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# The effects of self-management education tailored to health literacy on medication adherence and blood pressure control among elderly people with primary hypertension: A randomized controlled trial

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ABSTRACT

*Objective:* To evaluate the effects of self-management education tailored to health literacy on medication adherence and blood pressure control.
*Method:* This randomized controlled trial was conducted in 2018 with 118 elderly people with uncontrolled primary hypertension and inadequate health literacy. Self-management education was developed on the basis of the health literacy index. Medication adherence and blood pressure were assessed using 8-items Morisky Medication Adherence Scale and a mercury sphygmomanometer, respectively.
*Results:* At baseline, there were no significant between-group differences regarding participants' demographic characteristics, medical history, and medication adherence. After the intervention, between-group comparisons adjusted for pretest scores showed a significant reduction in the mean score of systolic and diastolic blood pressure and increase adherence to medication due to intervention ($P < 0.05$). However, the proportions of controlled systolic and diastolic blood pressure were not statistically significant different between-group ($P > 0.05$).
*Conclusion:* Self-management education tailored to health literacy significantly promotes medication adherence but has no significant effects on control of blood pressure.
*Practice implication:* To promote adherence to antihypertensive medications, tailored patient education to Health literacy is recommended. Limited pieces of evidence are available on the effectiveness of health literacy index-based interventions, so further studies are required.


## 1. Introduction

Hypertension, defined as blood pressure greater than 140/90 mm Hg [1], is one of the major and the most prevalent global health concerns. It can be an asymptomatic disease which is sometimes called the silent killer [2]. Hypertension affects more than 40% of the total population in Iran [3] and the world [4]. Its prevalence increases with age so that its global prevalence will increase exponentially in the near future due to the increase in the world's elderly population.

Hypertension causes vascular injuries and increases cardiac workload. Therefore, it can cause a wide range of serious health conditions such as heart failure, renal failure, stroke, and coronary artery disease. These conditions increase the use of healthcare resources and services and thereby, increase healthcare-related costs [5].

There are different methods for hypertension management, including dietary modifications, physical exercise, and medication therapy [6]. Yet, hypertension management is still poor even in developed countries, so that only 29%–50% of patients with hypertension who receive treatments have controlled blood pressure [6,7].

Poor medication adherence, either intentional or unintentional, is the leading cause of unsuccessful hypertension management [5,8,9]. The major factors behind poor medical adherence include the altered physical, mental and psychological function due to the aging process [10] and lack of knowledge about hypertension and its significant effects on health [5]. Therefore, patient education

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and behavioral therapy are suggested to promote medication adherence [11,12].

People with hypertension can learn strategies to manage their chronic condition and live a healthier life in self-management education (SME). Therefore, educational interventions have significant roles in effective hypertension management. Patient education improves patients' knowledge about the disease and its complications and treatments, helps them modify their lifestyles, and promotes their medication adherence. Yet, patient education is not always practically effective and previous study reported contradictory results about its effects on medication adherence [4].

Patient health literacy (HL) is a determining factor behind the outcomes of patient education programs [13]. Yet, studies in Iran [14] and other countries [15] reported that people have low HL. A study in Iran reported that the prevalence of limited HL was more than 50% [14]. HL is affected by different physical, mental, and psychological factors and decreases with age [13,16]. Limited HL is associated with poor medication adherence, high emergency admission rate, lengthy treatment course and hospital stay, and increased mortality rate [17,18].

Patient education tailored to patients' health literacy may help remove the negative effects of limited HL on the outcomes of education. In 2011, the Centers for Disease Control and Prevention developed an index, called the health literacy index (HLI), to assess the conformity of educational materials with learners' health literacy. In fact, this index helps develop educational materials which conform to patients' limited HL. HLI includes 63 indicators organized into 10 criteria: plain language, clear purpose, supporting graphics, user involvement, skill-based learning, audience appropriateness, user instruction, development details, evaluation methods, and strength of evidence. The definitions for each criterion and indicator were created by the team on the basis of the literature review. When a health information material is evaluated using HLI, it receives a "yes" or "no" score for each indicator. An overall index score is computed by taking the proportion of "yes" answers out of the number of applicable indicators. This score can, therefore, range from 0% to 100% [19]. Yet, there are limited data about the effectiveness of HLI-based interventions. One of the few studies in this area reported that patient education based on HLI significantly improved older adults' understanding of fall prevention strategies. Yet, that study highlighted the need for further studies to confirm the effects of HLI-based education [13]. A systematic review of nine studies into the effects of tailored educational interventions also reported that tailoring educational interventions to individuals' health literacy is potentially effective in significantly improving their knowledge. That study also emphasized the necessity of further studies in this area [20]. Therefore, the present study was conducted to evaluate the effects of SME tailored to HL on medication adherence and blood pressure control among elderly people with primary hypertension.

## 2. Methods

### 2.1. Design

This randomized controlled trial was conducted in January–March 2018.

### 2.2. Participants and setting

The study population comprised elderly people with uncontrolled primary hypertension and inadequate HL who referred to the cardiovascular clinic of Fayyazbakhsh hospital, Tehran, Iran. Eligibility criteria were an age of more than sixty, definite diagnosis of uncontrolled primary hypertension (blood pressure of 140/90 mm Hg or more), use of antihypertensive medications, ability to speak Persian, no affliction by cognitive or psychiatric disorders such as depression and dementia, no drug addiction, and inadequate HL determined by a score of less than 66% based on the Health Literacy for Iranian Adults (HELIA) scale [14]. Participants were excluded if they were unwilling to stay in the study, developed serious health conditions that led to hospitalization or death, failed to attend one face to face sessions of the study intervention, or did not answer two or more of our telephone contacts.

### 2.3. Sample size

The sample size was calculated using the sample size calculation formula for comparing two proportions (Fig. 1) and based on the results of a former study which showed that patient education and home monitoring increased medication adherence from 10% to 32% [21]. Accordingly, with a confidence level of 95%, a power of 90%, and a probable attrition rate of 10%, it was estimated that 59 participants per group were needed.

### 2.4. Sampling and randomization

All 353 elderly people who referred to the study setting during the study were assessed for eligibility. Accordingly, 118 eligible participants were consecutively recruited to the study and randomly allocated to a control or an intervention group through block randomization. The size of the blocks was four. The allocation sequence was generated using the online Research Randomizer (www.randomizer.org). For allocation concealment, numbered opaque envelopes were used. Subsequently, based on generated random sequence, cards A (intervention) and B (control) were placed in an opaque envelope. Then, envelope 1 was opened for the first participant and his group was identified based on the card in the envelope. The same technique was repeated for each participant. Sampling and group allocation in this method were continued until 59 participants were allocated to the control and 59 were allocated to the intervention groups. Allocation concealment and sampling were performed by two independent persons so that the person who performed allocation concealment was not involved in sampling.

### 2.5. Data collection

The primary outcome in this study was medication adherence status and the secondary outcomes were the proportions of participants with controlled systolic and diastolic blood pressures. The primary and secondary outcomes were measured at the beginning of the study and six weeks afterward. Data collection tools were a demographic questionnaire, the eight-item Morisky Medication Adherence Scale, and a datasheet for documenting systolic and diastolic blood pressures. The demographic questionnaire was developed based on the existing literature and included ten items on participants' age, gender, marital and employment status, educational level, income level, cigarette smoking, length of hypertension treatment, and comorbid conditions.

The eight-item Morisky Medication Adherence Scale was used for medication adherence assessment. This scale was developed by Morisky et al. in 2008 [22] and translated into Persian and

$$n = \frac{\left(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta}\right)^2 \left[P_1(1-P_1) + P_2(1-P_2)\right]}{(P_1 - P_2)^2}$$

**Fig. 1.** Sample size calculation formula.

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validated for the Iranian culture by Kooshyar et al in 2013 [23] and Ghanei-Gheshlagh et al in 2014 [24]. It includes seven dichotomous Yes/No questions and one question answered on a four-point Likert scale as the following: "Always": 1; "Usually": 1; "Sometimes": 0; and "Rarely/Never": 0. And so, as in the seven past items, Item 8′s responses have also been treated dichotomously. Thus, the possible total score of the scale is 0–8. This score is interpreted as follows: score 8: good medication adherence; scores 6–7.99: moderate medication adherence; and scores less than 6: poor medication adherence [22,25]. Studies in Iran reported acceptable validity and reliability for this scale [23,24]. In the present study, the reliability of the Medication Adherence scale was assessed by test-retest intraclass correlation coefficient of the scale ICC was 0.71 (95%CI: 0.23, 0.91).

Blood pressure of each participant was measured twice, with a ten-minute interval, from the right hand while the participant was in the sitting position for at least fifteen minutes. Participants were asked not to use caffeine or smoke cigarette for thirty minutes before blood pressure measurement. The blood pressure measurement device was a mercury sphygmomanometer. Its validity was also ensured based on its measurement precision (mm Hg) and the authenticity of its manufacturer (Riester, Germany). The reliability of the sphygmomanometer was assessed and confirmed through twice measuring the systolic and the diastolic blood pressures of twenty patients with a ten-minute interval and was 0.81 (95%CI: 0.31, 0.94) and 0.60 (95%CI: 0.05, 0.87) respectively. ICC estimates and their 95% confident intervals for Medication Adherence scale, systolic and the diastolic blood pressure measurements were calculated using SPSS statistical package version 16 (SPSS Inc, Chicago, IL) based on a single-rating, absolute-agreement, 2-way mixed-effects model [26].

### 2.6. Intervention

Participants in the intervention group received SME tailored to their HL in two 30–45-minute face-to-face weekly sessions held in the study setting in the first two weeks of the study. Face-to-face education was followed by four fifteen-minute telephone-based educational sessions held twice weekly in the afternoon. Educational materials were developed by searching the existing literature and tailored to participant HL. For this purpose, four experts (one critical care and three health promotion specialists) assessed the conformity of educational materials with the HLI. Accordingly the mean and standard deviation of raters' scores was $84.12 \pm 12.72$ which indicates that instructional materials are highly well-suited to HLI. Educational materials were related to hypertension definition and its risk factors, complications, medications, medication side effects, medication side effect management, medication adherence importance, and the importance of regular medical visits for blood pressure monitoring. Because of participants' old age and their inadequate HL, the teach-back method was used to provide educational materials in both face-to-face and telephone-based educational sessions. All educational materials for all participants in the intervention group were provided by the same instructor. Participants in the control group solely received care services routinely provided to all patients with hypertension who referred to the study setting, including medical visit, medication prescription, and blood pressure measurement.

### 2.7. Ethical considerations

This study obtained ethical approval from the Ethics Committee of Tehran University of Medical Sciences, Tehran, Iran (code: IR.TUMS.VCR.REC.1396.3687). It was also registered in the Iranian

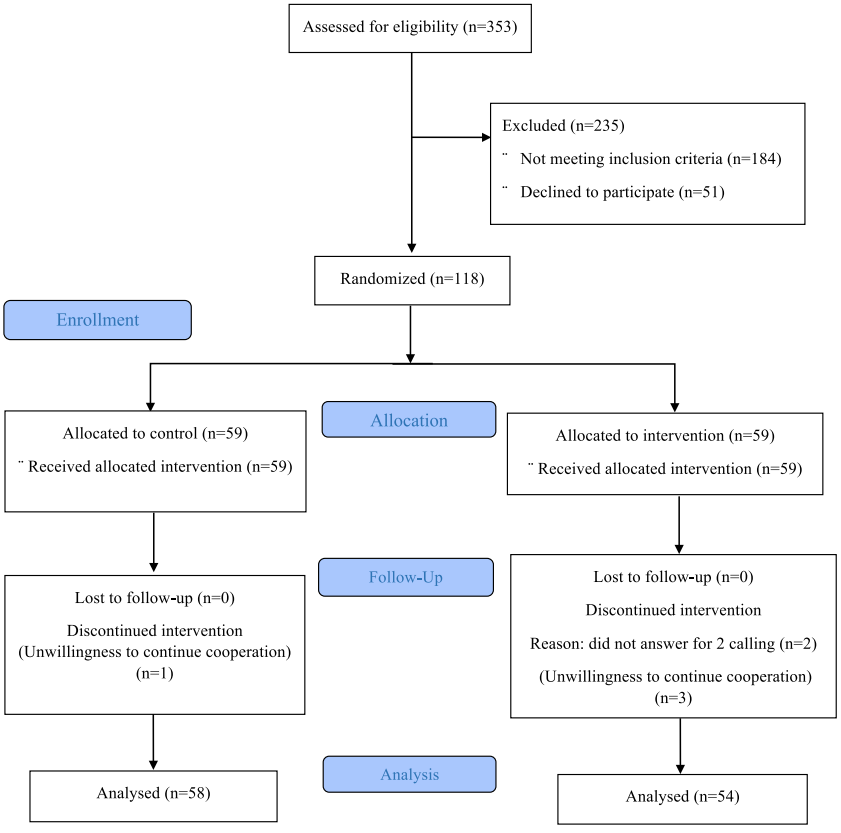


**Fig. 2.** The flow of participants in the study (CONSORT Flow Diagram).

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Registry of Clinical Trials (code: IRCT20171227038097N1). At the time of recruitment to the study, clear explanations were provided to participants about the study aim and confidential data management and written informed consent was obtained from each of them. After the posttest, educational materials were also provided to the participants in the control group and an educational session was held for them.

### 2.8. Statistical analysis

Data analysis was performed using the Statistical Package for Social Sciences (SPSS, version 16.0). The Fisher's exact and the Chi-square tests were used for between-group comparisons respecting categorical variables. The independent-sample *t* test and the Mann-Whitney U tests were performed for between-group comparisons respecting numerical variables. The paired-sample *t* test was employed for assessing within-group differences. The adjusted between-group analysis was performed using the analysis of covariance (ANCOVA) by considering baseline values as covariates [27,28]. All statistical analyses were performed at a significance level of less than 0.05.

## 3. Results

In total, 353 patients were assessed for eligibility, among them 184 were ineligible and 51 did not consent for participation. The remaining 118 patients were evenly allocated to the study groups. However, five patients from the intervention group were excluded due to either unwillingness to receive the study intervention (n = 3) or not answering to two of our telephone contacts (n = 2). Moreover, one patient from the control group voluntarily withdrew from the study and hence, was excluded. Consequently, the study was completed with 54 participants in the intervention group and 58 participants in the control group (Fig. 2).

At baseline, the Chi-square test revealed no significant between-group differences respecting participants' gender, marital and employment status, educational level, income level, and cigarette smoking ($P > 0.05$; Table 1). Moreover, the Mann-Whitney U test showed that the intervention and the control groups did not significantly differ from each other respecting the median of participants' age (64 vs. 63.9; $P = 0.887$).

Table 2 shows the pretest and the posttest mean scores of systolic and diastolic blood pressures in both groups. The results of between-group comparisons adjusted for pretest scores showed the effectiveness of the study intervention in significantly reducing the mean scores of systolic and diastolic blood pressures ($P < 0.05$; Figs. 3 and 4).

At baseline, most participants in the intervention and the control groups had poor medication adherence (78.5% vs. 82.7%), with no statistically significant between-group difference ($P = 0.639$). However, after the intervention, medication adherence status in the intervention group was significantly better than the control group ($P = 0.002$; Table 3).

One of the inclusion criteria of the study was uncontrolled primary hypertension. In other words, all participants had uncontrolled hypertension at baseline. After the intervention, the rates of uncontrolled systolic and diastolic blood pressures decreased in the intervention group; however, the between-group differences respecting these rates were not statistically significant ($P > 0.05$; Table 3).

## 4. Discussion and conclusion

### 4.1. Discussion

This study aimed to evaluate the effects of SME tailored to HL on medication adherence and blood pressure control among elderly people with primary hypertension. Findings revealed that the study intervention significantly promoted medication adherence and decreased mean of systolic and diastolic blood pressures but statistically, it had no significant effect on the ratio of controlled blood pressure.

In line with our findings, a study on 120 elderly people with hypertension reported significant effects of patient education on medication adherence, systolic, and diastolic blood pressures. In that research, participants were assigned to group A (who only received medication adherence education), group B (education on both adherence to medication and healthy lifestyle behaviors) and group C (control) [21]. The above research has some distinctions from the current research (education was not tailored to HL, also the means of systolic and diastolic blood pressures were compared).

Moreover, a study on 146 patients of African origin with uncontrolled hypertension reported that culturally-adapted patient education significantly promoted their adherence to healthy lifestyle behaviors. Also, it reduced their diastolic blood pressure, but had no significant effects on their medication adherence and systolic blood pressure [4]. Another study in the United States also indicated that a six-month tailored behavioral intervention significantly reduced hypertension rate among 533 patients with hypertension [29]. The interventions in two of the above researches were not tailored to HL, but similar to the current study, both regarded adherence to medication and blood pressure

**Table 1**
Between-group comparisons respecting participants' characteristics.

| Group Characteristics | | Intervention (n = 56) N (%) | Control (n = 58) N (%) | P value |
|---|---|---|---|---|
| Gender | Male | 23 (41.6) | 32 (55.2) | 0.183[c] |
| | Female | 31 (57.4) | 26 (44.8) | |
| Marital status | Single/Widowed | 10 (18.5) | 9 (15.5) | 0.672[c] |
| | Married | 44 (81.5) | 49 (84.5) | |
| Educational level | University | 10 (18.5) | 7 (12.1) | 0.746[c] |
| | Diploma | 20 (37.0) | 21 (36.2) | |
| | Below diploma | 19 (35.2) | 25 (43.1) | |
| | Illiterate | 5 (9.3) | 5 (8.6) | |
| Smoking | Yes | 8 (14.8) | 13 (22.4) | 0.303[c] |
| | No | 46 (85.2) | 45 (77.6) | |
| Employment status | Employed | 22 (40.7) | 20 (34.5) | 0.494[c] |
| | Unemployed, retired, or housewife | 32 (59.3 | 38 (65.5) | |
| Income | Sufficient | 42 (79.2)[*] | 47 (81.0) | 0.813[c] |
| | Insufficient | 11 (20.8)[*] | 11 (19.0) | |

[*] Missing values included.
[c] The results of the Chi-square test.

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**Table 2**
Comparing means of systolic and diastolic blood pressure at baseline and after the intervention.

| Group Outcomes | | Intervention (n = 56) Mean (SD) | Control (n = 58) Mean (SD) | P value[2] | Adjusted P value[3] |
|---|---|---|---|---|---|
| Systolic Blood Pressure | Pretest | 156.43 (12.38) | 154.22 (13.73) | 0.370 | 0.004 |
| | Posttest | 142.59 (11.56) | 148.45 (12.32) | 0.011 | |
| | P value[1] | < 0.001 | 0.005 | | |
| Diastolic Blood Pressure | Pretest | 96.11 (6.85) | 96.03 (7.06) | 0.954 | 0.023 |
| | Posttest | 88.52 (7.99) | 92.15 (9.33) | 0.029 | |
| | P value[1] | < 0.001 | 0.005 | | |

[1] Within-group comparisons through the paired-sample *t* test; [2]: Between-group comparisons through the independent-sample *t* test; [3]: Between-group comparisons adjusted for the effects of pretest mean scores through the analysis of covariance.

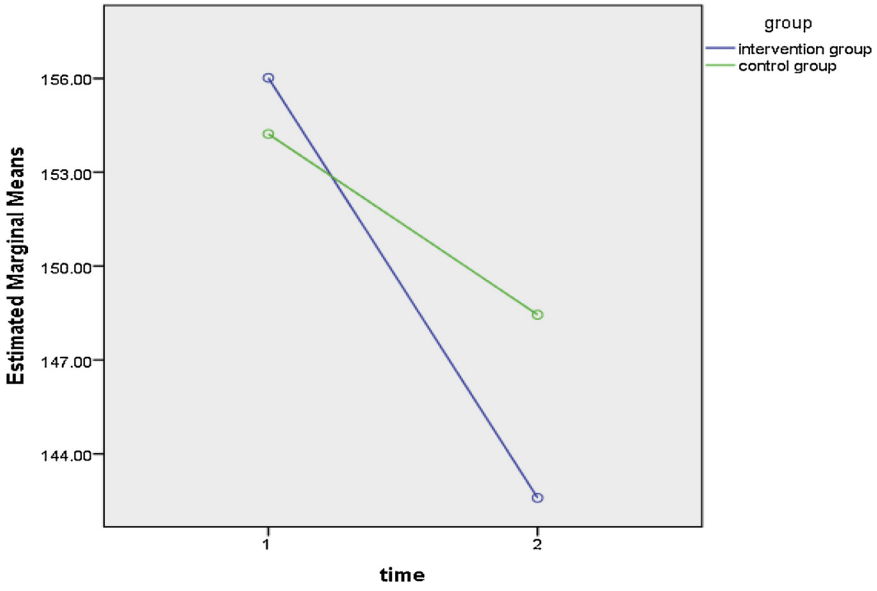


**Fig. 3.** Comparison the mean of systolic blood pressure at baseline and endpoint.

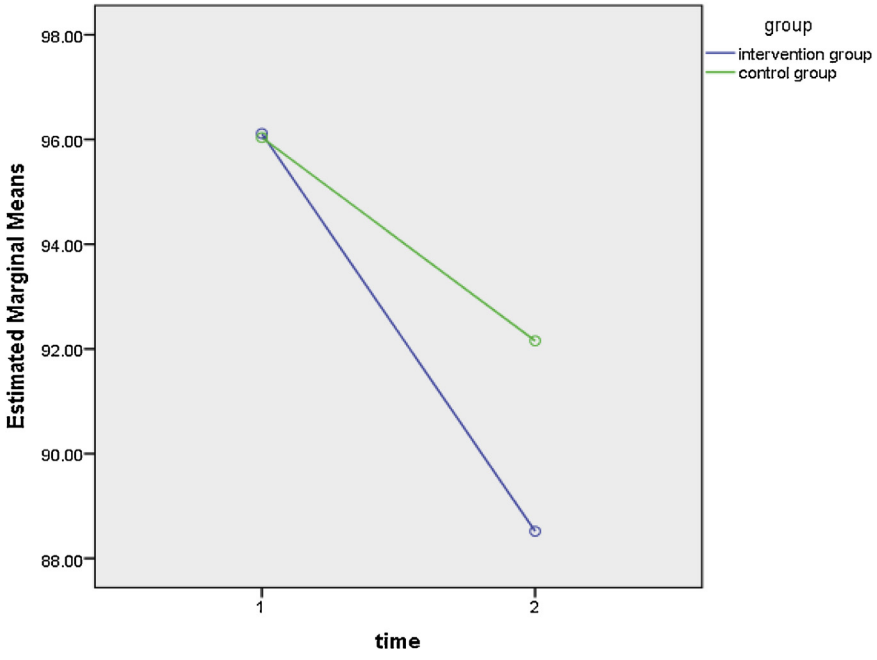


**Fig. 4.** Comparison the mean of diastolic blood pressure at baseline and endpoint.

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**Table 3**
Between-group comparisons respecting medication adherence status and blood pressure control.

| Group Outcomes | | Intervention (n = 56) N (%) | Control (n = 58) N (%) | P value |
|---|---|---|---|---|
| Systolic Blood pressure | Controlled | 11 (20.4) | 8 (13.8) | 0.354[C] |
| | Uncontrolled | 43 (79.6) | 50 (86.2) | |
| Diastolic Blood pressure | Controlled | 15 (27.8) | 11 (19.0) | 0.270[C] |
| | Uncontrolled | 39 (72.2) | 47 (81.0) | |
| Pretest medication adherence | Poor | 44 (78.5) | 48 (82.7) | 0.639[F] |
| | Moderate | 12 (21.4) | 10 (17.8) | |
| | Good | — | — | |
| Posttest medication adherence | Poor | 27 (50.0) | 46 (79.3) | 0.002[F] |
| | Moderate | 26 (48.1) | 12 (20.7) | |
| | Good | 1 (1.9) | 0 (0.0) | |

F: The results of the Fisher's exact-test.
C: The results of the Chi-square test.

as the outcomes. Furthermore, the trials mentioned above did not consider the HL level among the study participants.

A few studies assessed the effect of educational strategies tailored to HL on health-related outcomes. For instance, a study on the development of a fall prevention manual for elderly people reported that the use of HLI to tailor patient education significantly improved self-management and medication adherence [13]. A study on the effects of low HL flashcards and mobile video reinforcement showed that tailored education significantly improved medication adherence among patients with limited HL and hypertension [30]. This is in line with the findings of the present study.

In a cohort of patient with hypertension, implementing HL sensitive strategies reduced systolic blood pressure at 12 and 24 months within groups. However, this reduction was more in the low literacy group. Between the two groups, comparison revealed no statistical difference in 12 and 24 months [31].

A systematic review of nine studies evaluated the effectiveness of interventions tailored to HL. Three of such studies were about hypertension. Only one of them assessed the effect of intervention tailored to HL on medication adherence, which was effective [20].

In line with our findings, a previous systematic review of clinical trials showed that interventions such as pillbox use, motivational interviewing, and feedback giving were effective in significantly promoting medication adherence among adults with hypertension, particularly elderly people [12]. The aforementioned educational strategies are suitable methods of teaching people with low HL which is emphasized in HLI.

Although knowledge was not considered as an outcome in this research, previous studies showed that HL is associated with knowledge towards hypertension and its recognition [6,32,33]. A cross-sectional study of 402 patients from 2 racial categories which were from different urban health care facilities revealed that the 55 percent of people with inadequate HL could not identify 160/100 mm Hg as abnormal blood pressure [33].

Another study examined whether customizing educational material to the level of HL of patients affected their retention of information about hypertension [32]. It is evident that an understanding of blood pressure is associated with successful hypertension management.

Among the strengths of this study was the tailoring of educational materials to patients' health literacy. Given the high prevalence of HL inadequacy among elderly people, tailoring educational interventions to their HL can increase the success and the effectiveness of these interventions. On the other hand, the limitations of this study were related to its short intervention and follow-up periods and also probably unrealistic adherence-related responses of some participants.

### *4.2. Conclusion*

This study concludes that one-month SME tailored to patients' health literacy (based on HLI) can significantly promote medication adherence and decrease the mean of systolic and diastolic blood pressure among elderly patients with uncontrolled primary hypertension and inadequate HL. Despite the effect of study intervention on the mean of systolic and diastolic blood pressure, in post-test, the proportion of people in the intervention group with controlled blood pressure did not differ significantly from the control group. This may be due to the short intervention and follow-up periods.

Further studies with longer follow-up periods and with more objective medication adherence measurement methods are needed to produce firmer evidence regarding the effectiveness of patient education tailored to subjects' health literacy (based on HLI on medication adherence and blood pressure control). As well future studies could be conducted to assess the effectiveness of SME based on HLI on other chronic conditions.

### *4.3. Practice implications*

To promote adherence to antihypertensive medications, tailored patient education to HL is recommended.

Limited evidence is available on the effectiveness of HLI -based interventions, so further studies are required.

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## Declaration of Competing Interest

None.

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