90 mm Hg. The study compared subjects who received usual medical care with those who used a computer-controlled telephone system in addition to their usual medical care during a period of 6 months. Weekly, subjects in the telephone group reported self-measured blood pressures, knowledge and adherence to antihypertensive medication regimens, and medication side-effects. This information was sent to their physicians regularly. The main study outcome measures were change in antihypertensive medication adherence, SBP and DBP during 6 months, satisfaction of patient users, perceived utility for physicians, and cost-effectiveness. The mean age of the study population was 76.0 years; 77% were women; 11% were black. Mean antihypertensive medication adherence improved 17.7% for telephone system users and 11.7% for controls ($P = .03$). Mean DBP decreased 5.2 mm Hg in users compared to 0.8 mm Hg in controls ($P = .02$). Among nonadherent subjects, mean DBP decreased 6.0 mm Hg for telephone users, but increased 2.8 mm Hg for controls ($P = .01$). For telephone system users, mean DBP decreased more if their medication adherence improved ($P = .03$). The majority of telephone system users were satisfied with the system. Most physicians integrated it into their practices. The system was cost-effective, especially for nonadherent patient users. Therefore, weekly use of an automated telephone system improved medication adherence and blood pressure control in hypertension patients. This system can be used to monitor patients with hypertension or with other chronic diseases, and is likely to improve health outcomes and reduce health services utilization and costs. Am J Hypertens 1996; 9:285–292

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There is abundant evidence that only one-half of the 30 million Americans with hypertension have their blood pressure controlled despite the availability of a number of pharmacologic agents that effectively lower blood pressure and have minimal or no side effects for most patients.[1,2] Nonadherence of patients with treatment regimens, particularly medications, is an important factor affecting blood pressure control that persists despite its recognition in the medical community for a number of decades.[3] Although adherence to antihypertensive regimens appears to have improved since the mid-1970s, it is still a common problem, and is associated with poor blood pressure control[2] and reduced cost-effectiveness of hypertension management.[4]

A second factor potentially affecting blood pressure control is inadequate patient monitoring by physicians across the lifetime course of the disease. This is most evident in the statistics on the numbers of hypertensive patients lost to medical follow-up, estimated to be as many as 50%.[5,6] The problem of inadequate monitoring probably exists for patients who continue in the medical care system but who miss appointments, fail to follow their physicians' medical care plans, or who have changes in their blood pressure level not easily detected by periodic office visits with their physicians.[7]

We developed a totally automated telecommunications system that carries out telephone conversations with hypertension patients in their homes for the purpose of monitoring their blood pressure and treatment and for counseling them to be adherent to their medication regimens. We designed the system to emulate the monitoring and counseling strategies and conversational style of clinicians, and to be practical for use with large numbers of patients. This telecommunications system was evaluated in a community-based randomized trial of elderly persons with hypertension to assess its impact on antihypertensive medication adherence and blood pressure control.

METHODS

The Intervention: The Telephone-Linked Computer System The Telephone-Linked Computer (TLC) system is an interactive computer-based telecommunications system that converses with patients in their homes between office visits to their physicians. It is a supplement to the usual care patients receive from their providers. The technology underpinning TLC is described elsewhere.[8,9] TLC speaks to patients over the telephone using computer-controlled speech. The patients communicate using the touch-tone keypad on their telephones. TLC asks questions to ascertain a patient's clinical status and gives feedback to the patient to promote adherence to the treatment regimen.

In our study, patients called TLC weekly. Before calling, they measured their blood pressure using an automated sphygmomanometer with a digital readout (Omron Health Care, Vernon Hills, IL). During the conversation, patients reported 1) their blood pressure, 2) their understanding of their prescribed antihypertensive medication regimen (medication names, dosages, and frequency of administration), 3) their adherence to the medication regimen, and 4) whether they had symptoms known to be side effects of their antihypertensive medications. In addition to questioning the patients, TLC provided education and motivational counseling to improve medication adherence. The duration of TLC conversations depended on the patients' responses to questions. An average conversation in this study took about 4 min. At the conclusion of a TLC conversation, the information provided by the patient was stored in a data base. TLC transmitted this information to the patient's physician on a printed report similar to a computerized laboratory report in which data is displayed over time and clinically significant information is highlighted. (A detailed description of the Telephone-Linked Computer System, including the hypertension dialogue and report layout, is available from the National Auxiliary Publications Service as NAPS document no. 05-300.*)

Study Design The study compared patients with hypertension who were randomly assigned to TLC (and who continued to receive their regular medical care) and subjects who received their regular medical care alone. Screening for entry into the study was performed at community sites such as senior centers in 29 different communities within the Greater Boston metropolitan area selected to represent the demographic diversity of the region. To be considered for the study, a person had to be aged 60 years or older, be under the care of a physician for hypertension, and be prescribed antihypertensive medication. They needed to have systolic blood pressure (SBP) $\geq$ 160 mm Hg or diastolic blood pressure (DBP) $\geq$ 90 mm Hg based on an average of two determinations taken 5 min apart at the community sites. Individuals were excluded if they had a life-threatening illness, were not English-speaking, did not have a telephone or could not use one, or refused to consent to participate.

Individuals who met the above-described screening criteria were contacted by mail and subsequently by telephone to further describe the study and evaluate their eligibility. Potential participants were scheduled for a home visit. During the home visit a trained field technician confirmed final eligibility and completed baseline measurements, after which participants were randomly assigned to either the TLC or usual care groups using a paired randomization protocol. The field technicians were blinded to the group assignments

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until after the baseline measurements were completed. Subjects assigned to the TLC intervention group were trained to use TLC and an automated sphygmomanometer. All participants received a final home visit 6 months after entry into the study when all study measurements were readministered by technicians blinded to the study assignments.

A total of 964 potentially eligible subjects were identified from the 29 target communities. They met the age and blood pressure criteria and stated their interest in enrolling in the study. Subsequently, 7% of these individuals could not be reached by telephone, 3% were determined to be ineligible by telephone interview, and 30% refused to participate. The remaining 573 individuals were scheduled for a home visit during which 299 were confirmed as eligible and enrolled in the study. Of the 274 individuals determined to be ineligible during the home visits, 87% (239) did not meet the blood pressure criteria for entry. Two hundred and sixty-seven (89%) of the enrolled subjects completed the study and were used in the analyses, including 133 in the TLC group and 134 in the usual care group. The mean age of the study sample was 76.0 years; 77% were women, and 11% were black. The attrition rate for the TLC group was 15% (n = 23), and for the usual care group it was 8% (n = 11). Table 1 displays the characteristics of the patient participants at entry into the study. There was no statistically significant difference in any characteristic between individuals randomized to TLC or to usual care.

TABLE 1. BASELINE CHARACTERISTICS OF PATIENTS IN TLC AND USUAL CARE GROUPS*

Characteristic	TLC Group (n = 133)	Usual Care (n = 134)
Average age (years)	76	77
Sex, female (%)	75	79
Race, black (%)	10	11
Marital status, married (%)	32	24
Education (%)		
1–11	20	32
12	55	51
13–17+	25	17
Attitudes toward technology (mean score)	18.7	18.4
Employed (%)	9	10
Comorbid disease (%)		
Heart disease	29	34
Stroke	6	7
Diabetes	20	16
Other	80	82
Mean number of comorbid diseases	1.2	1.2
Health-related quality of life (mean scores)		
Physical functioning	72	71
Mental health	66	64
Energy/fatigue	53	53
General health perceptions	48	50
Mean number of antihypertensive medications	1.5	1.4
Mean medication adherence (%)	93	94
Mean systolic blood pressure (mm Hg)	169.5	167.0
Mean diastolic blood pressure (mm Hg)	86.1	84.0
Isolated systolic hypertension (%)	73	76

** There were no differences between TLC and usual care groups ($P < .05$).*
TLC, telephone-linked computer system.

Data Collection Data for analysis was collected during the two home visits, performed 6 months apart. Two blood pressure measurements were taken at each home visit by technicians who were trained to follow a standard blood pressure measurement protocol.[10] Antihypertensive medication adherence was assessed by a home pill count audit conducted by the field technicians, based on Haynes' protocol.[11] Structured interviews were conducted at baseline, including items to measure sociodemographics, comorbidity, health status, and attitudes toward the use of computer technology in medical care. Scales from the Short Form 36 (SF36) were used to measure health status.[12] A questionnaire developed by Brownbridge et al[13] was used to evaluate the participants' attitudes about computer technology applied to health care. At the final home visit, TLC participants responded to structured questions about their reactions to using TLC. In addition, their primary physicians (n = 123) were mailed a very brief questionnaire requesting information about their use of the TLC reports. Eighty-three percent (102) of the physicians returned this questionnaire.

Analysis Methods We computed the variable, antihypertensive medication adherence, as the total number of tablets, capsules, or patches dispensed minus the total number counted in the audit, divided by the number that should have been taken by each subject. SBP and DBP were calculated as the average of two blood pressure measurements taken at each home visit. Arcsine transformation of the adherence index was performed for stabilization of the variance. Systolic and diastolic blood pressure were normally distributed and did not require transformation.

For the variables medication adherence, SBP, and DBP, change scores were computed for each subject by taking the value of each variable at 6 months follow-up and subtracting the value at baseline. Initial comparisons of the change scores for TLC users and usual care subjects were made using *t* tests. Linear covariable adjustments were applied to the medication adherence

change scores to adjust for age, sex, baseline medication adherence, and intervention group (TLC *v* usual care) as main effects; and baseline medication adherence by intervention group as the interaction term. For the blood pressure change scores, similar models were constructed, with baseline blood pressure added as a main effect instead of baseline medication adherence. For all of these models, baseline adherence was a dichotomous independent variable, after Sackett et al,[14] such that patients who took 80% or more of their antihypertensive medications were defined as adherent. In a separate model with the same covariable adjustments, an additional interaction term was added for change in medication adherence (improvement or worsening) by intervention group. All variables in the models were selected a priori before any analyses. The models are presented in the Appendix.

Ordinary least squares regression was used to generate adjusted change scores to analyze differences between the two groups (TLC *v* usual care). If the results of the overall tests revealed a significant difference ($P < .05$) between the two groups, pairwise comparisons were performed using *t* tests. Because multiple comparisons were involved at this step, the exact *P* values are reported. For subgroup analyses using interaction terms, we computed least squares means with linear covariable adjustments for selected comparisons determined a priori.

To determine cost-effectiveness of TLC-hypertension, we calculated the expected operating costs of TLC in clinical practice based on the experience during the study, considering all computer and telecommunications costs, facilities charges, supplies, and support personnel for start-up and maintenance of the system. Cost-effectiveness ratios were computed for medication adherence improvement and DBP decrease using simple linear regression analysis.

RESULTS

Effects on Antihypertensive Medication Adherence Unadjusted analysis demonstrated little change over the 6-month study period in the adherence of patients in the two study groups to their antihypertensive medication regimens (2.4% mean increase for TLC users and 0.4% mean decrease for controls, $P = .29$). After adjustment, mean adherence improved 17.7% in the TLC group and 11.7% for usual care control subjects ($P = .03$) (Table 2). Among study participants who were nonadherent at entry into the study, that is, who took less than 80% of their prescribed antihypertensive medications, use of TLC was associated with statistically significant improvement in mean adherence (36% for TLC users *v* 26% for nonusers, $P = .03$). In contrast, for adherent subjects (adherence ≥ 80%), there was no statistically significant change in adherence, comparing TLC users and nonusers.

TABLE 2. CHANGE IN MEDICATION ADHERENCE* (%) BY STUDY GROUP

	TLC (n = 133)	Usual Care (n = 134)	*P*
Total study population (n = 267)†	17.7	11.7	.03
Nonadherent subjects (n = 26)‡	36.0	26.0	.03
Adherent subjects (n = 241)‡	0.6	3.0	.69

* *Percent adherence after 6 months follow-up minus baseline percent adherence.*

† *Values expressed as mean change in adherence adjusted for age, sex, baseline adherence (dichotomized as <80%, ≥80%).*

‡ *Values expressed as mean change in adherence adjusted for age, sex, baseline adherence (dichotomized as <80%, ≥80%) and baseline adherence by treatment group (TLC versus usual care).*

Effects on Blood Pressure During the course of the 6-month study period, mean SBP decreased approximately 11 mm Hg in both study groups (11.0 mm Hg decrease for TLC users and 10.6 mm Hg decrease for controls, $P = .85$). DBP decreased 5.4 mm Hg on average in the TLC group, and somewhat less among usual care participants (3.3 mm Hg, $P = .09$).

Table 3 shows the effect of study assignment, TLC or usual care, on blood pressure change during the 6-month study period after adjustment. There was a trend toward a greater drop in SBP among TLC users than usual care patients. This effect was limited to those subjects who were nonadherent to their antihypertensive medication regimens at baseline. Among these individuals the mean drop in SBP was 12.8 mm Hg for TLC users and 0.9 mm Hg for usual care participants ($P = .09$). The analysis of DBP change in the overall study population demonstrated that the average TLC user sustained a 5.2 mm Hg decrease, whereas the typical usual care subject dropped only 0.8 mm Hg ($P = .02$). Hypertensive patients who were nonadherent with their medications at baseline were most affected by the TLC intervention. For them, mean DBP decreased 6.0 mm Hg in the TLC group, but increased 2.8 mm Hg in the usual care group ($P = .01$). The main covariable effects for baseline DBP and age were significant ($P < .05$).

Relationship of TLC Use and Adherence Change to Blood Pressure Further analyses were performed to address the question of whether the effect of TLC on blood pressure was associated with the changes in antihypertensive medication adherence. Table 4 shows that for both SBP and DBP, TLC users who improved their adherence during the 6-month study experienced significantly greater blood pressure reduction than did TLC users whose adherence decreased. Mean SBP decreased 12.7 mm Hg for TLC users with adherence improvement, whereas it decreased only 2.5 mm Hg among those whose adherence worsened ($P = .03$). For

TABLE 3. CHANGE IN SYSTOLIC AND DIASTOLIC BLOOD PRESSURES BY STUDY GROUP*

	TLC	Usual Care	P
Adjusted mean systolic blood pressure change† (mm Hg)			
Total study population‡	11.5	6.8	.20
Nonadherent subjects§	12.8	0.9	.09
Adherent subjects§	10.3	12.8	.29
Adjusted mean diastolic blood pressure change† (mm Hg)			
Total study population‡	5.2	0.8	.02
Nonadherent subjects§	6.0	−2.8	.01
Adherent subjects§	4.5	4.4	.97

* *See Table 2 for sample sizes.*

† *Baseline blood pressure minus final blood pressure.*

‡ *Values expressed as mean change in blood pressure adjusted for age, sex, baseline adherence, and baseline blood pressure.*

§ *Values expressed as mean change in blood pressure adjusted for age, sex, baseline adherence, baseline blood pressure, and baseline adherence by treatment group.*

DBP, the mean decrease was 5.5 mm Hg for TLC users who improved their adherence and 0.6 mm Hg for those who did not ($P = .03$). For usual care subjects, there were no significant differences in blood pressure change among groups defined by adherence change.

Attitudes of TLC Users and Their Physicians Table 5 reports the responses of TLC users to questions about their assessment of the system. In addition, they indicated their overall satisfaction with TLC by scoring a visual analog scale on which "0" equaled "very dissatisfied" and "100" equaled "very satisfied. Sixty-nine percent of TLC users scored the item in the upper quartile of the scale (76 to 100). Fifty-four percent scored a similar scale for health benefit of TLC use in the upper quartile. Only 5% and 6%, respectively, scored the items in the lower quartile (0 to 24).

Eighty-five percent (n = 87) of the 102 physicians whose patients were TLC users stated that they read TLC reports regularly and 84% (n = 86) said that they put the reports in their patients' medical records. Forty percent (n = 41) claimed to discuss the information on the TLC reports regularly with their patients.

Cost-Effectiveness The computed cost per patient user for 6 months of use was $32.50. The cost-effectiveness ratio for adherence change after 6 months of TLC use in all hypertensive patients in the study was $5.42 per 1% improvement in adherence. For nonadherent subjects, cost-effectiveness ratios ranged from $3.25 per 1% improvement for patients whose baseline adherence was 80% to $0.80 per 1% improvement for those at 50% adherence. For DBP, the cost-effectiveness ratio for all hypertensive patients was $7.39 per 1 mm Hg decrease after 6 months of TLC use. For nonadherent subjects, cost-effectiveness varied between $3.69 per 1 mm Hg improvement in DBP at 80% baseline adherence to $0.87 per 1 mm Hg improvement at 50% adherence.

DISCUSSION

The telephone is commonly used in ambulatory care practice.[15–21] Depending on the specialty of the physician, the practice setting, and other physician and patient characteristics, between 10% and 57% of patient-physician contacts occur over the telephone.[15, 18–20,22] In only a few case studies have clinicians used the telephone to care for patients over extended periods of time as a substitute or supplement for office visits. Nail et al[23] reported that nurses in an ambulatory oncology center initiated 44% of their patient care telephone contacts, and that the content of these conversations included assessing patient status, evaluating response to treatment, and advising patients on self care. Wasson et al[24] demonstrated that clinician use of the telephone for routine follow-up of patients in a general medical clinic as a substitute for some clinic visits resulted in no significant differences in health outcomes over a 2-year period, but lower health care costs.

In our study, use of routine, weekly computer-based, automated telephone monitoring of hypertensive patients was associated with significantly reduced DBP and possibly lower SBP. Of particular note, the amount of DBP reduction attributable to TLC was similar to that shown in randomized clinical trials of antihypertensive drugs compared to placebo.[25–27] For TLC users, average adjusted DBP dropped 4.4 mm Hg more than it did for control subjects. In patients who were nonadherent to their medication regimen, the average improvement in DBP was 8.8 mm Hg more for TLC users. A meta-analysis of 14 placebo-controlled clinical trials of different antihypertensive

TABLE 4. EFFECT OF STUDY GROUP ASSIGNMENT AND ADHERENCE CHANGE ON CHANGE IN BLOOD PRESSURE

	Increased Adherence (n = 133)	Decreased Adherence (n = 134)	P
Adjusted mean systolic blood pressure change* (mm Hg)			
TLC (n = 100)	12.7	2.5	.03
Usual care (n = 77)	13.7	7.3	.19
P	.80	.36	
Adjusted mean diastolic blood pressure change* (mm Hg)			
TLC (n = 100)	5.5	0.6	.03
Usual care (n = 77)	1.2	1.5	.92
P	.02	.73	

* *Blood pressure change as described in Table 3 except that values were adjusted for change in adherence (dichotomized as improved, worsened) instead of baseline adherence (dichotomized as <80%, ≥80%).*

TABLE 5. TLC USERS' ATTITUDES AFTER 6 MONTHS OF USE*

	Agree† (%)	Neutral† (%)	Disagree† (%)
I would be better off with the TLC	85	11	3
TLC was easy to use	94	1	5
Telephone contacts with TLC were too many	3	2	95
TLC conversations were boring	11	3	87
TLC made me aware of my blood pressure	95	2	5
TLC relieved my worries about my hypertension	79	5	17
TLC helped me to improve my blood pressure	58	15	27
TLC kept me in touch with my doctor and doctor's staff	60	13	27
TLC helped me have a better relationship with my doctor and doctor's staff	43	17	41
TLC helped my doctor in making decisions about treating me	50	22	27

* *n = 132.*

† *Agree = 1-2, Neutral = 3, Disagree = 4-5 on a 5-point Likert scale where 1 = strongly agree and 5 = strongly disagree.*

medication regimens showed a difference in mean DBP to be about 5 to 6 mm Hg.[27] This was associated with 42% reduction in stroke and 14% less coronary heart disease. For TLC users, we would expect comparable reductions in cardiovascular disease risk.

In the study there were associations between TLC use, antihypertensive medication adherence, and blood pressure control. For TLC users, the most substantial improvements in blood pressure occurred in those who experienced an increase in adherence to their antihypertensive medication regimen during the study. These results suggest that the effect of TLC use on blood pressure may be mediated by TLC-induced improvement in medication adherence. This mechanism would be consistent with the known association between antihypertensive medication adherence and blood pressure level.[14,28]

Another potential mechanism of action of TLC monitoring might be to affect physician behavior. The system could accomplish this by providing information about the patient's blood pressure and medication adherence that would cause the physician to adjust the medication regimen or counsel the patient. The usefulness of regular home blood pressure monitoring to help physicians to adjust antihypertensive medication therapy has been proposed.[29,30] In our study no such effect was observed. There were no statistical differences between TLC users and controls in the number of antihypertensive medications prescribed at baseline, in the change in the number prescribed over the 6-month study period, or in the proportion of patients who had their regimen changed in any way during the study. These findings were replicated in analyses of subjects who were nonadherent with their antihypertensive regimen at baseline.

Could TLC have facilitated other physician-mediated effects on blood pressure? Most physicians of TLC users report reading TLC reports regularly and 40% claimed to discuss the content of the reports regularly with their patients who used TLC. However, we did not attempt to verify these reports or to evaluate whether the behaviors of the participants during physician-patient contacts had changed and, if so, whether the behavior change was correlated to TLC use and blood pressure change.[31]

There may also have been direct effects of the telephone conversations on blood pressure level. TLC users reported that use of TLC made them more aware of their blood pressure and relieved their worries about their disease. Could TLC have exerted a direct psychophysiologic effect on users that lowered their blood pressure? Although this is theoretically possible, behavioral interventions have not been shown to lower blood pressure in hypertension,[32] certainly not to the degree demonstrated by TLC.

Finally, it is possible that the effect of the intervention was due to home blood pressure self-monitoring. However, studies of blood pressure self-monitoring have failed to demonstrate its impact on medication-taking behavior or blood pressure control.[33,34] Thus, it appears most likely that TLC exerted its effect on blood pressure by affecting patient medication-taking behavior, and possibly by influencing physician counseling practice.

Not only is TLC effective; it is likely to be inexpensive to use. Its costs, about $65 annually per patient, are comparable to a regular physician office visit without laboratory testing or medications. Moreover, TLC is cost-effective in lowering DBP, especially in patients who do not take all of their antihypertensive medications. The system costs $0.87 to $3.69 per 1 mm Hg reduction in DBP, the amount depending on the degree of initial medication adherence (ie, 50% to 80%).

Use of TLC may also reduce overall health services utilization and cost. This conclusion is not derived from our study as health services utilization and cost were not measured, but by a study of the use of telephone monitoring of ambulatory general medical patients by clinicians.[24] A randomized trial of telephone monitoring, as a substitute for some clinic visits, compared to

usual care alone, demonstrated that telephone monitored patients had 19% fewer clinic visits, 28% fewer hospital days, and 41% less intensive care days. This resulted in 28% less expenditures for health services, with approximately two-thirds of the savings derived from reductions in hospital services and the balance from less ambulatory care services.

The generalizability of the study findings to other hypertension patients may be affected by features of the study design and execution. First, the participants were 60 years of age or older, and thus the study findings may not be applicable to younger patients. Nevertheless, approximately 55% of patients treated for hypertension in the United States are at least 60 years of age (extrapolated from Table 5 in Burt et al[35]). Second, the study dropout rate was higher among TLC users than usual care subjects [23 (15%) *v* 11 (8%), $P = .05$]. This is an expected finding as the burden of study participation was much greater for TLC users. Of importance, however, there were no significant differences in the characteristics of TLC users and nonusers who dropped out of the study.

Based on the results of this study, it might be reasonable to use a telecommunications system like TLC in the care of patients with hypertension to complement or substitute for some routine office visits. Physicians could prescribe TLC monitoring like they do other therapeutic and diagnostic services. TLC would be paid for like other services, and might be an attractive option for payers and providers of care because it improves blood pressure control at a very low cost, with potential cost savings. Although TLC could be used to monitor and counsel all patients with hypertension, more judicious use of the technology is warranted. We have demonstrated that patients who are nonadherent with their medication regimen would benefit with improved adherence and blood pressure control and that TLC is more cost-effective with these patients. Should other categories of patients also be targeted such as newly diagnosed hypertension patients or patients whose blood pressure is difficult to control, or patients for whom a medication change has been recently made? Further studies should be done to shed light on these issues. As difficult policy decisions are made in the future concerning the allocation of finite resources for health care, the use of technology-based telephone monitoring and counseling in hypertension and other chronic disease management might be an attractive option.

APPENDIX: MATHEMATICAL MODELS

1. Medication Adherence Regression Model

$$Y = b_o + b_1\text{age} + b_2\text{male} + b_3\text{adherence} + b_4\text{group} + b_j(\text{TLC} \times \text{adherence}) + \text{error}$$

Where Y = change in adherence (at baseline and 6 months); where indicator variables are "male" representing two categories (male, female), "adherence" representing two categories (<80% adherence and ≥80% adherence), "group" representing the two study groups (TLC and usual care), and "TLC × adherence," a multiplicative interaction term that allows different TLC effects for those with adherence < 80% and ≥ 80%.

2. Blood Pressure Regression Model

$$Y = b_o + b_1\text{age} + b_2\text{male} + b_3\text{BP} + b_4\text{group} + b_j(\text{TLC} \times \text{adherence}) + \text{error}$$

Same as equation 1, except that Y = change in blood pressure, systolic or diastolic (between baseline and 6 months); b_3BP is the systolic or diastolic blood pressure at baseline.

3. Blood Pressure Regression Model (with change in adherence added)

$$Y = b_o + b_1\text{age} + b_2\text{male} + b_3\text{BP} + b_4\text{group} + b_j(\text{TLC} \times \text{adherence}) + b_k(\text{TLC} \times \text{change in adherence}) + \text{error}$$

Same as equation 2 except that a variable was added: b_k(TLC × change in adherence), a multiplicative interaction term that allows different TLC effects for subjects with improvement and worsening in adherence during the 6-month study period.

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