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Effectiveness of tailored intervention with a salutogenic approach to improve adherence in adults with hypertension: a non-randomized trial

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Aims	Hypertension (HTN) is a chronic long-term, slowly progressing disease. For HTN control, management, and prevention of associated complications, adequate adherence to treatment is required. It has been proposed that tailored interventions to individual needs are required to address the phenomenon of adherence to treatment. However, studies evaluating the effects of tailored interventions to improve adherence are still scarce. The aim of this study is to evaluate the effectiveness of a tailored intervention using a salutogenic approach, to improve adherence in patients with HTN.
Methods and results	A non-randomized trial design was used in this study. Adult patients with HTN were allocated in two groups: tailored intervention ($n = 75$) and standard care ($n = 78$). The content of the tailored intervention was based on personal resources and elaboration of an action plan with objectives in agreement with the patients. Patient outcomes (treatment adherence, blood pressure) were assessed both at the beginning of the study and at the 4-week follow-up for the intervention group and the standard care group. The Treatment Adherence Questionnaire for Patients with Hypertension was used to measure adherence. The results of this study showed that the total score and each dimension of the adherence questionnaire (medications, diet, physical activity, weight control, stimulation, and stress relief) increased significantly in the experimental group compared with the control group ($P < 0.05$). For the group assigned to tailored intervention, the delta score of the total adherence score increased in the final evaluation to 9.4 (95% CI = 8.60–10.28).
Conclusion	A tailored intervention with a salutogenic approach appears to be effective for improving adherence in patients with HTN. Randomized controlled trials are required to confirm the effect of tailored interventions in this type of population.
Keywords	Hypertension • Tailored intervention • Nursing • Sense of coherence • Salutogenesis • Non-randomized controlled trials

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Implications for practice

- The focus of this research can be used to demonstrate how the holistic nature of caring practice provides patient-centred results.
- Tailored interventions constitute a strategy to incorporate into clinical practice, allowing such a strategy to work with individual abilities and resources for the promotion and maintenance of an individual's health.
- Tailored interventions can be used in a cardiovascular risk programme as a complement to the standard of care treatment.

Introduction

Hypertension (HTN) is a chronic non-communicable disease with a high prevalence in the adult population in low- and middle-income countries.[1] This condition is the main preventable risk factor for premature death and disability worldwide,[2] and its presence is associated with increased risk for disease for cardiovascular disease, stroke, and end-stage renal disease.[3]

For the management and control of HTN, several approaches have been implemented in terms of access to health services and medications; however, it is estimated that only 32% of patients receiving antihypertensive treatment actually have controlled blood pressure (BP),[4] a situation caused by lower levels of adherence, such as not taking medicine or not making lifestyle changes according to the recommendations of a healthcare provider. Despite the benefits of medication for controlling BP,[5] it is estimated that about half of patients prescribed an antihypertensive drug stopping taking it within 1 year,[6] individuals with HTN who are regularly seen by their primary care providers do not achieve and/or maintain BP goals, which leads to an increase in the complications of HTN, has negative effects on the quality of life, and increases healthcare costs.[7]

Research addressing adherence has focused mainly on behavioural determinants and methods to improve medication intake; comprehension of HNT using written communication as the main strategy was insufficient for producing changes in health behaviour, despite decades of research on the subject, progress in relation to adherence is still modest.[8] This situation has led to the search for perspectives and interventional approaches that promote active participation of the patient in the maintenance, optimization, and recovery of an individual's health.

Previous studies[9–11] have evaluated the effectiveness of simple and complex interventions to improve adherence, in which educational, behavioural, and motivational strategies have been used. These studies have concluded that the use of tailored interventions (TIs), needs, characteristics, and/or preferences of individual[12] is a pathway of providing personalized and patient-centred care.[13] Tailored intervention is considered complex since involve a combination of components and actions that are directed to different aspects or determinants of the problem. Their design is based on identification of an individual characteristic that is unique to a particular person and related to the outcome of interest. Development or selection of valid and reliable measures to assess selected characteristics, elaboration of a list of specific intervention strategies, and elaboration of a decision-making algorithms specify the rules that link the TI strategies with the selected individual characteristics.[14] The TI has been used to promote healthy behaviours and it is supported by cognitive-behavioural theoretical frameworks. However, it is unknown if this TI that encompasses cognitive, behavioural, and motivational elements in the individuals, is effective to improve health behaviours among patients with HTN. Therefore, we conducted a non-randomized study to assess the effectiveness of the intervention and provide meaningful evidence supporting the delivery of this kind of intervention under the usual conditions of a day-to-day practice before conducting a randomized controlled trial that it is considered the most appropriate design to determine the efficacy of the intervention under ideal conditions.

The interventions used in this study was based on the use of the individual's ability and active participation in maintaining their health and well-being as proposed by Aaron Antonovsky's salutogenic theory,[15] whose central concept is the sense of coherence (SOC). This concept has three components: (i) comprehensibility, (ii) manageability, and (iii) meaningfulness. This concept is defined as orientation towards life, which enables people to identify and mobilize their internal and external resources, to cope with life challenges; for this reason, it has been considered a useful theory in health promotion.[16,17]

The purpose of this study was to evaluate the effectiveness of TI developing individualized care plans, strength patients' comprehensibility, increase knowledge regarding HTN, enhance manageability by encouraging patients to improve their lifestyles through the incorporation of therapeutic regimens that make use of available resources, and finally, motivate them to participate in the decision-making process. In addition, we examined the possibility of empowering individuals and their families to use resources that are already available. According to the salutogenesis' conceptual framework, adequate use of these resources may promote health and therapeutic adherence.

Methods

Study design

A non-randomized trial with study and control groups who underwent pre- and post-test measurements. This study followed the recommendations of Transparent Reporting of Evaluations with Non-randomized Designs (TREND) statement.[18]

Setting

The research was conducted in a primary care clinic in a city with a population around 530 000 in Colombia between September 2018 and January 2019: The clinic was chosen because of the high number of registered patients that are diagnosed with HTN.

Sample size

Based on the results obtained in a pilot study that focused on the adherence score, the sample size was calculated according to the following specifications: a power of 95% (1-β = 95%), a level 95% confidence (1-α = 95%), an effect size with a delta or expected difference in the total

adherence score between both groups of $\Delta = 4.7$, a standard deviation of the scores of 7.5, and adjustment for losses of 30%, resulting in a sample size of 157 participants. The calculations were obtained with the Stata® 11.0 program.

Participants' recruitment and eligibility criteria

The selection of 157 participants from a pool of 213 patients was done on the basis of a simple random sampling using the random function of the Excel programme. The principal investigator invited selected patients to participate in the study, explaining to them what the research would entail and verifying they met all the inclusion criteria. If a patient did not meet the inclusion criteria and/or disagreed to participate in the study, the principal investigator chose the next patient on the random list.

The inclusion criteria were as follows: (i) patients older than 18 years, (ii) patients diagnosed with essential HTN by a physician, (iii) undergoing antihypertensive treatment for more than 6 months, (iv) residents in an urban area, and (v) had telephone service. The participants were excluded if they had pregnancy-associated HTN, diabetes, and target-organ damages (e.g. coronary heart disease, kidney disease, and nephropathy). From 213 patients evaluated, 56 were excluded due to the following reasons: they did not want to participate in the study, they did not meet the inclusion criteria, or they lived another town. The conformation of the two groups was according to the recruitment of the patients, the researchers decided that the first 79 recruited patients would go to the standard of care group and the remaining 78 patients to the TI group. The *Figure 1* illustrates the methodological framework of the study, which is based on the Consolidated Standards of Reporting Trials flowchart.

Data collection tools

The data collection was carried out by two research assistants, who were trained for a month in the handling of the instruments and in the clinical measurements performed on the participants. The principal investigator supervised the entire data collection process and guaranteed that there was no loss of data from the participants.

## Clinical and demographical characteristics of the patients

A data collection form was used to obtain clinical and sociodemographic information of the patients. This form contained questions aimed at determining sex, age, marital status, occupation, education level, socioeconomic status, time of diagnosis, and number of daily antihypertensive medications, systolic and diastolic BPs (SBP and DBP, respectively), and body mass index (BMI).

Physiological parameters

The SBP and DBP measurements of the patients were obtained baseline and the second evaluation was conducted at Week 4 at the end of the intervention using a calibrated auscultatory aneroid device before the measurements. The BP was assessed and classified in accordance with the Eighteen Colombian Hypertension Clinical Practice Guideline on Hypertension. Patients were seated comfortably for 5 min before the procedure, with one arm supported at the height of the heart and the sleeve rolled up. For the presentation of the results, values lower than 140/90 mmHg were considered as BP control.

Adherence

The study used a generic questionnaire, the Treatment Adherence Questionnaire in Patients with Hypertension (TAQPH). The scale was culturally adapted and validated to the Spanish language in Colombia,

Figure 1 Flow chart of selection and inclusion/exclusion of study participants.
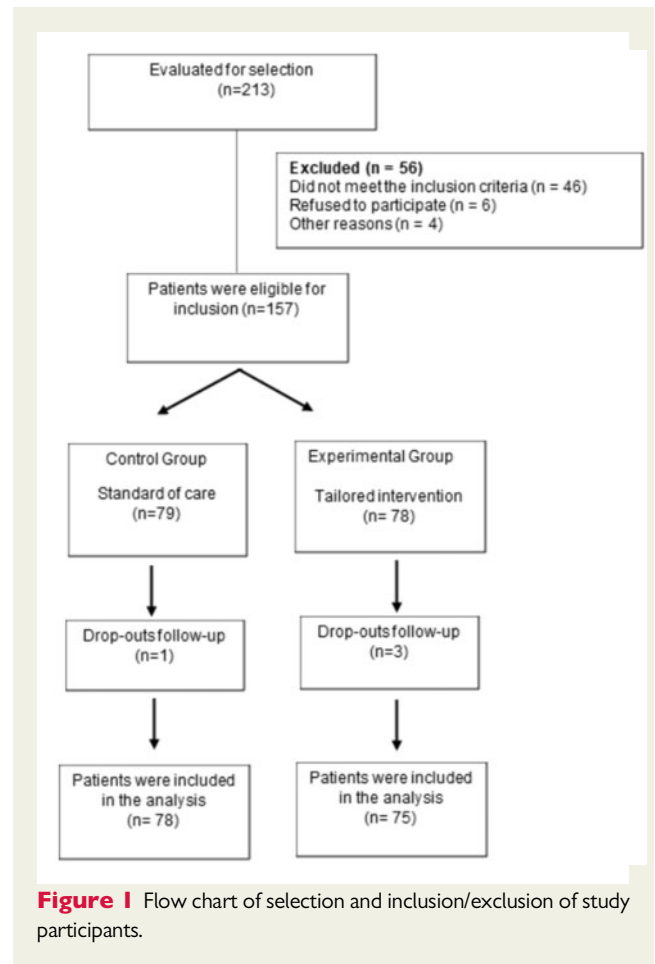
whose general Cronbach's alpha is 0.86.[19] The TAQPH questionnaire has 28 questions. The questions are divided into six factors labelled as follows: (i) medication, (ii) diet, (iii) exercise, (iv) weight control, (v) stimulation, and (vi) stress relief. Each item is scored between 1 and 4, as follows: (1 = never, 2 = sometimes, 3 = most of the time, 4 = all the time). The scores that are obtained from this questionnaire vary in the range of 28–112. These scores are summed to give a total range, higher score represented better adherence. A recommended cut-off point to identify clinically significant adherence for this instrument is 84.[20]

Sense of coherence

The SOC and its three components (comprehensibility, manageability, and meaningfulness) were measured the Orientation for Life Questionnaire, version-29 items of Antonovsky, was used, it has been translated into more than 33 languages and has demonstrated adequate psychometric properties,[15] whose response options include a semantic differential scale ranging from 1 to 7 points. The total score corresponds to the sum of the values of each question, reaching a minimum of 29 and a maximum of 203 points; the higher the total score, the stronger the SOC. The scale SOC-29 items were culturally adapted and evaluated for validity and reliability in Colombian population with HTN. The content validity index was of 0.87, and the Cronbach's alpha was 0.82 for the full scale.[21] This instrument was applied in both groups once, to assess the individuals' psychosocial characteristics and to develop the TI.

Interventions

Control group: standard of care

The control group received the standard of care, which consisted of follow-up every 3 months, medical control, a nurse, nutritionist, and psychological consultations in which the patient received information about the disease and recommendations to change unhealthy lifestyles, BP measurements, and medications. Adherence to treatment was evaluated in this group at baseline and at 4 weeks.

Experimental group: tailored intervention

The experimental group received the standard of care and a TI that was offered by a nurse who was part of the group of researchers. Tailored intervention included a weekly session for 4 weeks, and each session lasted ~20 min. In the initial session, after the medical consultation, the Orientation for Life and TAQPH questionnaires were applied. The results provided feedback to the participant, and later, using a decision-making algorithm, a matrix was applied that contained a list of predetermined actions, selected according to the type of SC identified via the Orientation for Life Questionnaire.[14] Based on each patient, relevant information was offered to improve the understanding of the health situation, or tools were provided to develop skills to assume healthy behaviours or individual motivations to assume health-related commitments were identified. In order to achieve effective participation in treatment, the patients were guided to find and use available individual resources to improve their lifestyles and adhere to treatment regimens. With this information, a personalized action plan was established upon which was mutually agreed and contained objectives, goals, and times. Investigators contacted patients every week by phone to re-evaluate their healthcare plans, modifying those plans as necessary, remind them of their consultation agendas, provide guidance for the adoption of healthy habits and disease control, and assess if mutually agreed-upon goals had been achieved. Each telephone session was ~20 min long. The participants received an educational material focused on encouraging patients to adhere to their regimen's topics such as the development of healthy habits, physical activity BP measurement, teaching goals around key self-care skill building, and chronic complications. In the final face-to-face session, the second evaluation adherence was conducted 4 weeks after starting the intervention, and the patients' performances and motivations towards persisting in the behaviours were evaluated. A research assistant, who was blinded to the intervention strategy, performed the measurements at the beginning and end of the study in both groups.

Primary and secondary outcomes

The primary outcome was the recognition of differences in the score of adherence between the two groups and within TI group from baseline to the end of the study. The secondary outcome was the recognition of differences in BP between the two groups and within the TI group from baseline to the end of the study. The patients of the two groups completed identical questionnaires in the two phases of the study.

Ethical considerations

Universal ethical principles of research in human beings in accordance with the ethical guidelines of the Council of International Organizations of Medical Sciences (CIOMS) and conforming to the principles outlined in the Declaration of Helsinki were followed. The research project was approved by the Ethics Committee from Faculty of Nursing at the National University of Colombia (2007/038-17) and permission from the institution in where the study was conducted. All participants provided verbal and written informed consent.

Statistical analysis

The variables in this study were processed statistically using the data analysis programme IBM SPSS Statistics version 22®. For quantitative variables, data normality was assessed with the Shapiro–Wilk test, and means and standard deviations were used when the distribution was normal; otherwise, in cases in which the distribution was not normal, the median and interquartile range were used. To compare baseline characteristics between the experimental and the control groups, the Student's *t*-test was used for the differences in independent sample averages when the assumption of normality was fulfilled; in non-normal cases, the non-parametric test Mann–Whitney *U* test was used. For categorical variables, relative frequencies were calculated that were accompanied by their respective confidence intervals. To determine the difference between the observed and expected frequencies between groups, the χ^2 test of independence was used. For intragroup comparisons, the Wilcoxon signed-rank or matched pairs test was applied. To assess the significance of the change between the degree of adherence between the experimental and standard of care groups, the McNemar's test was used. Finally, the effects of the intervention on the total adherence score were evaluated with an analysis of covariance (ANCOVA). All tests were two-sided, and *P*-values <0.05 were considered statistically significant.

Results

Baseline characteristics of the participants

A total of 73.9% of the 153 patients included in the study were women, and the mean age of all patients was 65.8 ± 7.5 years. There were no statistically significant differences in terms of sociodemographic and clinical characteristics baseline between the two groups, 0and consequently, the groups were found to be homogeneous (*Table 1*).

Adherence

At the start of the study, it was found that of the 153 participants, 54.9% were adherent, and 45.1% were not; however, statistical differences between the groups (*P* = 0.95) were not found. No differences in the total scores (*P* = 0.77) or in the dimensions measured by the TAQPH questionnaire were noted. At the end of the study after comparing the initial measurement with the final one, there was a significant increase in the total adherence score in the experimental group, and the initial median of this group went from 84 to 95. The same pattern of change occurred in each of the dimensions measured by the instrument. In contrast, in the control group, there were only significant changes in the stimulant control dimension (*Table 2*).

Blood pressure control

At baseline, 96% (*n* = 72) of participants in the TI group and 90% (*n* = 70) of the standard of care group had BP <140/90 mmHg. At the end of the follow-up, all the patients in the intervention group had controlled BP. In contrast, the standard care group maintained a similar percentage (92%) in their BP. There was a statistically significant difference in the TI group *P* = 0.02, which was not observed in the control group P = 0.56.

Table 1 Participants' baseline sociodemographic and clinical characteristics (n = 153)

Variables	Group				P-value
	Control (n = 78)	CI (95%)	Experimental (n = 75)	CI (95%)	
Age (years)[a]	65.6 ± 7.8		66.2 ± 7.3		0.619
Sex, n (%)					
Male	22 (28.2)	18.0 38.8	18 (24.0)	14.0 34.0	0.554
Female	56 (71.8)	62.0 82.0	57 (76.0)	66.0 86.0	
Education level, n (%)					
Primary school	24 (30.8)	20.0 41.0	18 (24.0)	14.0 34.0	0.607
Secondary school	33 (42.3)	31.0 54.0	33 (44.0)	33.0 55.0	
Technical or University studies.	21 (26.9)	17.0 37.0	24 (32.0)	21.0 43.0	
Socioeconomic level, n (%)					
Low	40 (51.3)	39.9 62.6	35 (46.7)	35.1 58.2	0.848
Medium	36 (46.2)	34.8 57.5	38 (50.7)	39.1 62.2	
High	2 (2.6)	-1.0 6.2	2 (2.7)	-1.1 6.4	
Occupation, n (%)					
Employment	16 (20.5)	11.3 29.7	11 (14.7)	6.5 22.9	0.818
Housewife	30 (38.5)	27.4 49.5	32 (42.7)	31.2 54.1	
Retire	18 (23.1)	13.5 32.6	18 (24.0)	14.1 33.9	
Independent worker	14 (17.9)	9.2 26.7	14 (18.7)	9.6 27.7	
Marital status, n (%)					
Unmarried	34 (43.6)	32.3 54.8	27 (36.0)	23.6 45.7	0.259
Married	44 (56.4)	45.2 67.7	48 (64.0)	54.3 76.4	
Do you live with sons at home?, n (%)					
No	37 (47.4)	36.1 58.8	39 (52.0)	40.4 63.6	0.572
Yes	41 (52.6)	41.2 63.9	36 (48.0)	36.4 59.6	
Enrolment time for the hypertension program in years[b]	8.8 (5.3)		9.4 (4.3)		0.182
Number of antihypertensive drugs[b]	1 (3)		1 (3)		0.344
Body mass index (kg/m^2)[b]	27.4 (5.7)		27.9 (6.6)		0.405
Systolic blood pressure in mmHg[b]	130 (16)		120 (20)		0.372
Diastolic blood pressure in mmHg[b]	80 (0)		80 (0)		0.352
Baseline adherence treatment score[a]	84.9 ± 5.8	83.6 86.2	84.6 ± 5.5	83.3 85.9	0.77

CI, confidence interval.
[a]Values are expressed as mean ± standard deviation (SD).
[b]Values are expressed as median (interquartile range).

Effect of the intervention on adherence

When comparing and evaluating the effect of the intervention, the ANCOVA showed an increase in the delta of the average adherence score achieved after the intervention by 9.4 (95% CI: 8.60–10.3) with a statistically significant difference (P < 0.0001).

At the end of the study of the 75 participants in the experimental group, 74 (98.7%) were adherent to treatment, and 46 participants (59%) in the control group were adherent.

Discussion

The main finding of our study indicated that a TI based on salutogenic principles compared with the standard of care led to an improvement in adherence in adults with HTN. Previous studies[9,11,12] have evaluated the efficacy of simple and complex interventions to improve adherence, showing that the use of a single strategy is insufficient to achieve therapeutic objectives. To achieve adherence, patients need to know what to do, how to act, find meaning in their lives, and commit to improving their health,[8] which would be possible with TI. In this study, the data reported a positive effect of TI on medication adherence and healthy lifestyle, which included consumption of a healthy diet, regular exercise, weight control, stress management, and decrease or abandonment in cigarette and alcohol use. Evidence exists that supports the finding that pharmacological treatment and lifestyle changes act concomitantly and offer a greater benefit in the control and management of HTN.[5,22]

Our findings are consistent with previous studies, which show that TI helps promote the adoption and maintenance of health-related behaviours, such as weight control,[23,24] physical activity,[25] cessation of smoking,[26] reduction of cardiovascular risks,[27] and medication adherence.[28] Cheung et al[24] reported that a computer-driven programme based on individual needs and aimed at establishing objectives, actions, coping strategies, in addition to the use of

Table 2 Comparison of the total adherence scores and dimensions between the two groups at two time points (*n* = 153)

Variables TAQPH dimension	Assessment	Standard of Care (n = 78)		Intragroup comparison P^a-value	Tailored Intervention (n = 75)		Intergroup comparison P^b-value	Intragroup comparison P^a-value
		Median	IQR		Median	IQR		
Medication	M1	34	3	0.29	35	3	<0.001	0.10
	M2	35	4		36	1		0.00
Dietary	M1	24	3	0.91	23	6	<0.001	0.02
	M2	24	4		27	5		0.00
Smoking and alcohol	M1	10	2	0.01	11	1	<0.001	0.01
	M2	10	2		11	1		0.00
Physical activity	M1	4	4	0.77	3	3	<0.001	0.09
	M2	4	4		6	2		0.00
Control weight	M1	6	2	0.77	6	1	<0.001	0.26
	M2	6	1		6	1		0.00
Relieving stress	M1	7	2	0.79	8	3	<0.001	0.17
	M2	7	2		8	3		0.00
Total score	M1	84.5	8	0.07	84.0	8	<0.001	0.93
	M2	85.0	6		95.0	8		0.00

IQR, interquartile range; M1, basal measurement; M2, final measurement; TAQPH, Treatment Adherence Questionnaire in Patients with Hypertension.
P^aWilcoxon signed-rank test.
P^bMann–Whitney *U* test.

personalized feedback on the progress achieved has a positive influence on behaviour change related to weight control. Melchart *et al.*[23] found a positive effect of TI based on the prior evaluation of individual physiological and psychological characteristics, motivational support, support sessions in the formulation of specific, measurable, achievable, realistic objectives, and time limits to reduce caloric intake, manage stress, and increasing exercise in overweight and obese people by achieving a decrease of 8.7 ± 6.1 kg in the intervention group ($P < 0.001$) compared with the standard of care group.

Traditionally, TI has been carried out based on cognitive-behavioural theoretical frameworks,[29] which evaluate the predictors and precursors of health behaviour; however, few studies have evaluated the contribution of other approaches as potentially important for focusing on health assets and factors that promote health and bring a sense of meaning and coherence to life that recognizes abilities, interests, and experiences as allowed by the salutogenic theory used in this study. As far as we know, TI with a salutogenic theoretical framework has only been evaluated in a multicomponent individual health management programme aimed at empowering people with cognitive, motivational strategies, and the use of personal resources to improve health.[30]

Our results add to the evidence described in previous studies showing that TI is effective in facilitating the adoption and maintenance of healthy behaviours.[31] One possible reason for good adherence in the group that underwent TI is that the components and actions are designed and intended to address specific and individual characteristics. This finding includes the SOC in which comprehensibility, the cognitive component, manageability of the instrumental or behavioural component, and meaningfulness of the motivational component are combined.[32] These features provide confidence and security to identify and make use of an individual's internal resources and the immediate environment and to confront and cope successfully with the disease; therefore, this type of intervention is better perceived by patients, who are also recognized according to their abilities and resources as active managers of their own health. It was demonstrated that this type of intervention is consistent with an integrative interactive nursing vision, which emphasizes the importance and value of each patient as an individual and as a key element in providing high-quality care and attention.[33]

A positive effect of TI was the control of BP in the patients that received this intervention. These patients controlled their BP better than those in the control group. Our findings are consistent with past results and show that TI administered by a nurse can help to control BP levels in adults with HTN. Friedberg found that people with HTN who received the intervention tailoring in primary care facilities improved multiple behaviours simultaneously, especially aspects of dietary behaviour such as decrease in the consumption of sodium and fat, and increase in the consumption of fruits and vegetables ($P < 0.01$).

At the baseline of this study, the proportion of participants with controlled BP was high, as a consequence of a biomedical approach to the cardiovascular risk programme that focuses on

antihypertensive therapy. However, the adherence and the BP control should add the therapeutic strategy, the promotion of lifestyle changes, body weight management, sodium restrictions, increasing intake of vegetables and fruits, reduction of alcohol consumption, and the effective treatment of other risk factors to reduce the residual cardiovascular risk.[34]

This study did not include the evaluation or monitoring of clinical variables such as, body mass index, serum creatinine, total cholesterol, triglycerides, low- and high-density lipoproteins due to the short period of the intervention. The changes in the biochemical markers require a longer period of follow-up. For that reason, we did not consider them in this study. Therefore, in a future study, a more extended duration of TI and the use of a validated electronic (oscillometric) device would be helpful to assess changes in BP values for hypertensive patients.

Study limitations

The study has some limitations that must be considered when applying the results to clinical practice. First, we used the self-report as an indirect measure to assess adherence. This creates the possibility of measurement bias that implies an underestimation or overestimation of the results. Future studies should enable the use of objective indicators of adherence. Second, we did not use the randomization method for the allocation of the participants in the groups. Third, due to the nature of the intervention, in this study, we did not use blinding. The patients in the intervention groups might have been influenced psychologically because they thought they would benefit from the interventions. Fourth, we collected data only in one place, a primary care clinic in a city in the interior of the country, which limits the generalization of our findings.

Conclusion

This study demonstrated that TI with a salutogenic approach applied to adults with HTN had a significant effect, mainly demonstrated by the improvement in the adherence. Thus, we suggest that this intervention care may be tested in future studies with randomized controlled trials applied to larger samples to test our findings in other primary care context.

Data availability

The data that support the findings of this study are available from the corresponding author (N.E.), upon reasonable request.

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