

INFLUENCE OF INDIVIDUALIZED PREVENTION RECOMMENDATIONS AFTER ONE YEAR ON THE CONTROL OF HYPERTENSION IN 3,868 FOLLOW-UP PARTICIPANTS OF THE ELITE STUDY

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SUMMARY

Objectives: The ELITE study (German acronym for “Nutrition, lifestyle and individual information for prevention of heart attack, stroke and dementia”) prospectively collects data on hypertension, cardiovascular risk factors (RF), dietary habits, physical activity, cognitive function, and quality of life in North-West Germany, which will then be improved through targeted individual information. The aim of the study is to improve the health of the participants in the long term and to identify reasons for a lack of implementation of prevention measures.

Methods: Of 4,602 included subjects, 3,868 could be studied so far at one-year follow-up. Blood pressure (BP) was measured according to the guidelines at admission and blood pressure history, premedication, sports behaviour and BMI were recorded by means of questionnaires and compared with the data collected in the follow-up examination after one year.

Results: The participants were evaluated in 4 groups (G): G1 – normotensive patients (n = 1,558), G2 – controlled hypertensive patients (n = 502), G3 – untreated uncontrolled hypertensive patients (n = 1,080), G4 – treated uncontrolled hypertensive patients (n = 728). In G1 blood pressure (RR) remained unchanged from 126.3/77.8 to 127.8/78.5, in G2 there was a significant ($p < 0.001$) RR increase from 128.1/77.0 to 134.9/79.8. In G3 and G4 RR decreased significantly ($p < 0.001$) from 149.9/90.0 to 143.5/86.9 and from 153.1/87.5 to 146.2/84.1 mmHg, respectively. In G3 and G4, RR decreased in 56.1% and 56.3% of subjects and increased in 18% and 21%, respectively. In contrast, RR increase was found more frequently in G1 and G2 (34.3% and 51%, respectively), and RR decrease less frequently (25.4 and 20.7%, respectively). The main reasons for RR decrease were weight loss, more exercise, and more antihypertensives. Frequently, improved compliance and dietary changes were given as reasons. As expected, the opposite often led to RR increase.

Conclusion: 56% of the hypertensive participants succeeded in lowering their blood pressure, whereas there was a significant increase in blood pressure, especially in those who were well controlled with antihypertensives. This underlines the need to further motivate normotensive patients to maintain their normotension. The results show that the combination of individual written education and lifestyle interventions are an effective tool for the public health sector to combat hypertension. In our participants, lifestyle interventions have a significant impact on BP change. It should be noted critically that there are still too many patients who have not been reached.

Key words: hypertension, lifestyle interventions, recommendations, blood pressure

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INTRODUCTION

The most important cardiovascular risk factor remains hypertension, which is the cause of 40% of cardiovascular deaths (1). In 2025, more than 1.6 billion people worldwide will be affected by arterial hypertension (2). The impact of hypertension on cardiovascular risk and the effectiveness of its treatment are well documented. Nevertheless, only every second hypertension patient in Germany is controlled (3). There is a big discrepancy between scientific knowledge and the clinical situation.

The decisive question is therefore what obstacles exist to implement effective measures by patients and whether sustainable individual information with regular individual examination and consultation can improve implementation.

Based on these considerations, the ELITE study (German acronym for “Nutrition, lifestyle and individual information for prevention of heart attack, stroke and dementia”) was developed.

The ELITE study is a prospective interventional cohort study (DRKS 00006813) in North-West Germany. The aim of this study is to encourage more people to reduce their cardiovascular risk

factors through intensive education and regular and recurring visits. A total of 4,602 participants aged 16 years and older were included in the study so far. Objectives include determining the frequency and distribution of risk factors for cardiovascular events in this region and improving the health of the participants through individual prevention recommendations. But not only the classic risk factors (hypertension, nicotine, diabetes, laboratory data) were recorded, but also data on nutrition, psychological stress, depression, physical activity, quality of life, well-being and brain performance, which have a significant influence on the long-term prognosis (4, 5). In order to investigate the feasibility and effectiveness of these recommendations, annual follow-up visits are carried out over a period of five years. The influence of cardiovascular risk factors on blood pressure control and mild cognitive impairment at the admission examination has already been published (6).

This paper investigates the influence of prevention recommendations on the control of hypertension in 3,868 participants who join the second visit after one year compared to the admission.

MATERIALS AND METHODS

This evaluation is based on the above-mentioned ELITE study. The study is conducted overall with a follow-up of 5 years. In this evaluation, the admission examination is compared with the follow-up examination after one year. A description of the study, methods and basic results have already been published (6–8).

Data Collection

The participants were recruited via newspaper articles, sports clubs, businesses and via letters of invitation based on extracts from the residents' register. Exclusion criteria were age under 16 years, lack of a declaration of consent and obvious difficulties in tracking the participant. Data were collected on age, height, weight, school-leaving qualifications, occupation, medication intake, previous illnesses, blood pressure, nutritional and sports behaviour, laboratory values, stress in everyday life/occupation, and brain performance. These data were collected by means of examinations, blood samples and standardized questionnaires about nutritional and sports behaviour, stress, and quality of life by trained specialists.

Standardized blood pressure measurements were carried out in the study outpatient clinic or with mobile teams in companies and societies such as rural women's association. After five minutes of quiet sitting, the blood pressure measurements were taken in three consecutive measurements with a one-minute break on both sides. The average value of the measurements of the body side with the higher values was included in the evaluation. The Microlife® "WatchBp office" device (oscillometric measurement) was used for this purpose. The blood pressure cuff was selected to fit the patient's upper arm circumference. The participant was asked for a known history of high blood pressure.

Definitions

Group 1 (G1) – normotensive: all participants with normotensive blood pressure values and without a history of medication and/or known hypertension in the medical history.

Group 2 (G2) – controlled hypertensive patients: all participants with blood pressure values < 140/90 mmHg and either antihypertensive therapy and/or already known hypertension.

Group 3 (G3) – untreated uncontrolled hypertensive patients: all participants with blood pressure values \geq 140/90 mmHg without antihypertensive therapy.

Group 4 (G4) – treated uncontrolled hypertensive patients: all participants with blood pressure values \geq 140/90 mmHg and who are already being treated.

Admission was compared with the first follow-up. Here, the movement between the groups was analysed. Improvement in blood pressure was assessed when blood pressure improved by 5 mmHg. A worsening was evaluated accordingly from a higher blood pressure from 5 mmHg.

The change in sports behaviour is the result of a paired comparison between admission and follow-up and of improvement, worsened or unchanged between the categories "much exercise" (1× daily and/or 2–3× per week), "moderate exercise" (1× per week and/or every 2 weeks) and "rare exercise" (1× per month and/or less often), which result from the multiple choice answers in the questionnaire to the question "how often do you exercise"?

The BMI was calculated by self-declaration of height and weight and was evaluated as improved (weight loss) if the weight loss was at least 0.3 kg/m² compared to the initial examination. If the change was between –0.3 and +0.3 kg/m², the BMI was evaluated as unchanged. If the BMI increased by more than 0.3 kg/m², it was evaluated as worsened (weight gain).

A change in the number of antihypertensive agents (less, equal or more antihypertensives) was evaluated when there was a change of at least one agent compared to the admission.

Information and Advice

Each participant was given an individual cardiovascular risk profile based on current guidelines of the various professional societies. Computer-based prevention recommendations were elaborated and sent to the participant by letter. Depending on the scenario (blood pressure known, unknown not treated or known but inadequately treated, etc.), intensive education about the disease, prognosis and long-term consequences took place first. If necessary, a 24h blood pressure measurement by the general practitioner (GP) was advised to confirm the diagnosis. Intensified blood pressure medication prescribed by the GP was also recommended, depending on the scenario. Conversely, this means that normotensive participants did not receive recommendations because they were already normotensive. Then the effectiveness of general measures such as exercise was emphasised and an increase in physical activity was recommended depending on the results of the questionnaires. Smokers were impressively shown the dangers of nicotine abuse and advised to give up nicotine. Here, too, outpatient help to quit was pointed out. In addition, the dietary habits were surveyed by means of a questionnaire and, depending on the scenario, an increase in the amount of fruit, a reduction in alcohol, salt or red meat and general recommendations for a balanced diet were made.

These recommendations were sent by letter after the admission. In the annual follow-up examinations, these recommendations are then evaluated by the participant for comprehensibility and objective practicability, among other things.

Analysis

A descriptive analysis was conducted for all variables. For metric type observations means and standard deviations were calculated. Grouped variables were evaluated by means of cross-tables.

When comparing the groups with metric characteristics, an analysis of variance was performed followed by post-hoc tests with Bonferroni correction. In order to compare quantitative values for groups observed at admission and the 1st follow-up the paired sample t-test was applied. The usual significance level α of 0.05 was used for all tests.

RESULTS

The changes of blood pressure between admission and the first follow-up are shown in Figure 1; 3,868 of the initial 4,602 (84%) participants were included in the evaluation, which is significantly higher than the expectations of approximately 70%.

Patients were divided into 4 groups based on blood pressure values at baseline. G1 – normotensive patients (n=1,558), G2 – controlled hypertensive patients (n=502), G3 – untreated uncontrolled hypertensive patients (n=1,080), and G4 – treated uncontrolled hypertensive patients (n=728).

Thus, a total of 2,058 participants had normotensive blood pressure values at admission and therefore did not receive specific further recommendations for blood pressure lowering; 1,808 participants had hypertensive blood pressure values at admission. They were strongly advised to lower blood pressure – especially in already treated but still hypertensive participants. Depending on the individual profile, weight loss, more exercise, dietary changes including less alcohol, no nicotine, especially less salt, less stress and, after consultation with the general practitioner, antihypertensives were recommended (Fig. 1).

In the normotensive group, mean blood pressure remained constant, whereas there was a significant increase in blood pressure in G2 – treated controlled hypertensives. In contrast, blood pressure dropped significantly in both hypertensive G3 and G4.

Figure 2 shows the number of participants who improved or worsened their blood pressure by at least 5 mmHg. In the overall

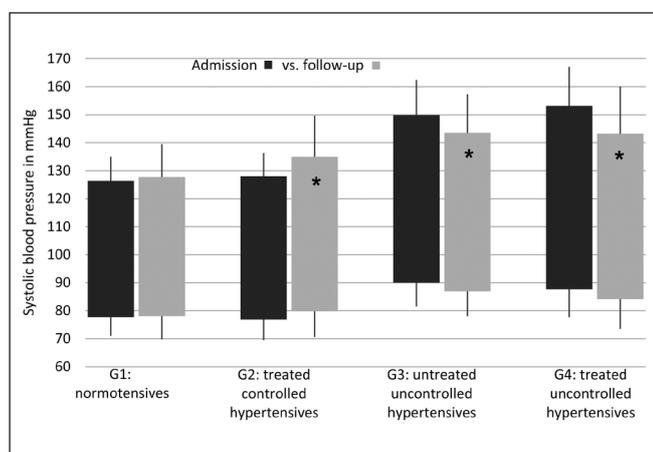


Fig. 1. Mean blood pressure in four groups at admission compared to the follow-up.

* $p < 0.001$

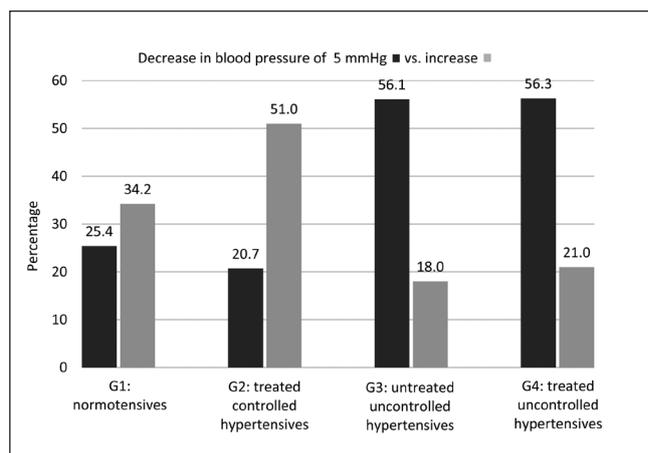


Fig. 2. Blood pressure increase and decrease of at least 5 mmHg in percentage.

All comparisons are highly significant ($p < 0.001$)

collective, 39.2% experienced a decrease in blood pressure and 29.4% experienced an increase. Blood pressure decreased in 25.4% of untreated normotensive participants and increased in 34.2%. Particularly striking were the previously controlled hypertensive participants, in whom blood pressure increased in 51% and decreased in only 20.7%. In contrast, blood pressure in the two groups of hypertensive participants (G3 and G4) decreased in 56.1% and 56.3% of participants, respectively, while blood pressure increases were much less frequent, occurring in 18% and 21%, respectively.

Figure 3 shows the lifestyle changes, such as BMI change, change in exercise activity, and blood pressure medication in the four groups categorized by blood pressure increase or decrease. In G1 of normotensives who were able to lower their blood pressure, 32% lowered their BMI, 21% increased physical activity, and only 2% took more antihypertensives. Conversely, among normotensives in G1 whose blood pressure increased, 45% increased BMI and 15% decreased their physical activity.

The values for G2, which was also normotensive, i.e. treated controlled hypertensives, are quite similar. However, 50% of the participants were able to improve their BMI. In the groups with hypertensive values, i.e. G3 and G4, the change in BMI is also most frequent.

In the 1-year follow-up questionnaire a total of 2,244 participants answered they received individualized recommendations (62.7%). Of these, slightly more were men (54.2%) than women; 893 participants (24.9%) stated that they had received new noticeable findings (Table 1); 1,571 participants (43.9%) found the recommendations helpful and 87.8% judged them to be appropriate and/or understandable (8% gave no indication here); 150 participants (4.2%) found the recommendations too long, too short or generally incomprehensible (Table 1); 84% of the participants with recommendations stated that they had implemented them.

Among all participants with improved blood pressure, 54.5% reported that they had implemented the recommendations. In contrast, 56.9% of the participants with worse blood pressure values stated that they had not implemented any recommendations. The most common reason for this was increased attention to healthy eating (37.5% of men and 35.9% of women) followed by increased

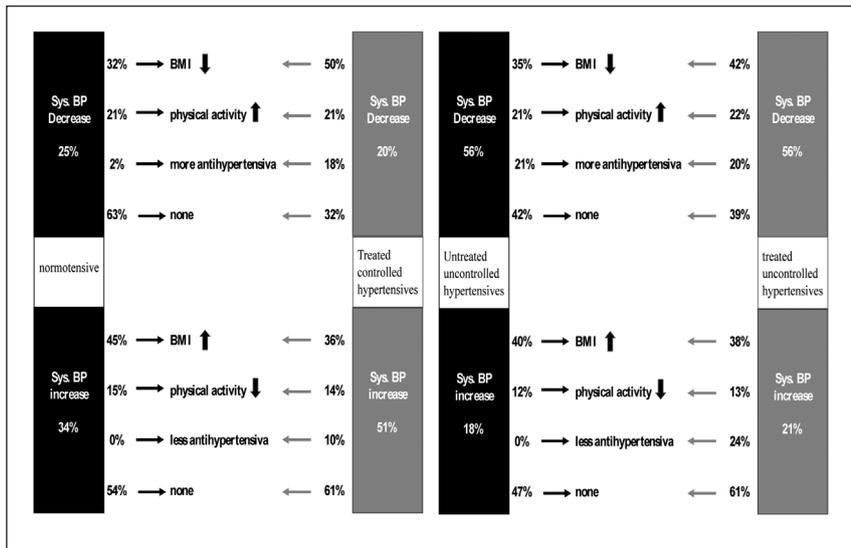


Fig. 3. Lifestyle changes in four groups in relation to increase or decrease of blood pressure.

Table 1. Frequency and characteristics of recommendations

	Males %	Females %
Were recommendations made?	64.4	61.2
Were there any abnormal findings that were new?	23.0	24.7
Were recommendations helpful?	46.5	41.7
Were results discussed with family doctor?	38.1	40.4
Recommendations understandable	61.0	68.7
Recommendations incomprehensible	2.3	1.4
Recommendations appropriate	26.3	19.5
Recommendations too long	1.3	1.4
Recommendations too short	1.1	1.1

Table 2. Implemented recommendations

	Males %	Females %
Pay more attention to nutrition	37.5	35.9
Could lower blood lipids	3.7	4.0
Was able to lower blood sugar levels	2.6	1.6
Could reduce stress levels	7.6	5.0
Could stop or reduce smoking	2.3	1.7

physical activity (22.3% of men and 22.1% of women). Stress levels were reduced by 7.6% in men and 5% in women (Table 2).

DISCUSSION

With almost 84%, significantly more participants came to the follow-up study than initially expected.

Our recommendations were evaluated by the participants. Over 60% found the recommendations understandable and only about 5% found them incomprehensible or too long or too short. Only about 50% of the participants found the recommendations help-

ful. Nevertheless, these results are very satisfactory for the first follow-up examination, since many participants wanted to wait for confirmation of their results in the second evaluation. This is clear from the small number of participants who responded negatively to the recommendations. It remains to be seen whether further follow-up studies will further improve the implementation rate.

A significant reduction in blood pressure was striking in subjects with hypertensive values on admission. Blood pressure decreased by 6.4 mmHg in untreated hypertensives and by 6.8 mmHg in treated hypertensives. This meant that 56.1% and 56.3%, respectively, in these groups were able to lower their blood pressure, while only 18% and 21%, respectively, increased on the other side. In contrast, the mean value in the previously normotensive subjects increased by 6.8 mmHg; 20.7% of subjects with a decrease contrasted with 51% with an increase. Among normotensives, blood pressure decreased in 25.4% and increased in 34.3%, although the mean value did not change. Obviously, persons with hypertensive blood pressure appreciate the intensive education about the dangers of hypertension with the concrete suggestions for blood pressure reduction as a cause for this result. With this education, a better compliance to prescribed antihypertensives may also be achieved.

The most common reasons for blood pressure decrease were in decreasing frequency: weight loss, increased exercise, and additional antihypertensives. Weight loss and increased exercise were significantly more likely in initially hypertensive patients who decreased blood pressure (G3 and G4) than in normotensive and treated controlled hypertensives (G1 and G2). In both groups, more antihypertensives were discontinued than newly prescribed. However, only in G2 blood pressure increased significantly, whereas in G4 it decreased significantly. The cause is not solely due to different prescriptions of antihypertensives. The positive effect of individual measures (e.g. sport or weight loss) is well documented (9–13). The direct effect of holistic prevention recommendations has so far been investigated mainly in small studies where the effect is mainly due to the improvement of drug therapy (10). Overall, weight loss and more exercise produced greater reductions in blood pressure in hypertensive baseline subjects than in normotensive subjects.

However, for many participants in the hypertensive groups, no clear explanation was found for the improved blood pressure values. In addition to better compliance, dietary changes such as salt and alcohol reduction, which were reported by about one-third, may have led to the reduction in blood pressure even without weight loss. Increased exercise may also reduce stress.

Above all, the combination of exercise and improved diet seems to be particularly effective. For example, Gaesser and Angadi indicated that risk factors associated with obesity are also improved by exercise independent of weight loss (15).

Normotensive participants were found to increase blood pressure more often than they decreased it. Here, the realization of having normal blood pressure may have led to neglect of a healthy lifestyle. A further explanation for the results in normotensive treated persons could be that the normotensives received fewer recommendations and at the same time less health education, which reflects the reality in practice. A conclusion for practice could therefore be that more time needs to be invested here as well. Furthermore, it is not enough to initiate drug therapy without referring to lifestyle interventions. In a large Finnish prospective cohort study, Korhonen et al. were able to show in 41,225 participants that taking preventive drugs, such as antihypertensives or statins, have a negative impact on lifestyle. The BMI increased and physical activity decreased in patients who started a drug-based preventive therapy (16). It is certainly impossible to prove which measures reduced blood pressure the most or led to a worsening of blood pressure. For clinical practice, it is crucial that blood pressure is lowered. Ultimately, a combination of lifestyle improvements and also adherence to antihypertensive medications will lower blood pressure and vice versa. It is encouraging that blood pressure can nevertheless be improved in a significant number of patients with hypertensive values through intensive education. Critically, too many patients have still not been reached. It is to be hoped that further improvements can be achieved in the course of the study. The hopeful result is that the improvement of blood pressure in 56% of the patients with hypertensive values at the beginning will reduce the risk of stroke or ischaemic heart disease (17).

In the Lifestyle Intervention against Hypertension in Eastern Finland (LIHEF) study, a randomized control study of 715 hypertensive patients, blood pressure was reduced by 4.2 mmHg within one year through intensive counselling on lifestyle measures on five dates per year. The measures related to health education and, in particular, weight reduction, salt restriction and reduction of alcohol consumption through dietary counselling, reduction of smoking and increased physical activity (18). In analogy to our study, lifestyle changes should therefore be made. Age and methodology of blood pressure measurements are also comparable (ELITE hypertensive patients – 56.1 years, LIHEF – 54.3 years).

The effort for patients and the study institute in the LIHEF study was significantly greater than in the ELITE study, although the effect on blood pressure was better in ELITE. In particular, we provided detailed written information about lifestyle and personal health risks. Public lectures or lectures in associations were held at irregular intervals. It is crucial how much effort can be expected of the patient to achieve a good overall social acceptance of primary prevention.

The LIHEF study was part of the North Karelia Project. The project was established in 1972 to reduce cardiovascular mortality in the region and later in Finland as a whole. In particular, the

control of hypertension was improved, cholesterol was lowered and nicotine abuse was reduced (19).

In order to further counter the increasing burden of cardiovascular disease, it is a good approach to take direct public health measures from an epidemiological survey, as we have done. The question should therefore be how to implement the findings easily and cost-effectively in the public health sector.

Victor et al. have measured the blood pressure of 319 uncontrolled hypertension sufferers in a randomized control study in American hairdressing salons (more precisely barbershops) and reduced their blood pressure by 27 mmHg by meeting with pharmacists. One advantage of this low-threshold prevention was that even a low-income population group could be reached and the resting blood pressure could be easily determined by sitting still for long periods (20).

At present, the integration of apps could be also a good way to better control blood pressure. Apps can be used to remind people to take medication (21) or to document the blood pressure in self-measurement, if necessary with medical evaluation and personal medical feedback via the app. Apps could also be used to measure dietary or sports behaviour more accurately. There are indications in the literature that the self-management of patients via app improves the blood pressure and, in some cases, shows advantages over the blood pressure control by standard self-monitoring at home, especially with personal connection. However, even larger, methodologically better randomized studies are needed (22–24). In a randomized control study, Moore et al. assigned a health coach to 20 patients via the “CollaboRhythm” app, who was able to answer individual recommendations and questions in real time, reminding them to take medication or take blood pressure measurements and giving lifestyle advice. In this way, blood pressure was reduced by 26 mmHg in 12 weeks and the control rate increased to 75%; 22 patients in the control group were able to lower their blood pressure by 16 mmHg through more conventional education by phone or e-mail (25). This impressive effect is offset by the high personal, time-consuming and cost-intensive effort.

CONCLUSION

The results of our follow-up study show that the combination of written education about the health risks of hypertension, education about self-measurement and 24-hour blood pressure monitoring, suggestions for lifestyle interventions such as weight loss, dietary tips and sports behaviour is an effective tool for the public health sector to combat hypertension, enhance compliance and improve control. Blood pressure decreased after 1 year in more than 56% of the patients with hypertensive values at admission.

Most common explanations for blood pressure reduction were weight loss, more exercise, additional antihypertensives. Improved compliance to the suggested measures or dietary changes such as less salt or alcohol may have contributed. On the other hand, normotensive patients more often experienced a rise in blood pressure than a fall. Therefore, it is extremely important to further motivate normotensive patients to maintain their good blood pressure.

It should be noted critically that there are still too many patients who have not been reached. The following examinations after

five years will show whether the lifestyle changes and thus the blood pressure control can be maintained in the long term. For this purpose, it is necessary to take a holistic view of the patient's state of health and formulate prevention recommendations as individually as possible. Here it must be taken into account that patients have different levels of knowledge about diseases and their prevention.

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Conflict of Interests

None declared

Adherence to Ethical Standards

All subjects gave their informed consent for inclusion before they participated in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of University of Göttingen (34/6/14).

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