Effectiveness of Structured Counseling Program for Patients with Newly Diagnosed Essential Hypertension

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ABSTRACT

Background: The burden of hypertension is high in our context. Poor adherence contributes to poor hypertension control. This pilot study aims to study the effect of structured counseling programs on antihypertensive therapy adherence and blood pressure control.

Methods: This is an effectiveness-implementation hybrid design type I- Quasi-experimental feasibility study. We recruited newly diagnosed hypertensive patients under antihypertensives with 50 each in the intervention and control group. We adapted existing guidelines to devise a structured counseling program. The intervention group underwent the counseling program. We called both groups after one month to assess the adherence and blood pressure control.

Results: We recruited 100 newly diagnosed hypertensive patients. Twenty-two participants dropped out in the one-month follow-up visit. Among the remaining 78 individuals, 73 (94%) demonstrated good adherence. The post-intervention median (IQR) of medication adherence scores assessed with the Medication Adherence and Report Scale (MARS) in the intervention and control groups after one month was 50 (48-50) and 48 (43.5-50) respectively (p=0.015). The immediate knowledge score increased significantly in the intervention group after the structured counseling. Nevertheless, there was no significant change in systolic and diastolic pressure recordings in the intervention group one-month post-intervention when compared to that of the control group.

Conclusions: The findings of this pilot study suggest that the structured counseling program should be tailored to local needs and should be compounded with regular follow-ups for reinforcement, drug reminders, and family and peer support along with a collaborative effort to ensure adherence and control.

Keywords: Adherence; antihypertensive; hypertension management; structured counseling.

INTRODUCTION

Hypertension (HTN) is a serious condition that increases the risk of serious diseases. The burden of HTN is very high in low and middle-income countries (LMICs)[1], with the prevalence in Nepal being 24.9%.[2] HTN is a preventive disease which if managed timely is cost effective than expensive interventions.[3] The use of antihypertensive drug therapy (AHT) reduces stroke and coronary heart disease risks.[4] Poor adherence contributes to poor HTN control.[5] Non-adherence in LMICs is due to socioeconomic factors like older age, female sex, and lack of knowledge.[6] Effective counseling encompasses three themes: improving health status with adherence, providing information on adverse effects and contraindications, and promoting healthy behaviors.[7] Studies have shown poor adherence to AHT in Nepal.[8-10] We conducted a pilot study to assess the effectiveness of structured counseling on AHT adherence as the primary outcome and blood pressure control as the secondary outcome.

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METHODS

This is an effectiveness-implementation hybrid design type I- Quasi-experimental feasibility study. This article presents the results of quantitative findings. The qualitative part of the study will be disseminated in the future. The individuals newly diagnosed with hypertension and prescribed antihypertensive medication within two weeks by their treating physician were enrolled to receive either structured counseling or the usual care with a 1:1 allocation ratio. There were two parallel groups: intervention and usual care group with no intervention.

We conducted this study at the medical outpatient department of Dhulikhel Hospital between January 2023 and January 2024.

Ethical approval was taken from the Nepal Health Research Council (Protocol Regd No.476/2021 P) and Institutional Review Committee- Kathmandu University School of Medical Sciences (Approval no. 48/22).

Eligible individuals who agreed to participate were invited to join the study, and written informed consent was obtained before data collection.

Newly diagnosed hypertensive patients above 18 years of age who have been prescribed antihypertensive medication within the two weeks before enrollment and patients who provide consent to come for regular follow-up as advised were included in the study. Pregnant women, patients with psychiatric illness among whom proper counseling cannot be done, patients with known major complications related to hypertension such as renal failure requiring dialysis, stroke, oculopathy, peripheral arterial disease, hypertension-mediated organ damage (HMOD), patients diagnosed with hypertension due to secondary causes like renal arterial stenosis were our exclusion criteria.

The sample size was calculated based on the report presented in a systematic review by Ogungbe et al.[11] The sample size was calculated to detect the mean difference in medication adherence between the intervention and control groups at the end of the intervention period. Given the mean difference of 0.03 (+/- 0.13) as reported in the systematic review, assuming a type-I error of 5% (α = 0.05) and power of 80%, and a 30% loss to follow-up, a minimum sample size of 100 participants calculated with 50 participants in each arm.

A research assistant, blinded to the intervention, recruited and randomly allocated participants to either the intervention or usual care group using a sequential allocation method. The research assistant provided a code to the participant, who was then referred to a healthcare provider for counseling. The healthcare provider was also blinded to the participant's allocation. The intervention group received structured counseling, while the usual care group received routine care.

We adapted structured counseling on hypertension based on Kaiser Permanente's guidelines.[12] The investigator trained the healthcare provider responsible for counseling to deliver the structured counseling to the randomly selected participants in the intervention group.

The counseling program comprised of the following sessions:

Session 1: The structured counseling session started with a self-introduction and getting general information about the patient. The session took 2 minutes to complete.

Session 2: A standardized video acceptable to the local community in the Nepali language was shown in a quiet room with no major distractions or interruptions. The video was pre-tested among 10% of the participants who were not part of the study before it was implemented. The audio-visual session consisted of an audiovisual clip delivering a structured education and counseling session by one of the researchers to ensure uniformity regarding the information delivered. The session was completed in 10 minutes.

Session 3: The counselor then engaged with the participants to explore their feelings and general thoughts about their decision to take the prescribed medications. Participants could ask any relevant questions, which would be answered appropriately within a 10-minute session.

The research assistant called participants by telephone as a reminder for the follow-up after one month. Any participant who did not attend the follow-up visit within 35 days even after two follow-up calls (done a day apart) was regarded as lost to follow-up.

The primary outcome was the rate of AHT adherence using the Medication Adherence Report Scale (MARS)[13] and the secondary outcome was the change in systolic and diastolic blood pressure at the one-month study visit.

All data was collected in the Kobo toolbox[14] and secured in the password-protected computer. The data were collected in three points (baseline and one month) using a semi-structured questionnaire. The sociodemographic

and clinical characteristics of the participants included age, gender, educational status, insurance status, smoking, alcohol, and comorbidities. The research assistant measured the blood pressure using an aneroid sphygmomanometer after the patient was seated for 5 minutes. Three different readings were measured, and the mean blood pressure of the final two readings was calculated and classified as hypertension following JNC 7 guidelines.[15,16] To avoid the observer bias, only one research assistant was involved in blood pressure measurement who calibrated the machine prior to the blood pressure measurement. Knowledge about normal blood pressure, prescribed medications, dietary sources of minerals, recommended salt intake, and lifestyle changes for lowering blood pressure was recorded before and after the counseling session.

We adopted the definition of Adherence by the World Health Organization defines adherence as " the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider".[17] During the follow-up visit, adherence to antihypertensive therapy was assessed using the Medication Adherence Report Scale (MARS).[13] MARS evaluates patients' self-reported medication adherence. The 10-item questionnaire requests the participants to rate their responses on a 5-point Likert scale where 5=Never, 4=Rarely, 3=sometimes, 2=often, 1=Always. (Supplemental file 2) The values for each item are added to get the total score. The higher the total score, the higher the level of medication adherence. The cut-off score of more than 80% (40/50) was considered adherent.

Data was collected electronically using the Kobo Toolbox, and analysis was conducted with IBM SPSS Statistics version 23. Categorical variables are presented as frequencies (percentages), while numerical variables are reported as mean ± standard deviation or median with interquartile range (IQR), as appropriate. Comparisons of categorical variables were performed using the chi-square test. The pre- and post-counseling knowledge tests were analyzed using a paired t-test, changes in blood pressure were assessed with an independent t-test, and adherence scores were evaluated with the Mann-Whitney U test. A p-value of <0.05 was considered statistically significant.

RESULTS

We recruited 100 newly diagnosed hypertensive patients with 22 dropouts in the one-month follow-up visit. Among the remaining 78 individuals, 73 (94%) demonstrated good adherence with a median adherence score of 50 (IQR 46-

50).

The sociodemographic characteristics of the participants in the intervention and control groups are demonstrated in Table 1. The mean age ± SD of the participants in the intervention and control group were 52.72±13.22 and 54.04±14.19 respectively. There was no significant difference between the two groups in terms of age (p=0.774) or gender (men 26 (53%) vs 27 (54%), p=0.841). There was no significant difference between the two groups in terms of educational status (p=1.0), smoking history (p=1.0), and history of alcohol intake (p=0.249). The prevalence of comorbidities like asthma, chronic obstructive pulmonary disease (COPD), diabetes, and hypothyroidism was 20% in the intervention group, and 28% in the control group, and the difference was statistically insignificant (p=0.349)

Table 1. Baseline demographic and clinical characteristics of participants in the intervention and control groups. (n = 100)			
Characteristics	Intervention group (n=50)	Control group (n=50)	P value
Age (in years)	52.72±13.22	54.04±14.19	0.774*
Gender			
Female	24 (48%)	23 (46%)	0.841**
Male	26 (53%)	27 (54%)	
Educational status			
Illiterate	23 (46%)	23 (46%)	1.0**
Literate	27 (54%)	27 (54%)	
Comorbidities			
Present	10 (20%)	14 (28%)	0.349**
Absent	40 (80%)	36 (72%)	
Current smoker			
Yes	8 (16%)	8 (16%)	1.0**
No	42 (84%)	42 (84%)	
Current alcohol intake			
Yes	9 (18%)	5 (10%)	0.249**
No	41 (82%)	45 (90%)	
Government insurance			
Yes	38 (76%)	39 (78%)	0.812**
No	12 (24%)	11 (22%)	

*Independent t-test. **Chi-square test

Forty participants and 38 participants in the intervention and control groups followed up in the one-month post-intervention visit respectively. The median (IQR) MARS score after one month in the intervention group was 50
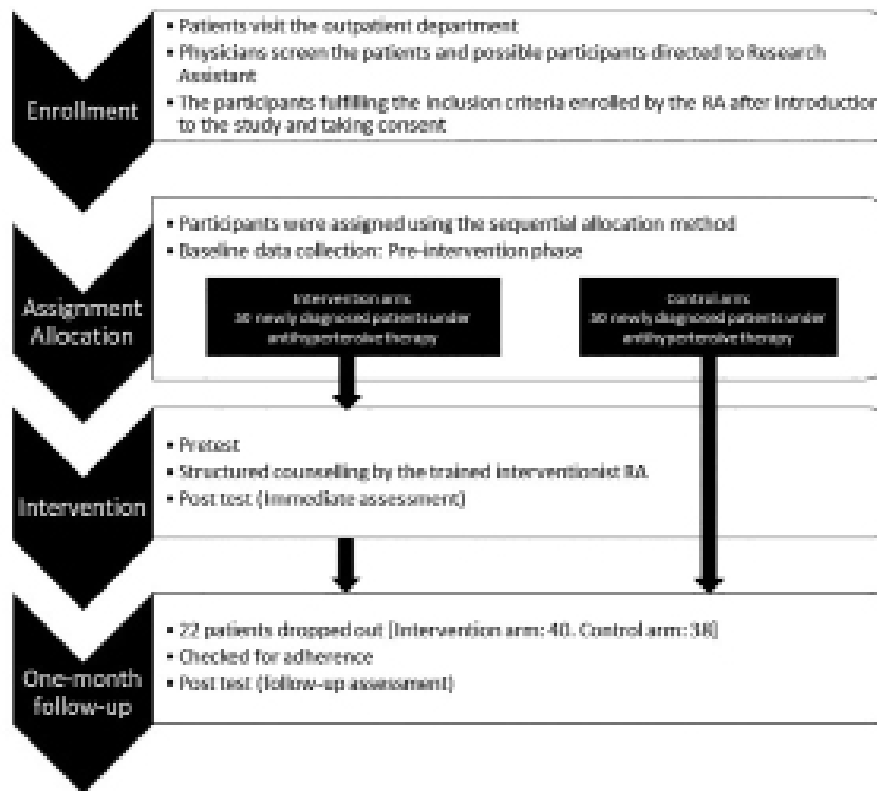
(48-50) and that in the control group was 48 (43.5-50). We observed a significant difference in adherence scores between the two groups (p=0.015, Mann-Whitney U test). (Table 2) However, there was no statistically significant difference in adherence status between the two groups when using a cutoff score of 40 (Table 3). The intervention group was also tested for their knowledge level before and after the structured counseling session. The mean pre- and post-counseling knowledge score was 4.5±1.21 and 6.6±1.29 respectively, which was statistically significant.

Table 2. Medication adherence score in the intervention and control groups one month post-intervention.

MARS	Total participants (n=78) Median (IQR)	Intervention group (n=40) Median (IQR)	Control group (n=38) Median (IQR)	P-value (Mann Whitney U test)
Score	50 (46-50)	50 (48-50)	48 (43.5-50)	0.015

Table 3. Adherence status among intervention and control groups after 1 month (n=78)

Group	Adherent (n=73)	Non-adherent (n=5)	P-value (Chi-square test)
Intervention group	36(49.9%)	4(80%)	0.184
Control group	37(50.1%)	1(20%)	

Further statistical analysis to identify factors associated with nonadherence was not feasible due to the small sample size. Among the five non-adherent individuals, three were male with a mean age of 46.6 years. Four were literate, and two had comorbidities. Additionally, two of the five individuals did not have government insurance. Knowledge scores among this group ranged from 1 to 8.

The mean ± SD of systolic and diastolic BP in the intervention group was 142.82± 15.47 and 94.80± 10.41 before the intervention, and 125.5 ± 12.3 and 83± 6.8 one month after intervention, thus representing a significant decrease (p<0.0001). In the control group, the mean ± SD of systolic and diastolic BP ▫was, respectively, 143.29± 13.37 and 91.58± 9.16 before the routine care, and 124.4± 11.31 and 83.1± 6.7 after the usual care, representing significant decrease (p<0.0001). There was no significant difference in terms of average changes in systolic BP between the intervention group (17.32± 18.46) and the control group (18.8± 16.90) (p=0.711). The average variation in diastolic BP in the

intervention and control group was 11.8± 11.29 and 8.47±10.40, respectively; there was no statistically significant difference between the two groups (p=0.181) (Table 4). The comparison of blood pressure control with cut-off value as per International Society of Hypertension 2020 guidelines[18] was not significantly different.

Table 4. Pre- and Post-intervention blood pressure in intervention and control groups. (n = 78)

Blood pressure		Intervention group (n=40) (mean± SD)	Control group (n=38) (mean± SD)	P-value*
Systolic	Baseline	142.83± 15.47	143.29± 13.37	0.887(-6.07-6.99)
	After 1 month	125.5 ± 12.3	124.4± 11.31	0.704(-6.37-4.33)
	P value**	<0.0001 (11.41-23.23)	<0.0001 (13.25-24.37)	
	Mean difference	17.32± 18.46	18.8± 16.90	0.711(-9.487-6.506)
Diastolic	Baseline	94.80± 10.41	91.58± 9.16	0.151(-1.209-7.651)
	After 1 month	83± 6.8	83.1± 6.7	0.945(-3.178-2.969)
	P value**	<0.0001(8.18-15.41)	<0.0001(5.05-11.89)	
	Mean difference	11.8± 11.29	8.47±10.40	0.181(-1.578-8.231)

*Independent t-test. **Paired t-test

Table 5. Pre- and post-intervention blood pressure in intervention and control groups (n = 78)

Blood pressure status after one month	Intervention group (n=40)	Control group (n=38)	P-value (Chi-square test)
Not under control (≥ 130/80 mm Hg)	16(40.00)	14(36.84)	0.774 (0.0821)
Under Control (<130/80 mm Hg)	24(60.00)	24(63.16)	

DISCUSSION

AHT adherence is a crucial element for HTN control and management. Our pilot study aimed to find the effect of structured counseling programs on AHT adherence and blood pressure control among 100 newly diagnosed hypertensive individuals. The intervention and control groups in our study were compared for factors namely age, gender, educational status, smoking, and presence of comorbidities. We found that there was no significant difference in these factors in the two groups which showed that they were similar in terms of these factors. The median AHT adherence score difference between the two groups was statistically significant. The systolic and diastolic BP of the two groups did not have a significant difference before the intervention. There was a statistically significant lowering of average systolic and diastolic blood pressure in both groups after one month.

In a multicenter randomized controlled trial, Perl et al highlighted the significance of a structured educational program mediated by better adherence and lifestyle changes.[19] This study emphasizes a multifaceted intervention program consisting of patient education with self-management promotion, clinician education, team change, and clinician feedback. Another study by Vrijens et al also has similar findings.[20] This study concludes the positive effect of patient-tailored and measurement-guided interventions on adherence to AHT. The study by Konrady et al explores the benefits of structured education program implementation on hypertensive management.[21] Their study showed an improvement in knowledge which is similar to our study findings. However, our study found no statistically significant difference in the lowering of blood pressure while comparing them between the intervention and control groups in a one-month follow-up. This comparable result in the two groups may be due to the active participants in the control group who might have participated in other counseling sessions as a part of usual care in the hospital or the community. Our finding also highlights a longer longitudinal follow-up duration of the patients to get a better conclusion on patient adherence and hypertension control.

Evidence provided by a study in India suggests that multiple factors like lack of awareness, treatment accessibility, and affordability undermine adequate adherence to AHT. Though a structured education program

may be in place, these are more challenging issues in the Indian setting.[22] Likewise, a recent systematic review [23] on medical adherence in elderly hypertensive patients suggests the need to identify critical areas like the number of medications, financial status, sex, age, disease duration, and comorbidities to be taken into account for the development of evidence-based programs to improve medical adherence. A review article on AHT adherence by Burnier and Egan extensively discusses suboptimal adherence and strategies to manage non-adherence.[24] Utilization of simple, low-cost screening tests, identification of high-risk patients likely to be non-adherent, and the need to do better with the AHT available are some of the strategies highlighted in this review article.

Nonetheless, there are some limitations to our data. Due to the higher dropout rate, the sample size was small in subsequent follow-up compromising the statistical analysis. This study was implemented among the patients visiting the outpatient department of Dhulikhel Hospital, therefore limiting the generalizability of the evidence. The quasi-experimental trial was conducted, while we sequentially allocated the participants, due to the chance of predictable allocation, this could lead to selection bias.

CONCLUSIONS

We found that there was a difference among the participants in their adherence and blood pressure level though it was not statistically significant between the two groups. The structured counseling should be provided but with increased duration and should be followed up frequently for the counseling. We also inferred that a structural counseling program alone may not be robust enough to positively impact hypertension management and AHT adherence. Other factors like regular follow-ups for reinforcement, drug reminders, family and peer support along with a collaborative effort may help enhance AHT adherence.

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CONFLICTS OF INTEREST

The Authors declare no conflict of interest.

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