

## Study Protocol

# The Effectiveness of Telerehabilitation in Hypertension Management of Adults in Communities: Protocol for a Systematic Review

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## Abstract

**Background:** The emergence of Telerehabilitation in managing hypertension showed positive outcomes as an alternative approach to deliver healthcare services. With the ongoing COVID-19 pandemic which necessitates less physical contact, the study aims to determine the effectiveness of Telerehabilitation versus the usual care in hypertension management among adults in communities, especially in rural settings. **Methods**: A comprehensive electronic search was conducted in the following databases: ProQuest, EBSCOhost, AHA Journals, PubMed, Google Scholar, Scopus, HERDIN, Web of Science, JSTOR, and ScienceDirect in March 2022 and was updated in August 2022. Inclusion criteria are randomized controlled trial studies that involve participants aged  $\geq$  18 years old with hypertension or baseline blood pressure of >140/90 mmHg and the use of technologies and digital services to address hypertension versus non-Telerehabilitation approaches in rural communities or through community-based rehabilitation. Exclusion criteria are non-randomized controlled trials, qualitative studies, unfinished and article type records. The revised Cochrane Collaboration Risk of Bias tool will be used to evaluate the content for risk of bias, quality, and internal validity. An electronic data collection form and Raxter will be utilized to extract and to organize the following: demographics, objectives, design, settings, interventions, outcome measures, and significant findings. Review Manager (RevMan) version 5.4 will be used to perform quantitative synthesis of the pooled data if homogeneity is observed in the outcomes. **Expected Results**: The study will determine the effectiveness of Telerehabilitation in managing hypertension and aiding in its implementation in response to the global trend of urbanization in rural areas.

Key Words: Telerehabilitation, Community Based Rehabilitation, high blood pressure

#### INTRODUCTION

The Coronavirus disease 2019 (COVID-19) pandemic has universally impacted the healthcare system, delivery, and access.<sup>1</sup> In the Philippines, community quarantines, along with various economic and financial challenges, afflict its health system, thereby, resulting in severe fragmentation of care, uneven distribution of health, resources, and inequity.<sup>1</sup> Healthcare services, including physical therapy, were compromised to meet the demands of restriction policies and prioritization of care for COVID-19 patients. The suspension of in-person rehabilitation services has hampered the management of non-communicable diseases, namely ischemic heart disease, stroke, and hypertension, which are still the most common causes of death and disability among Filipinos.<sup>2</sup> Thus, there is greater demand for healthcare efficiency in rehabilitation.

As the COVID-19 pandemic continues, Telerehabilitation (TR) has become an indispensable resource in medical rehabilitation. It is a blend of telemedicine and telehealth care. Telemedicine refers to the remote delivery of clinical services while telehealth care refers to

the management of disability and health.<sup>3</sup> Combining these two services then creates telerehabilitation which refers to the utilization of Information and Communication Technologies to deliver rehabilitation at a distance and has been used for over three decades.<sup>3</sup> It is a timely evidence-based practice that offers significant opportunities to enhance equal access to rehabilitation services, to improve health outcomes, and to promote cost-saving strategies for care. Together with telemedicine, it is predicted to be more widely used for acute and chronic illness management due to the aging population's longer life expectancy and better survival from cardiovascular events.<sup>4</sup> Controlling hypertension is the best target for telerehabilitation and telemedicine as it is the most critical risk factor for cardiovascular disease. Managing this could effectively tackle the hypertension burden in the Philippines evidenced to cause a morbidity rate of 434.7 cases per 100,000 population and a mortality rate of 25.9 per 100,000 population according to the Department of Health (DOH).<sup>5</sup>

The application of TR in hypertension management has wide-reaching implications in self-management, monitoring, education, communication, medication adherence, and treatment. It reinforced self-management through medication reminders and general notifications for treatment adherence, health, lifestyle. nutrition education. and sensors for monitoring vital signs.<sup>6</sup> One study found that textual-based rehabilitation was the most promising for medication adherence, precisely through the SMS method in which text messages are used to facilitate communication between patients and health care workers.7 Telerehabilitation methods resulted in a positive outcome of blood pressure control and improved effective communication between patients and clinicians. As part of the modern approach, which relies on new technologies, its use is most beneficial at the community level since it can provide care where people live; thereby, reducing health care costs and increasing patient access.8

Community-based rehabilitation (CBR) is a means of using local community resources to deliver rehabilitation services to people living in low-income communities.<sup>9</sup> These have been put in place to support people with disabilities (PWDs) and rural communities.<sup>10</sup> In achieving the optimal state of health, the challenges faced by Filipinos residing in rural communities are highly similar to those residing in urban ones. These challenges include poverty, poor health behaviors, and skepticism of the medical system caused by the lack of exposure to medical services. However, what sets rural communities apart is their shortage of healthcare practitioners, higher healthcare expenditure, lack of social support, and longer distance of travel to healthcare facilities.<sup>11</sup> Underserved communities would require innovative approaches in addressing their healthcare needs, one of which is through Telerehabilitation. The use of Telerehabilitation can be promising in the management of chronic diseases like hypertension.<sup>10,12</sup> In a survey conducted in other developing countries such as Hohoe Municipality, Ghana, hypertension prevalence is reportedly higher in rural areas at 57.3% in comparison to its urban counterpart at 42.7%.13 While in Pakistan, the prevalence of hypertension was 44.3% and 46.8% in urban and rural areas, respectively.<sup>14</sup> Although hypertension is evident in both areas, several studies have noted that most interventions are directed towards urban areas, while rural communities lack adequate resources for treatment and prevention, which are significant causes for its continued prevalence.<sup>15</sup>

**Objective.** Cognizant of the known knowledge gaps namely, the lack of TR in hypertension management conducted in the Philippines, the lack of studies investigating TR in the rural setting, and the lack of adequate knowledge of the status and barriers to healthcare in the Philippine rural setting, the study aims to determine the effectiveness of Telerehabilitation versus usual care or the non-Telerehabilitation approaches in hypertension management among adults, specifically in rural communities.

## **METHODS**

**Study Design.** The study will utilize a systematic review to evaluate and to synthesize evidence that will identify the effectiveness of Telerehabilitation in hypertension management.

It will run from September 2021 to December 2022.

The review will be reported following the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA 2020). The study protocol follows the PRISMA-P (PRISMA Protocol) 2015 statement and was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on March 12, 2022, with its registration number CRD42022309389.

Information Sources and Search Strategy. A systematic literature search will be performed in the following databases: HERDIN, ProQuest, EBSCOHost, Google Scholar, PubMed, Clinical Key, Western Pacific Region Index Medicus (WPRIM), Journal Storage (ISTOR), ScienceDirect, AHA Journals, and Web of Science. The initial search was conducted in November 2021 and updated in March 2022. The adopted search strategies and keywords will be taken from the medical subject headings (MeSH) list to maximize the search results. The literature search will be limited to the English language, either original or translated, by human subjects as the participants. These are the keywords used in our search strategy: Cochrane Highly Sensitive Search Strategies for identifying randomized trials. Telehealth, eHealth, mHealth, Mobile Health, digital health, Telerehabilitation, Remote Rehabilitation, Community-based rehabilitation/CBR, Community health services, Community health care, Rural, Provincial, Hypertension, and High Blood pressure. A sample of the search strategy and results can be found in Supplement B.

Boolean connectors such as OR, AND, and nesting and limiters such as language: English, publication type: journal articles, and articles from grey literature will be considered and modified based on the compatibility with each database. A librarian will work alongside the research team to validate the search strategy.

# Eligibility Criteria and Selection Process.

Figure 1 shows the flow diagram based on the PRISMA guidelines to showcase the number of studies included and excluded from the systematic review. In particular, completed studies must satisfy the following criteria:1) studies involving participants aged  $\geq$  18 years old, 2) medically diagnosed with hypertension or participants with baseline blood pressure measurement of >140/90 mmHg, which is categorized as hypertension according to the Joint National Committee (JNC 8) guidelines, 3) studies conducted in rural communities or through community-based rehabilitation, 4) studies that used technologies and digital services such as telehealth, telemedicine, eHealth, mHealth, Mobile Health and Telerehabilitation to directly or indirectly address hypertension remotely, and 5) versus usual care, traditional care, or other non-Telerehabilitation approaches. Conversely, the exclusion criteria are non-randomized controlled trial study designs, qualitative studies, protocols or unfinished, and article type records such as book chapters and miscellaneous.

Hand-searching, based on the perused reference lists, pearling, snowballing, and writing to experts, will be done to identify additional primary studies which are not on the electronic search for supplementary purposes. Two reviewers will independently screen the title and abstract of relevant papers consistent with the inclusion and exclusion criteria. Relevant papers that pass the first level of screening will be subjected to full-text article screening by the same reviewers. Zotero will be used to store the electronic copies of the relevant articles. To avoid duplication, the assigned reviewers will cross-check titles, authors, and recruitment sources. Any discrepancies will be resolved through a discussion led by a non-reviewer of the specific assignment.

**Data Collection and Data Items.** The Cochrane Handbook for Systematic Reviews of Interventions will be utilized as a guide in collecting data. Electronic data collection forms and Raxter, an artificial intelligence research assistant which facilitates researchers' linked workflow and hastens literature exploration by generating a summary of key sections, will be used to extract data from the selected studies.<sup>16</sup> Two independent reviewers will perform initial data collection per study. A third reviewer will compare the two sets of extracted data and decide on the final dataset to arrive at a consensus.

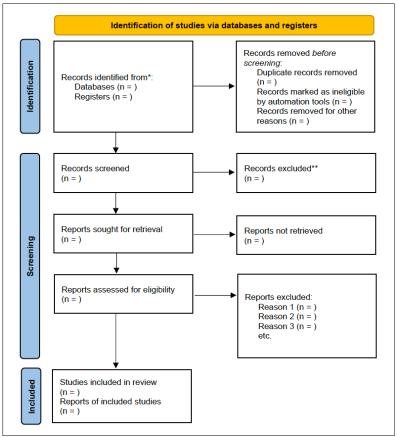


Figure 1. PRISMA 2020 Flow Diagram

In tabular form, data summarized from the studies will include the following information and variables: 1) participant demographic characteristics namely age, gender, sample size, and medical status, 2) study objective/s, 3) study design that follows randomization and methods used in the analysis, 4) study setting, 5) telehealth interventions using synchronous or asynchronous, technology, duration, and frequency used in experimental and control groups, 6) study outcomes, and 7) critical findings. Hypertension management involves pharmacologic and non-pharmacologic means; hence, primary outcome measures will include objective health measures including mean change in blood pressure, body mass index, blood lipids, waist-hip ratio, physical activity, and blood glucose levels.<sup>17,18,19</sup> Accordingly, there are no measured secondary outcomes for this study. Evidence of the assessment of these results, including the measurement tool or instrument used, will be reviewed. Specific metrics such as mean and standard deviation of measurements will be collected for the

appropriate calculation of measures of effects. All reported adverse events, either systematic or non-systematic, will be considered.

Study Risk of Bias Assessment. The study will utilize the Revised Cochrane Collaboration Risk of Bias tool (RoB 2) for randomized control trials to determine the methodological quality of collected clinical trials. The Cochrane tool has demonstrated overall interrater reliability of slight (*IRR* = 0.16, 95% *CI* = 0.08-0.24); IRR is moderate for the domain of the randomization process (*IRR* = 0.45, 95% *CI* = 0.37-0.53), slight for intended interventions (IRR = 0.04, 95% CI = 0.06-0.14) and, fair for the following domain: effect of adhering (IRR = 0.21, 95% CI = 0.11-0.31), missing outcome data (*IRR* = 0.22, 95% *CI* = 0.14-0.30), and selection of reported results (IRR = 0.30, 95% CI = 0.22-0.38).<sup>20</sup> Two independent reviewers will be assigned to appraise the selected studies with possible judgments of low risk of bias, some concerns, and high risk of bias, based on the following domains: selection bias, performance bias, detection bias, attrition bias, reporting bias, and

other relevant concerns related to bias. All disagreements will be resolved by discussion with the independent reviewers. For any unresolved disagreements, a third reviewer will be consulted.

**Level of Evidence.** Included studies will be assessed based on the guidelines and intervention criteria of the National Health and Medical Research Council (NHMRC). Level II will be the only level of evidence considered in this study.

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Level	Description
Ι	A systematic review of level II studies
II	A randomized controlled trial
III-1	A pseudo-randomized controlled trial namely alternate allocation or some other method
III-2	<ul> <li>A comparative study with concurrent controls:</li> <li>Non-randomized, experimental trial,</li> <li>Cohort study,</li> <li>Case-control study, and</li> <li>Interrupted time series with a control group.</li> </ul>
III-3	<ul> <li>A comparative study without concurrent controls:</li> <li>Historical control study,</li> <li>Two or more single-arm study, and</li> <li>Interrupted time series without a parallel control group.</li> </ul>
IV	Case series with either the post-test or the

**Effect Measures.** The weighted mean difference and effect size will be utilized to examine the effectiveness and relationship of Telerehabilitation in the management of hypertension. The weighted mean difference will be determined by the estimated change using the point estimate mean in the systolic and diastolic blood pressure when Telerehabilitation is applied to the intervention group. Results of the trials from each study that used the same outcome measure will be pooled. Correspondingly, the size of the trial will weigh each trial's results. The effect size of the included

pre-test/post-test outcomes

studies will be calculated for comparison and the treatment group results will be compared to the control group. A positive effect size will entail a better result for the treatment group than the control group.

**Synthesis Methods.** A quantitative synthesis of the pooled data will be performed if homogeneity is observed in the outcomes. Metaanalytic pooling using Review Manager (RevMan) version 5.4 developed by the Cochrane Collaboration will be used to analyze homogenous data. Conversely, a narrative synthesis will be done if the methodological process shows heterogeneity. It will provide information using text and tables to summarize and explain the findings of the included studies. The narrative synthesis will be reported following the Synthesis without meta-analysis (SWiM) reporting guidelines.

Statistical analysis of heterogeneous data will include the use of a random-effects model with 95% *CI*. Heterogeneity will be measured using the Chi-squared test and *I*<sup>2</sup> statistic. *I*<sup>2</sup>thresholds of 0%-40% will be considered signs of insignificant heterogeneity. Statistical analysis of effect size will include analysis of weighted mean differences and their 95% *CI*.

**Reporting Bias Assessment.** In reporting bias due to missing results on data assessed using the Revised Cochrane Collaboration (RoB 2), the group will specify the domain number and signaling question on the tool and explain the process used to reach the judgment of the overall risk of bias. A pair review will be implemented in assessing the possibility of bias due to the missing items. All the processes used to resolve disagreements between assessors will also be documented and reported.

Confidence in Cumulative Assessment. In assessing the strength and certainty of the evidence collected, the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) will be used. The quality of the evidence will be evaluated in the following domain: Risk of bias, Imprecision, Inconsistency, Indirectness, and Publication bias, with possible certainty ratings of very low, low, moderate, and high as shown in Table 2.

Certainty	What it means
Very Low	The true effect is probably markedly different from the estimated effect.
Low	The true effect might be markedly different from the estimated effect.
Moderate	The authors believe that the true effect is probably close to the estimated effect.
High	The authors have a lot of confidence that the true effect is similar to the estimated effect.

#### EXPECTED RESULTS

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The study will determine the effectiveness of Telerehabilitation in hypertension management among adults in communities based on the articles included in this review. This study will provide an increased understanding of addressing hypertension using Telerehabilitation in the Philippines, especially in rural settings where healthcare services are limited. The outcomes of this study may aid in standardizing and implementing Telerehabilitation, allowing it to be integrated as a feasible alternative in future healthcare practice. Furthermore, it may assist policymakers in making decisions about resource allocation and implementing successful policies in response to the global trend of urbanization in rural regions.

## **Individual Author's Contributions**

All the authors contributed to the design of the study and also conducted the search, appraised articles, and wrote the draft of this paper.

#### **Disclosure Statement**

This study will be funded by the Metro Health Research and Development Consortium (see Supplement A).

## **Conflicts of interest**

Valentin Dones III is a review board member of the Philippine Journal of Allied Health Sciences (PJAHS). Archelle Jane Callejo-Tiuseco is an editorial staff of the PJAHS. All other authors declare no conflicting interests.

#### Amendments

In the event of protocol amendments, the date of each amendment, the description of the change, and the rationale will be explained.

#### **Supplementary Materials**

Supplementary Materials A. Sample Search Strategy and Results

Supplementary Materials B. PRISMA-P Checklist

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