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Self-recording of blood pressure in the management of hypertension

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The efficacy of self-recording of blood pressure in the management of hypertension was assessed in a randomized clinical trial involving 140 persons who had been receiving antihypertensive therapy for a year or more, but whose diastolic blood pressure had remained at 95 mm Hg or higher. To control for the increased attention implicit in self-recording, which might affect blood pressure, the patients were assigned at random to one of four groups: self-recording and monthly home visits, self-recording only, monthly home visits only, and neither self-recording nor monthly home visits. This design also permitted assessment of the effect of home visits. During the 6-month experiment no significant differences were apparent between the groups in either compliance or diastolic blood pressure. However, both self-recording and monthly home visits produced a reduction in blood pressure among patients who admitted to difficulty remembering to take their pills; a reduction was not seen among patients who said they had no such difficulty. This confirmed an earlier observation suggesting that this easily identified group of patients may be the most responsive to intervention programs.

L'efficacité de l'autoenregistrement de la tension artérielle au cours du traitement de l'hypertension a été évaluée dans une étude clinique randomisée impliquant 140 personnes qui avaient reçu un traitement antihypertenseur pendant un an ou plus, mais dont la tension diastolique était demeurée à 95 mm de Hg ou plus. Pour tenir compte de l'augmentation de l'attention du patient occasionnée par l'autoenregistrement, augmentation susceptible d'affecter la tension artérielle, les patients ont été assignés au hasard à un de quatre groupes: l'autoenregistrement et des visites mensuelles à domicile, seulement l'autoenregistrement, seulement des visites mensuelles à domicile, ou ni l'autoenregistrement ni des visites mensuelles à domicile. Ce dispositif expérimental permettait également l'évaluation de l'effet des visites à domicile. Au cours des 6 mois qu'a duré l'expérience aucune différence significative n'a été observée entre les groupes en ce qui a trait à la fidélité au traitement ou à la tension diastolique. Toutefois, l'autoenregistrement de la tension artérielle et les visites mensuelles à domicile produisirent une baisse de la tension artérielle chez les patients qui admettaient avoir de la difficulté à se rappeler de prendre leurs comprimés; une diminution semblable n'a pas été observée chez les patients qui disaient ne pas avoir une telle difficulté. Ceci confirme une observation antérieure suggérant que ce groupe de patients facilement identifiable puisse-t-être le plus apte à répondre aux programmes d'intervention.

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Self-recording of blood pressure has been suggested from time to time as an aid to reducing blood pressure and maintaining the reduction among persons with hypertension,[1-3] and recently there has been increased commercial promotion of devices for this purpose. Although any measure that might lead to better control of blood pressure deserves careful evaluation, only two studies designed to test the usefulness of self-recording of blood pressure have been reported. In the first,[4] significant benefit for systolic but not for diastolic blood pressure

was derived from this procedure. In our previous trial, both compliance with medication therapy and blood pressure improved with an intervention program that included self-recording of blood pressure.[5] Neither trial was controlled for the increased attention paid to the subjects by the study personnel who trained and monitored them. Since this increased attention might have affected compliance and blood pressure control, and to determine the value of self-recording alone, we undertook the randomized controlled trial described below.

Subjects and methods

The subjects were 140 men and women aged 35 to 65 years who had previously volunteered for blood pressure screening in Hamilton shopping centres. At the beginning of this study each had been receiving antihypertensive therapy for a minimum of a year but their diastolic blood pressure had remained elevated, being 95 mm Hg or higher on each of two home visits 1 to 3 days apart. From each visit the average of the second and third of three measurements made at 5-minute intervals was used to assess eligibility for the trial. Once their informed consent was obtained the subjects were statified for age (less than 45 years old and 45 or older) and sex, then assigned at random to one of four groups in a 2 × 2-factorial design: (1) self-recording and monthly home visits; (2) self-recording only; (3) monthly home visits; and (4) neither self-recording nor monthly home visits. Monthly home visits were included in the study design to allow us to determine whether regular follow-up visits were required to make self-recording effective.

Subjects in groups 1 and 2 received a blood pressure kit (Taylor Sybron Corporation, Arden, North Carolina) and instruction in self-recording. They were shown how to keep charts of their daily blood pressure readings, and were requested to take these charts to their physician at each appointment. The subjects in groups 1 and 3 had their blood pressures measured in their homes every 4 weeks, and the results were reported to both the subject and the treating physician.

Each subject was visited at home 2 weeks after being assigned to a group, at which time the self-recording of those in groups 1 and 2 was rechecked and additional instruction was given if required. This visit was also made to those in groups 3 and 4, who simply had their blood pressure recorded, to equalize the attention given to all four groups.

Six months later all subjects were visited twice within 1 to 3 days by the visitor who had previously seen them. Standardized blood pressure measurements were made and compliance with therapy was assessed by interview and pill count (the percentage of prescribed pills that had been consumed was estimated by comparing pills on hand with prescription records of pills dispensed and the regimen prescribed).

Since the subjects in groups 1 and 3 had been receiving home visits by the same visitor, it was considered that a bias could be present in the last blood pressure measurements. Therefore, all subjects received a third home visit by an independent visitor who had no prior connection with the study. This visitor cannot be considered as totally "blinded" since the subjects could have informed her of their regimen during the study period. However, she had no knowledge of the study design or of the groups to which subjects had been assigned. To estimate change, the blood pressure measurement obtained on the day of randomization was compared with that recorded by the independent home visitor at the end of the study.

Decisions regarding treatment and medical care were left entirely to the subject's physician, and no attempt was made to directly influence compliance. Home visitors did not attempt to identify and solve compliance problems or even to suggest that it was important that the subject take the medication. Thus, this study restricted itself to an investigation of the influence of increased blood pressure monitoring, with readings given to both subject and physician, using self-recording and monthly home visits.

Results

Of the 140 subjects 136 completed the trial; 2 had died, 1 had refused to participate between randomization and the visit 2 weeks later, and 1 had moved away. The composition of the groups was similar with regard to age and sex (Table I).

Changes in diastolic blood pressure are shown in Table II. Since the initial blood pressure bears an important relation to the change in blood pressure over time,[6] the change scores were adjusted for differences in entry values by covariance analysis. In all the groups the diastolic

Table I—Composition of groups by sex and age in trial of self-recording of blood pressure and home visits for persons with hypertension

Regimen (and group no.)	No. of subjects			Mean age (yr)	
	Men	Women	Total	Men	Women
Self-recording and home visits (1)	22	13	35	53.9	53.1
Self-recording only (2)	22	12	34	53.1	53.7
Home visits only (3)	19	14	33	54.8	51.1
Neither (4)	19	15	34	54.5	49.2
Total	82	54	136	54.0	51.6

Table II—Changes in mean diastolic blood pressure

Regimen	Mean diastolic blood pressure,* mm Hg (and no. of subjects)		Mean change in diastolic blood pressure, mm Hg†
	At entry into trial	At end of trial	
Self-recording and home visits	104.2 ± 1.1 (35)	95.9 ± 1.6 (35)	−8.1 ± 1.5
Self-recording only	102.6 ± 1.2 (36)	94.1 ± 1.6 (34)	−8.9 ± 1.8
Home visits only	103.9 ± 1.1 (33)	95.2 ± 1.6 (33)	−8.5 ± 1.6
Neither	103.2 ± 1.7 (36)	95.7 ± 2.2 (34)	−7.6 ± 1.9

*Plus or minus one standard error of the mean (true also for subsequent tables).
†Adjusted for differences in entry values by covariance analysis (true also for Tables III and V).

blood pressure fell by a similar amount.

The compliance changes noted in Table III were also adjusted for differences in entry values by covariance analysis. The changes appeared to be greater among subjects doing self-recording but were not significant; this was also the case when those with poor compliance (i.e., less than 80%) were considered separately (Table IV).

Because our earlier study showed a trend towards greater benefit from interventions including self-recording of blood pressure among subjects who admitted at the time of entry into the trial to having trouble remembering to take their pills, we compared the effect of self-recording and home visits in patients who admitted to having such difficulty and those who claimed they did not have trouble. Analysis of variance revealed significant interactions between the response to the question on this matter, asked at the time of entry, and the two intervention strategies, at $P = 0.03$ for self-recording and $P = 0.004$ for home visits. The mean values in Table V show that the interventions had no effect on subjects who said they had no trouble remembering to take their medication (compare a with b and c with d), but did prove beneficial for patients who said they had such a problem (compare e with f and g with h).

It is important to consider whether the lack of significant overall benefit from self-recording might be explained by the patients' noncompliance with this type of intervention. Consequently, the blood pressure charts of the self-recording subjects for the final month of the trial were reviewed to determine the number of days on which a measurement had been recorded. Those who had received monthly home visits (group 1) recorded their blood pressure more frequently than those who were only doing self-recording (group 2): 72% of group 1 subjects but only 50% of group 2 subjects recorded it on 14 days or more ($P = 0.07$), and 46% of the former but only 15% of the latter charted it daily ($P < 0.01$).

At the end of the trial 90% of those who had received the equipment for self-recording indicated, in response to a questionnaire, that they thought it was a useful device, and 88% said they did not think it

made them feel more anxious about their blood pressure. With the use of a double stethoscope the home visitors compared their readings with those of the patients; agreement within 2 mm Hg was found in 92%.

An important question in this study was whether there would be a detectable change in the therapeutic regimen in response to the increased frequency of receipt of blood pressure information by physicians from the subjects doing self-recording or receiving home visits or both. The information about changes in the therapeutic regimen in each group, summarized in Table VI, shows no significant differences between the groups.

In assessing changes in blood pressure over time there is always the problem of establishing a proper baseline value at the time of entry into the trial and an appropriate

Table III—Changes in mean compliance with medication therapy

Regimen	Mean compliance, % (and no. of subjects)		Mean change in compliance, %
	At entry into trial	At end of trial	
Self-recording and home visits	65.5 ± 5.4 (35)	76.3 ± 4.6 (35)	10.1 ± 4.9
Self-recording only	65.8 ± 6.1 (36)	78.0 ± 5.4 (34)	11.8 ± 4.5
Home visits only	65.0 ± 6.2 (33)	68.3 ± 5.9 (33)	2.2 ± 5.6
Neither	70.1 ± 6.1 (36)	68.5 ± 7.3 (34)	1.0 ± 7.0

Table IV—Changes in mean compliance among subjects with initial compliance of less than 80%

Regimen	Mean compliance, % (and no. of subjects)		Mean change in compliance, %
	At entry into trial	At end of trial	
Self-recording and home visits	45.7 ± 5.5 (19)	75.7 ± 5.7 (19)	30.0 ± 8.2
Self-recording only	41.7 ± 7.2 (18)	66.6 ± 8.7 (18)	24.9 ± 7.7
Home visits only	39.5 ± 6.6 (16)	56.4 ± 9.0 (16)	16.9 ± 11.3
Neither	46.1 ± 7.5 (13)	61.1 ± 10.1 (13)	15.0 ± 10.5

Table V—Changes in mean diastolic blood pressure by type of intervention among subjects who admitted to having trouble remembering to take their medication compared with subjects who claimed they did not have such trouble

Intervention	Mean change in diastolic blood pressure, mm Hg (and no. of subjects)	
	No trouble remembering	Trouble remembering
Self-recording (groups 1 and 2)	a: −8.3 ± 1.28 (56)	e: − 9.1 ± 2.95 (13)
No self-recording (groups 3 and 4)	b: −9.3 ± 1.16 (51)	f: − 4.1 ± 3.48 (16)
Home visits (groups 1 and 3)	c: −7.8 ± 1.13 (53)	g: −10.0 ± 3.04 (15)
No home visits (groups 2 and 4)	d: −9.8 ± 1.30 (54)	h: − 2.4 ± 3.37 (15)

Table VI—Changes in strength of therapy during the trial

Regimen	No. (and %) of subjects			
	With decrease	With increase	With no change	Total
Self-recording and home visits	7 (19)	12 (33)	17 (47)	36 (100)
Self-recording only	7 (21)	8 (24)	18 (55)	33 (100)
Home visits only	4 (12)	13 (39)	16 (48)	33 (100)
Neither	8 (24)	10 (29)	16 (47)	34 (100)

measurement for comparison at the end of the trial. As Table VII shows, the two entry visits resulted in similar values, with a slight trend to a lower value at the second visit (mean values 105.0 ± 8.4 and 103.5 ± 7.4 mm Hg). A similar trend occurred during the three visits at the end of the trial (mean values 98.8, 97.5 and 95.2 mm Hg).

Discussion

Self-recording of blood pressure was used in our earlier trial among noncompliant steelworkers in whom the goal blood pressure had not been reached after the first 6 months of treatment.[5] This procedure was part of an intervention package that included the tailoring of medication to daily habits and rituals, as well as daily charting of the number of pills taken and missed, and increased attention from a lay health worker. The reduction in blood pressure (5.4 ± 1.7 mm Hg) and the improvement in compliance (21.3% ± 6.5%) obtained under the conditions of that trial were not duplicated in this one. The steelworkers were relatively young (mean age 41 years) men employed in industry, whereas our subjects were an older community group of men and women. The self-recording factor was similar but the attention factor was different. The steelworkers were seen fortnightly by a health worker in the plant, and efforts were made to support them in their pill-taking by tailoring their regimen to daily routines. In the community trial the home visitors dealt only with measurement of blood pressure, reporting their readings to both the

subject and the physician; no attempt was made to directly influence the taking of medication.

Was the sample size sufficiently large to detect a real difference between the four groups if it existed? Given the absence of an interaction effect between the two intervention techniques, the experimental design allowed the two groups that received home visits to be combined and compared with the two that did not; the design also permitted the two groups doing self-recording to be compared with the two not doing this. Considering a difference of 5 mm Hg in diastolic blood pressure and a difference of 20% in compliance between treatment groups as clinically important, we determined the probability that real differences of this size existed but were undetected owing to an insufficient sample size. The probability that an attention effect (due to the monthly visits) on diastolic blood pressure was undetected was 0.006, and for an effect on compliance it was less than 0.001. The probability that a self-recording effect on diastolic blood pressure was undetected was 0.005, and for an effect on compliance it was less than 0.001. Thus, our observed lack of experimental effect between the groups was real and not due to an inadequate number of participants in the trial.

Although the emphasis in this trial was on the effect of self-recording of blood pressure, the design permitted assessment of the effect of increased attention in the form of home visits. Both interventions were initiated not by the subject's physician, but by the study group, with the physician's con-

currence. Each physician treated his or her patient independently, and neither a standardized therapeutic regimen nor a goal blood pressure was advocated. Under these circumstances neither self-recording nor monthly home visits was shown to have a significant influence in promoting blood pressure control or compliance with therapy in this group of individuals with hypertension.

Although we observed no overall effect we did confirm our earlier observation that patients who admitted to difficulty remembering to take their medication showed the greatest benefit from interventions including self-recording of blood pressure. The finding in this trial that such subjects showed a significant improvement with both self-recording and monthly home visits suggests that this easily identified group are the most responsive to attempts to improve their blood pressure control.

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BOOKS

This list is an acknowledgement of books received. It does not preclude review at a later date.

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Table VII—Mean diastolic blood pressure at beginning and end of the trial

Regimen (and no. of subjects)	Mean diastolic blood pressure, mm Hg					
	At entry into trial		At end of trial			
	Visit 1*	Visit 2*	Visit 1*	Visit 2*	Visit 3†	
Self-recording and home visits (n = 35)	107.2 ± 9.4	104.2 ± 6.4	98.1 ± 9.6	98.4 ± 8.7	95.9 ± 9.4	
Self-recording only (n = 34)	104.6 ± 7.0	102.6 ± 6.9	99.7 ± 9.7	96.6 ± 10.2	94.1 ± 11.1	
Home visits only (n = 33)	104.0 ± 7.9	103.9 ± 6.1	97.6 ± 8.1	95.9 ± 8.7	95.2 ± 9.2	
Neither (n = 34)	103.9 ± 8.6	193.2 ± 9.4	99.9 ± 10.1	99.1 ± 10.6	95.7 ± 12.5	
Total (n = 136)	105.0 ± 8.4	103.5 ± 7.4	98.8 ± 9.9	97.5 ± 9.7	95.2 ± 10.7	

*For these visits the same person visited each subject.
†For this visit one person visited all subjects in the trial; she had no prior connection with the subjects or knowledge of the purpose or design of the study.