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Theory-based mobile phone text messaging intervention for blood pressure control (TEXT4BP) among hypertensive patients in Nepal: study protocol for a feasibility randomised controlled trial

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ABSTRACT

Introduction Uncontrolled blood pressure is one of the main risk factors for cardiovascular disease and death in Low-income and middle-income countries. Improvements to medication adherence and lifestyle changes can be assisted by using mobile phone text messaging interventions. This study aims to test the feasibility and acceptability of a text messaging intervention for blood pressure control '(TEXT4BP)', developed based on behavioural change theory to improve treatment adherence and lifestyle change among hypertensive patients in Nepal.

Methods and analysis The TEXT4BP intervention will be tested using a two-arm parallel-group, unblinded, individually randomised controlled trial. This feasibility study would recruit 200 clinically diagnosed hypertensive patients aged 18–69 years, currently receiving blood pressure-lowering medication for more than 3 months, visiting a tertiary healthcare facility in Kathmandu, Nepal. A nested qualitative study will assess the acceptability of the short message service intervention. The intervention group will receive text messages containing information on hypertension, diet, medication and physical activity three times a week for 3 months. The control group will receive standard care. At baseline and 3 months, measures of medication adherence, salt intake, physical activity and blood pressure will be collected. Feasibility measures, such as differential rates of recruitment and attrition rates, will be calculated. Acceptability of text message interventions will be studied using usability measures and in-depth interviews among intervention group participants. This pilot study is not funded.

Ethics and dissemination This study has received ethics approval from the University of New South Wales Human Research Ethics Committee B (HC190357), Nepal Health Research Council (302/2019) and Institutional Review Committee of Kathmandu Medical College and Teaching Hospital Kathmandu, Nepal (030520192). The findings of the study will be disseminated through peer-reviewed publications and conference presentations.

Trial registration number ACTRN12619001213134.

Strengths and limitations of this study

- This study uses short message service text messages which are affordable in Nepal, a low-income country, to overcome systemic constraints to improve the management of hypertension.
- The intervention has been developed using a formative qualitative research model guided by an accepted capability, opportunity, motivation, behaviour theoretical framework for behavioural change.
- The study will be novel in terms of the use of mobile technology for chronic disease management in Nepal.
- This feasibility study will be conducted in one hospital in Nepal, which limits its generalisability.
- The intervention does not allow blinding of participants and assessors of the outcome.

INTRODUCTION

An estimated 26% of the world's population have hypertension (HTN).[1] This figure is expected to increase to 29% by 2025, primarily driven by increases in low-income and middle-income countries (LMICs).[1 2] HTN is the highest risk factor for cardiovascular disease, of which ischaemic heart disease (IHD) and stroke are the first and fifth leading causes of death worldwide.[3] In Asia, the prevalence of HTN ranges from 15% to 35%.[4] Nepal, a low-income country in South Asia, has an estimated prevalence of HTN of 27.3%.[5] The study on burden of disease of Nepal in 2017 reported non-communicable diseases, such as HTN, is the leading cause of death (66%) where IHD is a significant contributor of death (16.4% of total death) and the highest cause of disability-adjusted life-years (7.6%) in Nepal.[6]

Despite available information for the effective treatment of HTN, more than half of diagnosed hypertensive patients have uncontrolled blood pressure in LMICs.[7 8] Low levels of adherence to antihypertensive medication have been reported as the main factor contributing to poor blood pressure control.[9] Though effective medications for blood pressure control are available, adherence to long-term therapies is low, and this is worse in developing countries and among lower socioeconomic groups.[10] In Nepal, controlled blood pressure among hypertensive patients varies by geographical region and ranges from 35%[11] to 49%[12] in the Central Development Region and only 15% in the Western Development Region of Nepal.[13] Studies in Nepal have shown that self-reported adherence to antihypertensive medication varies from 35.4% to 64.3%,[14–16] leading to many complications.

Along with adherence to medication, lifestyle modifications such as lowering salt intake and increasing physical activity are essential for blood pressure control.[17] A meta-analysis of studies of HTN and its management by Baena *et al*[18] found that lifestyle interventions could significantly lower BP levels in LMICs. Barriers to lifestyle change have been identified in previous studies of Nepal[12 19] and our formative qualitative study.[20] Therefore, there is a need for acceptable and affordable solutions appropriate for LMICs to increase medication adherence[21] and support lifestyle changes.[18] In recent years, mHealth has emerged as an efficient strategy to reach wider audiences to effect behavioural change.[22] Systematic reviews have shown the value of short message service (SMS) in promoting lifestyle change for chronic diseases, including HTN[23] and in significantly increasing the medication adherence in chronic diseases.[24]

Globally, there are an estimated 6 billion cell phone users, and more than 6 trillion text messages are sent each year.[25] Though a low-income country, the mobile phone penetration rate in Nepal is more than 90%. The use of mobile technology in the health system is limited to pilot projects by the government and some non-governmental organisations in Nepal.[26] At this point in time, there are no robust scientific interventions using mobile technologies to manage chronic diseases in Nepal. This study aims to test the feasibility and acceptability of a text message intervention developed based on behavioural change theory to improve treatment adherence and lifestyle change among hypertensive patients in Nepal.

AIMS AND OBJECTIVES

Primary objectives

To evaluate the feasibility and acceptability of a text message intervention providing support for medication adherence, lifestyle change, and blood pressure control delivered to hypertensive patients attending health facility in Nepal.

Secondary objectives

- To test the feasibility of delivery of text messages and its acceptability using a validated measure.
- To assess any differential recruitment and attrition rates across socioeconomic groups, gender and education.
- To test the validity of translated measurement tools for medication adherence and self-efficacy for medication adherence.
- To measure primary and secondary outcomes (mean blood pressure, medication adherence and salt intake) to allow estimation of the sample size for a definitive trial.

METHODS AND ANALYSIS

Standard Protocol Items Recommendations for Intervention Trials,[27] Consolidated Standards of Reporting Trials (CONSORT) for a pilot feasibility study[28] and Template for Intervention Description and Replication (TIDieR)[29] guidelines have been used for this feasibility study.

Study design

This feasibility study employs a two-arm parallel-group, unblinded, individually randomised control trial design to test a mobile phone text messaging intervention for blood pressure control (TEXT4BP) compared with standard care for 3 months among hypertensive patients attending a tertiary hospital in Kathmandu, Nepal. This study will use a nested qualitative design to assess the acceptability the SMS intervention. CONSORT diagram for a feasibility trial[28] has been used to illustrate the design of the study (figure 1).

STUDY POPULATIONS

Participants' eligibility criteria

Patients aged 18–69 years with a clinical diagnosis of HTN and currently receiving blood pressure-lowering medication for more than 3 months will be eligible. Participants need to have access to a mobile phone and be able to read a text message by themselves or with the help of family members. Participants need to be residing in the study area during the period of intervention to provide ease of contact.

Participants with current and past severe illness (myocardial infarction, stroke and kidney failure) which reduce their ability to participate in the study will be excluded. Patients with long-term disability due to mental illness, cognitive impairment or physical disability and women currently pregnant or in the postpartum period will also be excluded.

Study setting

This study is conducted in the cardiology and medicine outpatient department (OPD) at the Kathmandu Medical College and Teaching Hospital (KMCTH), Kathmandu, Nepal. In KMCTH, the Cardiology/Medicine OPD sees an average 15–20 adults daily for the care of HTN. In

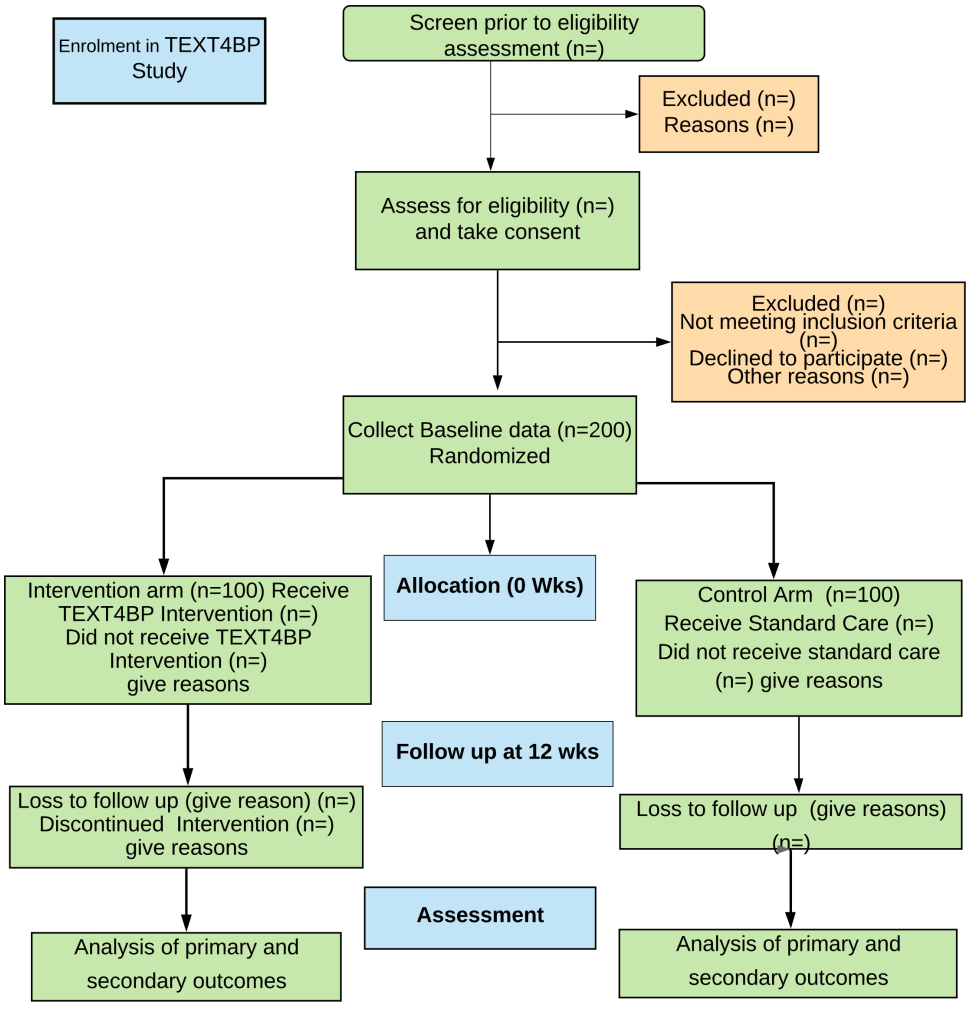

Figure 1 Pilot and feasibility RCT CONSORT flow diagram of the TEXT4BP study. CONSORT, Consolidated Standards of Reporting Trials; RCT, randomised controlled trial; TEXT4BP, messaging intervention for blood pressure control.

Nepal, treatment for HTN is not provided in all primary level healthcare facilities (Primary health care centers, Health posts), which was identified in the qualitative study. Therefore, a tertiary-level facility will be selected for the feasibility trial.

Recruitment of participants

All eligible hypertensive patients visiting in the cardiology/medical OPD of the KMCTH will be invited for participation in the study if they meet the eligibility criteria. Relevant health professionals (cardiologist, physician and nurses) will provide the information of the research and a study flyer describing the research to the interested eligible hypertensive patients. Those who are interested will be asked to contact the research team directly to register their interest to participate in the study. Once the interested participants initiate the contact, the researchers would describe the study, obtain written consent and carry out baseline data collection.

Intervention

The TIDieR[29] guidelines have been used to describe the intervention (see online supplementary 1).

Intervention development

The development of the intervention followed a theory-based approach after eliciting barriers and facilitators for treatment and control of HTN among a similar population to the target group for the trial.[20] Using a qualitative study of people with HTN, their family members and healthcare provider, barriers and facilitators to obtain and maintain treatment, a lifestyle change for low salt diet and physical activity were identified. Those barriers comprised of a lack of knowledge, misconceptions about disease and treatment, faith in other traditional medicines, irregularities in taking medications and beliefs about consequences, resistance to behavioural changes and stigma of the disease. Capability, opportunity, motivation, behaviour (COM-B) model and behavioural change techniques (BCTs) were used to categorise and map the findings under intervention functions of behaviour change wheel (BCW).[30]

The process used to identify and select content for text messages followed the guidance in Michie *et al*.[31] We first mapped the identified barriers under the components of COM-B model in the BCW. Then we linked the identified

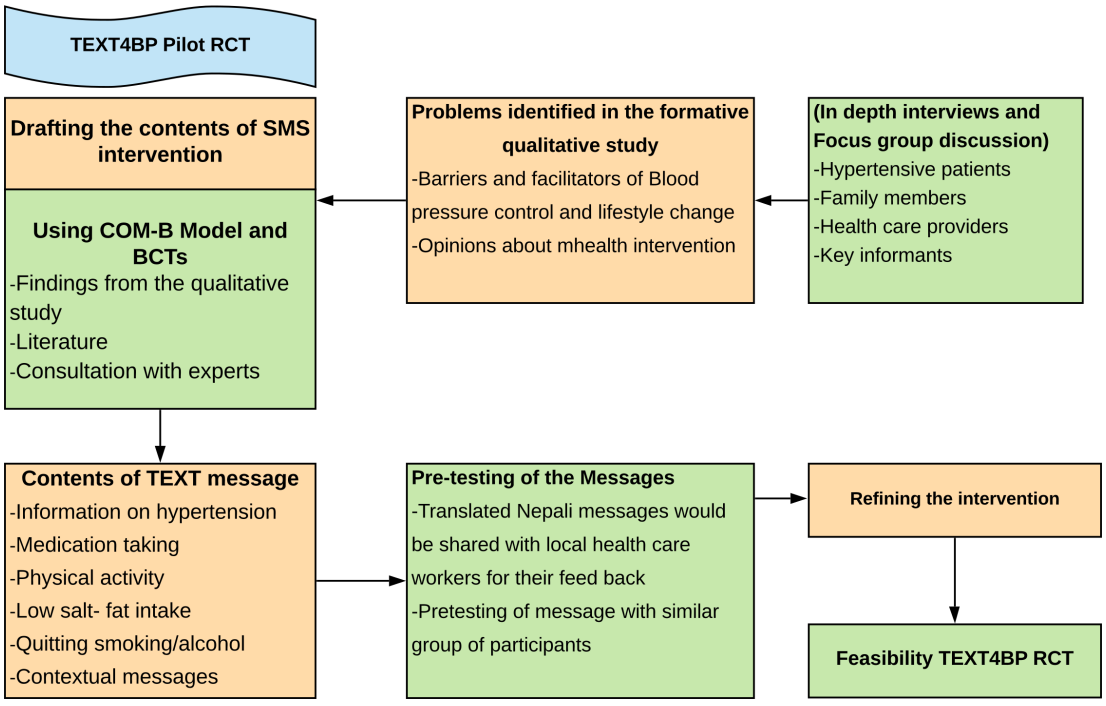

Figure 2 Process of TEXT4BP intervention development. COM-B, capability, opportunity, motivation, behaviour; RCT, randomised controlled trial; SMS, short message service; TEXT4BP, messaging intervention for blood pressure control.

barriers with the intervention functions of the BCW. To systematically address enablers and barriers, the content of the SMS intervention was developed using relevant BCTs[32] and literature.[33] The selection of BCTs was guided by the most frequently used list given by the Michie *et al* on linking intervention functions to BCTs[31], and the principal investigator's in-depth understanding of the context and analysis of the aforementioned qualitative study.[20] We were limited in the selection of some BCTs (eg, goal setting) as the intervention was unidirectional and could not include feedback on behaviour. We did not provide some of the other types of BCTs (eg, incentivisation). Example of the link between barriers and facilitators, BCTs and text messages is given in online supplementary 2.

The text messages will be translated into Nepali language and pretested with participants similar to the target group to improve on content and face validity. This whole process of intervention development is depicted in figure 2.

TEXT4BP intervention

Participants with HTN in the intervention group will receive mobile phone text messages in Nepali language containing information on HTN and its complications, taking medications, diet (low sodium, low fat) and physical activity (exercise), quitting/reduction of smoking and alcohol (tailored to the person for smoking and alcohol intake).

Intervention delivery

We would engage a recognised company (aakash SMS: https://aakashsms.com/) to deliver the text messages to our participants. The provider only requires a mobile phone number, and no sensitive personal information will be collected. The provider will use Nepal Telecom and NCell, the two largest mobile companies in the country to deliver the messages. Both companies are The Health Insurance Portability and Accountability Act (HIPAA) compliant and have stringent data security protocols in place to protect the privacy of their users.

Total number and frequency of text messages

Frequency of the text message was decided based on the response of the participants during the exploratory qualitative study. Text messages will be delivered three times a week for 3 months, a total of 36–40 text messages after enrolment in the study. The average length of the text message will be 160 characters.

Description of the standard care

The control group will be provided with the usual standard care. In Nepal, hypertensive patients usually receive a prescription of antihypertensive medicine and advise for follow-up as the standard care. At the end of the study (after 3 months), they will be provided pamphlets containing information about HTN and required behaviour modifications.

STUDY OUTCOMES

Baseline measures

The baseline data collection tools contain questions on (1) sociodemographic factors, medical and family history (2) lifestyle factors: dietary salt consumption based on the WHO STEPS survey questionnaire,[34] Hill-Bone

Table 1 Study outcomes and time points of measurements

Outcomes	Measures	0 weeks	12 weeks
Systolic blood pressure Diastolic blood pressure	Average of last of two measures of blood pressure.	√	√
Medication adherence Medication adherence self-efficacy	Hill-Bone compliance to high blood pressure therapy scale[35] (14 items), Medication adherence self-efficacy scale[36] (13 items)	√	√
Dietary habits (salt intake) Physical activity	Dietary salt (9 items)and physical activity(17 items)based on WHO stepwise approach to chronic disease surveillance scale.[34]	√	√
Knowledge and perceptions of hypertension and its treatment	The structured questionnaire developed by the researchers (21 items)	√	√
Acceptability of the text message intervention*	The Marshfield usability survey tools,[45 46](16 items)		√

*Feasibility and acceptability of intervention would only be assessed among intervention group participants.

compliance to High Blood Pressure Therapy scale,[35] Medication Adherence Self-Efficacy scale[36] and Knowledge and Perception of HTN questionnaire. Time points of measurement and follow-up measures are presented in table 1.

Validity and reliability of the tools

All of the measures will be translated to Nepali following accepted standard procedures given by WHO[37] by bilingual translators. Pilot testing of the translated tools to test face validity will be conducted. Factorial validity of the Hill-Bone Medication Compliance subscale and Medication Adherence Self-Efficacy scale will be carried out after baseline data collection. Composite reliability of scales will also be tested.

Physical measurement

Blood pressure, height, weight, waist and hip circumference will be measured by the researchers following standard guidelines. Blood pressure will be measured using the digital blood pressure monitor (Kenz BPM OS-30) following the 2018 European Society of Cardiology and European Society of Hypertension (ESC/ESH) guidelines[38] for the office blood pressure measurement. Before taking the measurements, participants will be asked to sit comfortably and rest for 5 min with legs uncrossed. Three readings of the systolic and diastolic blood pressure will be measured 1–2 min apart. The average of the last two reading would be calculated. Bodyweight will be measured using digital scale and height will be measured using a stadiometer and waist, and hip circumference will be measured using a constant tension measuring tape (Tape finger finder measure—PE024).

Sample size

One objective of the feasibility study is to estimate the sample size for the definitive trial. The feasibility trial is not powered to test the effectiveness of the intervention; however, the sample size for the feasibility study was based on the recommendation for determining the sample size for pilot randomised controlled trial (RCT) studies.[39] Whitehead *et al*,[39] give recommendations for pilot studies followed by definitive RCTs. They recommended, to obtain the main trial designed with 90% power, two-sided 5% and standardised effect sizes that are extra small (0.1), a pilot trial with sample size per treatment arm of 75 is needed. We erred on the conservative side using the sample size of 75 and added a high attrition rate (of 30%) to obtain a sample size per arm of 100. We used a conservative estimate for attrition, based on a recent study.[40] This is a parameter we would ascertain from this feasibility study to power the planned definitive study.

Randomisation, sequence generation and allocation concealment

Simple randomisation technique will be used for allocation.[41] A random sequence of 200 numbers will be generated in two columns (100 each) using an open-source random number sequence generator (an online website Random.org). It will generate the random number in two columns (each 100) from 1 to 200. After the random number sequence is produced, the numbers indicating the group allocation (ie, one column numbers for the control group and two column numbers for the intervention group) will be placed in opaque sealed envelopes. The opaque envelops will be numbered on the outside according to the generated numbers and kept sequentially.[42] The first author will generate a random number and prepare the envelopes. Then research assistant will assign the numbers to the respective participants after baseline data collection. Therefore, the investigator could not foresee which group each participant would be allocated to until the commencement of the baseline measurement and reduce the allocation bias. There is a risk of manipulation while using this method. Several steps will be taken to reduce this. First, we will use adequately numbered opaque sealed envelopes to maintain allocation concealment. The sealed envelopes will be stored in a safe and secure place in the office with only the principal

investigator having access to the keys. In addition, the principal investigator will supervise the process to ensure that envelopes are numbered in advance, opened sequentially and only after the baseline data has been collected, and participants' details are written on the appropriate envelope. The method of sealed envelopes is one of the methods suggested by Schulz and Grimes[43] for the allocation concealment to prevent selection bias.

The probability of unequal group sizes using this method of randomisation diminishes with large sample sizes (of 200 and over).[44] Any significant imbalance in baseline characteristics between the groups will be tested and adjustments made during the outcome analysis.

DATA COLLECTION PROCEDURES

Baseline data collection

Baseline data collection will be carried out using a structured computerised survey tool (Kobo toolbox) with in-built logic checks and skip patterns to minimise data entry error in the password-protected electronic device of the researcher. Measurements are listed in table 1. Details of physical measures are given above.

Follow up data collection

Follow-up data collection will be conducted 3 months following enrolment in the study and will follow the same procedures as at baseline. Participants in the intervention group will be asked questions on the acceptability of the text message intervention using modified Marshfield usability survey tools.[45 46] In-depth interview with intervention group (5-6) participants will be conducted to explore their perceptions and experiences of mobile phone text message interventions.

Retention of the study participants

To improve compliance and retention, participants will receive at least three phone calls to remind them of follow-up. If the researchers are unable to locate the participants after these attempts, then no further calls will be made, and they will be recorded as lost to follow-up. Participants will be provided with a small incentive (Nepalese Rupees 100, equivalent to AUD 1.28) during the follow-up visits as reimbursement for transportation costs.

Data management and analysis methods

At the first stage of analysis, we will compare the baseline characteristics of study participants in the study intervention group and follow-up status. Preliminary indicative estimates of differences in primary and secondary outcomes by the group will be obtained. We will power the future c-RCT predominantly based on magnitudes of effect that are of public health relevance rather than using magnitudes of effects obtained from the study.

Differential recruitment and attrition rates across socioeconomic groups, age, education and gender, will be analysed using a X^2 test and report on any associations with attrition rates. These data will be used to support the required sample size estimates for the definitive trial.

Feasibility and acceptability of the intervention will be assessed by the level of completeness and by follow-up qualitative interviews with a subsample of the intervention group participants. The acceptability of the text message intervention using Marshfield usability scale questions[45 46] would be assessed based on the age, gender and education using chi-square test. Qualitative interviews will be transcribed, and line-by-line coding will be conducted to generate the codes. Descriptive thematic analysis will be carried out using NVivo software V.12 (QSR International, London, UK and USA).

Patient and public involvement

This research is planned to conduct without patient or public involvement. Though, the intervention development was done with the input from respondents, key informants and healthcare workers in the formative research, participants were not invited to comment on the study design or to contribute to the writing of this manuscript.

Ethics and dissemination

A data monitoring board would be formed comprising three members (one from the representative of NHRC and two subject experts). The study will be conducted according to the protocol, and any deviations will be formally notified. Adverse events will be recorded in adverse events reporting form developed according to the guidelines provided by the University Human Research Ethics Committee.

Due to the nature of the non-clinical intervention, receipt of text messages does not pose any additional risks. Previous studies have not reported any adverse effects. We do not foresee any adverse effects due to non-clinical nature of the intervention. The result of this study will be published in scientific peer-reviewed journals and presented in scientific conferences. The research report will be disseminated to the related authority of the Ministry of Health and Population of Nepal for informing policy. The anonymity of the participants will be maintained by using deidentified information of participants.

DISCUSSION AND CONCLUSION

This TEXT4BP study aims to assess the feasibility and acceptability of mobile phone text message intervention for improving treatment adherence and lifestyle modifications among hypertensive patients in Nepal. While the use of SMS text messaging as an effective intervention has been reported in other countries,[23 24] it has not been tested in Nepal and this will be a first study in Nepal. Hence, the study could provide evidence of the feasibility and value of alternative solutions like mobile technology in contexts with high rates of uncontrolled blood pressure and poor public healthcare resourcing.

The feasibility TEXT4BP RCT study has many strengths. The intervention has been developed using robust methods by conducting formative qualitative research guided by the theoretical framework. The text messages were developed based on the needs identified linking with BCTs. The feasibility study will be conducted in one hospital and does not represent wider population in the country. The role of the feasibility trial is to test operational fidelity in a diverse group representing a broader sociodemographic and geographical location. Adherence to antihypertensive medication will be assessed using self-reported measure as more objective measures are not practicable in the setting. However, the standardised tool having a high rate of reliability and tested and developed specifically for the hypertensive patients would be used to reduce self-reported bias. Given the major workforce constraints in delivering services for chronic disease in LMICs the use of alternative strategies to reach and motivate patients with cardiovascular disease is an important strategy. The study will lead to a definitive trial to find evidence of the effectiveness of such interventions.

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