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A Controlled Trial of Health Education in the Physician's Office[1]

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Screening of 6,144 patients in a general practice clinic to assist physician case-finding uncovered 983 (16%) who were uncontrolled hypertensives. Following physician recommendation, 115 patients volunteered for a controlled trial to test the effectiveness of supplementary strategies to the pharmaceutical management of high blood pressure. A study of nonparticipants indicated that about 7% of the practice population was eligible for cardiovascular health education. One group received a health education program, a second was allocated to self-monitor their blood pressure for 6 months, a third group was allocated to both strategies, and the final group, acting as a control, continued to receive their usual care. Physician monitoring of patients continued for the duration of the study and blood pressures decreased in all patients. The study's most important outcome was the joint reduction of blood pressure and medication strength. These were assessed by a "blind" clinician before and after the interventions according to criteria set out in the "stepped-care" approach to management of high blood pressure. People allocated to a health education program conducted in the doctor's common room did twice as well on this measure as those who were not so educated. Daily self-monitoring of blood pressure for 6 months proved to be too much for the majority of those so instructed. It is concluded that the general practice setting remains an important place for health education to prevent cardiac disease and suggestions are made for incorporating this into everyday practice.

INTRODUCTION

This study set out to investigate the role of health promotion initiatives in a general practice setting. High blood pressure was selected as the major risk factor for intervention because recommendations for its modification attribute a major role to the physician and the use of pharmaceutical therapies. Just before commencement of the study, the Canadian Task Force (6) recommended that all men over 35 years of age have their blood pressure checked periodically. Further, an optimal stepped-care approach for pharmaceutical management of blood pressure had been presented (7). However, it was recognized that pharmaceutical care is maintenance care and that lifestyle change must be emphasized to maintain a

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satisfactory blood pressure level without medication. The subgroup analysis of the Multiple Risk Factor Intervention Trial (5), which suggests that mild hypertensives with abnormal ECGs might have a higher death rate when receiving treatment, offers further support to the importance of lifestyle change as a means of controlling blood pressure.

The health promotion strategies in this study were the self-monitoring of blood pressure and a health education program that promoted a healthy cardiovascular lifestyle. The aim was to identify the demand for these approaches as well as to assess their effectiveness in a controlled manner.

METHODS

The target population consisted of hypertensives attending a general practice clinic in South Perth, Western Australia (seven-member practice with 36,000 medical records), in 1977–1978, who doctors felt could benefit from a health education program in addition to, or instead of, the normal pharmaceutical management. Case-finding was facilitated by sample blood pressure screening in the waiting room by a trained nurse from the local domicilliary nursing organization (Silver Chain). The sampling unit was a 2-hr time period and initially the time was varied to include representation of all major surgery hours on the 5 working days of the week. However, this was later reduced to selecting those hours that gave the highest yield of hypertensives. All patients with blood pressures over 160 systolic or 95 diastolic on this rested, seated blood pressure measure were referred to their doctor for a second reading. Patients were eligible for the study if the doctor's reading confirmed that the blood pressure was high and if the person was under the age of 70, did not have significant co-morbidity, and lived in reasonable proximity to the clinic (this was to exclude country patients who may have traveled over 200 km for the consultation). Should the patient be eligible, doctors were requested to introduce them to the nature of the study and ask them to volunteer by signing the informed consent form at the nurses' desk. A study record was commenced noting the present blood pressure readings and levels of other risk factors such as smoking, cholesterol, and triglycerides. The current medication and the therapeutic goal were also recorded as well as any other comments thought relevant.

Study Design

The target population was divided into four groups to cover all combinations of the two interventions plus a control. One group received only the health education program and another only the daily monitoring. A third group was allocated to both programs, and the fourth acted as a control.

The health education program was prepared in a joint effort by the study staff, the Health Education Council of Western Australia, members of the Silver Chain Nursing Organization, and members of the School of Health Science at the Western Australian Institute of Technology. All materials were reviewed and accepted by all doctors at the clinic. The project team decided that the program should be constrained in the following manner to ensure a maximal effect in the normal general practice setting:

(a) that there should be only four meetings;
(b) that each meeting should be only 90 min duration;
(c) that the material should be of such a standard that it can be presented by a facilitator with minimal training in the health field, such as a health education auxilliary;
(d) that meetings should have a maximum of 12 participants;
(e) that patients should be strongly encouraged to come with a close friend;
(f) that participants should be encouraged to make action goals at the end of each session and that these should be reviewed at the start of the next session.

The first meeting reviewed the evidence that there were "risk factors" associated with heart disease with an emphasis on the importance of blood pressure. Technical information on measurement was presented on a videotape by the doctors and nurses on the study team. The emphasis in the second session was the importance of exercise and the discussion centered around how the patients could increase their own activity patterns.

Nutrition was the topic of the third session which was introduced by a dietitian discussing the selections that are and can be made in a supermarket. The fourth session introduced stress and simple relaxation techniques and finished with a discussion of the important role of medications and common problems with compliance.

The daily monitoring program involved a 30-min briefing of patients on the use of the aneroid sphygmomanometer which was supplied to the study participants by Merck Sharpe & Dohme Pharmaceutical Company. A simple method of measurement was described on the back of a monthly recording chart as a reminder. Participants were recommended to take their pressure at approximately the same time of day each day and to graph both measurements on the chart. New charts were mailed to participants each month. The program called for 6 months of monitoring in this group, and those who had not returned the previous month's chart in the prepaid envelope supplied were followed up. If a person indicated an unwillingness to continue, no more charts were posted.

The allocation procedure to one of the four groups followed the minimization program described by Taves (9). This procedure has considerable advantages over normal stratification when there are numerous categories that need to be taken into account. A computer program was written to perform the continuous balancing of the groups across the major variables which were specified as initial blood pressure, age, medication, sex, and general practitioner. Although this was not strictly a randomization procedure, none of the study team was able to predict to which group a person would be allocated.

An initial survey was conducted in the home of the participant within the first month after he or she had volunteered for the study. Variables that might be predictors of outcome (2, 8) were measured to ensure comparability between the four groups. This interview was by appointment and was conducted by trained interviewers from the Bureau of Census and Statistics and was approximately 1 hr in duration. The following constructs were measured: family history of heart

disease, perceived present health, attitudes toward high blood pressure, pill-taking habits, satisfaction with patient–doctor relationship, knowledge of current therapy, knowledge of risk factors for heart disease, as well as sociodemographic variables.

Compliance with medications is a specific confounder in a study of hypertensives, most of whom are on some pharmaceutical therapy. Measurement of compliance was done in a household oral medication survey which included questions on all drugs that could be identified in the home and a count of all hypertensive medications. Because an accurate date of purchase of medications was not always possible, knowledge of the purpose and recommended dosage of each medication was assessed prior to self-reported compliance. This survey was conducted by a trained nurse from the Silver Chain Nursing Organisation and took approximately 45 min to complete. These measures were combined into three broad categories of compliance by a senior nurse who was "blind" as to which group the individuals had been allocated.

The outcome of importance in this study relates to a decrease in blood pressure and a decrease in the strength of medication. Given the complexity of this measure, it was decided that "global" assessment of the severity of the blood pressure and the strength of the medication would be made in a "blind" manner by a physician who had membership in the College of General Practitioners and who had graduate training in public health. At the completion of the study, this physician was given all the study medical records and was asked to give an assessment of each of these factors on the patient's entry into the study and again on the first date of physician contact following 1 year in the study. Both the medication and the blood pressure were scored on a 1–5 scale of severity with the criteria taken from the different steps in the stepped-care approach to management of hypertension (7). Patients who did not return to the general practice during the period from the 9th to the 18th month after entry into the study were considered lost to follow-up. It is possible that this clinician measurement might be biased because the "blinding" was ineffective. At the completion of scoring, the physician was asked to categorize the participant into one of the four study groups. The accuracy of these predictions was equivalent to chance.

RESULTS

Program Demand

Of prime interest to this study is the level of demand for such a program in a general practice. Of the 6,144 patients screened in the doctor's waiting room, 983 (16%) had blood pressures over 160 systolic or 95 diastolic at the first reading. From this population and others who did not go through the screening process, 115 (46 men, 69 women) volunteered to enter the study; however, 2 changed their minds after being allocated to the daily monitoring group and before the initial interview.

A sample of 187 of those screened with blood pressures over 200/110 were selected and the doctors were asked for reasons for their noninclusion in the study. It was noted that 30% of this group would have been disqualified by age,

TABLE 1
COMPARABILITY OF STUDY GROUPS ON ENTRY

	Group 1	Group 2	Group 3	Control
Sample (*N*)	29	30	27	29
Age				
$\bar{X}$	57	58	56	58
SD	(8)	(8)	(12)	(10)
Sex				
Female	16	18	17	18
Male	13	12	10	11
Blood pressure				
Systolic				
$\bar{X}$	180	181	184	179
SD	(22)	(23)	(22)	(26)
Diastolic				
$\bar{X}$	105	108	106	103
SD	(7)	(7)	(8)	(11)
Income				
<$8,000	10	10	7	11
$8–20,000	13	11	14	14
>$20,000	4	3	3	1
Reported tablet consumption				
1/day or less	13	14	8	13
>1/day	16	16	19	16

Note. Group 1 was allocated to the health education program. Group 2 was given the health education program and the daily monitoring device. Group 3 received only the daily monitoring device.

and a further 30% were 60 to 70 years old. Doctors indicated that the age was too high in half of this second group. An additional 10% were excluded for reasons of co-morbidity and 10% for reasons of distance from the clinic or difficulty in attending. The patient was said to be unwilling in 4% of cases. This left 16% of cases for which the doctors, even with the help of the medical record, could not recall a reason for nonentry. It was known that one of the seven doctors was not cooperating with the study, and this could account for many of these cases. Making the adjustments for exclusions, the real target population within a general practice for programs of this type—that is, for uncontrolled hypertensives considered amenable to a lifestyle change program—is closer to 7% of the total practice population. Of this 7%, only a fraction were willing and able to participate, probably between 5 and 10%.

Comparability of Groups

The effectiveness of the minimization program in achieving comparable groups can be seen in Table 1. In particular, the groups were highly comparable in age, sex, and blood pressure, and reasonable comparability was noticed on income level and on the self-reported regularity of taking pharmaceutical medication, with the exception of Group 3 which had less people reporting taking one dose a day

or less. Further, there was no significant difference between any of the groups on other variables such as family history of heart disease, perceived present health status, attitudes toward health and high blood pressure, and satisfaction with their doctor–patient relationship.

The above variables are those which the health belief model (2, 8) predicts might affect an individual's compliance with medication prescription or their overall willingness and preparedness to make a change in their lifestyle.

Process measures. Fifty-nine people were allocated to attend the health education program. Of these, 17 found that they could not fit in with any planned schedule in the first 4 months after entry into the study. A further 5 attended less than three meetings. Thus, 37 people (63% of those allocated) were able to adhere to the intervention satisfactorily. The fact that this represents 88% of those who attended *any* session is a measure of the acceptance of the program. The anonymous process evaluation which was sent to all those who had attended any sessions was unanimously positive toward the program. Ninety-four percent used the superlative for the resource person, 81% for the pamphlets that accompanied each session, 75% for the discussion period in each meeting, and 56% for the videotape presentations.

The process evaluation from the facilitators again was unanimously positive. Superlatives were almost unanimous for patient level of interest and discussion. An indication that the program material might still be improved came from the fact that one-third of this group thought that it was only "satisfactory."

Compliance

Unannounced pill counts were conducted in the homes of all study participants and knowledge of the use of prescription drugs discovered was measured. Using the medication study record (completed by doctor) as a guide, all participants were classified by one of us (T.G.) into three broad categories of compliance.

This was then used as a dependent variable in a multiple logistic regression model (GLIM) controlling for any lack of comparability in the groups on medication knowledge, health beliefs, initial status, or demographic variables. There was no significant difference between the groups on compliance or knowledge of medications (Table 2).

Outcomes

Over the duration of the study there was a marked decrease in both systolic and diastolic blood pressures of all the participants, irrespective of group. From Table 3 it can be seen that both the systolic and diastolic blood pressures had reductions of over 10 points in the majority of the population. A change of this order would be expected given that the majority were on pharmaceutical therapy which is known to be efficacious (10), and the change was in the direction expected for a "regression to the mean" effect.

Also presented are the clinician's assessments of the severity of the blood pressure and the strength of the medication according to the criteria in the stepped-care approach (7). This measure was taken without knowledge of the group to which the patient had been assigned and is considered to be more ap-

TABLE 2
COMPLIANCE AND MEDICATION KNOWLEDGE IN STUDY PARTICIPANTS

	Group 1	Group 2	Group 3	Control
Sample (*N*)	29	30	27	29
Assessed compliance				
Good	8	9	7	7
Fair	13	15	13	12
Poor	8	6	5	10
Assessed medication knowledge				
Good	16	11	13	13
Fair	8	16	9	12
Poor	5	3	3	4

Note. Group 1 was allocated to the health education program. Group 2 was given the health education program and the daily monitoring device. Group 3 received only the daily monitoring device.

propriate as it takes into account other factors that were recorded on the medical record.

The assessment of medications indicated that the majority of the study group did not have the strength of their pharmaceutical therapy reduced over the year

TABLE 3
CHANGE IN CLINICAL MEASURES OVER YEAR OF STUDY

	Group 1	Group 2	Group 3	Control
Blood pressure reduction				
Systolic				
40 mm Hg	9	12	11	14
10–40 mm Hg	15	13	9	13
10 mm Hg	5	5	5	2
Diastolic				
25 mm Hg	4	11	6	7
10–25 mm Hg	21	15	12	16
10 mm Hg	4	4	7	6
Clinician assessment				
Large	8	14	10	8
Some	18	9	7	11
None	3	7	8	10
Medication change				
Clinician assessment				
Reduction	8	7	7	5
No change	8	11	10	12
Increase	5	5	3	8

Note. Group 1 was allocated to the health education program. Group 2 was given the health education program and the daily monitoring device. Group 3 received only the daily monitoring device.

TABLE 4
CLINICALLY ASSESSED OUTCOMES BY HEALTH PROMOTION STRATEGY

	Blood pressure reduction	Medication reduction	Reduction in both
Health education [No. (%)]			
Received	49/59 (83)*	15/44 (34)	15/44 (34)*
Not received	36/54 (67)	12/45 (27)	7/45 (16)
Daily monitoring			
Received	40/55 (74)	14/43 (33)	12/43 (28)
Not received	45/58 (78)	13/46 (28)	10/46 (22)

Note. Blood pressure and strength of medication were scored on a point scale on entry into the study and 1 year later. The scale was based on the stepped-care approach to management of hypertension (7).

* $P < 0.05$.

period. Of interest is the fact that in approximately 25% of each group, the strength of medication increased.

The effect of health education and daily monitoring on the reduction of blood pressure and medication is presented in Table 4. The effects were tested using a multiple logistic regression model (GLIM) controlling for compliance and differences in the comparability of the groups. Those people who were allocated to the health education meetings had a significantly better outcome than those who were not allocated both when the considered outcome was assessed blood pressure reduction and when it was the combination of blood pressure and medication reduction. The reduction in the numbers of the denominator of those receiving medication reflects the fact that 24 of the study participants were not receiving medication for hypertension at any point during the study.

The daily monitoring intervention did not have a statistically significant effect on either outcome variable. This could relate to the fact that only 13 of the 57 people allocated completed 5 months of monitoring.

DISCUSSION

This study aimed to test the effectiveness of health education and daily monitoring of blood pressure as supplementary interventions to the normal pharmaceutical management of high blood pressure in the general practice setting. A major design constraint of these programs was that they were to be conducted within any normal practice with a minimum of reorganization. There are two elements important to the assessment of effectiveness. The first is whether those who volunteered for the study derived any benefit from the intervention to which they were allocated. The second element relates to the relevance of the interventions to the general practice setting. This involves an assessment of the number of people who would be eligible for this type of program within a general practice

as well as those willing to attend. It is to be expected that willingness to attend will be affected by the degree to which the intervention has proven worth. Demonstration of the effectiveness of this study should lead to stronger suggestions to patients to consider participating in such an intervention.

The derivation of benefit in this study was defined as both a reduction of blood pressure and a reduction in the strength of medication. These program benefits need to be accepted by general practitioners as meaningful, and, to this end, it was considered important that the assessment was carried out by an independent clinician who was both a general practitioner and a graduate of a public health program. This assessment used the criteria for stepped care set out in the recommendations of the Joint National Commission on the Detection, Evaluation and Treatment of High Blood Pressure (7).

A comparison of benefits derived by the interventions on this measure demonstrated that the health education program was twice as effective as either the daily monitoring program or the normal pharmaceutical treatment. Attributes of the health education program which contributed to its success seemed to include each of the following: motivation by the family physician to reduce the level of risk through lifestyle change; the fact that the program was based on small groups and used facilitators; that locally available pamphlets were used to give participants the necessary background for discussion; that the discussion prompted both the setting and the review of realistic action goals. Although the evaluation considered all those who were allocated to the health education program, not everyone was able to adhere to what was considered adequate for the intervention to work. However, it is important to note that very few people actually dropped out of the program once they had attended the first meeting.

No significant benefit was seen from the daily monitoring program. People started dropping out from the time they heard that they had been allocated to this intervention. There were two instances where the doctor had to request that the patient be removed from this intervention because of unfavorable patient response to the monitoring. In both instances, patients had started to refuse to do anything which elevated their blood pressure in any way.

In other cases, patients reported to their doctors that they were having great difficulty getting a reading. Perusal of the returned charts indicated that a third reason for dropping out was the inconvenience of taking a regular daily measure. A number of people completed the whole form without taking the measure more than once or twice.

The evidence from this study strongly suggests a renewed emphasis on the role of the physician and the general practice in discussions of health promotion. This role should be to promote focused lifestyle change among those identified as having a problem or otherwise concerned enough to seek advice or treatment to improve their health status. Using the physician's office to influence such people to change should then be a major strategy in the preventive medicine approach. The assessment of who within a general practice might benefit from a health education program of the type described depends on how representative the study population is of normal general practices. The seven-member general practice that was the site of this program is situated in an inner suburb of Perth, the capital of

Western Australia. It may be that this practice has a higher proportion of both older patients and younger itinerant patients than other practices. Accordingly, it is thought possible that the 7% estimate of eligibility within the practice population may be a low estimate for many other practices. The size of the estimate probably also reflects the unwillingness of men between the ages of 30 and 50 to attend general practitioners before the onset of symptoms.

However, it cannot be expected that all those eligible will ever come to a program. In this study, it is estimated that those who volunteered represented between 5 and 10% of those who were eligible. In future studies, general practitioners may be more willing to encourage patients strongly to participate, and this extra motivation could raise the participation rate by a factor of 3.

Although there was considerable time and effort put into the development of this health education program, the evaluation suggests that such a complete package is not essential. The important element seems to be the small group discussion among patients and their friends which is action-oriented and reinforced by health pamphlets (which are usually freely available from health departments, etc). There is some organization required in putting together such meetings, but this could easily fit into the coordination role of the local health education officer or of a nurse–practitioner.

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