

## Study Protocol

# Impact of educational intervention on hypertension management by primary care physician (PUMP trial).

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## Abstract

**Background:** To date, no optimal way of organizing and delivering care to hypertensive patients at the primary carer level has been identified, due to which a significant number of patients fail to meet the treatment goals. The current study aims to observe hypertension educational intervention's effect on general physicians (GPs) to indirectly improve blood pressure control and patient outcomes.

**Methodology:** In this randomized control trial, GPs will be divided into 2 groups and both groups will be asked to fill hypertension awareness questionnaire at baseline and, after randomization. GPs of the group I will receive (1 day) face-to-face education with structured educational material on hypertension management strategies. GPs of group II will receive the print version of educational material (structured educational material) on strategies of structured hypertension management. Both groups of GPs will recruit 10 (5 newly diagnosed + 5 already diagnosed patients) from the study site. The patient will be asked to fill hypertension awareness questionnaire at baseline and share a 12-hour blood pressure measurement. GPs and patients will be reassessed after 3 months of intervention.

**Discussion:** The purpose of designing this study is to observe the effect of hypertension educational intervention for general physicians to improve blood pressure control and patient outcomes indirectly. Results of this study may provide a basis for developing a hypertension educational program targeted at general physicians.

**Trial registration:** The trial was registered with ClinicalTrials.gov NCT05038774.

## Keywords

Educational Intervention, Hypertension Management, Primary Care Physicians.



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## Introduction

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Hypertension is considered one of the main risk factors for cardiovascular diseases and stroke. It is suggested that approximately 17 million deaths occur annually worldwide due to hypertension<sup>1</sup>. The prevalence of hypertension is higher among low to middle income developing countries. This high prevalence rate is suggested to be the major cause of increased mortality rate, which accounts for major economic burden<sup>2</sup>. Pakistan estimated crude prevalence of hypertension is 35.1% and age-standardized prevalence is 34.4%, causing severe challenges to healthcare system. It is observed that despite many effective pharmacological approaches for controlling high blood pressure, complications associated with hypertension has increased globally<sup>4&5</sup>.

In Pakistan, hypertension is one of the most common reasons to visit a physician. It is characteristically diagnosed and treated in outpatient settings<sup>6</sup>. The burden of this disease is undeniably high in Pakistan since almost a quarter of the adult population aged 50 years and above generally have hypertension<sup>6</sup>. Therefore, getting control of this asymptomatic disease might be considered one of the most important preventive measures taken by physicians<sup>7</sup>. Several studies have documented the need to improve blood pressure control<sup>8&9</sup>. Various interventions have been suggested to improve hypertension. These interventions include patient-centered approaches, physician-centered strategies, and many other<sup>10, 11</sup>. It is suggested that unsatisfactory blood pressure control in hypertensive patients is due to multiple causes. One of the main causes that received particular attention is the physician's behaviour and patient's compliance<sup>12</sup>.

Studies have shown that educational interventions combined with adequate clinical management, when given to the physician, show improvement in clinical decision-making and also amounted to better blood pressure control<sup>13</sup>. The study conducted by Inui TS and colleagues suggests that single teaching session tutorials given to physicians show increased patient knowledge and more patient beliefs regarding hypertension and its

treatment given by the allocated physician<sup>14</sup>. It is expected that with effective medical education, the relationship among the educational method, physician performance, and patient outcomes that are associated with a specific disease also grow. Therefore, it is suggested that physician educational interventions tend to improve the follow-up of hypertensive patients<sup>15</sup>. Thus, the purpose of the current study is to observe the effect of hypertension educational intervention for general physicians to improve patient outcomes indirectly. Moreover, it is believed that the results of this study may provide a basis for developing a hypertension educational program targeted at general physicians.

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## Methodology

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### Objective of the study

The purpose of designing this study is to observe the effect of hypertension educational intervention on patient outcomes indirectly.

### Study design

In this randomized trial, GPs will be randomized into 2 groups (Random sampling), and each GP will then recruit 5 newly diagnosed + 5 already diagnosed patients (Convenience sampling), i.e., General Physician-Patient Ratio 1:5.

### Study Sites

The data will be collected from 42 sites from major cities of Pakistan, including Karachi (10), Lahore (8), Peshawar (8), Islamabad (8), Quetta (4), and Multan (4).

### Ethics

The study will be conducted following the declaration of Helsinki. Ethical approval was obtained from the Pakistan medical association committee on ethics (Reference no. MN/1513/LSQ/18; Dated 5th September 2021).

## Eligibility criteria

### ❖ Inclusion criteria

- GPs who have at least three years of practice experience in the broad disciplines of primary care.
- Patients must be 18 years and above.
- Patients with uncontrolled blood pressure according to Pakistan hypertension league guidelines.
- Patients must be able to give informed consent and be able to read and comprehend in Urdu (National Language).
- Patients access to a digital BP apparatus.
- Patients must have a phone with a camera and internet.

### ❖ Exclusion criteria

- GPs who had attended a planned Hypertension educational program during last 6 months.
- Patients with a recognized psychiatric disorder as per the Diagnostic and Statistical Manual of Mental Disorders.

## Interventions

### ❖ Group I

GPs of the group I will receive (1 day) face-to-face education with structured educational material on hypertension management strategies by a senior cardiologist.

### ❖ Group II

GPs of group II will receive the print version of education material (Structured educational material) on strategies of structured hypertension management.

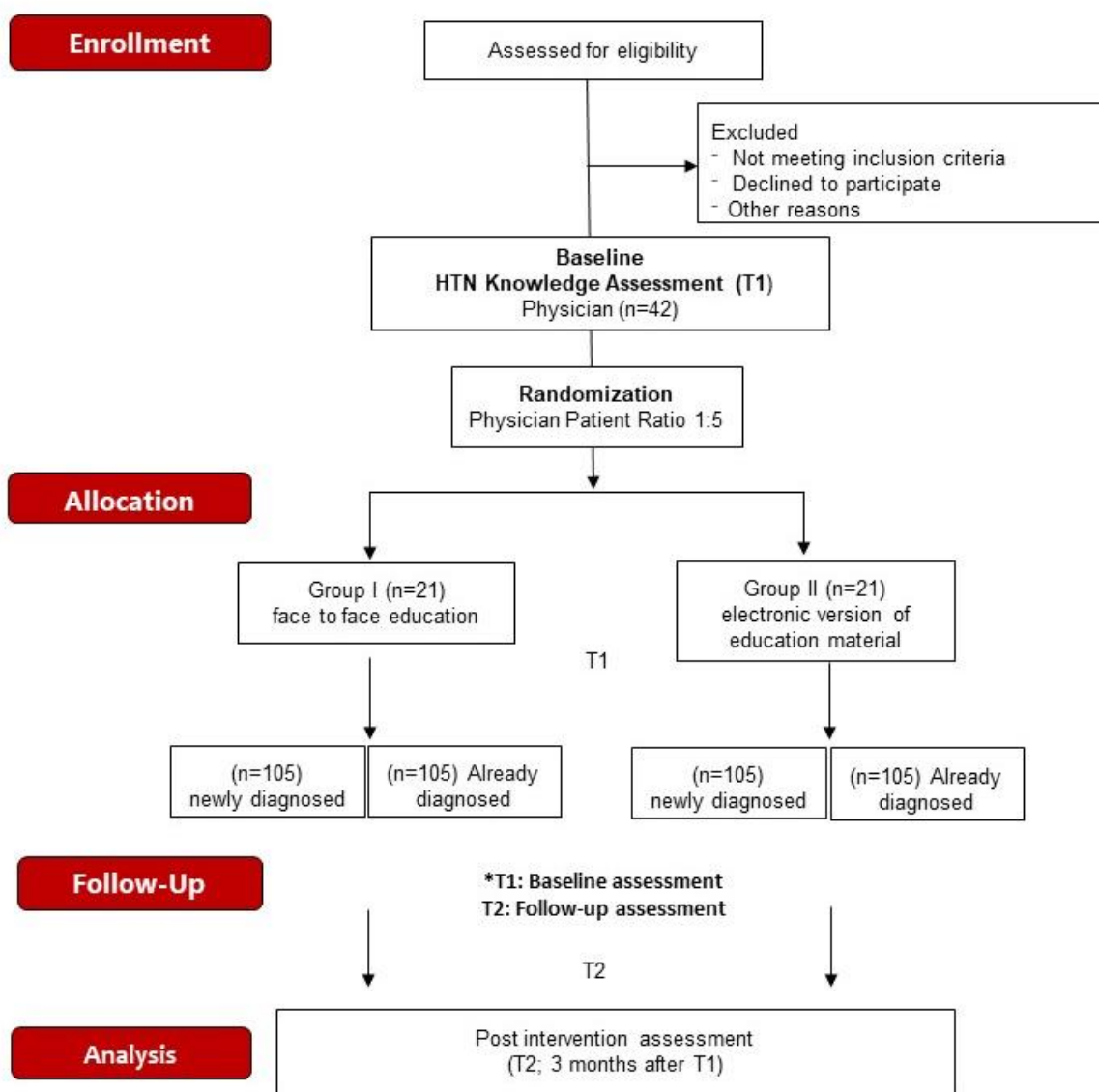
## Structured educational material

The following structured educational material will be provided to both groups with different methods:

1. Key points of current hypertension guidelines.
2. 10-step checklist on how to obtain standardized upper arm blood pressure readings according to guidelines.
3. Template of a blood pressure documentation sheet for serial documentation of blood pressure values by patients.
4. Checklists to assist in the diagnosis of secondary hypertension.
5. Patient information leaflet about hypertension.

## Study Procedure

1. Screening of General Physicians as per inclusion criteria and recruitment of GPs by clinical research associate after obtaining informed consent.
2. GPs will be asked to fill hypertension awareness questionnaire at baseline
3. Both groups of GPs, with the help of a clinical research associate, will recruit 10 patients from the study site.
4. After obtaining informed consent, the patient will be asked to fill hypertension awareness questionnaire at baseline or recruitment day and 12-hour blood pressure measurement (from digital BP apparatus).
5. GPs will then be randomized into 2 Groups.
6. After randomization, Group 1 GPs will receive (1 day) face-to-face education, and Group 2 GPs will receive the print version of educational material.
7. After the GPs educational intervention, patients will be invited for a regular checkup at the GPs clinic.
8. The patient will be again asked to fill hypertension awareness questionnaire after 3 months and share pictures of 12-hour blood pressure measurement (from digital BP apparatus) with a clinical research associate. (1st, 2nd & 3rd Month).
9. GPs will be asked to fill hypertension awareness questionnaire again after 3 months (Post-intervention).



**Figure 1: Flow chart of the study procedure.**

### Outcome measures

#### ❖ Primary endpoint

Pre & Post-change in the blood pressure control rate, defined as the percentage of patients with an average 12-hour blood pressure <130/80 mmHg.

#### ❖ Secondary endpoints

- Pre & Post changes in average systolic and/or diastolic blood pressure and changes in

practice-specific hypertension management stratified by the intervention status of the practice.

- Pre & Post knowledge enhancement among GPs and patients regarding hypertension management.

### Assessment Procedures

- Patient hypertension awareness questionnaire at baseline and 3 months follow-up of both groups.

- Patients' 12-hour blood pressure measurement will be monitored (home-based) at baseline and 3 months follow-up of both groups.
- GPs hypertension awareness questionnaire at baseline and 3 months follow-up of both groups.

### Sample size

A total of 42 physicians will be selected from 6 major cities of Pakistan via the probabilistic sampling technique. Recruited physicians will recruit 5 newly diagnosed and 5 already diagnosed patients via the non-probabilistic convenience sampling technique.

### Statistical hypotheses, methods & analyses

- The Pre & Post-change in the blood pressure control rate will be analyzed using a chi-square test.
- Paired sample t-tests will be used for analyses of secondary endpoints within each group using.
- Differences in the mean will be tested for significance using an adjusted t-test for independent samples.
- Bivariate analyses will be used to assess the effect of single hypertension management strategies on blood pressure.
- Predictors of blood pressure control at follow-up will be determined by a generalized linear mixed model.

## Discussion

The current study will be conducted to observe the effect of hypertension educational intervention for general physicians to indirectly improve patient outcomes. It is believed that the results of this study will provide basis for developing a hypertension educational program targeted at general physicians. Since hypertension is one of the main causative factors for developing cardiovascular diseases and stroke<sup>16</sup>. A systematic review conducted in 2005 suggested that an organized system of regular follow-up along with a review of the hypertensive patients, need to be established and practiced in general practices in the community-based clinics<sup>17</sup>.

Several studies have shown that hypertension is not only a risk factor for cardiovascular diseases but also account for bulk of non-communicable diseases (NCDs). Developing countries have shown to have a prevalence of hypertension from 18.8% to 41.8%. This low prevalence rate is mostly seen in underdeveloped or developing countries<sup>3</sup>. This makes poor people more vulnerable due to the burden of hypertension and their inability to afford the needed long-term treatment<sup>3</sup>. Talking about developed countries like Australia and the US, the rates of awareness for hypertension are quite prominent. However, the control rates of 24% and 35% of this disease show discouraging results<sup>18</sup>. The scenario in Pakistan is similar, where the National Health Survey of Pakistan has estimated hypertension in 18% of Adults and 33% above 45 years of age, out of which 50% get diagnosed, but only half of those diagnosed patients are treated<sup>19</sup>.

## Conflicts of Interest

The authors have declared that no competing interests exist.

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