Development and feasibility trial of a text messaging mHealth intervention to improve blood pressure control among patients with hypertension in Nepal

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Development and feasibility trial of a text messaging mHealth intervention to improve blood pressure control among patients with hypertension in Nepal

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Thesis Title

Development and feasibility trial of a text messaging mHealth intervention to improve blood pressure control among patients with hypertension in Nepal.

Thesis Abstract

The burden of hypertension is increasing worldwide, with higher rates in Low- and Middle-Income countries (LMICs), like Nepal. Despite the availability of effective interv entions, uncontrolled blood pressure remains a major challenge contributing to significant morbidity and mortality. Nonadherence to treatment and improper understandi ng of reasons for poor adherence are attributed to this phenomenon. It is widely understood that LMICs are impacted by financial pressures and a health workforce short age to tackle these problems. Mobile phone uptake is high in LMICs and provides an opportunity to deliver tailored messages to improve medication adherence and con tribute to blood pressure control. We aimed to develop and evaluate the feasibility of a text messaging mHealth intervention to improve blood pressure control among pa tients with hypertension in Nepal.

We performed our research in two phases. In Phase I, a formative qualitative study (using a theoretical approach) was conducted to understand the barriers and facilitato rs for blood pressure control among patients with hypertension This study provided detailed insight into individual barriers to blood pressure control, such as low literacy of hypertension, non-adherence to treatment, and system-level barriers such as poor communication between providers and patients. In addition, we explored stigma an d non-disclosure issues and social-cultural barriers attached to behavior modification in this setting. The second part of this formative study reported the high potential o f mHealth intervention in the study setting.

Informed by the qualitative study, we co-designed a text messaging intervention (TEXT4BP) as part of Phase II. The feasibility of the TEXT4BP intervention was tested us ing a pilot randomized control trial study design. The TEXT4BP intervention was effective ($p<0.001$) in reducing systolic and diastolic blood pressure, improving blood pr essure control, and medication adherence among the intervention group when compared to the control group receiving usual care. In addition, the TEXT4BP intervention was found to be feasible and acceptable in the study setting.

Our research has generated novel evidence on the co-design process of a mHealth intervention and demonstrated the effectiveness and acceptability of the intervention for hypertension management. The findings will inform further large-scale mHealth research and contribute to clinical practice with evidence-based adherence guidelines in Nepal

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Publication Details #1

Full Title:	Barriers and facilitators for treatment and control of high blood pressure among hypertensive patients in Kathmandu, Nepal: a qualitative study informed by COM-B model of behavior change
Authors:	Buna Bhandari, Padmanesan Narasimhan, Abhinav Vaidya, Madhusudan Subedi, Rohan Jayasuriya
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Candidate's Declaration

I confirm that where I have used a publication in lieu of a chapter, the listed publication(s) above meet(s) the requirements to be included in the thesis. I also declare that I have complied with the Thesis Examination Procedure.

Dedication

My PhD thesis is dedicated to my mother, Mrs Radha Bhandari and my father, Mr Umakant Bhandari, who gave me wings of education to fly and explore the world to chase my dream. They always believed in me and taught me the value of kindness and curiosity of learning in each step of life.

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Bhandari B, Narasimhan P, Jayasuriya R, Vaidya A, Schutte AE. Effectiveness and acceptability of a mobile phone text messaging intervention to improve blood pressure control (TEXT4BP) among patients with hypertension in Nepal: A Feasibility Randomised Controlled Trial. Global Heart. [Submitted 30th July 2021]

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Additional list of publications during PhD candidature

- Rishal P, Devi Pun, K Schei B, **Bhandari B,** Kumar Joshi S, Swahnberg K, Infanti JJ, Lukasse M.; the ADVANCE study group. Improving Safety Among Pregnant Women Reporting Domestic Violence in Nepal—A Pilot Study. International Journal of Environmental Research and Public Health. 2020;17:2268.
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RESEARCH STUDENT AWARD

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In recognition of your outstanding contribution to your research environment and higher degree research community.

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Abstract

The burden of hypertension is increasing worldwide, with higher rates in Low- and Middle-Income Countries (LMICs), like Nepal. Despite the availability of effective interventions, uncontrolled blood pressure remains a major challenge contributing to significant morbidity and mortality. Nonadherence to treatment and improper understanding of reasons for poor adherence are attributed to this phenomenon. It is widely understood that LMICs are impacted by financial pressures and a health workforce shortage to tackle these problems. Mobile phone uptake is high in LMICs and provides an opportunity to deliver tailored messages to improve medication adherence and contribute to blood pressure control. We aimed to develop and evaluate the feasibility of a text messaging mHealth intervention to improve blood pressure control among patients with hypertension in Nepal.

We performed our research in two phases. In Phase I, a formative qualitative study (using a theoretical approach) was conducted to understand the barriers and facilitators for blood pressure control among patients with hypertension This study provided detailed insight into individual barriers to blood pressure control, such as low literacy of hypertension, non-adherence to treatment, and system-level barriers such as poor communication between providers and patients. In addition, we explored stigma and non-disclosure issues and social-cultural barriers attached to behaviour modification in this setting. The second part of this formative study reported the high potential of mHealth intervention in the study setting.

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($p<0.001$) in reducing systolic and diastolic blood pressure, improving blood pressure control and medication adherence among the intervention group when compared to the control group receiving usual care. In addition, the TEXT4BP intervention was found to be feasible and acceptable in the study setting.

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List of Abbreviations

ACT	Awareness, Control and Treatment
BCTs	Behaviour Change Techniques
BCW	Behaviour Change Wheel
BMI	Body Mass Index
BP	Blood Pressure
CAD	Coronary Artery Disease
CDSS	Clinical Decision Support System
CKD	Chronic Kidney Disease
CVD	Cardiovascular Disease
CONSORT	Consolidated Standards of Reporting Trials
COPD	Chronic Obstructive Pulmonary Disease
COM-B	Capability, Opportunity, and Motivation- Behaviour
COVID	Coronavirus Pandemic
DASH	Dietary Approaches to Stop Hypertension
DALYs	Disability-Adjusted Life Years
DBP	Diastolic Blood Pressure
DoHS	Department of Health Services
ESC	European Society of Cardiology
ESH	European Society Hypertension
ESRD	End-Stage Renal Disease
FCHV	Female Community Health Volunteers
FGDs	Focus Group Discussions
HBM	Health Belief Model
HCW	Health Care Workers
HICs	High Income Country
HIV	Human Immunodeficiency virus
HTN	Hypertension
HPs	Health Post
IHD	Ischaemic Heart Disease
JNC	Joint National Committee
IDIs	In-Depth Interviews
ISH	Internal Society of Hypertension
KI	Key Informants
KMCTH	Kathmandu Medical College and Teaching Hospital

LMIC	Low and Middle-Income Countries
LIC	Low Income Country
MCH	Maternal and Child Health
MI	Myocardial Infarction
mHealth	Mobile Health
MMM	May Measurement Month
MOHP	Ministry of Health and Population
NCDs	Non-Communicable Diseases
NDHS	Nepal Demographic Health Survey
NHRC	Nepal Health Research Council
NTA	Nepal Telecom Authority
P	Patients
PDAs	Personal Digital Assistants
PEN	The Package of Essential Non-communicable Diseases
PHC	Primary Health Care
PHCCs	Primary Health Care Centres
PL	Primary Level
PURE	Prospective Urban Rural Epidemiologic
RCT	Randomized Controlled Trial
SAARC	South Asian Association for Regional Cooperation
SBP	Systolic Blood Pressure
SCT	Social Cognitive Theory
TRA	Theory of reasoned Action
SMS	Short Message Service
STEPS	Stepwise approach to Surveillance
SPRINT	Systolic Blood Pressure Intervention Trial
TAM	Technology Acceptance Model
TEXT4BP	Text Messaging Intervention for Blood Pressure Control
TPB	Theory of Planned Behaviour
TTM	Transtheoretical Model
TL	Tertiary Level
UTAUT	Unified Theory of Acceptance and Use of Technology
WHO	World Health Organization
Y	Years
YLL	Year of Life Lost
YLD	Year of Life Lived with Disability

Chapter 1: Introduction

1.1 Background

When I witnessed the death of a young relative (in his 40s) due to a heart attack, I was shattered. Particularly since he was a diagnosed patient with hypertension with prescribed antihypertensive medication. At the same time, I questioned why people with hypertension still have uncontrolled blood pressure and suffered from complications despite the availability of treatment and wondered what can be done to prevent such premature death in society. This was the beginning of my journey researching the management of hypertension – from my undergraduate studies to my PhD thesis. (Personal experience: Buna, PhD candidate)

Noncommunicable diseases (NCD) are a leading cause of death, contributing to 71% (41 million) of global deaths. NCDs disproportionately affect Low- and Middle-Income Countries (LMICs), where more than three-quarters of deaths (85%) are ascribed to NCDs.[1] In addition, the total Disability Adjusted Life Years (DALYs) due to NCDs has increased by 43.2% from 1990, accounting for two-thirds (63.8%) of total DALYs in 2019.[2] Among NCDs, cardiovascular disease (CVDs) is the leading cause of preventable death and disability along with cancer, chronic respiratory diseases, diabetes and other NCDs.[1] CVDs accounted for 18.6 million deaths and 393 million DALYs in 2019. In that same year, ischaemic heart disease and stroke were the foremost causes of DALYs in persons above 50 years of age.[2] High blood pressure (BP) (or hypertension) is the leading risk factor for CVDs,[3] especially stroke and ischaemic heart disease.[4]

Though the risk factor burden of CVDs is low in LMICs, mortality attributed to CVDs are higher in LMICs compared to HICs, as evidenced in the Prospective Urban Rural Epidemiologic (PURE) study.[5] A possible reason for this low mortality may be due to better management of risk factors for CVDs in HICs.[6] LMICs are confronted with the rapid changes in various social and commercial determinants of health, such as unhealthy dietary practices, urbanisation, globalisation, sedentary behaviour and economic transition.[7] This led to the emergence of many behavioural and metabolic risk factors such as hypertension, contributing to the high burden of NCDs in LMICs.

The situation in LMICs and Nepal

Hypertension (HTN) is escalating globally, mainly affecting LMICs, including South and East Asia and Sub Saharan African regions.[8] Globally, an estimated 31.1% (1.39 billion) adults had HTN in 2010,[9] and it was predicted to increase by 60% from 2000 and reach about 1.56 billion in 2025.[10] The World Health Organization (WHO) reported that one in four men and one in five women had HTN in 2015 and two-thirds of them live in the LMICs.[11] HTN is responsible for 45% of deaths due to heart disease and 51% of deaths due to stroke,[12] and accounted for 10.8 million deaths and 9.3% of the global DALYs lost in 2019.[13] The burden of HTN is decreasing in HICs, but increasing in LMICs[14] as evidenced by a 2.6% decreased age-standardised prevalence of high blood pressure in HICs, and 7.7% increase in LMICs from 2000 to 2010.[15] Pooled data from 44 countries reported the prevalence of HTN as 17% in LMICs in 2019.[16] However, proportion of HTN was higher (29.3%) in South Asia based on the data of May Measurement Month (MMM) 2019. MMM is a low budget voluntary blood-pressure screening campaign where BP is not measured in optimal condition leading to potential bias.[17] A similar trend of 27% was reported in the South Asian Association for Regional Cooperation (SAARC) countries in a meta-analysis conducted in 2014, with the highest prevalence in Nepal (33.8%) and lowest in Bangladesh (17.9%).[18]

Nepal is a landlocked South Asian country with an estimated population of 29 million[19] where NCDs are the major contributor to deaths and disability, accounting for two thirds (66%) of total deaths and 59% of DALYs reported in a Global Burden of Disease study of Nepal in 2017.[20] In particular, ischemic heart disease is a significant contributor to death (16.4%) and DALYs (7.6%) among all the NCDs in Nepal.[20] The overall pooled prevalence of HTN in Nepal was reported as 28-32% in systematic reviews published in 2021[21, 22] which was around 25% based on the National representative STEPS survey in 2019.[23] Between 2008 and 2019, the prevalence of HTN in Nepal was increased by 6%.[24] In addition, the DALYs attributed to HTN was 6.7% of the total DALYs in Nepal in 2017.[20] The major cardiovascular risk factors identified in Nepal are physical inactivity, high salt intake, smoking, alcohol intake and obesity, contributing to high BP and cardiovascular disease.[23,25]

Globally, there is a huge challenge for the control of the HTN after diagnosis, where more than 50% of patients diagnosed with HTN remain with uncontrolled BP in HICs and LMICs.[26, 27] Nepal is no exception, where a large proportion of hypertensive patients are only diagnosed in their later years.[28] In 2016, the Nationally representative Nepal Demographic Health Survey (NDHS) estimated that 56.9% of Nepalese living with hypertension were undiagnosed.[29] Furthermore, diagnosed hypertensive patients in Nepal often are untreated or have poor BP control.[21] Based on the recent systematic reviews in 2021, only 45-50% of patients with hypertension in Nepal were aware of their disease, only 27-32% of them were treated, and only 38-44% had their blood pressure controlled.[21, 22] These findings are consistent with international studies.[26, 27]

Contributing factors to poor blood pressure control

Non-adherence to antihypertensive medication is one of the major therapeutic challenges leading to myocardial infarction, stroke and other complications associated with HTN. Non-adherence to an antihypertensive regimen consists of not taking the medication regularly, and also not adequately engaging in recommended behaviours such as exercise, diet, and unhealthy behaviours such as smoking and excessive alcohol consumption.[30] In Nepal, adherence to antihypertensive drugs ranges from 35.4% to 64.3%.[31-33] However, studies conducted to date in

Nepal only highlighted the prevalence of treatment and control of BP.[21, 22] The factors underlying these issues are yet to be explored and managed effectively.

Lifestyle modification is an essential supportive factor for preventing and controlling high BP and treatment adherence.[34] For optimal control of BP, long-term commitment to lifestyle modifications and pharmacologic therapy is required. Evidence shows that patient, provider, or system-related factors act as barriers to treatment and control of BP among patients with HTN.[35] It is established that a reduction in BP reduces the risk of CVD and all-cause mortality.[36] There is evidence that reducing the 5mmg of SBP would reduce the risk for major CVD events by 10% based on the analysis of 44 randomised controlled trials.[37] Therefore, a diagnosed patient needs to adhere to the instruction provided by health care workers on recommended behaviour modification. It has been suggested that patient-focused strategies for improving BP control requires a systematic approach that should include behaviour modification (e.g., diet, exercise, quitting smoking, reducing alcohol consumption, and medication adherence), knowledge (e.g., accurate risk perception), adequate cognitive function and support.[38, 39]

LMICs face significant challenges related to management of hypertension. LMICs tend to have smaller health workforces relative to population size. The WHO estimates LMICs will have a shortage of approximately 30 million health workers by 2030.[40] The coronavirus pandemic (COVID-19) may significantly add to this shortfall-burden. In the context of scarce human resources to deliver an effective intervention to improve BP control, an alternative medium to staff-intensive interventions may be necessary in LMICs.

While LMICs struggle with a shortage of finances and health workers, mobile phones are vastly integrated into daily life in LMICs.[41] This is also true for Nepal, where a rapid technological transition has resulted in an average of more than one mobile phone per person, and where 63% of the population have some access to the internet.[42] Mobile phones have a great potential to be incorporated into regular health care and support information delivery,[43] evidenced by earlier studies conducted in HICs and some LMICs.[44, 45] However, the contextual design of the mobile-phone interventions is a fundamental requirement for successful outcomes. Therefore, I aimed to co-design and evaluate the feasibility of a text messaging mHealth intervention for improving the treatment adherence and control of BP among patients with HTN in Nepal.

1.2 Significance and rationale of the study

As highlighted above, more than 50% of diagnosed patients with hypertension in Nepal have uncontrolled blood pressure due to not taking BP-lowering medication regularly and not following recommended lifestyle behaviour modifications.[21, 22] This suggests a need for effective and convincing interventions to improve blood pressure control in Nepal.[21] Potential interventions range from non-pharmacological interventions such as self-monitoring of blood pressure; educational activities focused on the patients or health care providers, health professional-led care (nurse, pharmacist, community health workers), organisational interventions and appointment reminders.[46, 47] With rapid technological advancements, mobile phones have become an essential part of everyday life in LMICs. Mobile phone penetration is estimated to be around 99% globally and 94% in LMICs.[41] Mobile phones have great potential to offer a simple and effective mode to deliver health care interventions to NCD patients in LMICs and other low-resource settings.[48] Through mobile phones, health care messages can be delivered effectively and can be a tool for better access, coverage and overcoming the equity gap in a limited-resource setting for chronic disease management.[48, 49]

The WHO Global Observatory for eHealth has defined mHealth or mobile health "as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices".[43] mHealth consists of mobile phones, tablets, and biosensors used to send and record messages from and to healthcare providers and patients. mHealth may offer a simple and less demanding strategy to deliver lifestyle-focused interventions and reminders to improve blood pressure control.[50, 51] Previous studies have evaluated the use of mHealth to manage smoking cessation, long-term illnesses like diabetes, HIV and reduce risk factors for CVDs.[52-54] In addition, educational interventions using mobile phone text messaging is known to be effective and has been conducted in HICs and some LMICs for managing cardiovascular diseases.[50, 55]

In LMICs, text message interventions are becoming popular due to the need for limited resources and minimal skills to operate such interventions. There is evidence for the effectiveness of mHealth interventions in improving BP control and medication adherence.[56, 57] However, most of the evidence is confined to HICs. In Nepal, very few studies are focused on interventions to improve BP control. A study conducted by Neupane et al. in the Western region of Nepal used Female Community Health Volunteers (FCHV) to deliver educational interventions and reported the intervention was effective in reducing blood pressure.[58] However, the discussed intervention targeted the general population, including normotensive, prehypertensive and hypertensive patients. In addition, FCHVs are overburdened with maternal and child health care and other infectious diseases programs in Nepal,[59] thus, the long term sustainability and feasibility of using FCHVs in hypertension management is still unclear.

Despite the high penetration rate of mobile phones in Nepal, the potential of mobile phones as a healthcare intervention is relatively under-researched. Although rural telemedicine services were piloted in 25 rural districts in Nepal,[60] mobile phone use in the health system is limited to pilot projects by the government and non-governmental organisations in Nepal.[61] The potential to use mHealth for chronic disease management, such as hypertension, has yet to be developed and evaluated.

The co-design of mHealth interventions is important for effective implementation and achieving desired outcomes.[62] The co-design process involves identifying the needs of the target users and involving other concerned stakeholders in the process of intervention-development and delivery.[63] Co-designing an mHealth intervention[62] thus requires an in-depth understanding of the contextual needs and preferences of participants[64] to achieve desired outcomes. In Nepal, differential economic, political and social factors contribute to great disparities in lifestyles, including dietary practices and understandings of disease and treatment practices.[65] With this in mind, this study employs a co-design process for contextual need identification to inform the text messaging mHealth intervention development among patients with HTN in Nepal.

In Phase I of this PhD thesis, a formative qualitative study was conducted to inform the design and contents of Phase II, namely an mHealth intervention using text messages. The qualitative study in Phase I provided an opportunity to gather in-depth insights into the problems faced by patients with hypertension and guided the intervention development process. There is evidence of the positive impacts of an intervention if its design is guided by the behavioural framework.[66] Therefore, the COM-B (Capability, Opportunity, Motivation and Behaviour) model of the behavioural change wheel (BCW)[67] (discussed in details Chapter 2- Section II and Chapter 3) was used in the formative study to systematically categorise the barriers and facilitators and guide the intervention development. The perspectives of key stakeholders on using the mHealth for hypertension management were explored as part of the formative qualitative study informed by Technology Acceptance Model (TAM model).[68](Presented in details in Chapter 2- Section II and Chapter 4)

In Phase II, the text messaging intervention (TEXT4BP) was co-designed and evaluated as informed by the formative studies and literature. To our knowledge, this is the first study that used a text messaging mHealth intervention targeted to patients with HTN for the management of uncontrolled BP in Nepal. The evidence generated from this study can inform future initiatives to achieve effective BP control and to widen the horizon of HTN management in Nepal.

1.3 Aim and objectives of the study

The main aim of this PhD thesis was to develop and evaluate the feasibility of a text messaging mHealth intervention for the treatment and control of blood pressure among patients with hypertension in Nepal.

Specific objectives of the study

Phase I: Qualitative study

1. To explore the perceived barriers and facilitators of treatment and control of high blood pressure among patients with hypertension in Nepal.
2. To explore the perspectives of patients and providers on the acceptability of a text messaging mHealth intervention in improving blood pressure control among patients with hypertension in Nepal.
3. To inform the design of a text messaging mHealth intervention in Phase II to improve the treatment and control of high blood pressure in patients with hypertension in Nepal.

Phase II: Pilot Randomised Controlled Trial

1. To co-design a text messaging mHealth (TEXT4BP) intervention to improve treatment and control of high blood pressure among patients with hypertension in Nepal.
2. To evaluate the feasibility, effectiveness, and acceptability of a text messaging mHealth (TEXT4BP) intervention to improve treatment and control of high blood pressure among patients with hypertension in Nepal.

1.4 Thesis structure

Introduce the research topic and objectives of this thesis.

Chapter 1: Introduction
This chapter provides a brief background of the burden of hypertension, issues of treatment and control of hypertension and highlights the rationale of the study followed by aims and objectives of this thesis.

What is already known on the topic and what are the gaps that can be filled by this thesis?

Chapter 2: Literature review
Section I
- Explores the literature on the burden of hypertension, challenges of the treatment and control of BP among patients with hypertension globally, and with a focus on Nepal.
-Highlights the mHealth intervention to improve hypertension management
Section II
- Overview of different health behavioural models
- Critically discusses the COM-B Model and relevance of its use in the study

Phase I: Formative study

Presents the need of the study population and their perspective and preference on using mHealth for hypertension management.

Chapter 3: Barriers and facilitators for treatment and control of raised BP: A Qualitative study
- This chapter provides the overview of research design, study setting, sample, methods of data collections and analysis
- Reports and discusses the main themes generated from the study on the barriers and facilitators of the control of blood pressure using the COM-B model **[*Published - BMC Public Health*]**

Chapter 4: Acceptability of the mHealth intervention: A Qualitative study
-This chapter provides the overview of the research design, study setting, sample, methods of data collections and analysis.
– Reports and discuss key themes generated from the study on the acceptability of the text messaging mHealth intervention using TAM model for the management of HTN in the study settings.

Phase II: Development and evaluation plan of the mHealth (TEXT4BP) intervention

Chapter 5: Methods of TEXT4BP intervention
-This chapter discusses the co-design process of the TEXT4BP intervention development
-Discuss the methods, study settings, study population, randomization, and data analysis plan of the TEXT4BP study.
[Published - BMJ Open]

Chapter 6: TEXT4BP RCT findings
-This chapter presents the implementation methods of TEXT4BP study, including recruitment, randomisation, data collection and analysis process.
– Reports and discuss the findings of the TEXT4BP intervention, including its strengths and limitations. ***[Under review - Global Heart]***

Discussion of major findings of the thesis, its implications and conclusion

Chapter 7: Discussion and Conclusions
- This chapter discusses the main findings with overall strengths and limitations of both Phase I and II studies and highlights key implications of this thesis on future research, practice and policy in Nepal, followed by overall brief conclusions of this thesis.

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Chapter 2: Literature Review

This literature review consists of two sections (I and II). Section I focuses on the burden of hypertension, its risk factors, and complications with reference to Nepal. In addition, it focuses on the different measures, barriers, and facilitators for treatment and control of hypertension. I also highlight the global, regional, and country level mHealth initiatives for managing blood pressure among patients with hypertension. The final part reviews the programs, policies, and initiatives and gaps for hypertension management in Nepal. I have employed a theory-based intervention for my research. Therefore, section II provides an overview of the different behavioural change theories, models, and frameworks. This section critically discusses the COM-B (Capability, Opportunity, and Motivation- Behaviour) and TAM (Technology Acceptance Model) Model and their relevance to this study.

Methodology

The main objective of the literature review is to critically discuss the epidemiology of hypertension, its treatment and control with a particular focus on mHealth initiatives. I have also explored different behavioural theories/models with a specific focus on the COM-B and TAM Models. I primarily searched the PubMed/Medline, Embase, CHINAL, and Google Scholar database. In addition, Nepal journals online (Nepjol) were also searched to identify different articles published in local journals. A related publication from the Ministry of Health and Population (MoHP), the Department of Health Service of Nepal (DoHS), StepWise Surveillance to NCDs (STEPS Surveys) Nepal, Nepal Telecom reports and the World Health Organization (WHO) bulletin were also reviewed as needed. Additionally, when needed, we searched reference lists of included publications. The keywords used for the literature search are provided in Appendix 1. There was no limitation in the date with a focus to cover the recent literature until July 2021. However, I have referred to the empirical studies, especially the theoretical model, to determine the evolution trends of different theories, models, and frameworks.

Section I

1. Burden of Hypertension

1.1 Global Burden

Non-communicable Diseases (NCDs) are the leading cause of global mortality and morbidity.[1] The global burden of NCDs is escalating as evidenced by its increased prevalence by 11.6% within less than a decade (from 2010 to 2019).[2] NCDs were responsible for 71% (41million) of all preventable deaths globally in 2016,[1] which was predicted to be 75.2% by 2030.[3]

Table 2. 1: The percentage change of age-standardized rates of global prevalence, incidence, deaths, and DALYs of NCDs between 2010 to 2019

NCDs	Prevalence	Incidence	Deaths	DALYs
Both sexes	11·6% (11·5 -11·6)	12·8% (12·4 -13·2)	18·5% (13·1 -23·7)	13·6% (10·1 -16·9)
Male	11·7% (11·6 -11·8)	12·6% (12·2-13·1)	17·3% (9·8 -24·4)	12·5% (7·4 -17·5)
Female	11·4% (11·4 -11·5)	12·9% (12·5 -13·4)	19·8% (13·3 -26·7)	14·7% (10·9 -18·6)

Source: Institute Health Metrics and Evaluation, Global health metrics, 2019[4]

Importantly, more than two-thirds (85%) of the NCDs deaths were confined to Low and Middle-Income Countries (LMICs).[1] In addition, the total Disability Adjusted Life Years (DALYs) due to

NCDs accounts for two-thirds (63.8%) of total DALYs in 2019.[2] The mortality and DALYs due to NCDs is increased by 18.5% and 13.6% respectively from 2010 to 2019 as depicted in table 2.1

The four major contributors to NCD mortality that caused 80 per cent of the NCD deaths reported by the World Health Organisation (WHO) are cardiovascular disease (CVD), cancer, chronic obstructive pulmonary disease (COPD), and diabetes[1] as depicted in figure 2.1.[5] Among these NCDs, CVD was one of the leading causes of premature death (38%) and disability.[6] CVD was responsible for 18.6 million deaths in 2019,[4] which was 32% of the global deaths in that year. CVD also disproportionately affects LMICs, where two-thirds of CVD deaths took place.[6]

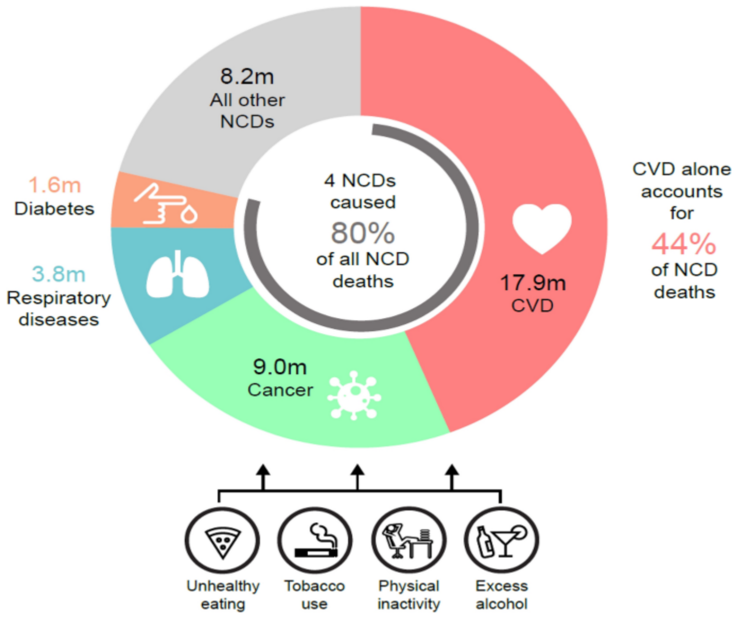

Figure 2.1: Global annual deaths by key NCDs

Source: Kelly H. Zou et al, 2021[5]

Among CVDs, ischaemic heart disease (IHD) and stroke were the leading causes of death, accounts for 85% of total CVDs death.[6] In addition to that, IHD and stroke were the first and second causes of DALYs of 50 years and above based on the Global Burden of Disease Study 2019.[2] The major modifiable risk factors for NCDs, including CVDs includes tobacco use, unhealthy diet, obesity, physical inactivity and alcohol consumption.[6] Importantly, hypertension, obesity, hyperglycaemia and hyperlipidaemia are the major metabolic risk factors.[1]

Hypertension (HTN), a significant risk factor for CVD, especially IHD,[7] is escalating globally, mainly (two-thirds) affecting LMICs including South and East Asia and Sub Saharan Africa.[8, 9] Globally, an estimated 1.39 billion people had hypertension in 2010.[10] This number is predicted to reach 1.56 billion in 2025.[11] One in every four men and one in every five women had hypertension in 2015 based on WHO factsheet.[12] A study of worldwide prevalence of blood pressure reported that the global age-standardised prevalence of hypertension was 24.1% (2·4–27.1) in men and 20·1% (17·8–22·5) in women in 2015.[13] HTN is responsible for 45% of deaths due to heart disease and 51% death due to stroke,[14] which accounts for an estimated 10.8 million deaths and 9.3% of the global DALYs lost in 2019.[15] Similarly, high Systolic Blood Pressure (SBP) was ranked as the top cause (15%) of DALY in both sexes in 2019.[4] (Figure 2.2)

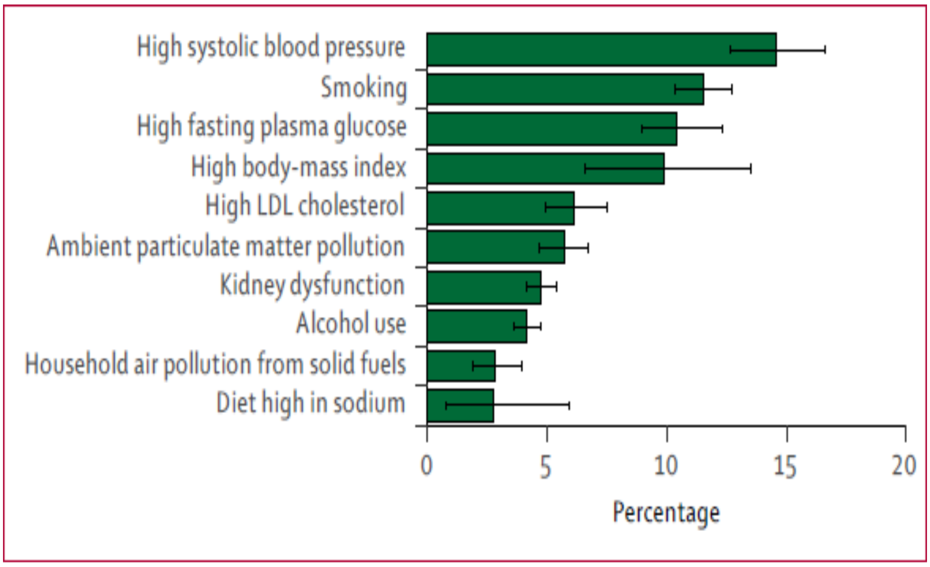

Figure 2.2: Percentage of DALYs attributable to top risk factors for both sexes combined, 2019

Source: Institute Health Metrics and Evaluation GBD data, 2019 [4]

The mortality and DALYs attributed to high SBP increased by 18.1% and 14.9% respectively in both sexes between 2010 and 2019. A higher increase (18.2%) was seen among females, as depicted in table 2.2.

Table 2.2: The percentage change of age-standardized rates of global deaths, YLLs, YLDs and DALYs due to high systolic blood pressure for both sexes combined females and males between 2010 and 2019

High SBP	Deaths	YLLs	YLDs	DALYs
Both sexes	18·1% (11·9 - 24·3)	13·7% (7·1 -20·1)	28·1% (25·1 31·2)	14·9% (8·8 -20·9)
Male	18·0% (10·0 - 25·8)	13·2% (5·0 - 21·1)	27·6% (24·3- 30·7)	14·2% (6·4 - 21·6)
Female	18·2% (10·6 - 26·7)	14·4% (5·7- 23·5)	28·5% (23·6 - 33·2)	15·8% (7·8 - 24·2)

YLL: year of life lost, YLD: Year of life lived with disability; Source: Institute Health Metrics and Evaluation, Global health metrics, 2019, [4]

Notably, the burden of HTN has shifted from high-income countries (HICs) to LMICs in South Asia, Sub-Saharan Africa, Central and Eastern Europe.[16] Similarly, in 2019, the individual level population-based pooled data of 44 countries reported the prevalence of HTN as 17.5 % in LMICs.[17] In LMICs**,** urbanization, globalization, ageing of the population, changes in lifestyle and dietary habits, and social stress are causing an escalation of different risk factors of hypertension.[9] The trends of high SBP in different World Bank regions from 1990 to 2019 is depicted in figure 2.3.[9] It shows the increasing trends of HTN in Sub Saharan Africa, including South and East Asia and the Pacific region, where 23% of high BP adults lived in South Asia and 21% in East Asia.[13]

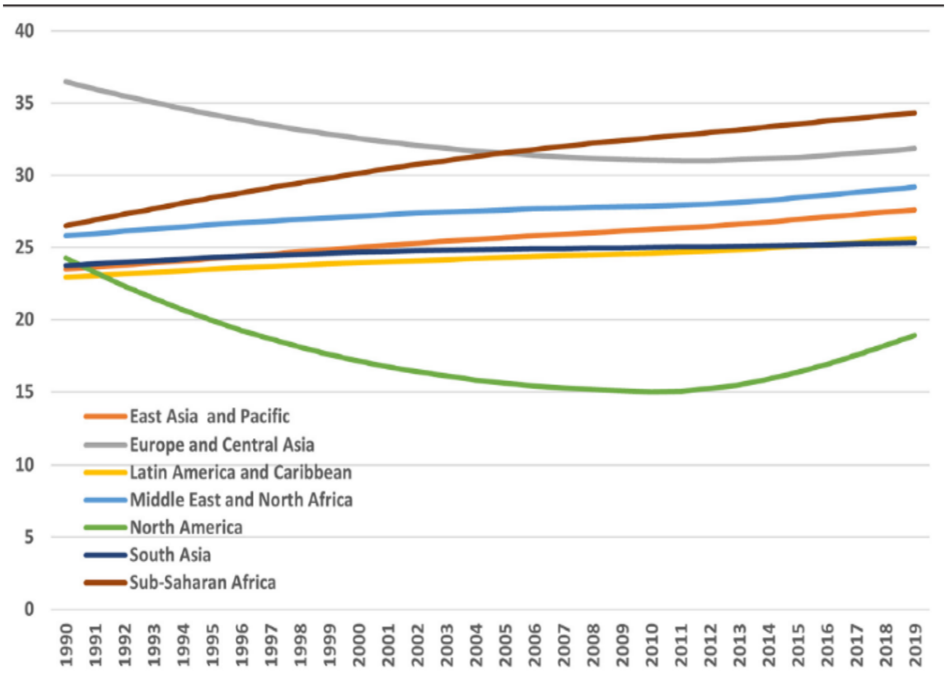

Figure 2.3: Trends in age-standardized summary exposure value of high systolic blood pressure, for the World Bank regions from 1990 to 2019

Source: Schutte AE et.al[9]

1.2 Regional prevalence of hypertension

Like other LMICs, South Asia has a high prevalence of HTN.[13] The May Measurement Month (a global initiative for BP measurement) campaign reported that among the total number of participants screened in South Asia in 2019 (1,508,130), 29.3% had HTN.[18] A similar trend was reported in a meta-analysis of studies from the South Asian Association for Regional Cooperation (SAARC) countries (Nepal, India, Bangladesh, Bhutan, Sri Lanka, Pakistan and Afghanistan) in 2014 that showed a 27% prevalence of HTN in this region and higher prevalence was reported in urban areas than to rural.[19] Similarly, the highest prevalence was reported in Nepal (33.8%)[20] and least in Bangladesh (17.9%)[19] among the SAARC countries. The highest prevalence in Nepal might be due to changes in behavioural risk factors and population aging, which is discussed in detail in the following sections. Similarly, the WHO report showed the highest prevalence of hypertension in Myanmar and Indonesia among South-East Asian Region.[21, 22] This variation might be due to differential age, methodology used, and a number of BP measurements in these studies.

1.3 Hypertension in Nepal

Nepal is a landlocked South Asian country with an estimated population of 29 million in 2021.[23] Nepal is one of the least developed countries with a human development index of 0.602 in 2020, where one quarter (25%) of people live below the poverty line (US $ 1.9 person/per day).[24] The country is primarily mountainous terrain which is divided into three geographical regions, namely Mountains (Himal), Hills (Pahad) and Plains (Terai). Administratively, the country was divided into five development regions (Eastern, Central, Western, Mid-Western and Far Western) and 75 districts until 2015. After the adoption of the new Constitution of Nepal on 20 September 2015,[25] the country was administratively divided into seven provinces. These provinces include Bagmati (P 3), Gandaki (P 4), Lumbini (P 5), Karnali (P 6), and Sudurpachim (P 7). Provinces 1 and 2 have not been named at the time of writing this thesis (July 2021). (Fig 2.4 and 2.5)

Similar to other LMICs, in Nepal, the burden of NCDs is increasing along with the existing burden of communicable and emerging diseases.[28] Two-third (66%) of total deaths and 59% premature deaths and DALYs in Nepal are attributed to NCDs.[29]

Figure 2. 4: Nepal (in red) in Asia

Source: SMART- Server Medical Art [26]

Figure 2. 5: Map of Nepal with seven provinces

Source: Nations Online Project with permission [27]

Among NCDs, IHD is the leading cause of death, accounting for 16.4% of deaths. The change in rates between 1990 and 2017 is depicted in figure 2.6. The increasing burden of NCDs in Nepal might be due to the changes in age structure, lifestyle including sedentary habits, food habits and increased use of tobacco and alcohol, which are discussed in detail in following section.[29]

Rate per 100,000	**1990 Risk**			**2017 Risk**	**Rate per 1,00,00**	**% Change**
143.05	Lower Respiratory infections	1	1	Ischemic Heart Disease	100.45	60.17
137.17	Diarrheal diseases	2	2	COPD	60.15	14.57
67.72	Ischemic Heart Disease	3	3	Diarrheal diseases	36.12	-73.67
61.24	Neonatal encephalopathy	4	4	Lower Respiratory infections	31.10	-78.26
52.49	COPD	5	5	Intracerebral haemorrhage	23.39	-3.55
51.49	Drug susceptible tuberculosis	6	6	Ischemic stroke	19.53	20.25
44.50	Tetanus	7	7	Asthma	15.54	-46.62
44.45	Measles	8	8	Drug susceptible tuberculosis	13.99	-72.78
30.42	Other Neonatal Disorders	9	9	Alzheimer's Disease	13.98	>100
29.11	Asthma	10	10	Neonatal encephalopathy	12.70	-79.27
24.25	Intracerebral haemorrhage	12	17	Other Neonatal Disorders	7.77	-74.46
16.24	Ischemic stroke	15	21	Tetanus	1.06	-97.61
6.74	Alzheimer's Disease	29	19	Measles	0.44	-99.00

Communicable diseases   *non-Communicable diseases*

Figure 2.6: Top 10 causes of deaths in Nepal by all age per 100,000 population for both sexes and percentage change from 1990 to 2017

Source: Adapted from burden of disease Nepal, 2017[29]

High SBP was the leading risk factor for mortality in Nepal which accounts for 13.5% of total deaths and DALYs attributed due to HTN was 6.7% based on the global burden of disease study in Nepal 2017.[29] In Nepal, the prevalence of HTN increased over time based on the national representative STEPS survey findings of 2003- 2019,[30-33] as depicted in figure 2.7. In 2019, the STEPS Survey was conducted among 5593 respondents of age 15-69 years. STEPS found that the overall prevalence of hypertension was 24.5% (22.4-26.7), where the prevalence was higher among males (29.8%) than females (19.7%), including those on medication.[33]

Though HTN is slightly lower (24.5%) in 2019 from the previous STEPS survey findings (25.7%) in 2013,[34] the burden of HTN is still high in Nepal. A higher prevalence is reported among males than females throughout the 16 years. The study findings must be interpreted with its limitations. For example, the prevalence of HTN in 2003 was confined to a sample size of 2030 individuals aged between 25-64 years of Kathmandu Municipality only. [30] However, in 2008, the STEPS survey was conducted among 4328 individuals of ages 15-64 years.[31] Similarly, in 2013, STEPS was conducted among the 4130 individuals of aged of 15-69 years[32] and 5593 among 15-69 years in 2019.[33] Nevertheless, it is the only representative study of the country conducted with robust methods.

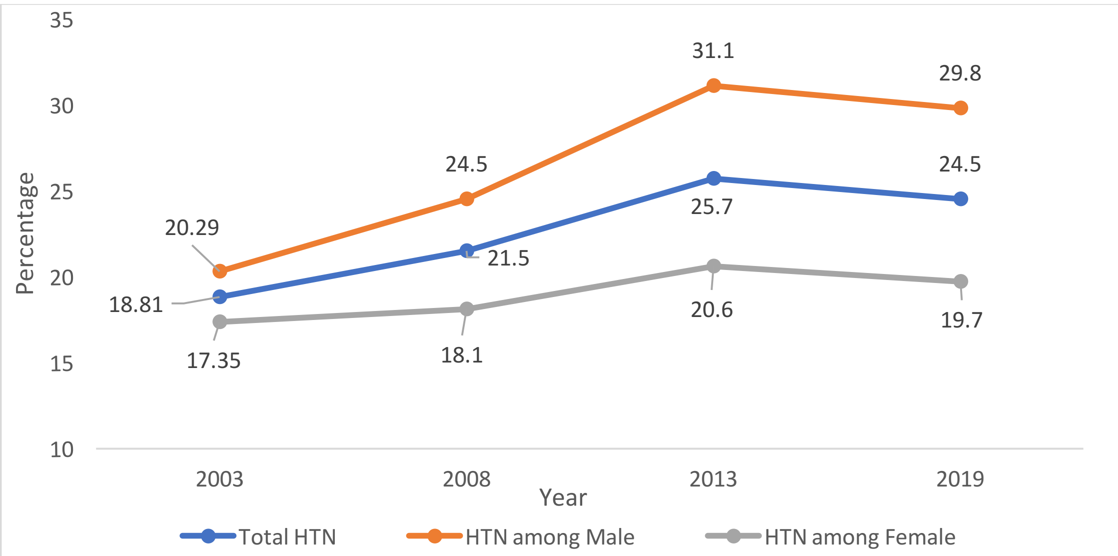

Figure 2.7: Trends of National Prevalence of Hypertension over 16-year period based on STEPS survey findings

Additionally, recently published systematic reviews in 2021 reported the pooled prevalence of hypertension (2000-2020) as 28.5% among 40 studies (n=13393),[35] and another reported 32% among the 32 studies of the 84,006 participants.[36] However, the difference in overall prevalence might be due to their differential inclusion criteria. The former review[35] included participants aged 18 years, and excluded hospitalised participants. Later reviews included participants aged above 15 years and excluded studies with smaller (fewer than 400 participants) sample sizes.[36] Similarly, a study by Adhikari et al. reported 27% of HTN among 15, 561 volunteers aged 18 years above who participated in the May Measurement Month global initiative (MMM) in 2018[37], which was 24.4% among 5972 participants aged ≥18years participated in 2017 MMM.[38]

1.3.1 Regional Variation

Most studies from Nepal presented findings based on the developmental regions (Eastern, Central, Western, Mid-Western, Far Western), though country is divided into provinces after promulgation of a new constitution in 2015. I have discussed regional variation of HTN prevalence based on the development region. Studies conducted in the last two decades (2000-2021) in Nepal show the prevalence of HTN ranges from 18% to 44.9% in different developmental regions and different subsets of the population over time (Table 2.3).[20, 34, 37-56] The regional studies of the prevalence of hypertension are primarily reported from the Central, Eastern Development Region and some from the Western, Mid-Western and Far-Western Development Region are as follows:

Central Development Region: Studies conducted in the Central Development Region using the same diagnostic guidelines for hypertension (>140/90 mm of Hg or on medicine) showed the prevalence of HTN between 19.7%[54] to 44.9%[39, 40, 44, 51-53] among those aged 18 years and above. These cross-sectional studies were conducted from 2005 to 2020. The validity of the comparison of these studies is limited as there is methodological variation among the studies. This differentiation includes different inclusion criteria, different age categories, rural-urban variation, and different ethnic groups that might lead to prevalence variability.

Eastern Development Region: Studies from the Eastern Development Region of Nepal also reported a prevalence of HTN from 22.1%[55] to 34%.[20, 41] These studies also had signficiant divergences between groups of participants. The lowest prevalence reported by Vaidya et.al (22.1%) included only males over 35 years (n=1000) in 2005. In contrast, a 2011 study by Sharma et al. (34%) included the 14,425 participants of age 18 years and above.[53] Differences in age, sex, and study-time might have resulted in the varied findings.

Western and Mid -Western regions: Similarly, a cross-sectional study conducted in the Western part of Nepal reported the age-sex standardized prevalence of hypertension as 28% (n=2815) among 25 to 65 years of age, with the higher rate among males 38% (compared to 23% in females) in 2013-2014.[56] Study by Khanal et al. in the Mid-Western region among 1159 individuals of more than and equal to 30 years age has reported the prevalence of 38.9%, with higher prevalence in males (48%, n=161) Vs 35% (n=290) among females in 2016.[43]

Though these studies employed similar diagnostic criteria, there are other methodological variations based on the study's inclusion criteria. The variation in ethnicity and socio-cultural influence in lifestyles across the different regions, as well as age and gender distribution included in these different studies conducted in different periods might have resulted in variation in the prevalence of HTN. The inclusion of younger age brackets may have resulted in a lower overall prevalence of HTN than older age brackets. Essentially, and despite some variability in methodologies, all of the studies reported a gradual rise of the prevalence of HTN in different regions and different subsets of the population of Nepal.

Table 2.3: Trends in Prevalence of hypertension in different Studies published from 2000 to 2021 in Nepal

Year/authors	Place	Rural/Urban	Age	Gender	Sample size	Diagnostic Criteria	Prevalence of HTN (%)		
							Overall	Male	Female
2004- 2005/ Vaidya et al	Dharan, Eastern Part of Nepal,	Urban	≥35 years	Male	1,000	WHO classification >140/90 or medicine	-	22.7%	-
2005/Sharma D et al	Kathmandu valley	Suburban area	≥18 years	Both	1114	JNC VII Criteria >140/90 or medicine	19.7%	22.2%	17.3%
2006/ Vaidya et al	Bhadrabas, Central Nepal	Urban	≥21 years	Both	1218	JNC VII Criteria (≥140/ ≥90 or medicine) And >160/95 mmHg	33.8% 18%	38.3% 20.3%	30.8% 17.1%
2006/Shrestha UK et.al	Not specified	Urban	≥40 years	Both	1012	JNC VII Criteria >140/90 or medicine	22.7%	22.2%	23.3%
2006–08/Rumana J Khan et al	Sarlahi, Central Nepal	Rural	≥16 years	Female	15,934	JNC VII Criteria	- -	- -	3.3% 14.4%
2009/Manandhar K et.al	Banepa Municipality, Central Nepal	Urban	≥50 years	Both	405	JNC VII Criteria (≥140/ ≥90 or medicine)	44.9 %	47.75%	42.73%
2010/ Sharma SK	Eastern part of Nepal	Semi Urban	≥20	Both	8,398	JNC VII Criteria (≥140/ ≥90 or medicine)	36%	42%	32%
2011/ Chataut J,et.al	Central Nepal	Rural	≥18 years	Both	527	JNC VII Criteria >140/90 or medicine	22.4%	32.7%	15.3%
2011/ Mehata KD		Rural and urban	≥30	Both	1,935	JNC VII Criteria (≥140/ ≥90 or medicine)	31.7%	NR	NR
2011/Sharma et al	Eastern part of Nepal	Urban	≥20 years	Both	14,425	JNC VII Criteria >140/90 or medicine	34%	40.7%	30.0%
2013/ Koju R et al	Nationwide Sample Survey	Both	18-65 years	Both	2,100	(>140/90 mmHg on ≥2 readings)	15.1%.	21.7%	10.5%
2013/Aryal KK et.al	Nationwide sample Survey	Urban/Rural	15 - 69 years	Both	4,200	JNC VII Criteria >140/90 or medicine	26%	31.1%	20.6%
2014/Adhikari K	Mountains, Hills and Terai of Central Development Region	Urban/Rural	15-64	Both	1240	JNC VII Criteria >140/90 or medicine	22.3%	24.8%	19.3%
2015/ Dungana RR et al	Central Development	Semi-urban	18 - 70 years	Both	587	JNC VII Criteria >140/90 or medicine	32.5%	38.4%	28.4%
2017/ Khanal et al	Surkhet, Mid-Western	Semi urban	≥ 30years	Both	1159	JNC VII Criteria >140/90 or medicine	38.9%	48%	35%
2017/ Maharjan B et al	Kritipur municipality	Urban	20-59 years	Both	580	JNC VII Criteria >140/90 or medicine	37.0%	41.6%	32.2%
2017/ Karmacharya et al	Dhulikhel central Nepal	Urban	≥18 years		1073	JNC VII Criteria (≥140/ ≥90 or medicine)	27..8%	37.4%	20.9%
2017/Neupane D et.al	Pokhara, Western region	Semi Urban	25-65 years	Both	2,815	JNC VII Criteria >140/90 or medicine	28%	38%	23%
2018/ Mehta et al	DOHS data		15-69 years	Both	13 598	WHO recommended category	18%	22%	15%

2. Risk factors for hypertension in Nepal

Risk factors for hypertension are mainly categorized as modifiable and non-modifiable. Older age, gender (male), and family history are non-modifiable risk factors for hypertension. Some studies also reported racial and ethnic differences as risk factors for hypertension.[57] Obesity, physical inactivity, unhealthy dietary (high salt/fat) habits, high cholesterol, smoking, alcohol consumption, and a stressful lifestyle are modifiable risk factors for hypertension.[7, 58-61] (Figure 2. 8) On the one hand, population age structure is changing in Nepal as life expectancy has increased by 14 years for females (from 59 to 73 years) and 11 years for males (58 to 69yrs) from 1990 to 2017.[27] This might be responsible for the high cadre of older people leading to an increased burden of hypertension in Nepal. On the other hand, globalisation and the adoption of urban lifestyles including to sedentary behaviours and consumption of junk and proceed foods, tobacco use and higher consumption of alcohol among the Nepalese population is increasing, fostering the rise of hypertension in Nepal.[27]

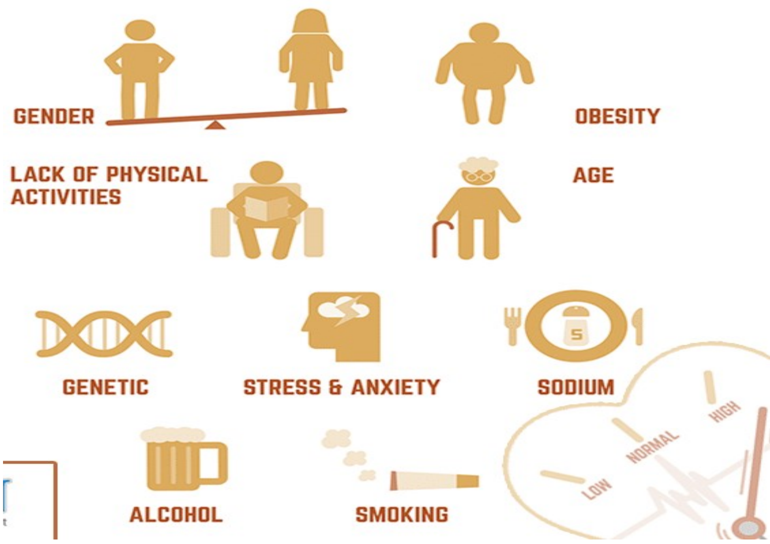

Figure 2.8: Risk factors for the development of hypertension

Source: Pacific Open Learning Health Net, 2018 (62)

In Nepal, no robust studies (cohort/case-control studies) have been conducted to establish a causal relationship between risk factors and the increasing burden of hypertension. However, the STEPS survey findings and other small-scale studies are reviewed to assess the modifiable risk factors of hypertension in Nepal. The Nepal Health Research Council conducts STEPS survey in collaboration with the Ministry of Health and WHO every five years. It is one of the country's best geographically representative national surveys to determine different risk factors of NCDs. Trends of NCD risk factors based on the STEPS Survey findings over 11-years are depicted in Fig 2.9. It shows the obesity, smoking and intake of fewer fruits and vegetables are in increasing trends.[31-34, 63]

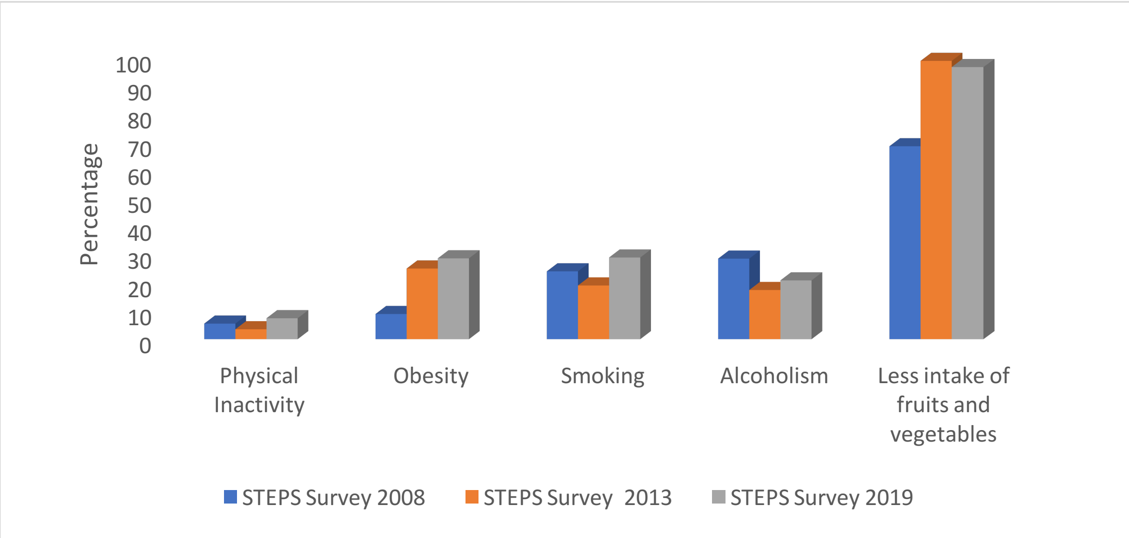

Figure 2.9: Trends of NCDs Risk Factors from 2008-2019 in Nepal

Physical inactivity is defined as less than 150 minutes of moderate-intensity activity per week, or equivalent.[33] Physical inactivity is a significant identified risk factor for cardiovascular diseases; especially, it increases 30-50 per cent of the risk of having HTN.[61, 64] In addition, mortality risk is also higher among the less physically active people, as evidenced by the study among 10,665 adults with hypertension by Brown RE and Colleagues.[65] This study reported after 8.6 ± 4.8 years of follow up, a higher risk of mortality among physically less-active people than physically active adults with hypertension compared to the inactive people irrespective of their treatment and BP control status as depicted in figure 2.10.[65]

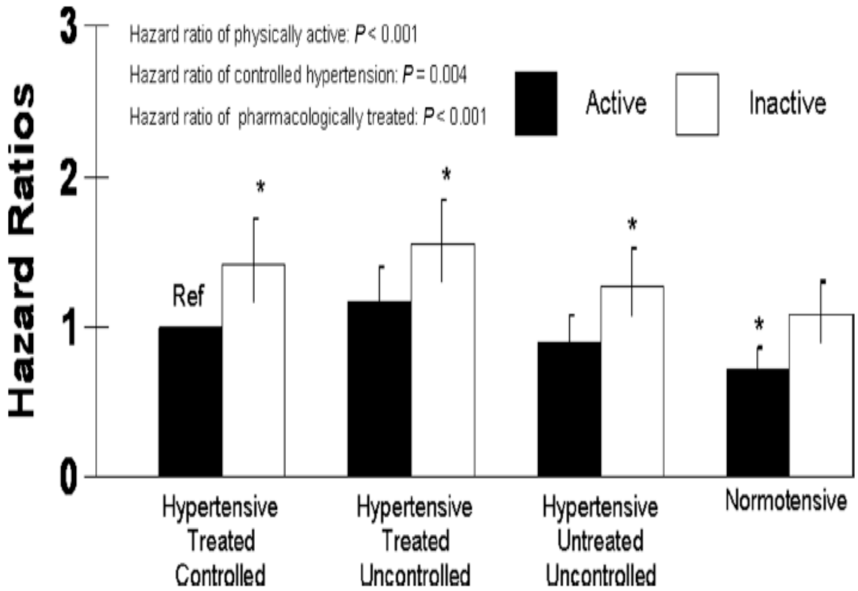

Figure 2.10: Mortality risk by physical activity level, antihypertensive treatment status, and blood-pressure control status

Source: Brown RE e.t al, 2013[65]

In Nepal, the STEPS survey 2019 reported 7.4% (95% CI:5.7–10.1) of people did not meet the WHO recommendation for physical activity for health according to MET-minutes per week.[33,63] Low physical activity was observed more among males than females and people residing in the Terai Region compared to the mountain area in Nepal.[33] Physical inactivity is increased from STEPS survey findings of 2008 and 2013, as shown in figure 2.9.[34,31] The different levels of physical inactivity in different provinces based on the STEPS survey 2019 findings,[33] reported Province 3 and Gandaki province had the highest physical inactivity percentage. This may be because these are the most urban provinces in Nepal. There are geographical (lowland, hill and mountains) variations in different regions, which might lead to differential lifestyles and access to transportation influencing physical activity patterns in Nepal.

Obesity: Obesity is an important risk factor for the development of hypertension.[66] With increasing Body Mass Index (BMI), there is evidence of increased risk of hypertension among children[67] and young, middle and older age groups.[59] Globally, there were more than 650 million obese people in 2016, triple the number recorded in 1975, and this number is growing.[68] In Nepal, urbanization was 20% in 2019, which was increased by 4% in the last ten years.[69] Urbanization leads to changes in lifestyle, including sedentary habits and consumption of junk food with high fat, salt, and sugary products. Urbanization is correlated with rising rates of obesity in Nepal[70] as evidenced by the findings of the STEPS survey conducted by NHRC over 16 years. In addition, figure 2.11 show that obesity and overweight is highest among the 40-54 yrs of age group (33.2%), among the wealthiest wealth quintile (36.7%) and people residing in the metropolitan area (33.1%) based on the STEPS survey report 2019.[33]

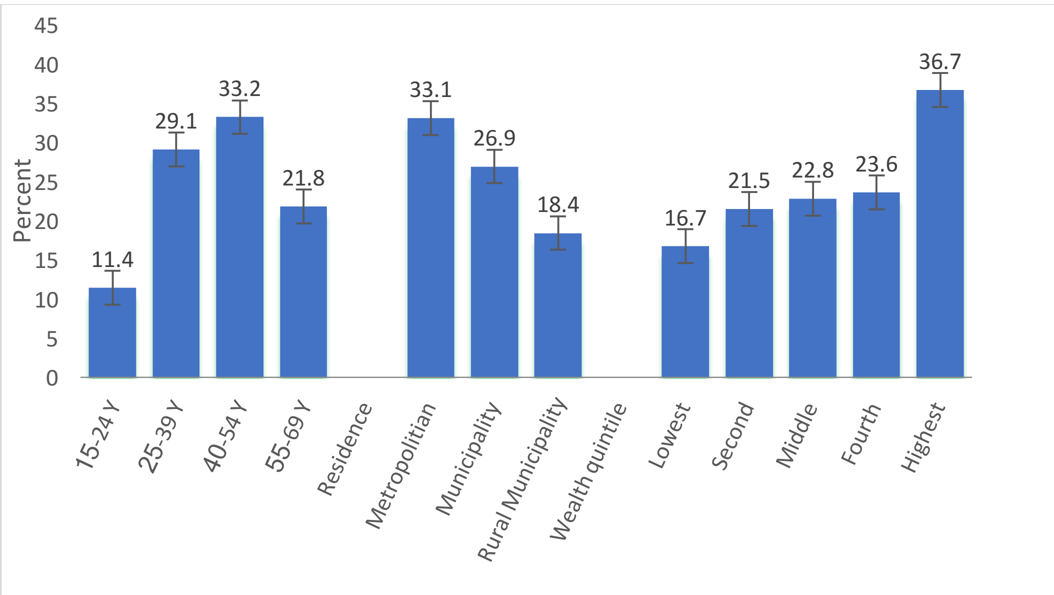

Figure 2.11: Prevalence of overweight and obesity based on age, residence, and wealth level among 15-69 years adults in Nepal

Source: STEPS Survey Nepal, 2019[33]

This indicates that obesity is one of the risk factors responsible for the increasing burden of hypertension in Nepal. Lifestyle modification and changes in dietary practices and physical activity should be encouraged to reduce the burden of obesity and overweight to prevent non-communicable diseases, especially hypertension.

Dietary factors: There are around 27 dietary factors reported as either protective or adverse risk factors for the development of hypertension.[71] Importantly, sodium, potassium, fruits and vegetables and alcohol intake are directly related to hypertension. In the interaction between cardiovascular disease and alcohol, the harmful effect of alcohol in the form of binge or cumulative lifetime consumption is evident. However, determining measuring the strength of this correlation is complicated by the association of heavy drinking with other HTN risk factors, including a sedentary lifestyle, smoking, and dietary habits, including salty food.[72]

There is ample evidence of the links between increased blood pressure and a high intake of salt. Sodium retention leads to expansion of extracellular volume, resulting in higher cardiac output. This leads to increase peripheral resistance by peripheral tissue vasculature through activating autoregulatory vasoconstriction[73] (Fig 2.12).Therefore, reducing salt intake by 40-50 mmol/day can reduce high blood pressure among hypertensive patients.[73] There is evidence of reduction of stroke and IHD risk by 10% with a reduction of 3 g/d salt intake and with a 6 g/d reduction of salt, and these effects are doubled and tripled with a 9 g/d reduction.[74] High salt intake is a major concern in Nepali society. High salt and fat intake is associated with festive seasons and traditional foods. STEPS survey 2019 conducted by NHRC (n= 5593, 15-69 years) reported nearly 9.2% added salt either always or often while cooking or preparing food at home.[33] Some participants (19.5 %) also reported that they always or often consumed processed food containing high amounts of salt.[33]

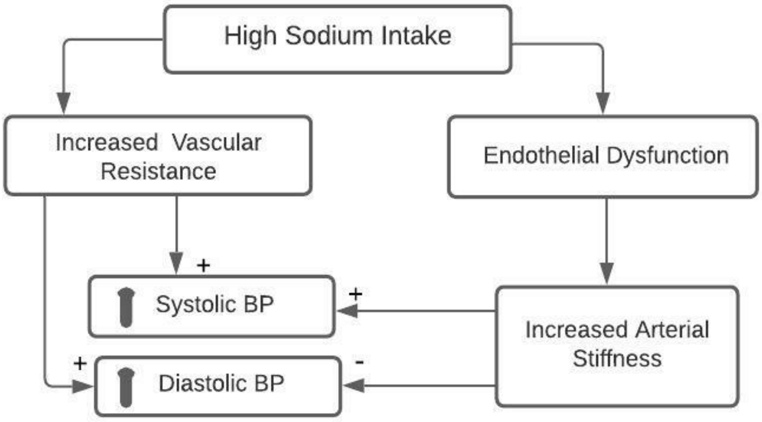

Figure 2.12: Mechanism of blood pressure increase by salt intake

Source: Adapted from Grillo A et.al, 2019[75]

The estimated salt intake in all age groups in Nepal is higher (fig 2.13) than the recommended salt intake of less than 5g/day for the control of the blood pressure based on the findings of STEPS survey report 2019 of Nepal.[33]

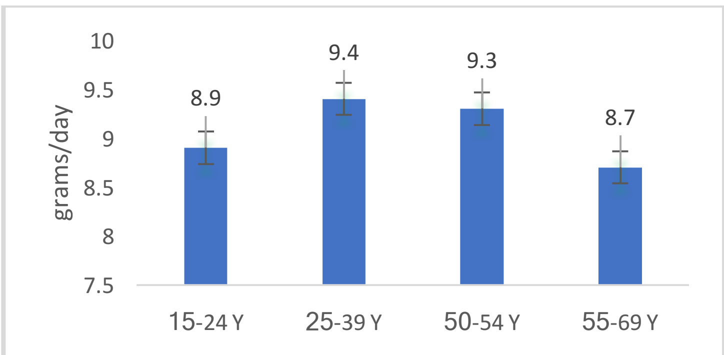

Figure 2.13: Estimated average salt intake by age groups among 15 to 69 years population

Source: STEPS Survey Nepal, 2019[33]

However, in these studies, the measurement of salt intake is self-reported, not based on the urinary excretion of sodium chloride. Therefore, biochemical studies are warranted to confirm the findings more accurately. In this context, Neupane and colleagues attempted to conduct a salt intake study with 24 hr urine measurement campaign of the 451 participants in the western part of Nepal. This study reported that 98% were consuming more than the WHO recommendation for salt intake (<5g/p/d) and found a significant association of SBP with high salt intake.[76]

Figure 2.14: Commonly used processed food high in salt in Nepal

Source: STEPS Survey Nepal, 2019[33]

Fast-food culture is flourishing in Nepal, promoting unhealthy dietary habits. Widely consumed canned and processed foods contain high amounts of added salt. Figure 2.14 shows the most used snacks/foods in Nepal that have high salt content. So, there should be culturally sound intervention to reduce salt intake at the population level, especially targeting hypertension.

In Nepal, a study by Vaidhya et al. reported around 90% of people did not consume the recommended amount of fruit and vegetables (<5 servings of fruit and vegetable/day) in 2014,[77] which is an essential cardiometabolic risk factor. A similar finding (90%) was reported in a study from the Western development region of Nepal by Neupane D et al. in 2017.[56] Further, the NCD risk factors survey 2019 reported almost all of the participants (96.7%) consumed below the recommended intake for fruit and vegetables.[33] This signifies a high burden of dietary risk factors of HTN in Nepal.

Additionally, the harmful use of alcohol is another concern in Nepal. A study by Neupane D et al. in the Western part of Nepal reported that 12% of the population consume alcohol to a harmful degree (women >8 standard drink/week and men >15 standard drink/week).[56] Moreover, a study from the Midwestern region of the country by Khanal et al.; reported that 56.5% of alcohol consumption among hypertensive patients at levels associated with hypertension.[43] Similarly, the STEPS survey 2019 reported 17.4% of current alcohol consumption among study 5593 among 15-69 years.[33] Fig 2.15 shows the higher prevalence of alcohol consumption in all age groups and increases with increasing age.

The variation of alcohol intake might be based on the age groups included in the study and ethnicity variation. Some ethnic groups used alcohol as a culturally approved celebrated food in their feast and festival in Nepal.

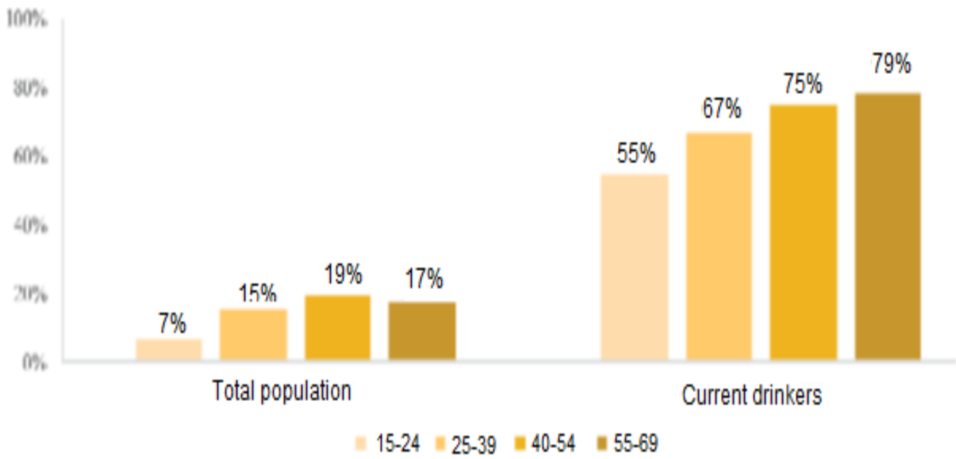

Figure 2.15: Consumption of alcohol by age groups in Nepal

Source: STEPS Survey Nepal, 2019[33]

Smoking: Cigarette smoking increases the risk of hypertension through sympathetic stimulation of the nervous system.[60] Tobacco smoking encourages inflammation, stimulates the central nervous system, sympathetic activity leading to metabolic alterations, a significant risk factor for hypertension is presented in figure 2.16.[78]

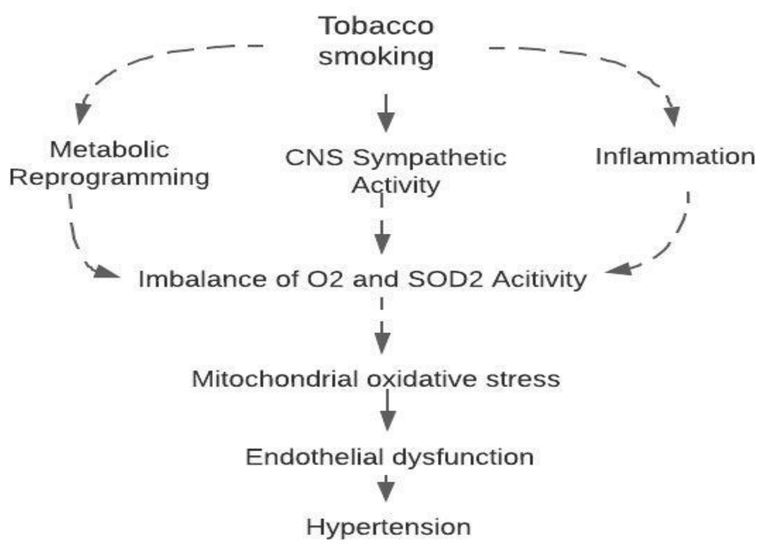

Figure 2.16: Tobacco smoking-mediated endothelial dysfunction and hypertension

Source: Adapted from S. Dikalov et.al,2019(78)

Smoking is a significant public health issue in Nepal as shown in fig 2.17. The overall prevalence of smoking is observed among 17.9% of 15-69 years, more among males than females (28% Vs 7.5%) in the STEPS survey 2019 of Nepal.[33] Moreover, a study conducted by Khanal et al. in the Mid-Western region among 1159 participants of age 30 yrs. and above showed that 64.4% of current smokers had high blood pressure, significantly associated with hypertension.[43] However, the overall prevalence of daily tobacco consumption has slightly decreased to 19% in 2019, having been 24% in the 2008 STEPS Survey and almost comparable 20.7% to the finding of secondary data analysis of NDHS 2006 of Nepal.[79] This might be due to the implementation of a comprehensive tobacco control law in 2011 in Nepal. Still, there is a need to monitor the effective implementation of this law regarding smoking in public spaces to prevent and control smoking and its health effects.

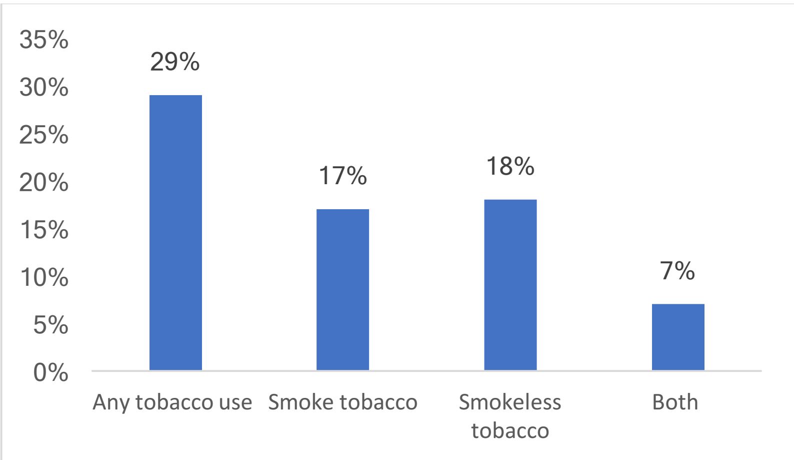

Figure 2.17: Percentage of adults that used any tobacco products in Nepal

Source: STEPS Survey Nepal, 2019[33]

Similarly, different small-scale community-based studies conducted in a different part of Nepal reported smoking,[39, 40] consumption of alcohol,[39, 40, 49, 56, 80, 81] high-fat diet,[80] high BMI,[39, 49, 56, 80-82] less physical activity[39,40,80] and consumption of non-vegetarian diet[81] as associated factors of hypertension. The life expectancy of the Nepalese population is also increasing. The latest census report showed the average life expectancy of Nepalese is around 70 [83, 84] which is the second-highest in the SAARC region. This is a sign of improvement in the health sector of Nepal. However, the health care system should be prepared to tackle geriatric problems like hypertension. Thus, different small and some representative national studies reported mounting trends of risk factors of hypertension. Hence, there should be some effective preventive strategies to mitigate the problems. Then only a low-income country like Nepal could manage the burden of non-communicable diseases such as hypertension.

3. Complications of hypertension with reference to Nepal

Hypertension mediated organ damage refers to the functional or structural changes in arteries or organs like the heart, brain, blood vessels, kidneys, eyes resulting from elevated blood pressure, which is common in severe or long-standing hypertension but can also be found in less severe hypertension.[85, 86] Therefore, HTN is already identified as a significant risk factor of different NCDs, especially cardiovascular diseases. There is a higher risk of getting CAD, IHD, stroke, heart failure, renal failure, renal disease, hypertensive retinopathy, and many others complications if the blood pressure is not controlled.[12] I have briefly discussed the significant complications burden in the context of Nepal. However, there are no robust cohort or case-control studies that establish the association between hypertension and different complications in Nepal. Therefore, small scale cross-sectional studies were reviewed to estimate the complications.

Cardiovascular disease, especially CAD and IHD: Coronary artery disease (CAD) is the most critical complication of uncontrolled hypertension. There are solid epidemiological relationships between CAD and hypertension. The INTERHEART study has demonstrated that hypertension can account for 25% of the population-attributable risk of myocardial infarction.[7] Similarly, there was a lifetime doubling the risk of mortality due to CAD with every 20/10 mmHg of increased blood pressure.[87] Further, hypertensive patients have a three-fold increased risk of congestive heart failure than normotensive patients.[88] Hypertension predisposes to cardiac arrhythmias, most commonly atrial fibrillation,[89] which is a manifestation of hypertensive heart disease.[90] Additionally, left ventricular hypertrophy was found in more than a quarter of hypertensive patients,[91] a major risk factor for CVD mortality and morbidity. Significantly, 45% of death due to a heart attack is attributed to hypertension.[92]

In Nepal, IHD was responsible for 16.4% of total deaths and 7.6% of DALY, where 6.7% of DALY was attributed to high SBP.[27] In 2009-2010, NHRC conducted a hospital-based study in 31 non-specialist hospitals (n=400) showed the proportion of CVD as 40% among other NCDs where HTN was a major (47%) CVDs. Other cardiovascular diseases were cerebrovascular accident (16%), congestive cardiac failure (11%), ischemic heart disease (7%), rheumatic heart disease (5%) and myocardial infarction (2%).[93] However, all of these studies are small-scale cross-sectional, so we must evaluate the results cautiously, considering the possibility of confounding variables.

Stroke: The evidence of a significantly increased risk of stroke with increased diastolic blood pressure (DBP) is well-established.[94] Similarly, different trials have shown a beneficial effect on reducing the risk of stroke with antihypertensive drugs.[95-98] It has been reported that both high and low blood pressure is an independent risk of poor outcomes among already confirmed stroke patients[99] and around 51% of stroke patients' deaths are due to HTN.[92] A review study by Oil et al. reported that among stroke patients in Nepal (n=683), 42% had hypertension in a retrospective hospital-based study.[100] Another study by Devkota et al. on 2000 to 2005 among 72 stroke patients in a tertiary teaching hospital of central Nepal reported 68% ischemic stroke and 40% hemorrhagic stroke, where hypertension (42%) was reported as the main predisposing factors along with smoking, alcohol consumption and older age.[101] Similarly, in a study conducted in 2010-2011 in the central referral hospital of Nepal, among 286 stroke patients, 38% were found to have HTN.[102] Hence, small-scale cross-sectional studies from Nepal reported the relationship between stroke and hypertension; however, a causal relationship cannot be established.

Chronic kidney disease: HTN is considered a major risk factor for the development and progression of chronic kidney disease (CKD) and end-stage renal disease (ESRD). However, the relative risk of severe renal damage among uncomplicated hypertension is low. Most of the hypertensives develop mild nephrosclerosis, and few develop ESRD.[103] A multi-country study was conducted by Sharma et al. in 2010 showed the proportion with decreased eGFR (glomerular filtration rate) as 14% and the proportion of participants with proteinuria as 7% in Nepal.[104] Similarly, a screening study (n=1000) conducted in the Eastern part of Nepal by Sharma et al. in 2013 detected 10.6% of chronic Kidney disease based on proteinuria as a screening test.[105] However, the above mentioned studies were all conducted in the eastern parts of Nepal, so we cannot generalise the findings to the whole of Nepal. Nevertheless, these small-scale study's findings signify the issue of uncontrolled blood pressure in Nepal.

Retinopathy, visual impairment, peripheral artery disease and aortic dissection are also distressing complications associated with hypertension.[22] The prevalence of hypertensive retinopathy was 0.88% in the Bhaktapur glaucoma study (n=3966) in central Nepal.[106] Similarly, fundus change of eye was observed among 63.6% of hypertensive patients in a study (n=302) conducted in central Nepal by Karki et al. in 2003. This study by Karki et al. also reported 72.18% had uncontrolled blood pressure among the participants.[107] Therefore, it is essential to keep the target blood pressure among patients with HTN to prevent devastating complications. As discussed above, Hypertension manifests as severe complications in Nepal. However, most of the studies are small-scale cross-sectional, so actual cause-effect relationships could not be confidently established.

4. Treatment and control measures of Hypertension

For the effective management of blood pressure, non-pharmacological (lifestyle management) and pharmacological (drug treatment) are two well-established strategies. For few cases with low or borderline hypertension, only lifestyle strategies can be sufficient; however, most patients with hypertension require drug treatment and lifestyle management.[86, 108] It has been recommended that the reduction of 5mm of Hg blood pressure at the population level could reduce 14 % overall reduction in mortality due to stroke.[109] Some hypertension-mediated organ damage can be reversed by adequate management of hypertension, mainly when used early, but with long-standing hypertension, it may become irreversible despite improved BP control.[110]

Lifestyle modification: For optimal control of blood pressure, along with the clinical treatment, lifestyle modification programs focusing on risk factors such as obesity, high intake of dietary sodium, physical inactivity, and inadequate intake of fruits and vegetables, smoking, and excessive alcohol use are important.[111] The recommended different lifestyle measures include salt restriction, reduction of alcohol consumption, high intake vegetables and fruits, reduction of weight, and regular physical exercise. Additionally, smoking cessation and other lifestyle measures are also beneficial for blood pressure control based on the recent Internal Society of Hypertension (ISH) global hypertension practice guidelines and European society of cardiology/hypertension guidelines (ESC/ESH) for hypertension management. [86,108]

A meta-analysis showed the effectiveness of sodium restriction in reducing BP. It showed the reduction of the 4.2/2.1 mmHg SBP/DBP with the reduction of 1.75g sodium per day where more effect was found on people with hypertension (-5.4/ -2.8 mmHg).[112] The 2020 ISH guidelines recommended the reduction of salt intake and avoiding or limiting the processed food containing the high salt.[86] The ESH/ESC guidelines has recommended the 2g/day sodium (5g/d salt) intake for general and hypertensive patients for blood pressure management.[108] Therefore, WHO member states have adopted the voluntary target of a 30% reduction of mean population salt intake by 2025 as an NCD and hypertension management strategy.[113] Similarly, a healthy balanced diet including vegetables, fruits, low-fat dairy products, wholegrains, fish, and low consumption of red meat and saturated fatty acid are recommended for patients with hypertension to control their blood pressure.[108]

In addition to dietary changes, physical activity and weight loss are also recommended for effective hypertension management.[114] Regular aerobic physical activity was found to reduce the SBP and DBP by 3.5/2.5 mmHg in general populations based on the meta-analysis of the RCT of aerobic endurance training. It found more effective (8.3/5.2 mmHg) among the hypertensive participants.[115] Therefore, hypertensive patients are advised for at least 30 min of moderate-intensity aerobic exercise such as walking, jogging, cycling, or swimming for 5–7 days per week.[108] Similarly, reduction of alcohol consumption and cessation of smoking are recommended lifestyle interventions for the hypertension management.[108]

However, despite adequate treatment and control measures for high blood pressure, most patients with hypertension either have inadequate treatment or poor blood pressure control. Different studies reported that antihypertensive therapies achieved only 25-40% of target blood pressure goals among hypertensive patients.[116] In this context, understanding the barriers and facilitators for blood pressure control among patients with hypertension is crucial, which I will discuss briefly in the following section.

Pharmacological treatment: There is robust evidence of the effectiveness of the antihypertensive medication for treating and controlling hypertension. [108,117] Timely diagnosis and regular use of antihypertensive medication is essential for preventing the complications of the HTN. Additionally, there is a compelling beneficial effect of antihypertensive treatment on reducing the risk of adverse events.[118] The Systolic blood pressure intervention trial (SPRINT) provided evidence of reduction of the major CVD events and mortality with intense blood pressure-lowering (less than 120mm of Hg) using antihypertensive therapy among the cohort of 75 years and older.[119] In addition, Heart Outcomes Prevention Evaluation (HOPE) trial-3 also provided evidence of beneficial effects of the antihypertensive therapy in the upper third of the participants with hypertension.[120] Similarly, the recent meta-analyses showed the reduction of CV events by 20%, all-cause mortality by 10-15 %, stroke by 35%, coronary events by 20% and heart failure by 40% with every 10-mmHg reduction in SBP and 5 mmHg reduction in DBP with the use of antihypertensive therapy.[118,121] Others have demonstrated a similar risk reduction with more intensive BP control.[122] So regular taking of antihypertensive medicine is critical in controlling blood pressure among patients with hypertension.

5. Uncontrolled blood pressure among patients with hypertension

Most of the diagnosed patients with hypertension remained with uncontrolled blood pressure leading to high morbidity and mortality.[123] Though there is evidence of effective treatment and control of hypertension, most people with high blood pressure remained untreated or had poor control.[124] With the increasing prevalence of hypertension, poor awareness, control and treatment (ACT) of blood pressure is another issue for managing blood pressure.[125]

The challenge of control of blood pressure is more in LMICs compared to HICs. It was evidenced by a study by Mills KT and colleagues on systematic analysis of population-based studies of 90 countries, which reported increased awareness, control and treatment of hypertension in HICs and less improvement in LMICs from 2000 to 2010.[8] In addition, the Prospective Urban and Rural Epidemiology (PURE) study, conducted by Chow CK et al. in 2013 among 142,042 adults of age 35 to 70 years from 17 high, middle and low-income countries, reported only 32.5 % (95% CI, 31.9%-33.1%) of the study population had controlled blood pressure despite being on treatment. Similarly, ACT of hypertension was found lower in rural areas compared to urban areas (urban vs rural, P <.001), especially in LMIC settings and education was associated with the lower ACT in Low-income countries, not in HICs.[124]

Further, a systematic review conducted by Pereira M et al.; among 35 studies from developed and developing countries reported 40.6%, 29.2% and 9.8% ACT of hypertension, respectively, in developing countries and 49.2%, 29.1% and 10.8%, respectively, in developed countries.[126] Awareness was little higher in the developed countries; however, treatment and control were comparable. Another study from LMICs among older adults reported low awareness and control of blood pressure where obesity and sex were associated with control of blood pressure.[123] Similarly, a study among Asian women aged 35-70 in India by Gupta and colleagues in 2012 reported a very low awareness and control of blood pressure, where only 3.9% (rural 1.3, urban 5.9) had their blood pressure controlled.[127] The evidence of these studies reflects the central issue of uncontrolled blood pressure among patients with hypertension.

5.1 Uncontrolled blood pressure among patients with hypertension in Nepal

Like other LMICs, Nepal is also facing similar challenges for hypertension management. On the one hand, hypertension remains hidden in the community in Nepal.[128] It is evidenced by a Haider MR and colleagues study in 2020. They analysed the national representative Nepal Demographic Health Survey (NDHS) 2016 data of 2831 hypertensive patients and found that three-fifths (56.9%) of hypertensives were undiagnosed.[128] This study reported that old age, obesity, and high wealth quintiles had fewer chances of being undiagnosed. Importantly, poor patients had a higher (poor Q1-to-rich Q5 ratio:1.57) prevalence of undiagnosed hypertension. It reflects the disproportionate access to health services like screening facilities to poor people in Nepal. This figure resembles the tip of the iceberg concept where hidden cases need to be identified and treated timely.

On the other hand, blood pressure is poorly managed even after the diagnosis of hypertension and treatment.[129] Recent systematic review by Shrestha et al. in 2021, which included 44 studies, reported that only 45% of patients with hypertension were aware of their diseases, only 32% were under treatment, and only 44.4% had their blood pressure control.[35] These findings corroborated with another systematic review by Dhungana RR and colleagues of the same duration (2000-2015) (included 32 studies - 84006 participants). It reported that only 50% of the patients were aware of the hypertension status, and only 27% were receiving treatment, and among them, only 38% had control of the blood pressure.[36]

Additionally, small-scale studies conducted in the different subsets of populations of Nepal in the past decade (2010-2020) also reflected the similar challenge of uncontrolled blood pressure in different subsets of the population.[56,129-131] Despite being on medication, around 67% of hypertensive patients had uncontrolled blood pressure in a hospital-based study in Central Nepal.[130] A similar trend was observed in studies conducted in the outskirts of Nepal in a study by Devkota et al. where only 35.3% to 49.4% of hypertensives patients had their blood pressure controlled.[131] This variation in blood pressure control could be differential criteria used in different studies. A survey conducted in the Western part of Nepal by Neuapne D and colleagues found that only 46% of hypertensive patients were aware of their high blood pressure status, 31% were taking antihypertensive medication, and only 15% had their blood pressure controlled.[56] A similar trend was reported in a study of the central part of Nepal. They found 43.6% of participants were aware of their disease status, only 76.1% of aware patients were taking antihypertensive medication, and only 35.3% had their blood pressure controlled.[129]

Though slight variation based on region and different subsets of populations is reported, treatment and blood pressure control are significant challenges in Nepal. It reflects the disproportionate treatment of blood pressure even after the diagnosis and the gap in control even after being on treatment. These findings are very alarming, and it is imperative to understand the underlying factors of poor blood pressure control for timely intervention to prevent complications burden among hypertensive in Nepal.

6. Barriers and facilitators for the treatment and control of hypertension

Blood pressure control could not be achieved only by patients' efforts; multiple factors such as treatment adherence, behaviour modification, and support from the family and health care providers play crucial roles, as discussed earlier. Therefore, various studies reported barriers to blood pressure control related to patients, providers, and system-level.[132-137] Patient-related barriers may be not giving importance to treatment, not taking the medication regularly, having no awareness about target blood pressure and hesitation to increase medication, poor medication adherence, beliefs about hypertension and its treatment, depression, health literacy, comorbidity, and patient motivation.[137,138] The majority of provider-related barriers are reported as clinical inertia. The stated reasons for the clinical inertia are an overestimation of the number of care physicians provide, lack of training, and clinician avoidance for treatment intensification.[137]

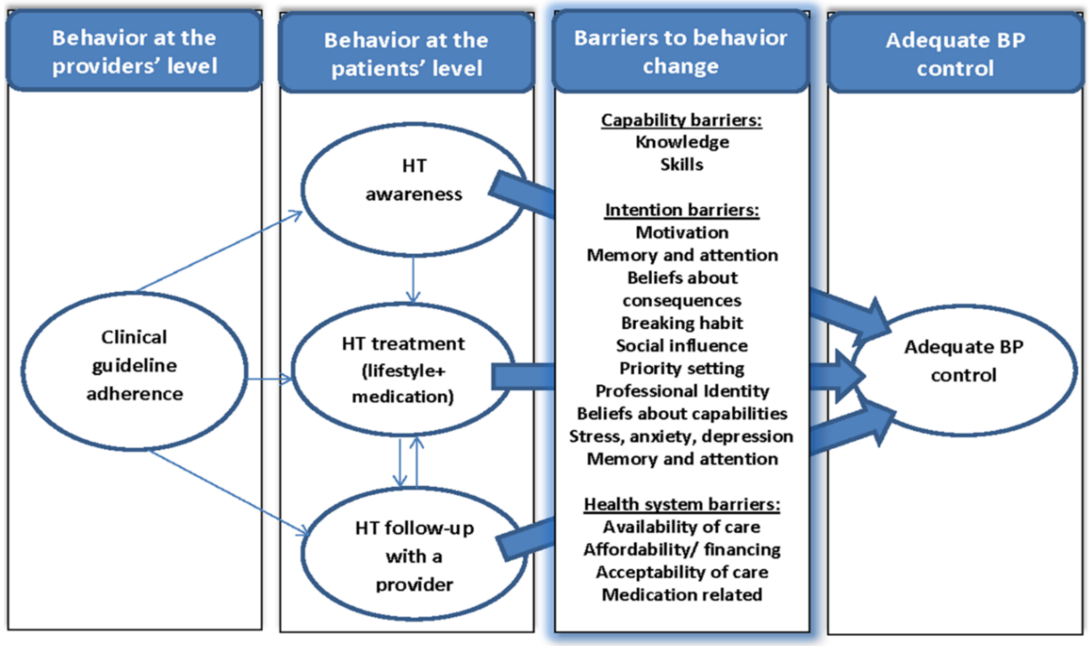

Figure 2.18: Barriers to control of blood pressure

Source: Khatib et.al, 2014 [132]

A systematic review conducted by Khatib R et al. in 2015 of 25 qualitative and 44 quantitative studies that assessed the barriers to the ACT of blood pressure using the COM-B model (section II of this chapter discussed COM-B model).[132] It highlighted that health system-level barriers were primarily found in the qualitative studies, and disagreement with a clinical recommendation was the most common healthcare-level barrier reported among healthcare providers (fig 2.18). Additionally, it stated that the lack of knowledge as a common barrier to awareness and stress, anxiety, and depression, which delayed behaviour modification and forgetting, was the most common barrier to treatment adherence.[132] (fig 2.18) However, many of the included studies were from high-income countries, especially the USA, and only 20% were from LMICs. So, there is a need for further research in the context of LMICs.

In the context of HICs, a study from Canada reported adherence to medication and life stress as an associated factor with uncontrolled blood pressure among hypertensives patients.[139] Similarly, lack of patient motivation, time constraints and coexisting health conditions are also reported as barriers to lifestyle modification among hypertensive patients.[140] Likewise, a qualitative study conducted among African Americans in 2013 reported the patient's and their family members' perceived facilitators and barriers to hypertension self-management. They identified the facilitators reported by patients as family members support and positive relationship with doctors. A family member identified their participation in patients' doctor's visits and discussion with their doctors outside of visits as facilitators. Additionally, barriers identified by the patients were competing health priorities, lack of knowledge about hypertension and poor access to community resources which hamper their self-management of hypertension. Moreover, a family member reported barriers to limited health knowledge and the patient's lack of motivation to follow hypertension self-management behaviours.[133] However, the co-payments for medication, transportation costs to health care facilities, unavailability of drugs, poor access to specialist care as a barrier to accessing the treatment among hypertensive patients as a barrier to accessing treatment from a study in Colombia.[141]

Some studies of the LMICs reported similar findings as HICs, and some are particular to LMIC settings. A qualitative study conducted in Eritrea by Gabreski MT et al. in 2017 looked at the barriers at the individual patient, family and community and health care level. They identified economic barriers, stress, non-adherence to medications due to traditional remedies, difficulties and misconceptions about the following physical activity guidelines as the significant barriers at the individual level.[134] Such stigma and use of traditional remedies barriers are primarily reported from the LMICs context. Similarly, low community awareness, community stigma and inadequate health promotion materials as the barriers at the community and health system level. In contrast, individual knowledge, family, and government support were identified as essential factors for hypertension management.[134]

Additionally, a qualitative study conducted in Nigeria by Odusola AO et al. in 2014 reported the main facilitators of medication adherence as affordability of care, trust in orthodox" Western Medicine and doctor and the threat of hypertension, and prayer to support the efficacy of the pills. They reported the barriers to medication adherence as inconvenient clinic operating hours, long waiting time and under dispensing of prescriptions, fear of dire effects of the pills, faith system leading to change of medication regimen, herbal supplementations of the tablets, and ignorance at an individual level. Food preservation, negative cultural images associated with body size and physical activity as significant inhibitors for adopting healthier behaviours.[136] The affordability is reported as the facilitators; it may be due to a study conducted among the insured patients. So, it signifies the need for insurance or a supply of free medications to the patients with hypertension to increase adherence and better BP control. However, this study reported many other patient's and healthcare-level barriers though patients were insured, so there is a need to focus on cost and other behavioural and cultural factors.

In the South-East Asia Region, a multi-country qualitative study conducted by Legido-Quigley H et.al in 2019 in Bangladesh, Pakistan, and Sri Lanka, examined the patient's experiences on accessing health care services for the management of hypertension.[135] This study was conducted among 60 hypertensives participants, with 20 in each country using semi-structured interviews. They reported lack of knowledge on treatment and control of hypertension and main barriers in accessing the health services and inadequate services and poor quality of the facilities, shortage of the medicine supply, the busyness of the doctors due to high patient flow, long travel distance to reach facilities and long waiting times. Cost and adherence to medication were also reported as barriers to the management of hypertension.[135] However, this study mainly explored the system-level factors in assessing the services for managing hypertension among the participants from the ongoing randomised control trial. They reported the findings of the three countries, which might have missed the country-specific results. However, they only presented the country-specific findings of Bangladesh about the patient's pathways and perceptions of hypertension treatment, management and control from the 20 in-depth interviews among hypertensive patients. This study reported that patients were aware of hypertension before diagnosis and its consequences, though there was little knowledge about the treatment and prevention strategies. They also reported that though patients were informed of the dietary advice, mostly they were sedentary.[142] However, this study primarily focused on system-level barriers. So, there is a need of understanding the patients and family level of barriers and the system level in LMICs settings like Nepal.

6.1. Barriers and facilitators for the treatment and control of hypertension in Nepal

In Nepal, most studies are conducted on the prevalence of ACT of high blood pressure, as discussed earlier. Only a few studies explored the barriers to blood pressure control among hypertensive patients. One of the studies conducted in the semi-urban area of the central developmental region of Nepal by Devkota S. and colleagues reported the use of combination therapy, adherence to medication and follow up care and counselling by the health care providers and waiting time in the hospital as the significant factors associated with the blood pressure control. And from the qualitative exploration (2 FGD among 20 hypertensives and 2 IDI with cardiac physician), they reported being worried about taking lifelong medicine, lost to follow up, inadequate counselling from the physician and lack of national guidelines for hypertension treatment were reported as barriers to treatment and control of the blood pressure.[143] However, in this study, they have not done exploration at a different level and different stakeholders.

Similarly, a qualitative study conducted by Shrestha S et al.; among the 35 newly diagnosed hypertensive patients using focus group methods reported the lack of knowledge, misbeliefs about hypertension and its treatment as primary barriers for hypertension management. Additionally, they stated the absence of symptoms, reluctance to take medication, the low perceived threat of disease and challenges for behaviour modification, lack of family support and lack of communication between doctor and patients as an essential barrier and fear of the consequences of illness and family support were identified as the significant facilitators.[144] However, this study was conducted among newly diagnosed hypertensive patients, so long-term barriers cannot be understood. Further, noncompliance to antihypertensive medication is a significant predictor of blood pressure control which is reported as 54.6% in a survey of the Eastern part of Nepal.[145] However, there is limited understanding of the barriers to treatment adherence and blood pressure control among hypertensive patients in the context of Nepal.

It demands further studies to elucidate the possible barriers to controlling blood pressure among patients with hypertension. Then promising intervention can be designed for effective control of blood pressure among patients with hypertension in Nepal. Therefore, our Phase I formative study presented in Chapter 3 was conducted to explore the barriers and facilitators to blood pressure control in Nepal, representing all groups, gender and level of hypertensive patients, their family members, primary and tertiary level health care workers, and key stakeholders, including policymakers. Moreover, this study used the COM-B Model (details of Model in section II) to explain the interaction of multifaceted levels of barriers of individual internal and external factors, thereby informing the contextual intervention for improving the treatment and control of the blood pressure among the Nepalese population and other similar settings.

7. Interventions for the management of hypertension

As discussed earlier, hypertension treatment required multiple strategies such as pharmacological and non-pharmacological interventions. One global initiative includes the global action plan for the prevention and control of NCDs 2013-2020, which was endorsed by the WHO and the United Nations General Assembly (UNGA) High-Level Meeting in 2011 and adopted by the multiple WHO member states. Among the various nine voluntary targets set for NCDs control, directly related to the hypertension control includes 25% reduction and containment of the prevalence of hypertension and other targets are related to the reduction of the risk factors of NCDs, including hypertension.[146]

Various interventions are being conducted for hypertension management in line with the WHO global NCDs control initiatives. However, there is limited evidence on organised delivery of the interventions to hypertensive patients to improve their blood pressure control.[147] Reduction of cardiovascular risk factors is identified as one of the effective strategies for hypertension management.[148] Similarly, the Cochrane systematic review conducted by Glynn LG et al. in 2010, which included 72 RCTs, identified the ranges of interventions such as self-monitoring of blood pressure, the educational intervention to the patients or health care providers, health professionals led care (nurse, pharmacist, community health workers), organizational interventions and appointment reminders system conducted for improving the blood pressure control among hypertensive patients.[147] Self-monitoring of the blood pressure reported to have a beneficial effect in reducing systolic (SBP -2.5 mmHg, 95% CI: -3.7 to -1.3 mmHg) and diastolic blood pressure (DBP: -1.8 mmHg, 95% CI: -2.4 to -1.2 mmHg). Additionally, it reported that educational intervention led by HCWs (Nurse or pharmacist-led care) to hypertensive patients were promising and most influential in overall and systolic blood pressure reduction but not with diastolic blood pressure that required further evidence. Further, this study reported increased follow up with an appointment reminder system among hypertensives. However, intervention directed towards only patients or health care providers did not effectively reduce blood pressure. Therefore organised approaches such as registration, recall and regular review with antihypertensive drugs treatment were recommended as an effective intervention; however, further evaluation is warranted.[147]

Additionally, a recently published systematic review in 2021 by Treciokiene I. et al. that included 34 RCTs of 22,419 hypertensive patients reported health care professional-led interventions on lifestyle modification was influential in the reduction of the SBP (MD − 4.41 mmHg − 5.52 to − 3.30) and DBP (MD− 1.66 mmHg;− 2.44 to − 0.88) among the intervention group compared to the usual care.[149] However, various barriers could affect such intervention implementation, such as traditional structure and practice, stereotypical attitudes of health professionals and development and delivery of interventions.[150]

It should be noted that LMICs are struggling with the lack of human health resources, as evidenced by the WHO projection of 18 million the shortage of health workforce by 2030 in the LMIC setting.[151] Therefore, in the context of the limited human health resources to deliver such interventions, finding an alternative/complementary solution or medium is crucial. With the broader penetration of the technology in LMICs, mHealth can potentially manage chronic diseases, including hypertension. Therefore, the scope of mHealth for hypertension management is reviewed and discussed in the following section.

8. Review of Mobile phone interventions (mHealth)

Globally, mobile phone use has increased exponentially in the last decade, as depicted in figure 2.20. Nearly 62% of the world's population (estimate 4.88 billion) have a mobile phone where 48.3% (estimate 3.8 billion) had smartphone ownership; it is increased from 33.5% in 2016 (fig 2.19).[152] Surprisingly, based on the Global system of mobile communication (GSMA) real-time intelligence data, there are more than 10.97 billion mobile connections globally which is 3.11 billion higher than the global population. [152] The smartphone users is expected to reach 7.5 billion by 2026.

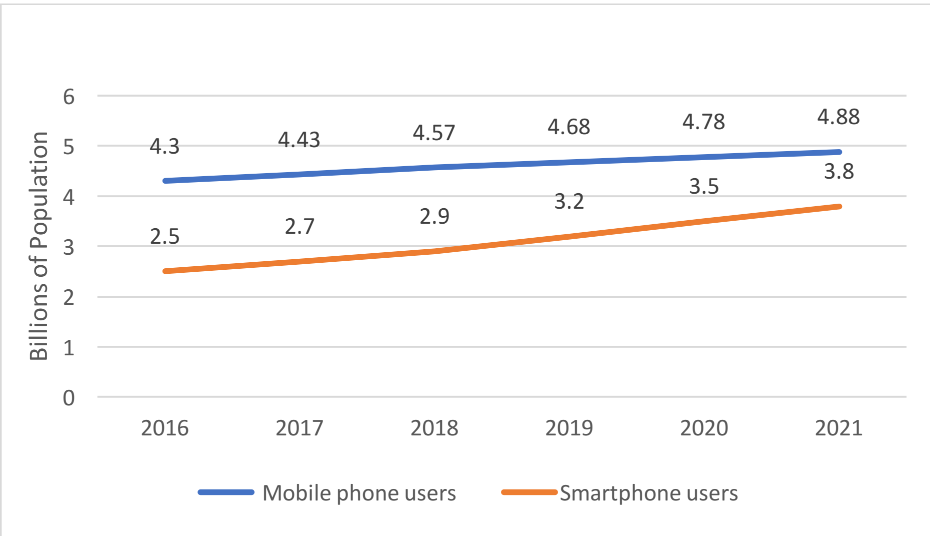

Figure 2.19: Trends of number of Smartphones and Mobile Phone users worldwide (Billions)

Source: Babycell; Statista[152]

However, we must note that not all people have a mobile phone, but the higher rate might be due to having multiple devices and dual sim by a person. Similarly, based on the International

Telecommunication Union estimate, mobile phone penetration is around 99% globally and 94% in the LMICs.[153] However, access to a smartphone is higher in HICs (76%) than LMICs (45%).[154]

The digital tools, including mHealth, are popular for detecting, preventing, and managing specific diseases. The use of digital health apps is emerging with over 3,18,000 health apps and 340 worldwide consumer wearable devices globally in 2015.[155] The digital health tools include consumers wearables, mobile apps, telemedicine, patients information collection tools, health system disease management apps, web-based interactive programs, text messaging or emails, biometric sensors etc as presented in figure 2.20.[155]

Figure 2.20: The Digital Health tools

Source: IQVIA Institute[155]

However, in LMICs where there is less smartphone and internet access,[154] use of simple mHealth can be a viable option which is the main focus of this thesis. Moreover, mobile app-based intervention might not be feasible in the LMIC setting due to smartphone access and mobile phone literacy. In this context, a simple text message intervention can be a suitable medium, especially at LMICs. Therefore, I mainly discussed the use of mHealth, especially text messages (SMS), for chronic disease management with the main focus for hypertension management in the following sections.

With globalisation and rapid technological advancement, mobile phone is becoming part of everyday life even in the LMIC settings. mHealth is an emerging platform and has the potential to support health care delivery. The Global Observatory for eHealth (GOe) defined mHealth or mobile health "as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices".[156] It consists of mobile phones, tablets, and biosensors used to send and record messages to health care providers and patients. Internet and mobile phone use drastically increased in the past decade, increasing the possibility of shifting health care provision and monitoring through health technology.[157] Digital health technology, including mobile phones, sensors, and online social networks, is being explored to increase the capacity to understand behaviour.[158] mHealth can offer a simple and effective mode to deliver health care intervention to the participants, especially in poor resource settings.[159] It is projected that by 2018 there will be around 1.7 billion estimated mHealth users.[160] Mobile health could be a promising tool for better access, coverage, and equity gap for chronic disease management in LMICs.[161] The following section discusses the use of mHealth for NCDs management with a particular focus on HTN management.

8.1 Use of mHealth for NCDs management

With the high burden of NCDs coupled with the high penetration rate of mobile phones, mHealth for the self-management of chronic disease is emerging globally.[162]It has been used for the management of various disease conditions and service provision in many HICs. It has been reported that 52% of smartphone owners use at least one mHealth app to manage their disease condition.[163] There is an increasing amount of evidence that mHealth can support behaviour change.[164] It can support the self-management of disease and reduce the number of visits to the health centre.[156] Mobile phones can enable the patients to self-manage their chronic diseases through a personalized feedback system based on their needs.[165] In mHealth various measures were reported to use chronic disease management such as apps, blood sugar monitors, blood pressure monitors, pedometers, accelerometers, sensors, and SMSs. However, SMSs were reported as most used for chronic disease management.[162] The different kinds of intervention function of mHealth for chronic disease self-management includes information, instruction, recording, guiding, reminding and communication. Studies have used mHealth to manage long-term illnesses like diabetes,[166] HIV,[167] and reduction of risk factors of cardiovascular diseases, smoking cessation, mental health and COPD management.[155, 168-170] mHealth for diabetes management found effective in improving glycaemic control, self-management of diabetes[166] and some reviews reported mixed results.[171]

The use of mHealth for CVD management also showed the mixed effect based on the study outcome and context. A systematic review conducted by Hamine et al. in 2015 included the 107 studies with various chronic diseases; among them, seven studies reported the improvement of BP, weight, lipid profiles out of 13 studies related to CVD. Moreover, half of the studies reported improved BP control and HbA1c among four interventions designed for the DM and CVD participants. SMS was the most common used mAdherence tool among 40% of the included studies.[172] However, a systematic review conducted by Allet et al. 2010 included four studies that used wearable motion-sensing technology and a review by Free et al. 2013 that included five papers on using the wearable system for CVD management found mixed results.[167, 173] However, recently published systematic review by Al-Arkee. et.al 2021,[174] which included 16 RCTs published within six years, reported significant improvement in medication adherence in CVD using the mobile apps. A meta-analysis of six RCTs also reported the favourable outcome in the app intervention group (Mean difference 0.90, 95% CI 0.03-1.78). Additionally, seven RCTs also reported the apps intervention's effectiveness in improving SPB, DBP, and total cholesterol in the intervention arm. Different RCTs in this review used different functions in apps. Two RCTs used education, seven used reminders, and seven RCTs combined the reminders and education.[174] Hence, mHealth seems promising for improving medication adherence for CVDs.

Notably, among the mHealth, SMS is reported as a preferred and effective method, especially in the LMIC setting. One of the systematic reviews on mobile phone text messaging for health reported that such intervention effectively addresses diabetes self-management, weight loss, physical activity, smoking cessation, and medication adherence; however, evidence regarding integrating text message intervention into public health practice is unclear.[175] A meta-analysis of mobile phone text messaging for medication adherence in chronic disease reported that mobile phone text messages would double medication adherence odds.[176] Similarly, Text2Quit effort for a smoking cessation program is quite successful in New Zealand, and now it's been adopted in Canada as well.[177] Text messaging has been used for health care appointments and medication reminders, and preventive services.[178] Additionally, in 2015, Chow et al. conducted the Tobacco, Exercise and Diet Messages (TEXT ME) RCT in Australia, among the 710 patients of coronary heart disease where they sent the four text messages per week (advice, reminders and lifestyle change support messages) to intervention arm. After six month, they found the modest improvement in LDL-C level and reduction of BP and BMI and smoking and increased physical activity.[179]

Hence, text messaging interventions are becoming popular due to the resources need for such intervention. A text message is a cost-effective and accessible method of intervention. It is also less time-consuming, as it saves patients time for searching needed information as it is directly delivered to them.[180] SMS intervention effectively improves patient's care and is accepted by both the patient and provider of the service.[181] However, there is a need to determine the long-term effectiveness[182] and feasibility of using mobile phones and SMS to deliver the complicated self-management interventions to improve various clinical and behavioural outcomes,[183] including hypertension management.

8.2 mHealth intervention including TEXT message for hypertension management

With the growing inclination towards the mHealth initiative, various mHealth application included text messaging intervention has been tested globally to manage hypertension. mHealth initiatives have been widely used in different aspects of disease management. Among those for the treatment compliance initiatives, 35% of WHO member states used this initiative. The highest (50%) use was in the South East Asian region and lowest in the Western Pacific Region (23%).[156]

Communications, reminders, education, and feedback were the most common functionalities used in mHealth studies for hypertension management among 11 included RCT in the systematic review by Lu X et. al in 2019.[184] The meta-analysis conducted by Lu X et al.; in 2019 among 4271 hypertensive participants of 11 RCTs reported the significant change of SBP (-3.85 mm Hg; 95%

CI, -4.74 to -2.96) and DBP (9 -2.19 mm Hg; 95% CI, -3.16 to -1.23) among the interactive mHealth intervention group compared to the control group. [184] Similarly, a systematic review by Choi W et al. in 2020 reported that mHealth has been used for self-management, decisions support and shared decision-making in managing hypertension and diabetes based on the 11 included study. [185] Among the included study, five focused on the patients' health outcomes, whereas the other six focused on the users' experiences for mHealth technology. This review also reported the promising outcomes of mHealth; however, the strength of evidence was not strong due to the lack of robust study design of the included study. [185]

However, a Cochrane review conducted a decade ago by De Jongh et al. in 2012 did not find any difference in blood pressure control among the intervention group, though reported statistically significant improvement in medication adherence.[186] However, they had included only one study related to HTN, and the quality of the study was reported as poor. So, the effectiveness of the intervention is differential based on the design, context, and period. A recent systematic review that included 24 mHealth studies among hypertensive patients provided promising evidence of improved blood pressure control and medication adherence among hypertensive patients.[187] The meta-analyses revealed a more significant reduction of both SBP and DBP among the mHealth intervention groups compared to control groups SBP −3.78 mm Hg (P<.001; 95% CI −4.67 to −2.89) and DBP −1.57 mm Hg (P<.001; 95% CI −2.28 to −0.86).

Additionally, 16 studies had reported improved medication adherence. Most of the studies used the combined feature of the tailored messages, included interactive and multifaceted intervention.[187] These studies findings reflected that mHealth could be integrated into the regular health care system to manage hypertension.[187] However, almost all of the studies were confined to high-income countries settings, which cannot be generalised to the LMIC context. So, understanding the effectiveness and feasibility in the LMIC setting is very important.

SMS is widely used in health care research as a communication tool between patients and health care providers. It could be a potential tool for managing hypertension by overcoming structural barriers of health care access and utilization. Vargas G et al. conducted a systematic review in 2017 among six studies that used text messages to manage hypertension and reported that SMS intervention for hypertension management practices helped improve BP among the three studies. [188] Most of the studies used text messages to improve adherence to medication,[189-192] and only some used for other behaviour changes like diet,[193] weight reduction,[194,195] smoking cessation,[193] and improvement of knowledge about hypertension.[196] Few studies used the text message intervention combining with other interventions as well.

Another systematic review by Shariful Islam SM et al. in 2019 on text messages to prevent CVD (TEXT2PreventCVD) included nine studies involving 3779 participants. Five studies (2612) were included for the meta-analysis. This review findings are promising in the effectiveness of text messages intervention in the reduction of the SBP (−4.13 mm Hg (95% CI −11.07 to 2.81, p<0.0001); DBP −1.11 mm Hg (−1.91 to −0.31, p=0.002) and BMI −0.32 (−0.49 to −0.16, p=0.000) among the intervention groups compared to the control/usual care groups. This review showed that the text messages intervention has a modest effect on BP and BMI but insufficient evidence to reduce the multiple risk factors.[197]

Similarly, other individual studies conducted in different parts of the world also reported favourable outcomes. In 2019, Varleta et al. used text messages for medication adherence and healthy lifestyles among 314 hypertensive patients in their Chilean study. After six months of follow up, this study reported an increased antihypertensive medication adherence from 49% to 62.3% (P=0.01) among text messages intervention groups compared to those who did not receive the text messages.(189) Similarly, an HTA-ALERT study conducted in Spain by Contreras EM et al. in 2004 among 67 hypertensive patients using text messages and reminders twice a week for four months reported no improvement in compliance (from 85% to 84.4%) to therapy among intervention arm.[198] These findings reflect the differential outcome in a different setting, so contextual intervention should be developed. Most of these studies were confined to high-income settings, so understanding the mHealth effectiveness in the LMIC and the regional setting is prime, discussed in the next section.

8.3 mHealth including SMS initiative for hypertension management at LMIC settings including South Asia

There is limited information available on the usage of text messaging for HTN management in LMIC settings.[199] In South Africa, an UMIC, two studies used mobile tools for the management of high blood pressure. In the first study by Bobrow K et al., a Support Treatment Adherence in Adults with High Blood Pressure **(**STAR) three-arm randomised trial was conducted among hypertensives (n=1347) attending the public clinic of Cape Town, South Africa, in 2015. In this trial, informative SMS only (n=457) and Interactive SMS (n=458) was compared with usual care (n=457). After 12 months of intervention, the mean adjusted change of systolic blood pressure was −2.2 mm Hg (−4.4 to −0.04) with information-only SMS and −1.6 mm Hg (−3.7 to 0.6) with interactive SMS groups compared to usual care. They reported some improvement in adherence to antihypertensive medication among the intervention groups. However, this study did not find any difference between the interactive SMS and SMS only groups. Moreover, this study also reported that blood pressure reduction was like other face-to-face behavioural interventions.[192]

The later study by Hacking D et al. in 2016, conducted in the outpatient clinic at the community health centre of Cape Town, South Africa, among 109 hypertensive patients, assessed the improvement in health knowledge and self-reported health-related behaviours through a short message service (SMS). Intervention group (n= 109) received 90 SMS over a period of 17 weeks and control group (n= 114) received usual care. This study did not report any significant changes in overall health knowledge between the control and intervention groups(P> 0.05). However, they found positive increases in self-reported behaviour changes (81% vs 94%, p<.05) among the intervention group.[200] Therefore, there is no clear-cut evidence of mHealth intervention's effectiveness in managing hypertension based on these two studies.

Similarly, Maslakpak et al., in 2016, conducted an RCT among the 123 hypertensive patients at the medical centre of Iran. They reported a significant difference (P<0.001) in the mean score of adherence to antihypertensive medication among control groups (46.63±2.99) compared with the text messaging group (57.70±2.75) and reminder card groups (57.51±2.69). However, the result showed no difference between SMS and reminder card intervention (P=0.667).[190] This was a small scale study for a three-month duration, so we cannot confirm the long term effectiveness. Similarly, clinic-based randomised controlled trials in two countries (Mexico and Honduras) were conducted among 200 hypertensive patients with the intervention of weekly automated monitoring and behaviour change telephone calls from the server in the United States and home BP monitor. During follow up at six weeks, the systolic blood pressure of the intervention group decreased by 4.2mm Hg (-9.1, 0.7; p=0.09) compared to controls. Similarly, intervention patients reported fewer depressive symptoms (p = 0.004), fewer medication problems (p < 0.0001), better general health (p < 0.0001), and greater satisfaction with care (p ≤ 0.004) compared to control during follow up. This study concludes that home blood pressure monitoring plus automated telephone calls could effectively manage blood pressure in LMICs.[201] However, this is also a small-scale study (n=100) and did not focus on the SMS intervention. Previous studies reported the differential findings based on the different geographical locations. To get the desired outcomes, there is a need to contextual design and implement the mHealth intervention in the LMICs,[202] to get the desired outcomes.

Mobile health intervention is becoming popular for behavioural change interventions in the Southeast Asian Region as well. Most of the studies are emerging from India, Pakistan, Bangladesh, and Sri Lanka, and some qualitative studies are conducted in Nepal too. In their systematic review in India, Bassi A et al. 2018 reported that though the public health intervention using mHealth is exponentially growing, there is a need for high-quality evidence on the efficacy, acceptability, and cost-effectiveness of the mHealth intervention in supporting the health care system.[203] The SMART health study conducted in Andra Pradesh, India, used community health workers (ASHA) to identify cardiovascular risk factors using the Clinical Decision Support System (CDSS) mobile application. They trained the ASHA for using the CDSS tools to identify cardiovascular risk factors and refer them according to the risk score. They also trained physicians and evaluated the feasibility of using CDSS tools. This study reported that tablet-based CDSS tools could be a potential tool to improve cardiovascular disease outcomes.[204] However, this study was not conducted among hypertensive patients, and the cost-effectiveness of using such intervention was not clear.

Alternatively, Prabhakaran D et al. 2018 conducted clustered randomised control trials in 40 community health centres (n= 3698) in India[205] reported no benefit of the mWelfare using the in the management of the chronic condition (hypertension, diabetes), which compared the mHealth based clinical decision support system and storage of electronic health records, combined with usual enhanced care with usual care. There was no reported difference in SBP (-0.98; 95% CI, -4.64 to 2.67) and glycated haemoglobin 0.11; 95% CI, -0.24 to 0.45) and tobacco and alcohol intake. [205]

Additionally, mHealth intervention in Pakistan using text messages reported the effectiveness in the uptake of the vaccination[206] and increasing medication adherence among stroke patients.[207] The study among stroke patients in Pakistan used a parallel-group, assessor-blinded, randomised controlled behavioural intervention trial among adult participants (n=200) on multiple medications using an SMS reminder for two months. After two months of intervention, this study reported a higher adherence score and lower mean diastolic blood pressure than the control group.[207]However, they have not studied the effectiveness of intervention for blood pressure control.

Bangladesh has also initiated some mHealth interventions on teleconsultation, prescription and referral, mainly focusing on the health management information system. [208] However, those studies did not focus on hypertension management; few trials are ongoing in Bangladesh,[209] and Sri Lanka[210] and their results are pending. With this evolving evidence of the mHealth initiative, LMIC such as Nepal has a broader scope of implementing the mHealth intervention for hypertension management. However, it's crucial to understand the health system and structure for incorporating such initiatives in Nepal.

9. Health system and health policy of Nepal with relevance to Hypertension control

Health is identified as the fundamental human right in the new constitution of Nepal 2015. Recently, the Nepal government has adopted the federal government system based on the newly developed constitution 2015.[25] The government has initiated reforming the health system based on the newly formed federal government's three tires (state, provincial and local). It has already completed functional analysis and formed a federalism implementation unit.[211] However, modification of the health system structure based on the federal system is not entirely operational.

In Nepal, both the public (government) and the private sector provide health care services. In the public health system, Nepal's Ministry of Health and Population (MOHP) is the central responsible body. The primary health care concept and decentralization approach are used in health service delivery from MoHP.[212] The Department of Health Services (DoHs), provincial and local level government operate the overall health care system of Nepal. DoHs is responsible for providing preventive, promotive, diagnostic and curative services through its networks all over the country (fig 2.21). The health care system of Nepal is based on the primary health care concept. Primary health care centres and health posts provide services to the country's grassroots level providing primary health care services. Additionally, Female Community Health Volunteer (FCHV) also provides services at the home level in the community. [213]

The recent National Health Policy 2014 aims to improve accessible and equitable health care services by providing primary health care services free of cost.[214] Therefore, the health system of Nepal is committed to accelerating universal health coverage. This was reflected in the strategic plan of Nepal Health Sector strategy 2015-2020, which has outlined health system reform, equitable access, improved quality of services and multi-sectoral approach as the significant directions.[215] The country is highly susceptible to natural disasters like earthquakes, landslides, and frequent floods. Recently the country was hit with the second wave of COVID-19, where more than 9900 people died to date (4th Aug 2021), and more than 700 thousand suffering from disease, whereas around 600 thousand already recovered.[216] The health system of Nepal is not structurally well placed to deal with the multiple burdens of diseases such as infectious, non-communicable, emerging diseases like COVID-19 and natural calamities.[217] One of the significant challenges faced by Nepal's health system is the shortage of health manpower as it was only 0.29 health workers per 1000 population which is very lower than the WHO recommended 2.3 per 1000 populations.[218]

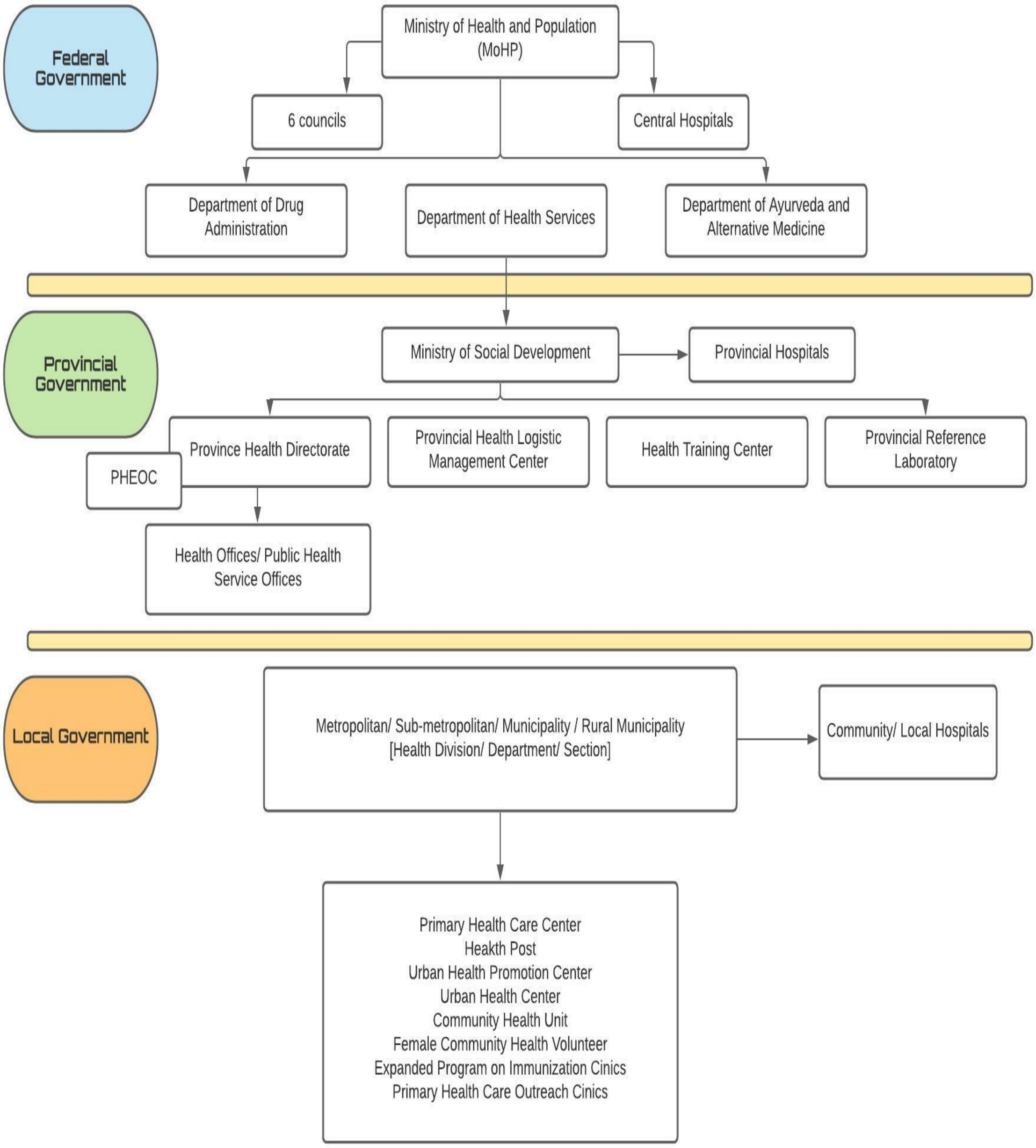

Figure 2.21: Structure of Nepal Health care system after federalism

Source: Adapted from Poudel S, Public health update [219]

In addition, there is only 0.7 physician per 1000 populations, 3.1 nurses and midwives per 1000 populations which is lower than the WHO recommendation.[220] There is a high rate of unfulfilled positions in the health centre, especially in the primary health care centre, which was reported as only 81%.[221] In this context, these structural barriers act as challenges for universal health coverage in the country.

9.1 Hypertension management initiatives in Nepal

Traditionally, Nepal's health system prime focus was on infectious diseases and maternal and child health (MCH) care. There has been significant progress in reducing maternal and child mortality and infectious diseases burden. However, with the rapid urbanisation and lifestyle changes, the prevalence of NCDs is escalating especially cardiovascular diseases.[27] The health system primarily designed to tackle MCH and infectious diseases; is not prepared to tackle this burden due to NCDs. It is gradually taking baby steps to manage NCDs. National health policy 2014 has tried to address this issues,[214] and a separate NCD policy was drafted.

The World Health Organization has also recommended integrated interventions mainly focusing on high-risk groups to address the gap of high blood pressure management. The Multisectoral action plan (2014-2020) on the prevention and control of NCDs in Nepal was developed in 2014. It has set a 25% reduction in both mortality due to cardiovascular diseases and the overall prevalence of high blood pressure among the ten other targets.[222] Other targets related to reducing CVD risk factors include 30 % reduction of mean salt intake, 30% reduction of tobacco use, 10% reduction of harmful use of alcohol, 10% reduction in physical inactivity, and halt the obesity.[222] Interestingly, it has also recognised the need for technology in NCDs management as evidenced by the 10th target as 80% availability of affordable essential technologies. However, the implementation of those policies is still an issue.

Nepal government has invested primarily in the curative aspect, providing financial support for treating CAD (Angiogram/Angioplasty) for needy patients.[223] However, these specialised services are limited to the urban and specialised area. Regarding the preventive aspect of cardiovascular diseases from the government, there is limited progress to date. Recently, the WHO package of essential non-communicable disease (PEN) is one of MoHP Nepal's promising interventions to prevent and control the significant NCDs,[224] piloted in 30 districts. The main aim of the PEN package program is to screen, diagnose, treat, and refer CVDs, COPD, cancer, diabetes, and mental health problems at the primary health care levels (health post, PHCCs, and district hospitals) for early detection and control of mentioned NCDs. However, the limited capacity of health institutions and systems, such as lack of training, health human resources, supply, equipment, and diagnostic issues, might be structural barriers for successful implementation and outcomes.[225] There is a need to evaluate and monitor these programs and use alternative mediums like mHealth to complement the efficient health service delivery in this setting.

In the context of scarce interventional studies among hypertensives, promising intervention to manage and control high blood pressure among hypertensives is urgently needed in Nepal. There are many cross-sectional studies conducted on the prevalence and awareness of hypertension in Nepal, as discussed in the earlier sections. However, interventional studies for the management of blood pressure among hypertensives are limited. The Nepal Health Research Council, in collaboration with the MoHP Nepal, has initiated a Community based Intervention for Prevention and Control of NCD (CIPCoN) risk factors study in the year 2016 to assess the effectiveness of primary intervention package in decreasing the prevalence of NCD related risk factors and changing the knowledge and awareness level of NCD and its related factors.[226] This study was planned in 12 selected Village Development Committees (VDCs) of Ilam district, Eastern Part of Nepal. The primary intervention package consists of mobilising the Female Community Health Volunteer (FCHV) in providing health education to the community, School Health Education program and health system support strengthening activities. However, only baseline report of this study is published with the prevalence of CVD risk factors, and there are no updates about the outcome of the intervention and its status.

Similarly, Sharma S et al. conducted a community pharmacist-based pre/post educational intervention study among patients with hypertension in the western part of Nepal in 2014. Community pharmacist-provided individualised educational intervention of three counselling sessions over six months to the hypertensive patients (n=50) attending a pharmacist-led hypertension clinic. They reported a change in knowledge, practice and decreased systolic and diastolic blood pressure through educational intervention by a community pharmacist.[227] However, this study was conducted on a small scale (n=50) among hypertensive patients visiting the pharmacist-led hypertension clinic with no control group. So it can not be generalised to other settings.

In 2014, community-based cluster randomised trials using female community health volunteers (FCHV) led educational intervention for blood pressure reduction (COBIN Study) was conducted by Neupane D et al. in the Western part of Nepal. Target groups of this study were normotensive, hypertensives patients and this study provided positive findings in reducing the systolic blood pressure through the FCHV led educational intervention.[228] However, FCHVs in Nepal are overburdened with implementing the MCH, vaccination program, and other primary health care services. So there is a need of doing a feasibility study in incorporating FCHV in NCD management. In the context of lack of human resources,[217] alternatives/ complementary mediums should be sought.

9.2 mHealth initiatives for hypertension management in Nepal

In this context, mHealth can be a potential tool for complementing the services and information delivery to address the communication gap between providers and patients due to scarce human resources.[221] Mobile phone users are increasing in Nepal, as discussed in the earlier sections. The Nepal telecom authority reports 38.21 million mobile phone users in mid-January 2021, 34.64 per cent higher than the country's total population.[229] It might be due to using more than one sim card usage by an individual. Though the mobile penetration rate is very high, mobile health use in the health system is only initiated to some pilot projects by the government and some non-governmental organisations in Nepal.[230] Its use is especially limited to MCH services.

The Ministry of Health has recently shown its commitment towards mHealth by integrating mHealth into health service delivery in MCH care. It piloted the mobile application and SMS services in two rural districts to track pregnant mothers for the regular ANC check-ups reported in the trusted national newspaper from Nepal,[231] and finding of the study is yet to be published. Among mHealth SMS could be a potential tool for sending the health information and reminder to the patients as it does not require high cost. In Nepal, the cost per SMS is NPR 1 (0.001 USD). However, the potential of mHealth for the management of NCDs such as hypertension is not studied yet.

There are some emerging studies on the feasibility of mHealth in nutrition counselling[232] and complementing the work of FCHV for hypertension management.[233] The results showed that more than 70 % of the participants had access to mobile phones with text message service and were interested in receiving information through mobile phones. This study also recommended the use of mHealth in complementing the work of FCHV in the management of hypertension.[233] However, there was already a published study that reported the failure to implement the mobile community health workers program in rural Nepal due to a lack of proper management and planning of the program[234] as discussed already; therefore, contextual understanding is prime for informing the intervention development.

In summary, there are no robust studies to evaluate the effectiveness and acceptability of a mHealth (text messages) intervention for managing hypertension in Nepal. This focus of this thesis was therefore to develop and test the feasibility and acceptability of a text messaging mHealth intervention to manage hypertension in Nepal.

10. Summary of literature review

This review discussed the increasing burden of NCDs, especially CVDs, where hypertension is a significant risk factor. The burden of hypertension is increasing globally, particularly in LMICs, such as Nepal. The uncontrolled blood pressure among the diagnosed patients with hypertension is a significant therapeutic challenge, leading to high mortality and morbidity. There is a need to understand and address the barriers and facilitators of uncontrolled blood pressure to design the appropriate contextual intervention to reduce millions of preventable deaths from hypertension. In LMICs, there is a lack of resources and healthcare workers. With the increasing popularity and access of mobile phones in LMICs, it has high potential to be integrated into health care delivery to manage hypertension. However, there is evidence of the failure of such interventions in other countries.

There is a dearth of evidence for hypertension management intervention in Nepal, and some studies are focused on community health worker-led interventions. Due to scarce human resources and already overburdened role of community health care providers, it may be challenging to task them also in NCD management. The increasing popularity of mobile phones in Nepal can assist the healthcare work force in hypertension management. Some robust studies reported that simple text messaging interventions could be feasible and cost-effective for improving high blood pressure treatment and control. However, mostly those studies are confined to HIC settings, and differential findings are reported to improve adherence to treatment and blood pressure control.

In the context of Nepal, there are not any robust studies conducted using mHealth to date in the management of NCDs like hypertension in Nepal. Therefore, the feasibility and acceptability of a mobile phone text messaging intervention using robust methods among hypertensive patients is a need for evidence generation and support in this area.

Section II

2. Health behaviour theories, models, and frameworks

This part 2 of this literature review distinguishes between the three concepts: Theory, Models and Frameworks. The literature review then provides an overview of commonly used health behaviour theories, models, and frameworks in previous research. In addition, this section also discusses the COM-B Model and Technology Acceptance Model (TAM), its use in mHealth acceptability studies and its relevance in this PhD study.

2.1 Background

Health promotion is an integral part of public health implementation science.[235] It is very challenging to change entrenched behaviour, which is an essential determinant of health.[236] A broad recognition of the use of health behaviour theories, frameworks and models for public health intervention development and implementation has emerged.[237]Health behaviour theories offer a clear description of how and why specific behaviours lead to specific outcomes.[237]Theories act as a foundation for understanding health-impacting behaviours and offer a useful guide when designing and evaluating behaviour change interventions. [238] In any public health program planning, theory can be used to understand why the people are not following the particular behaviours and then guide on the development and selection of the appropriate strategies so that it can reach the targetted audience and have a better impact. [239] There is also evidence that interventions designed based on theory have better outcomes.[240] However, the three concepts: frameworks, models, and theory, are usually used interchangeably without having clarity of their differences.[241] Some of the more influential concepts are briefly presented in the following section.

Health behaviour theory: Defined in various ways, a comprehensive definition given by Kleiner is "a theory is a set of interrelated constructs (concepts), definitions and propositions that present a systematic view of phenomena by specifying relations among variables, to explain and predict the phenomena".[242] Bandura (1986) highlighted that "theories are interpreted in different ways depending on the stage of development of the field of the study".[243] The concise definition given by the Glanz (2008) is "interrelated concepts, definitions, and propositions that explain or predict events or situations by specifying relations among variables".[239]It should be logical and tested by previous researchers in a similar context. Therefore, the theory should be chosen based on the target population and area of research.[244] Theory will also help to frame the study questions and develop hypotheses, thereby clarifying the constructs to be measured.[245]

Models: Models are developed using a number of theories better to understand the specific problems of a particular setting.[239] Models are guided by one or more theories and based on the empirical findings as well.[246] Though it is difficult to differentiate between theory and models, the model is descriptive with a narrowly defined scope of explanation, whereas theory is both explanatory and descriptive.[247]In health promotion, various models are used to support program planning and implementation.[239]

Frameworks: A framework provides a structure, outline or plan of the relationship between the different categories such as concepts, constructs and variables that are assumed to cause certain phenomena of interest.[237] According to Swanson et al. “The theoretical framework is the structure that can hold or support a theory of a research study”.[248] It provides a structure for what to look into the data, how to fits data together and helps to discuss the findings based on the existing theory.[249]

2.2. Review of commonly used health behaviour theories, models, and frameworks

Over time, different human behaviour theories/models/frameworks have been used. Among all, the followings theories and models are being widely used i)The Health Belief Model (HBM) [250] ii) The Theory of Planned Behaviour (TPB) [251] iii) Transtheoretical Model (TTM)[252] iv) The Social Cognitive Theory (SCT)[243] v) Behaviour Change Wheel- COM-B model.[236] In a recent review of 82 behavioural change models and theories, TTM, SCT, TPB and HBM were reported as most widely used in the literature.[253]

Health Belief Model

The Health Belief Model (HBM) has been used since 1950s to explain human behaviour for decision-making processes related to health.[250] Social scientists wanted to explain why people were not using services like X-rays though they were available free of charge. They discovered that people’s beliefs about the severity and consequences of disease affected their decision to use relevant health services. This model was later expanded to include six constructs, as opposed to four initially. The constructs are perceived susceptibility, perceived severity, perceived benefits, perceived barriers, perceived self-efficacy and cues to action.[250, 254]

Theory of Planned Behaviour

The Theory of Planned Behaviour is an extension of Fishbein's Theory of Reasoned Action (TRA).[255] The TRA focused on behavioural intention as the determinant of behaviour.[256]However, it was criticised that component of the TRA, complete volition control, was not sufficient to predict human behaviour.[239] Later, Ajzen and colleagues created the TPB by adding the perceived behavioural control to TRA.[257] The primary constructs of the TPB are attitudes, behavioural intentions, subjective norms, social norms, perceived power and perceived behavioural control that represent the person's control over the behaviour.[254]

Transtheoretical Model

The Transtheoretical Model (TTM) is an extensively used model for behaviour change. This model views health behaviour progression through five stages: pre-contemplation, contemplation, preparation, action and maintenance.[258] TTM recognises that there are specific needs of information about the change at each stage of behaviour change. At the centre of this theory are self-efficacy and decision-making balance.[259] However, the stages of behaviour change, the time needed for change, and the effectiveness of interventions are arbitrarily defined, and measurement of the stages varies based on how the researcher sets the cut-off point of each stage of behaviour.[260, 261]It has been criticized that not all behaviours have a clear stage required in the TTM.[254] There is a need for studies to incorporate all dimensions and stage-specific processes of change specified in the model to determine the effectiveness TTM.[262, 263]

Social Cognitive Theory

Social Cognitive Theory (SCT) operates under the concepts of opinion, beliefs, thoughts, and support of the surrounding people, which might influence someone's behaviour and reciprocally affect those people. The social environment includes family members, friends and co-workers.[244] According to the concept of the SCT, a person learns behaviours through observing others' behaviours. Reciprocal determinism, behavioural capability, observational learning, reinforcement, expectation and self-efficacy, are the main constructs of the SCT that might affect a person's behaviour.[243, 264] A central construct of the SCT is self-efficacy. Self-efficacy is related to people's beliefs about their capabilities to perform some activities in a prospective situation. SCT identifies the four primary ways of developing self-efficacy: mastery experience, vicarious experiences, improving physical and emotional states, and social persuasion.[265] Self-efficacy beliefs determine how people motivate themselves and face difficulties by setting the goals and outcome expectancies that lead to success or failure.[266] However, the SCT is broad in its attempts to explain all kinds of human behaviour. Because of this, the SCT has not been tested as extensively as other health behaviour models.[239]

The need for using many theories

Behaviour change presents unique challenges. It is also important to note that a single theory cannot explain multiple health behaviours compared to theories specific to certain behaviours.[236] Behaviour change interventions should be designed to target the specific behaviour, which needs a systematic understanding of the behaviour and systematic design. The need for theoretical approaches for the maintenance of health behaviour, which are distinct from initiation of behaviour, has been pointed out by some researchers.[267] Additionally, the need for empirical studies on general versus specific theories has also been raised.[268] There have been many attempts at systematic intervention design, including MINDSPACE used by the UK government[269] and intervention mapping[270] adopted by many other countries. However, none of the available frameworks cover the comprehensive interventions of all available options.[271] With the realisation of the need to have a platform that can tap into the best theories and models that suit all conditions, Miche et al. commenced a project to develop a comprehensive behaviour change model[236, 271] for understanding the health behaviour that can systematically guide the intervention design. This is presented and discussed in the next section.

Behaviour Change Wheel (COM-B Model)

The BCW was developed by Michie et al. with the consensus of 33 researchers based on evidence from numerous studies in health psychology and implementation research.[236] In a systematic review, Michie et.al; defined 26 theory-linked behaviour change techniques used in the intervention.[272] At first, they identified 33 theories and 128 constructs; incorporating those into one framework created the behaviour change wheel. Michie et al. proposed 12 sub-themes and organised them under three main themes for identifying the implementation of evidence-based practice.[273] The main aim of this work was to provide a framework that helps to understand health behaviour better and address the deficits of behaviour.[236, 271] Without a clear picture of behaviour change techniques, it is challenging to identify the factors that contribute to an intervention's effectiveness.[272] The BCW, depicted in Figure 2.22, consists of three circles where the inner circle is the source of behaviour that causes and maintains the behaviour or prevents it from changing. The middle circle of the wheel contains nine (education, persuasion, incentivisation, coercion, training, enablement, modelling, environmental restructuring, restrictions) different intervention functions that address one or more behavioural function deficits. The outer circle of the wheel is divided into seven different categories of policy, guidelines, environmental/social planning, communication/marketing, legislation, service provision, regulation, and fiscal measures. This hub of the behaviour change wheel defines a problem, specifies the target behaviour, and identifies an area that needs change. Thereby, this model helps to understand and define a person's health behaviour. This hub of behaviour systems termed the COM-B model, involves three interacting essential components, capability, opportunity and motivation:[271]

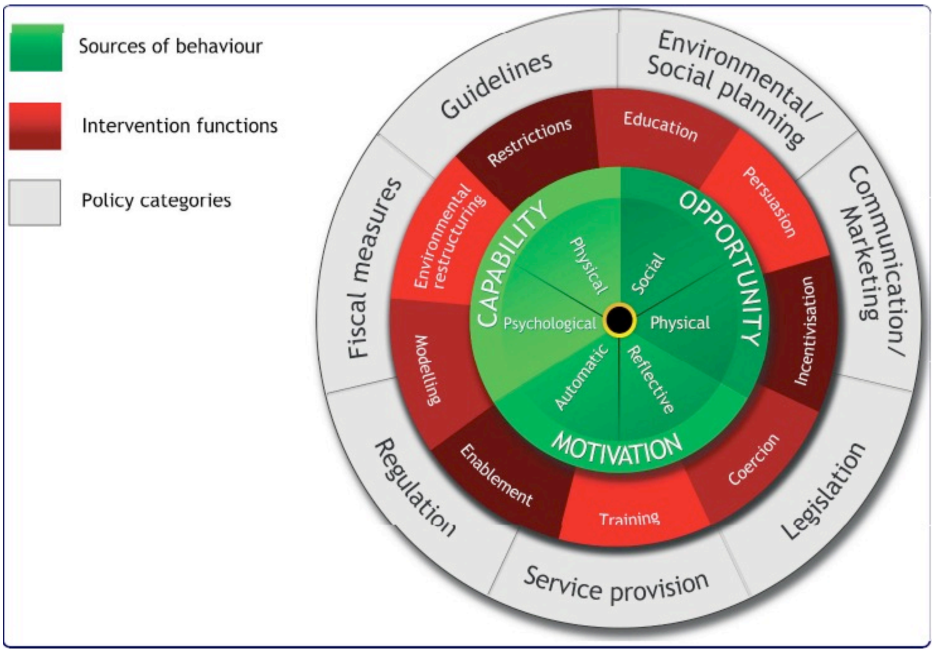

Figure 2.22: Behaviour Change Wheel

Source: Miche et.al [236, 271]

Components of the COMB model

The model assumes that interaction among the three components, Capability, Opportunity, and Motivation (COM), causes behaviour (B). (Fig 2.23)

Capability: Capability is defined as an "individual's psychological and physical capacity to engage in concerted activity", which includes having necessary skills and knowledge. Capability is divided into "psychological capability (capacity to engage in necessary thought processes) and physical capability (capacity to engage in necessary physical processes)". [236, 271]

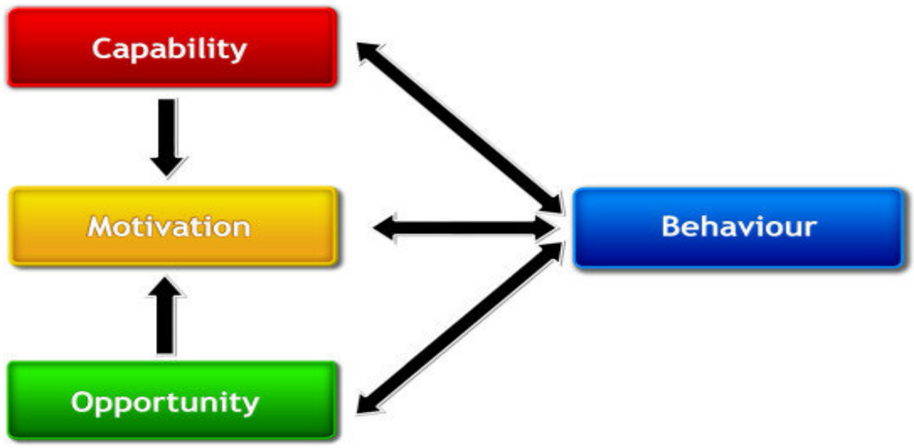

Figure 2.23: COM-B Model

Source Miche et.al [236, 271]

Motivation: Motivation comprises 'all the brain processes that energise and direct behaviour, not just one's goals and conscious decision making, but also their habitual processes, emotional responding and analytical decision-making". [236]

Opportunity: Opportunity comprises the external factors for an individual that make behaviour change possible or prompt the change. Opportunity is divided into a "physical opportunity (provided by the environment) and social opportunity (cultural factors that determine the person's behaviour)". [236] It includes a person's physical and social environment that might facilitate or impede their health behaviour. Opportunity explicitly considers the external resources that are not usually included in other health behavioural models

As depicted in Figure 2.23, the COM-B model shows that capability and opportunity influence motivation and behaviour. So, if there is higher capability and opportunity, chances of behaviour change are high due to more influence on the motivation. It also shows that feedback from the behaviour to all the three precursors can be positive or negative based on the situation.[274] This reflects the need for a strong commitment to change (intentional factors), the necessary skills and abilities to perform the behaviour (capability factors), and addressing constraints imposed by the health system (opportunity factors) for a behaviour change.[273] Through this model, a rationale for not engaging in a specific recommended behaviour can be identified and addressed. Nine intervention functions encircle this hub and address deficits in one or more behaviour related to a particular health condition. The outer wheel, the policy categories, includes broader population-level strategies that enable the behaviour. This model is a reformulation of previous behavioural research and is a very useful guide for classifying the possible drivers of behaviour and the design of behavioural interventions.[275]

2.3. Summary of applications of above-discussed models/theories

As discussed above, each theory has some unique construct within its tenets. Despite their wide use, these theories are not free of shortcomings. The 'Perceived Threat' construct of the HBM is unique compared to constructs contained in the TPB and the TTM.[254] Perceived barriers and self-efficacy explicitly inhibit behaviour change in the HBM, TPB and TTM. The central component of the HBM and TTM is a readiness to change.[239] Some models have mainly been used in specific areas such as safer sex [276,277] and alcohol use.[278] For instance, for examining behaviour such as preventing complications of illness and enhancing perceived susceptibility and severity, the HBM could be appropriate. In rational behaviour, where there is a strong link with theory, the TPB may be appropriate.[279,280] For deliberate behaviour (such as exercise), the TTM is most appropriate. This theory is less appropriate in simple automatic behaviour (habits), such as using seat belts.[281] However, many of these theories contain similar overlapping constructs but use different terminology and present these constructs differently.[271] There is a lack of consensus regarding the names of certain constructs, which has resulted in fragmented literature.[268]

The Health Belief Model (HBM) and Social Cognitive Theory (SCT) are examples of complementary health behaviour theories that can help to understand the broader range of behaviours. The HBM considers an individual solely-responsible for the maintenance of health behaviour,[250]whereas the SCT considers an individual in the context of their social environment.[243]For understanding behaviours regarding the recommended lifestyle changes for hypertension, including perceived susceptibility, perceived severity, perceived barriers and self-efficacy, many constructs of the HBM are helpful.[282] However, these existing models do not address the crucial roles of impulsivity, habit, self-control, associative learning, and emotional processing.[236,283] Over the decade, many models have been used to understand the foundations of health behaviour, as discussed earlier. Still, it is also essential to understand the behaviour that needs to target through appropriate intervention. Existing models and frameworks have also been criticized as not comprehensive. They neglect automatic processes such as habit; [243, 250-252] dynamic behaviours are not elaborated properly as beliefs about health issues. These existing models/frameworks often neglect factors at health system levels like opportunities and availabilities for the intended behaviour change.[284]

In this context, the behaviour change wheel – including the COM-B model, has been put forward as a comprehensive model for understanding the behaviour, and designing the intervention systematically targeting the specific behaviour. Based on the aims of this study, the COM-B model developed by Miche et al[271] was found to be relevant to explore the barriers and facilitators of blood pressure control in Phase I and guide the intervention development in Phase II of this PhD thesis.

2.4 Application of Behaviour Change Wheel (COM-B Model) in previous studies

Since the development and dissemination of the BCW and COM-B model, it has been used in many areas as a useful model for implementation science.[284-294] Some studies have used this model in other disease management programs, such as in systematic reviews on the barriers and facilitators to chlamydia testing,[295] understanding the barriers and facilitators to maintain healthy postnatal lifestyles in the UK,[291] development of mHealth interventions among diabetes patients in Bangladesh [296]and in identifying the facilitators and enablers of the Healthy Kids Check program in Australia.[292]

The primary focus of this section is to discuss the use of the COM-B model in studies focusing on CVD and HTN management, such as medication adherence and lifestyle changes (exercise, alcohol, physical activity, dietary changes etc.). This model has also been used by the researchers as a framework to structure and analyse systematic reviews such as on adherence to medication,[284] barriers to awareness, treatment and control of high BP[132] and strategies to improve CVD medication adherence among the disadvantages people.[297] Review by Jackson et al. [284] has used the COM-B model to identify the associated factors of nonadherence and interventions based on identified factors. This review recommended the achievement of physical and social opportunities through environmental change.[284] Similarly, Laba et al. has used this model for categorising the specific types of intervention for improving adherence to cardiovascular medicine in a systematic review.[297] In 2014, Khatib et.al. utilised this model in grouping barriers faced by patients and health care providers on hypertension awareness, treatment and follow-up.[132] Through this model, they have presented the different individual and system-level barriers systematically. This reflects the utility of this model in various systematic reviews related to the CVD and hypertension management.

Additionally, this model was utilised for exploring the barriers to CVD medication at LMIC [285] and some interventions development as well.[287-289, 294] In 2021, Mishra et.al. utilised this model for categorising different barriers to CVD medication explored through the qualitative studies in two LMIC countries, Indian and Ghana.[285] Mishra et al. used this model for informing their study tools and analysis. Similarly, there were fifteen ongoing projects funded by the Global Alliance of Chronic Diseases (GACD) focused on implementation research to combat the burden of chronic diseases in LMICs and in vulnerable populations of high-income countries presented in a study by Peris et al. in 2015.[294] All of these studies focused on decreasing blood pressure-related problems. They used the BCW, including the COM-B model, to post-hoc analysis of behaviour change strategies in their intended projects.[294] They used this framework to map the capability, opportunity and motivation of the different factors related to the project, like non-physician health workers, community members and doctors working in primary health care facilities.[294] They mapped their work in the early stages of the 5-year GACD Hypertension Research Programme to see the progress after implementing the planned studies. However, they have not tested the usability of this model in the implementation of these individual research projects, only used this model for categorising the intended intervention strategies in the planning phase of each project.

Similarly, Jatau et al. used this model in their review to demonstrate the factors affecting the participation in the undiagnosed atrial fibrillation in the community-based screening. They mapped the 28 factors of undiagnosed atrial fibrillation into the COM-B Model based on the 21 study's findings in the review. In addition, they recommended 24 strategies and seven steps based on the BCW to design and implement the intervention to improve atrial fibrillation detection in the general community.[288] This model was planned to be utilised in other studies like understanding financial barriers to care among patients with cardiovascular-related chronic disease,[298] for development the intervention for improving the self-care adherence of patients with heart failure.[287] It showed the broad applicability of the COM-B model in explorative research and guidance in intervention design and implementation.

2.5 The rationale for using the COM-B Model in this study

The Behaviour Change Wheel (BCW), developed by Michie and colleagues,[271] was used as the underpinning framework in this study for exploring the perceived barriers and facilitators to treatment and control of high BP among patients with hypertension in Nepal (Chapter III). This COM-B Model was already applied in similar studies to explore barriers, facilitators, and intervention development, as discussed earlier.[132, 284, 294, 299] Furthermore, it can lead to more accessible ways for identifying the appropriate intervention based on the lack of any COM factors in the behaviour. Thereby, it can guide selecting the appropriate intervention by linking with intervention functions and policy strategies of the Behaviour Change Wheel.[236]Therefore, this model was also used to design the text messages intervention for treatment and control of BP by linking with the identified barriers and facilitators under the COM-B model as discussed in Chapter 5.

There are many challenges in managing hypertension, such as a lack of understanding of the condition and its effects, which lead to decreased perceived severity and susceptibility regarding the consequences of HTN. In addition, medication adherence is a critical predictor of blood pressure control,[282] which was one of the focuses of this PhD thesis. Earlier studies have focused on communication between healthcare providers and patients for improving their blood pressure control.[300,301] However, only providing the information might not be effective in changing the behaviour of the patients; factors preventing the health behaviour need to be identified.

In this context, the COM-B model is promising, comprehensive, developed considering all other implementation science theories. It is a psychological model which explains a range of health-related behaviours and their causes.[236] It can help in understanding the factors related to adherence and other behaviours for chronic disease management.[284] In addition, this model attempts to include all of the determinants of health, not just focusing on the individual phenomena. It tries to incorporate the factors outside an individual, such as physical and social opportunities, essential for chronic disease management. Therefore, based on its applicability and scope in a similar context, the COM-B Model has been identified as the most relevant model in this thesis.

2.6 Different theories/models for the digital technology acceptance

The theory and models are increasingly being used to provide valuable insights into implementation and evaluation of digital health research.[302] Various health behaviour theories/models (such as the Health Belief Model, Transtheoretical Model, Theory of planned behaviour, Theory of Reasoned Action and Social Cognitive Theory) as discussed in the earlier section have been used for the digital intervention development.[302, 303] The most common information technology models/theories used to understand the acceptability and adoption of the new technology are the Technology Acceptance Model (TAM) and Unified Theory of Acceptance and Use of Technology (UTAUT) model.[304] TAM was developed by Davis (1989)[305] based on the theory of reasoned action by Ajzen and Fishbein.[306] Later ,Venkatesh and colleagues developed the UTAUT model , an extended version of original TAM, considered the performance expectancy, effort expectancy, social influence mainly predicts the behavioural intention of using the technology; facilitating conditions and behavioural intention predicts the technology usage directly.[307] The UTAUT model has been utilised for assessing acceptance of the mobile apps for the self-management of hypertension[308]and other mobile payment apps adoptions.[309] Most of the research has used the Technology Acceptance Model to understand digital technology acceptability.[310] Though some efforts are made to extend the TAM model, such as TAM-2 and UTAUT,[310] this study utilised the pragmatic TAM model based on its applicability, as discussed in the next section.

2.7 Technology Acceptance Model

Our study used the TAM model developed by Davis[305] as an overarching model to understand the acceptability of the proposed text messaging mHealth intervention as presented in Chapter 4. This model has two main concepts: perceived usefulness and ease of use, as the main factors for an individual's acceptance of the technology. Perceived usefulness is defined as "the extent to which a person believes that using the system will enhance his or her job performance".[305] Perceived ease of use is defined as "the extent to which a person believes that using the system will be free of effort". The TAM model hypothesizes a strong relationship between a person's intention to use and actual use of technology. [311] The main concepts of the TAM model are presented in figure 2.24. This model proposes that external factors would affect the individuals' perceived usefulness and ease of use, which mediate the actual system use. External factors could be socio-cultural (language, skills, facilitating conditions) or political factors. In addition, this model also theorizes that perceived ease of use of technology also affect the perceived usefulness of the technology.[310] The attitude to using the technology is concerned with the user's evaluation of the desirability of using a technology. Intention of use is the probability of a person using the technology.[312]

This model is valid, robust and has been widely used in understanding human behaviour in the acceptance of technology.[313-315] Nguyen et al. used this model as a guiding theoretical framework for exploring the health care providers and administrators' perspectives on using technology for palliative care in Canada.[316] Similarly, a systematic review by Bahlol et al. in 2018 reported that the use of the TAM model in telemedicine, electronic health records, and mobile applications was included in 134 studies. In addition, this review also showed the use of the modified TAM model by adding other concepts such as subjective norm, self-efficacy etc. in some of the included studies.[314]

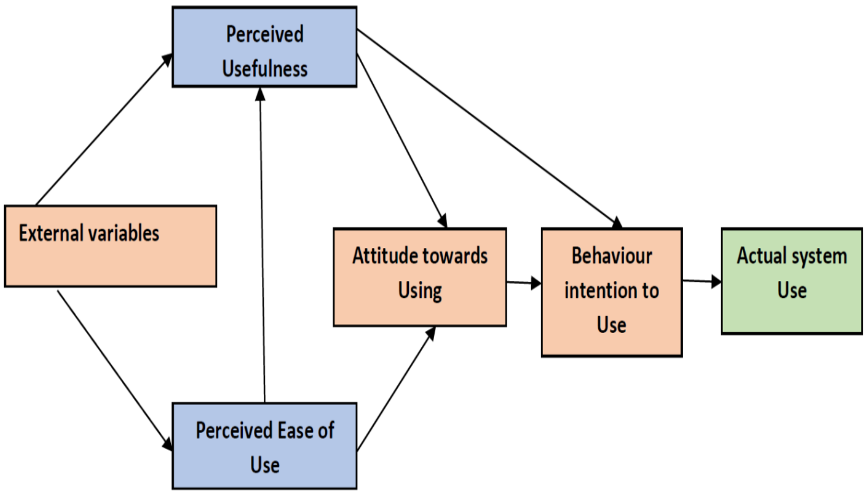

Figure 2.24: Technology Acceptance Model

Source: Davis FD, 1989 (305)

Similarly, Xue et al. utilised this model to assess the perception of aging women in using mobile technology for getting health information.[317] The meta-analysis conducted by William et al. reported wide use of the TAM model in 88 included studies due to its understandability and simplicity.[313] It reflects the wider use and popularity of the TAM model, though there are some additions or extensions of this model based on the research context.[310]

This PhD study utilised this model based on its applicability and simplicity in understanding the acceptability of text messaging mHealth intervention of the prospective users that might affect the actual use of the intervention.

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Chapter 3: Barriers and facilitators for treatment and control of high blood pressure among hypertensive patients in Kathmandu, Nepal: A qualitative study informed by COM-B Model of behavior change

Link to thesis

Based on the gap identified in the literature review (Chapter 2), qualitative study was conducted to explore the barriers and facilitators for the treatment and control of blood pressure among hypertensive patients in Nepal. This chapter presented findings of the qualitative study which informed the content of the text messages of our second phase TEXT4BP intervention presented in the Chapter 5 and 6. This study was published in the BMC Public Health and is presented in this chapter as it is published in the journal. **https://rdcu.be/ct7sa**

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Barriers and facilitators for treatment and control of high blood pressure among hypertensive patients in Kathmandu, Nepal: a qualitative study informed by COM-B model of behavior change

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Abstract

Background: Nepal has a high prevalence of hypertension which is a major risk factor for cardiovascular diseases globally. It is inadequately controlled even after its diagnosis despite the availability of effective treatment of hypertension. There is a need for an in-depth understanding of the barriers and facilitators using theory to inform interventions to improve the control of hypertension. This formative study was conducted to address this gap by exploring the perceived facilitators and barriers to treatment and control of hypertension in Nepal.

Methods: We conducted in-depth interviews (IDIs) among hypertensive patients, their family members, healthcare providers and key informants at primary (health posts and primary health care centre) and tertiary level (Kathmandu Medical College) facilities in Kathmandu, Nepal. Additionally, data were collected using focus group discussions (FGDs) with hypertensive patients. Recordings of IDIs and FGDs were transcribed, coded both inductively and deductively, and subthemes generated. The emerging subthemes were mapped to the Capability, Opportunity, and Motivation-Behaviour (COM-B) model using a deductive approach.

Results: Major uncovered themes as capability barriers were misconceptions about hypertension, its treatment and difficulties in modifying behaviour. Faith in alternative medicine and fear of the consequences of established treatment were identified as motivation barriers. A lack of communication between patients and providers, stigma related to hypertension and fear of its disclosure, and socio-cultural factors shaping health behaviour were identified as opportunity barriers in the COM-B model. The perceived threat of the disease, a reflective motivator, was a facilitator in adhering to treatment.

Conclusions: This formative study, using the COM-B model of behaviour change identified several known and unknown barriers and facilitators that influence poor control of blood pressure among people diagnosed with hypertension in Kathmandu, Nepal. These findings need to be considered when developing targeted interventions to improve treatment adherence and blood pressure control of hypertensive patients.

Key words: Hypertension, Adherence, Stigma, formative study, lifestyle

Background

Hypertension is a major risk factor for cardiovascular disease (CVD).[1] It is reported to be a leading contributor to premature death and disability in the Global Burden of Diseases study in 2017.[2] The global Disability-Adjusted Life Years (DALYs) due to hypertension has increased by 40% from 1990 to 2016.[3] In low and middle-income countries (LMICs), the prevalence of hypertension is reported to have increased by 7.7 % between 2000 and 2010.[4] In a 2014 study, 27% of participants in the South Asian Association for Regional Cooperation (SAARC) region were found to have hypertension. [5] Nepal has witnessed an increment in hypertension from 21.5%[6] in 2008 to 24.5%[7] in 2019, as reported in the STEP Wise Approach to Surveillance (STEPS) surveys.

Despite clear evidence regarding the effective treatment of blood pressure using medication, global studies have reported that around half of diagnosed hypertensive patients remain untreated and more than half of those being treated continue to have uncontrolled blood pressure.[8] Studies in Nepal have found unacceptably high rates of uncontrolled blood pressure including 67% of the patients under treatment in a hospital-based study;[9] 65% in a community-based study of Central Nepal;[10] and 85% in diagnosed patients in a community-based study of Western Nepal.[11]

Systematic reviews on barriers to management of high blood pressure have reported factors related to patients, providers and the health system.[12, 13] Several reviews have identified factors related to medication adherence for hypertension. [14-16] Recent studies conducted in Nepal also have shown inadequate knowledge of hypertension and its treatment, poor medication adherence, irregular follow-up, lack of availability of uniform treatment guidelines , and the inability of healthcare providers to deliver lifestyle modification messages as major challenges for high blood pressure management.[17, 18] However, there are no clear insights into the underlying factors of treatment adherence and blood pressure control to facilitate the design of appropriate interventions. There is an evidence that supports the use of behavioural theory in designing health interventions for effective outcomes.[19] Therefore, this formative study was conducted using a well-accepted theory, the COM-B Model[20] for behaviour change to not only identify and analyse facilitators and barriers to treatment and control of high blood pressure among hypertensive patients, but also to inform the development of behaviour change interventions.

Methods

Study setting: Nepal is a Low Income Country (LIC) where 25.2% of people are living below the poverty line.[21] In Nepal, out-of-pocket healthcare expenditure was 57.8% of the share of the total healthcare expenditure in 2017.[22] Primary care is delivered through a network of health posts (HPs), and primary healthcare centres (PHCCs) which are the first points of contact with the health system. Patients suffering from non-communicable chronic diseases are usually referred to hospitals with specialist facilities generally located in urban areas. We initially selected HPs and PHCCs of the Kageswori Manahara Municipality of Kathmandu, a semi-urban area. However, we found that hypertensive patients were visiting Central tertiary level healthcare facilities to receive treatment. Hence, this study was also conducted at Kathmandu Medical College and Teaching Hospital (KMCTH) to obtain a comprehensive picture of barriers and facilitators faced by hypertensive patients at different levels of the health system. KMCTH is a tertiary level referral health facility, where patients come from various parts of the country.

Study methods: A qualitative study was conducted among patients and providers to explore their perspectives on barriers and facilitators to treatment and control among hypertensive patients in Nepal. Qualitative methods are appropriate for formative research where there is a need to explore determinant factors that are specific to a context and where literature is limited. Qualitative methods can provide deep insights into the problem being studied.[23] The findings of this formative study were used in informing the intervention (TEXT4BP), a pilot randomized control trial being tested among hypertensive patients in Nepal.[24]

Study participants: To obtain diverse views from all critical stakeholders, we included hypertensive patients, their family members, healthcare providers working at different levels of the health system and key informants. We included patients (ranging from 30-70 years old) who had been diagnosed with hypertension and were prescribed anti-hypertensive drugs by a qualified medical practitioner. To ensure maximum variability, we undertook purposive sampling of patients with diverse characteristics (age, sex, level of education, duration of disease and status of control). We excluded hypertensive patients with serious complications (e.g., stroke, myocardial infarction, kidney diseases etc.) and those with co-morbidities requiring advanced care at a secondary or higher-level hospital as these limited their ability to participate in the study. However, we included patients with co-morbidities who were not serious and did not require immediate treatment. Patients with severe mental and physical disabilities and pregnant women were also excluded. Healthcare workers from PHCCs and HPs of Kageswori Manahara Municipality (primary level) and KMCTH (tertiary level) were interviewed.

Recruitment: Healthcare workers distributed a study flyer containing information on the objectives, eligibility, and nature of the study to eligible hypertensive patients at selected health facilities. A list of those who agreed to participate was provided to researchers along with participant contact details. Participants, of both FGDs and IDIs, were asked to nominate and obtain consent from those family members who were involved in their care so that the researchers could contact family members purposively. The healthcare providers from selected sites were also invited for an interview to obtain their perspectives. To gather policy-level perspectives on challenges faced by the patients, key informants working in the Non-Communicable Diseases (NCDs) management (policy makers, researcher, NCDs program focal persons at Department of Health services, MoHP) were interviewed in the study. Details are presented in the table 3.1 and 3.2.

The behavioural model informing the study: Barriers to high blood pressure treatment and control were defined as any factors restricting the performance of recommended behaviours for patients to maintain optimum blood pressure control and treatment (medication and lifestyle). [25] The COM-B model a component of the Behaviour Change Wheel (BCW), developed by Michie et al.[20, 26] was used as the overarching model in this study. The study utilized this model to understand the capability, motivation and opportunity barriers and facilitators for treatment and control of high blood pressure faced by patients. In addition, providers perspective was sought on the relevant components of the COM-B Model, for instance, opportunity barriers faced by patients in seeking and maintenance of treatment. This model has been used in similar studies in other settings[27-30] to understand the perspectives of both the service users and providers.[31-33]

The COM-B model (Fig 3.1) involves three interacting components: Capability, Opportunity and Motivation. These components are further divided into six sub-components.[20, 26] Capability comprises psychological and physical capability. Psychological Capability is the capacity to engage in necessary thought processes, while physical capability encompasses the capacity of any individual to engage in a necessary physical process to modify their lifestyle and adapt to change [20] The component opportunity refers to the external factors of the individual that makes behaviour change possible or prompts change, comprising two components–physical opportunity and social opportunity. Physical opportunity is provided by the environment; Social opportunity is the cultural milieu and social norms which dictates the way an individual thinks about things.[20] Motivation refers to ”all the brain processes that energize and direct behaviour, not just one's goals and conscious decision making”[20] and includes habitual processes, emotional responses, and analytical decision-making.

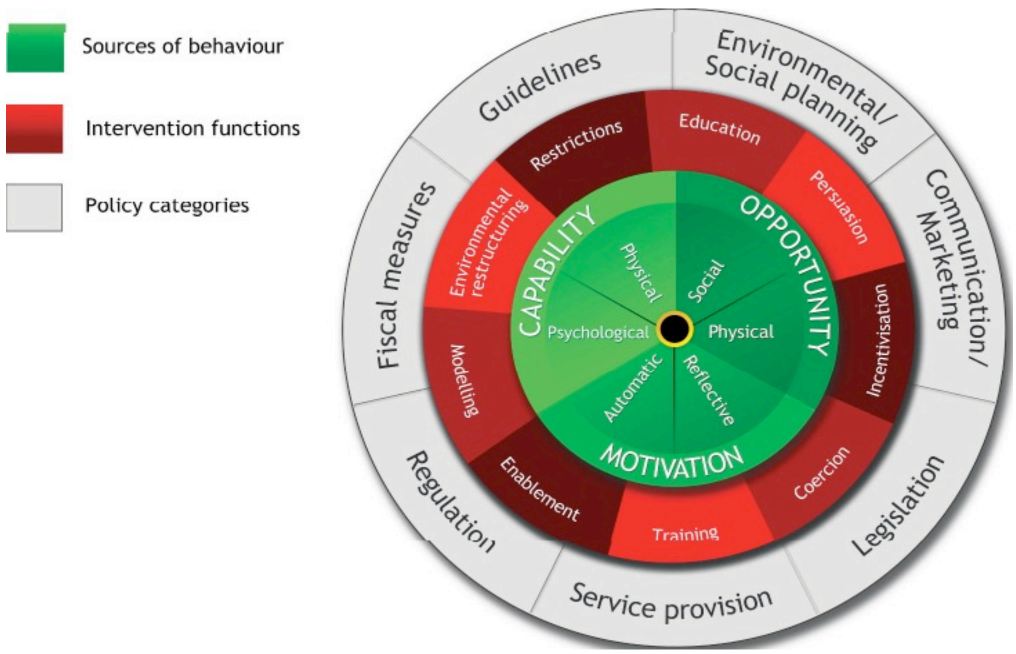

Figure 3.1: The Behaviour Change Wheel

[published with permission from Miche S] [20, 26]

There are two components of motivation in the COM-B model: reflective motivation and automatic motivation. The former involves evaluations and plans; the latter deals with emotions and impulses. [20] We used the COM-B model in developing interview guides to elicit barriers and facilitators during data collection. During analysis, the COM-B components were used as a framework to categorise the emerging sub-themes during thematic analysis.

Data Collection: We used in-depth interviews (IDIs) and focus group discussions (FGDs) methods to collect data from March to July 2018. All IDI and FGD topic guides were translated into the Nepali language and were pilot tested (Additional file 1: IDI and FGD guides). We conducted 25 IDIs among hypertensive patients (13 primary level, 12 tertiary level), five IDIs among family members, 11 IDIs among healthcare workers (five primary level, six tertiary level) and four IDIs among key informants. There were no refusals to participate in the IDIs and FGDs. The first author (BB, PhD fellow), a native female health professional with over ten years' experience in NCDs as a faculty and researcher trained in qualitative methods, conducted all interviews at selected venues that provided privacy for participants (private rooms of OPD of the selected health centres and at the homes of the participants at the primary care level). An audio-recorder was used to record the interviews. Field notes were taken by the interviewer and used during the analysis to understand the context and nuances of the responses. IDIs took 35 to 60 minutes each. Repeat interviews were not required. Two FGDs (8 patients in each) were conducted among 16 hypertensive patients who represented a diverse group of participants (Tertiary level). The first author (BB) facilitated the FGDs in the Nepali language. Each FGD lasted 60 min to 90 minutes. At both venues there were no additional people present apart from the interviewer during IDIs and FGDs. The number of participants for FGDs was based on the standard recommendations for FGDs (34) and patient-availability. The number of IDIs for patients was determined to obtain wide diversity by age, sex, level of education, duration of disease and controlled/uncontrolled blood pressure. Similarly, diversity was sought among the providers. The numbers were limited by reaching saturation in new findings. After each interview, the interviewer prepared the summary to see if any new ideas were emerging from IDIs to decide on the saturation of information.

Data Analysis: The first author (BB) transcribed 25% of the transcripts, and a qualified transcriber, fluent in both English and Nepali transcribed the remaining audio-recorded FGDs and IDIs. Before direct English transcription, three interviews were transcribed in Nepali and translated into English by the qualified transcriber. The English language transcripts were back translated by BB, and translation reliability and accuracy were compared with the original Nepali transcript. This process ensured the presence of no significant differences in translation. The transcripts were checked against audio recordings, and pseudonyms were applied to participants to maintain confidentiality.

QRS NVivo 12 software[35] was used for data management and coding using a codebook. Thematic analysis process outlined by Braun and Clarke [36] was used to analyse the data which involved searching, coding and categorizing words by words, lines by lines, and codes by codes throughout the dataset to identify a repetitive pattern of themes.[36]

All transcriptions were coded independently by the first author (BB). A random sample of three transcripts was shared with a co-author (RJ) for independent coding verification. Any discrepancies were resolved and agreed upon between investigators. We have used different methods of data collection like IDIs and FGDs and included the perspectives of diverse groups (patients, their family members, healthcare providers and key informants) in the study. Different methods and sources of data complemented the findings of each other. The initial codes generated from inductive coding were merged into subthemes and those emerging subthemes were mapped under the COM-B model using a deductive approach. For example, the codes that emerged inductively ("Fear of teasing/exclusion by friends; taking medicine secretly; not disclosing reasons for low salt diet; marriage prospects low on disclosure") generated the subtheme "Stigma of disease and fear of disclosure". We then mapped out these subthemes to themes based on the COM-B model using a deductive approach. The Consolidated Criteria for

Reporting Qualitative Studies (COREQ) 32-item checklist[37] was followed to ensure reporting consistency.

Results

The characteristics of hypertensive patients who participated in IDIs and FGDs are presented in table 3.1**.** The mean age of participants in IDIs was 50.2 years and in FGDs was 44.9 years. There were 44% males in IDIs and 56% in FGDs; 64% and 69% of patients were literate in IDIs and FGDs, respectively. The distribution of patients with blood pressure control was 60% in IDIs and 56% in FGDs.

Table 3.1**:** Sociodemographic profile of the study participants (Hypertensive patients)

Characteristics	**Categories**	**Hypertensive patients IDIs (N=25) (%)**	**Hypertensive patients FGDs (N=16) (%)**
Age (years)	30-40	6(24)	4(25)
	40-50	5(20)	6(38)
	50-60	7(28)	5(31)
	60-70	7(28)	1(6)
	Mean age ± SD	50.2 ± 11.3	44.93 ± 10.9
Sex	Female	14(56)	7(44)
	Male	11(44)	9(56)
Education	Literate	16(64)	11(69)
	Illiterate	9(36)	5(31)
Occupation	Employed	15(60)	14(87)
	Unemployed	10(40)	2(13)
Blood pressure status	Controlled (<140/90)	15(60)	9(56)
	Uncontrolled (≥140/90)	10(40)	7(44)

Duration of diagnosis of hypertension	Less than a year	2(8)	3(19)
	1-5 years	12(48)	10(62)
	More than five years	11(44)	3(19)

Detailed characteristics of other participants (HCWs, Key informants, family members) are provided in Table 3.2.

Capability

Psychological Capability: Sub themes under psychological capability comprised of:

Poor Knowledge and understanding of disease and treatment. Responses showed that many patients lacked necessary knowledge and understanding of various causes and risks associated with hypertension. Some were not aware of symptoms of hypertension and that it can be an asymptomatic disease. As one participant described:

> *"If it is increased… what will happen... like... [Inaudible]... if increased may be unconscious or fall… may faint… I don't know what happens." (P08:50-55Y, PHC level)*

Many study participants did not have adequate knowledge about the complications of hypertension and were unaware of the consequences of uncontrolled blood pressure. They did express the need for more information about risk factors and treatment of hypertension.

Table 3.2: Characteristics Health care providers, Key informants, and family members of hypertensive patients included in the study

Characteristics of health care providers (N=11)	Characteristics of key informants (N=4)	Characteristics of family members (N=5)
Sex		

Female	4	1	Female	3
Male	7	3	Male	2
Position			**Education**	
Cardiologist	3	NCD Policy maker -1	Literate	3
Physician and medical officer	3	NCD program focal person at DoHS, Ministry of health – 2	Illiterate	2
Health Assistant and Community Medical Assistant	3	NCD Researcher - 1	**Relationship with hypertensive patients**	
Nurse (ANM, Staff nurse)	2		Wife	1
Work experience			Husband	1
1-5 years	4	1	Daughter	1
5-10 years	4	1	Son	1
More than 10 years	3	2	Daughter in law	1
Level of health care				
Primary level	5	Both level - 4	Primary level	3
Tertiary level	6		Tertiary level	2

The themes and sub themes derived from the study are presented in Table 3.3.

Table 3.3: Mapping of themes to the COM-B Model

Emerging sub-theme from the transcript	Sub-components of the COM-B Model	Broad components of COM-B Model
Poor knowledge and understanding about the disease and treatment (B)	Psychological Capability	Capability
Misconceptions about the disease and treatment (B)		
Physical challenges in taking treatment and modifying behaviour(B)	Physical Capability	
Affordability: Cost of the hospital, medicine, investigation, travel costs (B)	Physical Opportunity	Opportunity
Availability: Hospitals, medicine, investigation, chemist shop (B)		
Communication between providers and patients (B)		
Stigma of disease and fear of disclosure (B)	Social Opportunity	
Socio-cultural beliefs shaping health behaviours (B)		

Beliefs about consequences of disease and treatment (B,F)	Reflective Motivation	Motivation
Belief and trust in alternative medicine (B)		
Difficulty in changing habits (B)	Automatic Motivation	

B= Barriers, F= Facilitators

Many were not aware of recommended behaviour modifications for blood pressure control. They did share their knowledge regarding the significance of exercise and salt reduction in their diet to control blood pressure; however, they did not know about the kind of exercises required for this and expressed their concern about salt intake. For example,

> *"Another thing is ... neither I know what exactly salt will do or how it will affect in my pressure... I don't have exact information." (FGD1- P02: 40-45Y, tertiary level)*

Many study participants reported the misinformation that adding water to their diet would reduce the amount of salt in it. On the other hand, if they were advised to reduce salt, the health providers were worried that they would restrict salt to such an extent that there would be other issues like hyponatraemia. As one health provider explained:

> *"Yes, they are cooking food without salt and taking out vegetables for them, and they will add salt for the family members… They are not taking salt completely, and another problem will arise. (HCW 01, PHC level)*

Some were aware that heart attack and sudden death could be a result of uncontrolled blood pressure.

Misconceptions about the disease and its treatment

Participants revealed many prevailing misconceptions related to the association between disease and age. Some stated that hypertension is a disease of old age, and therefore, medicine should not be started at a young age. They stated that if people get hypertension in their youth, they should delay the treatment until they reach fifty. One participant summed this approach up aptly:

> *"Half of the people I met said that I am too young to take medicine for pressure. They said that I should not be taking medicine before fifty years of age." (P014: 30-35Y, tertiary level)*

Patients considered anti-hypertensive medication as the last option after trying other alternatives. Hence, they were taking the anti-hypertensive medicine after getting complications and at late stage. Moreover, they were worried about taking medicine for a long time. Participants also expressed that they do not need to take medication until and unless they felt symptoms such as pain or discomfort. Healthcare providers agreed that patients usually do not start their treatment on time, and if started, it was after trying all other alternatives. Patients were likely to discontinue the treatment when their pressure was under control. As one participant described:

> *"I went to see the doctor (A-pseudonym) … Doctor checked my pressure, and it was 170/100. He gave me medicine... I took the medicine for 3-4 days and my pressure was in control, and I stopped that medicine." (P020: 35-40Y, tertiary level)*

It was evident that deeply rooted perceptions were guiding the hypertensive patients' behaviour, either they were not taking treatment or stopping them in between and not following recommended behaviour.

Physical capability During analysis, the following sub-themes related to physical capability were identified:

Physical challenges in medication adherence and lifestyle change There were many barriers and challenges in taking the medication regularly. Among those related to physical capability were (i) forgetfulness, (ii) inconvenience, and (iii) being too busy with other commitments. Forgetfulness or memory was also reported as a reason for not taking medicine on time. Though forgetfulness is a psychological factor, it resulted in challenges to the physical act of taking medicine. This was reported not only by elderly participants but even by young participants. For instance, a young participant expressed the need for a reminder to take his medication: "If there would be something to remind me, then that might be easy for me".

> *"And yes, sometimes I forget to take medicine as well. Medicine which needs to be taken in the morning, sometimes I forget and take that in the evening. Sometimes, I don't remember that as well." (P021: 35-40Y, tertiary level)*

It was evident that most patients faced challenges in changing their lifestyles. They reported a lack of skills and difficulty in managing time for exercise, giving exercise a low priority, negligence to take medicine and not following the recommended behaviour as the main challenges. One patient briefly explains:

> *"For physical activity, it would be good If I walk in the morning, but I don't feel waking up from the bed in the morning." (P011: 60-65Y, PHC level)*

Mostly female participants explained that they could not manage their time for the required physical activity due to their household commitments. Differentially assigned roles based on patient sex might also have affected their ability to modify behaviour in the study setting.

Opportunity: Physical opportunity

Availability and affordability of the health services

Access to health services and affordability of the treatment were expressed as important system-level challenges. Given the shortcomings in access to healthcare services for most patients in Nepal, there were many issues that pertained to a lack of appropriate medicine, no clear guidelines, a lack of skilled health workers, and a lack of training on NCDs at the primary healthcare level. A major barrier to treatment and follow up is a lack of universal access to health services and the requirement to access care at the tertiary level. Costs of medicine and diagnostic tests, lack of health insurance and heavy workloads of doctors at the tertiary level resulted in many participants discontinuing their treatment or inconsistent follow up.

> *"But here people in rural areas are not able to get proper treatment. There is less amount of health posts in those areas and with very little manpower. There is also a problem related to the availability of drugs. First is the geographical barrier; second is transportation problem; third is lack of health-related infrastructure; the fourth is lack of manpower and the fifth is the cost factor." (KI 04)*

In Nepal, anti-hypertensive medicine is not provided free of cost through the healthcare system. In PHC level, even participants expressed the concern of non-availability of antihypertensive medicine/pharmacy in nearby places.

> *We cannot buy these medicines (antihypertensive) around here. We must go there (city) for buying it. We must go till Chabahil (name of city -2-3 hr travel). Yes, must go that much far for buying it. I usually buy for a month for my mother. (Son of P01, 60-65Y, PHC level)*

Medicine needs to be taken continuously for the patient's life, so the issues of availability, cost of anti-hypertensive medicine and diagnostic tests were raised by the study participants. One of the key informants expressed that a *"country like ours haven't [sic] got the insurance policy and patient must buy the medicine from their own money and affordability is also one major barrier."*

<u>Communication between providers and patients:</u> Poor communication between providers and patients was one of the most important sub-themes that was elicited during IDIs. Many patients complained that their provider did not tell them about their diagnosis, medicine, and recommended behaviour modification. Some patients learned about their high blood pressure status after taking medication for almost two years.

> *"Now…. in the hospital, they will not tell in detail … They say, "your pressure is high, so you have to take medicine and write the name of the drug directly without any explanation." (P04: 60-65Y, PHC level)*

Healthcare providers admitted their shortcomings in counselling to make the patient understand their disease and treatment. They stated that they could not give enough time to patients for counselling, due to heavy workloads.

> *"One is the patient-doctor ratio. Especially in the government sector, there will be much rush. Must give plenty of time but we are not able to give that time." (HCW 010, Tertiary Level)*

Key informants also expressed that *"if the counselling is not done properly, they won't start taking medicine." (KI 02)*

Good communication plays a crucial role in enhancing the good relationship between the healthcare provider and patients. It helps patients to open-up about their problems, remove their doubts and enhance their trust in treatments.

Social opportunity is related to those cultural factors which determine a person's behaviour.[20] The sub-themes of social opportunity that directly affect a patient's behaviour are discussed below in detail:

The stigma of disease and fear of disclosure

Participants expressed fear to disclose their disease due to the social stigma attached to hypertension in their vicinity. For example, people with hypertension are considered generally weak and unable to perform their duties properly. Moreover, young, and unmarried male participants shared that it would be difficult for them to find a bride if they disclose their hypertension status. Two patients have expressed this stigma in detail:

> *"But I feel like… after knowing this my friend might tease me about this. Maybe there will be a difference in their behaviour regarding taking food, and there might be some limitation. I cannot tell other people... I feel ashamed." (P021: 35-40Y, tertiary level)*

> *"They think that if they marry a person who has high pressure, they will be barriers to their marriage… Yes, people try to hide it also. They never say they have it even though they have pressure." (HCW 05, PHC level)*

Stigma attached to hypertension, may have influenced health seeking behaviours, and follow up of treatment leading to uncontrolled blood pressure and complications. This was more evident with younger participants.

Socio-cultural norms shaping health behaviour

In some ethnic groups in Nepal, alcohol is associated with good luck (Sagun), as an offering to God during worship, and is also consumed on special occasions. Such cultural norms encourage alcohol consumption. A healthcare worker describes this cultural practice:

> *"In some community, it is like in their Sanskritic (cultural) program; alcohol is like necessary item. Drinks and alcohol should be there. Because of that, they are regularly consuming alcohol." (HCW 011, Tertiary Level)*

Furthermore, oily, and fatty foods are considered to be superior and delicious items and are commonly provided in feasts and festivals and offered to guests as a mark of hospitality. Consumption of salt also holds cultural importance. When there is a death of a close family member, people restrict salt in their diet to express their grief.

> *"We have deeply rooted old superstition and tradition as if anyone left salt, they ...people will say ...look she is unfortunate (aalacchini ...) look she is not taking salt as if there is death in the family. aalacchini …look…. who died in your family, so you are not taking salt...? people will say like this." (P05: 50-55Y, PHC level)*

The tradition and practice of salt intake during grief was a new insight for the researcher (BB) who is a member of the same society with the same cultural understandings of the process of death. Traditional and cultural norms associate obesity with good luck and wealth. These deeply engrained norms may discourage hypertensive patients from losing weight and negatively affect blood pressure control.

Motivation: In this study, two sub-themes of reflective motivation were identified.

<u>Beliefs regarding consequences of disease and treatment:</u> Beliefs about the consequences of disease were identified as a motivator for behaviour modification, especially in taking anti-hypertensive medicine. Several participants admitted that they were taking medication or following the recommended behaviour due to a fear of complications. For instance, participants thought that they might have a heart attack or suffer paralysis if they stopped the treatments prescribed by doctors.

> *"I am taking medicine. If I left 1-2 days, then I get afraid that I might get paralysis. (Laugh)... … I get scared of dying… and if I don't take medicine, then I can't sleep as well." (FGD2-06: 30-35Y, tertiary level)*

They feared consequences of complications of the disease. They were scared that if they were paralysed, their social life would be disturbed, they will be a burden to the family and may not get enough care. Participants also expressed fears of side effects of the medication and developing addiction to the medicine due to prolonged intake. Some hesitated to start taking the medication and discontinued after commencement. One participant describes this hesitation as:

> *"I left completely.... it would become my addiction and habit… it would be like Nasha (addiction) so, I felt sad about... that I had to take it always, so I left that medicine." (P021: 35-40Y, tertiary level)*

As for treatment, some participants believed that missing a single dose of anti-hypertensive medication could lead to instant death. Therefore, they preferred uncontrolled blood pressure over starting the prescribed medication.

<u>Belief and trust in alternative medicine</u>: Participants stated that they had more faith in homoeopathy, ayurveda and other traditional herbs and bitter vegetables as remedies for high blood pressure as compared to allopathic (Western) medicine. Due to their strong trust in traditional medication, locally available remedies remained their first preference to Western medication. Some patients expressed their belief in the consumption of bitter substances as a supplement to cure or control of high blood pressure.

> *"It's been around one month that my pressure is little higher.... I used to drink the juice of bitter melon (karela) before… my children used to give me that. So, I did not take medicine." (FGD1- 07: 40-45Y, tertiary level)*

The use of the juice of Jamara (green wheatgrass or barley sprouts) by Nepalese hypertensive patients was also reported during IDIs and FGDs. This is a recently introduced as a remedy for non-communicable diseases in Nepal. It also holds religious significance as it is used as a blessing during Dashain festival in Nepal.

> *"While going to walk, he usually takes Jamara's juice. That is only recently… and he also takes aloe vera juice. It's like if he heard anything like that will have a good impact on his health not only for the pressure; he usually takes that…" (wife of P014: 40-45Y, tertiary level)*

These kinds of practices were favoured because they were understood to have less side effects, were easily accessible, were low cost, were advocated by close relatives and had religious significance.

Automatic Motivation

Difficulty in changing habits: Participants also expressed behavioural inertia in changing lifestyles. For example, some were not following a recommended low salt and a low-fat diet.

Participants also found it challenging to shift to a low-fat diet as oil was an integral part of their daily diet. In Nepalese society, a low salt and low-fat diet are considered to be diet for an ill person. These kinds of perspectives may shape their behaviour, choosing foods with high salt and fat to consider themselves healthy. Even family member admitted such challenges of changing in dietary practices.

> *My wife (patient) loves eating fried meats and oily pickles (salty) a lot. I told her there is no use in having oily foods; control it. But it is the same. Nothing has changed. (Husband of P03: 35-40Y, PHC level)*

Similarly, participants confessed to being unsuccessful in trying to change their habits of smoking and consuming alcohol. An older participant residing in a rural area stated that she has been smoking since her childhood. Due to her long-term addiction, she was unsuccessful in her attempts to quit smoking even after being diagnosed with hypertension. She said, "yes, I tried many times to stop smoking but could not."

> *"I know everything... it will harm my pressure as well, but I am drinking(alcohol). It is like my challenge. I am taking medicine and taking alcohol, as well. It's all due to my habit." (FGD2- 09: 55-60Y, Tertiary Level)*

Hence, participant behaviours were guided by their entrenched lifestyles which are not easily modified**.**

Discussion

We conducted a formative qualitative study guided by an evidence-based tool, the COM-B Model of Behaviour Change Wheel,[20] to understand facilitators and barriers to the treatment and control of high blood pressure among hypertensive patients in Nepal and to inform our

TEXT4BP intervention study.[24] This study used theory-based formative research to develop interventions for hypertension management in Nepal. [24] The study explored the knowledge and misconceptions of the disease and treatment, access to reliable information and health services and many social and cultural factors as the main barriers. Under-resourced clinicians, high costs, low health literacy and poor communication between patients and providers compounded issues relating to opportunity and equity of treatment. Perceived threats of disease were identified as the facilitators for behaviour modification. Importantly, this study has identified the stigma of the disease and fear of disclosure as one of the barriers to treatment and control of blood pressure, which is the unique finding of this study. The discussion that follows will look at the main barriers that can be targeted to design behavioural interventions in the study setting.

Capability factors

Under the ‘capability’ theme, inadequate knowledge and various misconceptions about hypertension and its treatment were identified as barriers. These findings are consistent with previous studies conducted in Nepal[17, 18] and other similar LMICs.[12, 38, 39] In LMICs, illiteracy and inadequate access to information may significantly impact the knowledge and misconception of the disease and treatment. A lack of awareness and knowledge about hypertension may interfere with the timely diagnosis and management of blood pressure.[12] It plays a crucial role in modifying behaviour and seeking treatment which needs to be enhanced. The capabilities of patients with hypertension can be enhanced by providing education and skills training based on the BCW’s intervention functions.[20] The effectiveness of such educational interventions in improving knowledge about hypertension and treatment has been demonstrated by previous studies.[40-42] However, education alone might not be sufficient for the overall reduction of blood pressure.[43]

Our study has identified forgetfulness and being too busy as barriers for medication adherence under the component of physical capability, where the former was reported even by younger patients. This may explain the findings of quantitative studies from other LMICs, where old age was associated with higher adherence.[16] Several systematic reviews [14, 16, 44] have discussed the poor medication adherence as one of the main barriers for hypertension control following diagnosis. Previous studies in Nepal have also documented low adherence to medication in the range of 35% to 64%. [45, 46] Many reviews have followed the five dimensions of the World Health Organization (WHO) Multidimensional Adherence model [47] to identify and classify barriers for medication adherence. [14, 16, 44] Our study found patient-related capability, motivation barriers, and provider-related opportunity barriers for medication adherence to be prominent of the five dimensions. Moreover, participants expressed their need for reminders to take medications. A study from three South Asian countries reported that family members reminder in taking medication improved medication adherence.[48] Reminders from the family, setting the alarm on mobile phones and using text messages have proven effective in improving adherence in previous studies in high-income countries (HICs) and in some LMICs.[49, 50] However, the feasibility and effectiveness of intervention using mobile technology in Nepal's context is yet to be studied. This formative study findings were used to inform the design and contents of our planned mHealth intervention for the patients with hypertension in Nepal.[24]

Motivation factors

Additionally, a strong belief and trust in locally available herbs and bitter foods was identified as a barrier to the initiation and maintenance of allopathic medicines. Similar finding, where traditional medicines were preferred as a perceived cure for hypertension was reported in a study from Ghana. [51] A qualitative study from the Eastern part of Nepal also found the use of traditional medicines and herbs for the self-management of chronic obstructive pulmonary disease.[52] Participants might be more inclined to use those remedies due to local availability, encouragement by family members and beliefs that traditional medicines have no side effects and are low cost. There is no empirical evidence to support these beliefs in the efficacy of traditional remedies to control blood pressure to-date. These findings suggest that interventions need to address such beliefs in this setting. However, it is challenging to break that faith-thread shaped by culture. Further research can be done to investigate the efficacy of the holistic approach using alternative/complementary practices to control blood pressure.

The elicited theme 'beliefs of consequences of disease and treatment,' fits reflective motivation, another COM-B Model component. Participants identified fears of complications related to the disease as a prime motivator in starting medication and adhering to treatment. On the other hand, fear of the side effects and long-term usage leading to addiction resulted in either delaying initial treatment or stopping treatment shortly after commencement. Similar findings have been reported in Nepal, [17, 18] Malaysia [53] and Colombia.[38] Fear of "dependence" on medication was reported in a systematic review [12] and other studies with a similar socioeconomic background.[15, 54] There is a need for adequate provision of information about disease and medication in the study setting.

Opportunity factors

There were various physical opportunity barriers (related to healthcare systems and providers) elicited in our study. Previous reviews have often classified these under availability, affordability and accessibility barriers.[12] Similar accessibility barriers have also been reported in a multi-country study of rural areas of Pakistan, Bangladesh and Sri Lanka.[48] Such barriers can result in late diagnosis and irregular follow up. To address system-level barriers, equipping primary healthcare facilities for treatment of hypertension by strengthening capabilities of healthcare workers, development, and provision of contextual guidelines for hypertension treatment and adequate and timely supply of medicine should be reinforced. Recently, the government of Nepal piloted the Package of Essential Non-communicable Diseases (PEN) at health posts, primary healthcare centres and district hospitals of some districts for early detection and management of chronic diseases within the community,[55] which might address some of these accessibility barriers. However, such program should be expanded to the whole country, and continuous monitoring/evaluation of the program is warranted to get the desired outcome.

The most significant barriers to behaviour change reported under the physical opportunity theme is "communication between providers and patients". Thus, demanding workloads, a lack of time, a lack of counselling skills, and negligence were primary factors that resulted in poor doctor-patient relationships and led to mistrust in treatment and non-adherence to medicine. This finding is consistent with previous studies in Nepal [17, 18] and in other settings, as reported in a systematic review of qualitative and quantitative studies.[12] In the context of Nepal, where human resource shortage and work overload prevents required provider-patient communication, an alternative solution may be using mobile phone text messages to increase awareness and treatment adherence. [50] Training allied health staff or nurses in counselling [56] or involving family members [57] and peer groups in promoting self-care for hypertensive patients is another feasible option. There are tested strategies to improve provider communication at primary care levels in the west, [58, 59] but these need to be adopted in Nepal.

Social influence was identified as both a barrier and facilitator for hypertension control in a systematic review.[12] Our analysis using the COM-B framework identified two themes (stigma of the disease and fear of disclosure, and socio-cultural beliefs shaping health behaviour) categorized under the component of social opportunity. Stigma was not elicited as a factor in previous studies in Nepal. [17, 18] However, some studies in Africa have reported that stigma was a barrier to treatment of hypertension.[60] Stigma has been documented as a barrier to care-seeking and treatment adherence for other diseases such as cancer.[61] Social opportunity factors such as social drinking as a cultural norm, obesity as a sign of wealth and low salt intake as bad luck were reported as major barriers to behaviour change. These were novel findings in our study compared to previous studies of Nepal. [17, 18] Many of these social influences require multifaceted interventions to change health behaviour guided by cultural norms, specifically, diets high in salt. A greater understanding of the causes and treatment of hypertension may reduce barriers due to stigma. Studies have used the health stigma and discrimination framework[62] in other settings to overcome barriers due to stigma.

Implications for the policy and programs

All the barriers identified in the study are interrelated, so a holistic approach is required to address it at multiple levels such as patient, health system and community. It demands a policy-level action and commitment from the government and multiple other stakeholders such as civil society, academia, the private sector, and international organizations, in line with the recently endorsed Multi-sectoral Action Plan for the Prevention and Control of NCDs in Nepal (2014–2020) (63). Primary health care facilities which are the first point of contact to the health system, should be well equipped for the management of NCDs such as hypertension. It requires training of primary HCWs, infrastructure development, adequate supply of anti-hypertensive medication, development, and implementation of uniform guidelines for diagnosis and treatment of hypertension. There is a need for culturally informed personalised education about hypertension and its treatment to the high-risk group at the individual and community level to address misconceptions and stigma in Nepal. Training of allied health workers, utilizing digital technology and using mass media such as radio and television for the information dissemination could be an alternative strategy to address the issue of scarce human resources for counselling patients at both levels of health care in Nepal. Further study is recommended to develop the contextual strategy at the country's geographically disadvantaged areas, which was out of the scope of our study.

Strengths and limitations of the study

This study's strength lies in the data collection and analysis, which was informed by a behavioural model. It is the first formative study on hypertension management in Nepal to our knowledge. The study included participants from different healthcare systems and providers, unlike similar previous studies in Nepal. [17, 18] Additionally, we ensured trustworthiness [64] of data using (i) Different methods of data collection (IDIs and FGDs) (ii) Including different cadres of participants (patients, their family members, healthcare providers and key informants) and (iii) Member checking by summarizing and clarifying information and getting the participants' validation during interviews. Participant validation was obtained to ensure representation of the respondent's perspective.[65, 66] However, we did not provide a transcript to participants for their validation.

All interviews were conducted by the first author (BB), a native researcher sharing a similar cultural and linguistic background to the participants**.** One limitation is, as the researcher was a professional working in a tertiary centre, some participants may have assumed that she was familiar with the issues being discussed. However, to overcome this bias, the researcher probed each question. The finding of the study is not representative as it was conducted in one part of the country. It might not reflect the perspectives of the participants from the geographically disadvantaged parts of Nepal who depend on available local health facilities.

Conclusions

This formative study, using the COM-B model of behaviour change, allowed the confirmation of several known and unknown barriers and facilitators that influence poor medication adherence and lifestyle change for control of blood pressure among hypertensive patients in Kathmandu, Nepal. This included stigma attached to hypertension, misconceptions about lifestyle change, and perceptions that low salt intake is bad luck, and that obesity is a sign of wealth. The findings can be a reference for academics, researchers, and policymakers of related fields for planning intervention programs to address the identified issues and for further research for better management and control of blood pressure among hypertensive patients.

List of abbreviations

BCTs: Behaviour change techniques; BCW: Behaviour Change Wheel; CVD: Cardiovascular Disease; COM-B: Capability, Opportunity, and Motivation- Behaviour; DALYs: Disability-Adjusted Life Years; DoHS: Department of Health Services; FGDs: Focus Group Discussions; HCW: Health Care workers; HICs: High Income Country; HPs: Health Post; IDIs: In-Depth Interviews; KI: Key informants, KMCTH: Kathmandu Medical College and Teaching Hospital; LMIC: Low and Middle-Income Countries; LIC: Low Income Country; MOHP: Ministry of Health and Population; NCDs: Non-Communicable Diseases; P: Patients; PEN: The Package of Essential Non-communicable Diseases; PHC: Primary Health Care; PHCCs: Primary Health Care Centres; STEPS: Stepwise approach to Surveillance; WHO: World Health Organization; Y: Years;

Declarations

Ethics approval and consent to participate.

Ethical approval for the study was obtained from Human Research Ethics Committee A of University of New South Wales, Australia (Ref no: HC17753) and Nepal Health Research Council (Reg no 21/2018). Informed written consent was taken from all participants of FGDs and IDIs. In case of illiterate participants, verbal consent, which was witnessed by their relatives, was obtained. The verbal consent procedure was approved from both (UNSW and NHRC) ethics committees. All participants were informed about the confidentiality of collected data.

Consent for publication

The participants gave consent for use of interview data in publications, including direct anonymized quotes from the interviews and focus group discussions.

Availability of data and materials

Data is available on request from the corresponding author.

Competing interests

The authors declare that they have no competing interests.

Funding

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Authors' contributions

All authors contributed to the preparation of research design, data management, and data interpretation. BB conducted the fieldwork and wrote the first version of this manuscript. BB and RJ participated in the analysis of the data. All the authors BB, RJ, PN, AV, MS were involved in the revision and finalization of the manuscript. All authors read and approved the final version of the manuscript.

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Additional files

I. In-depth Interview Guideline (for patients with High Blood Pressure)

1. Icebreaker

- How are you doing?

- What kinds of work are you doing these days?

2. Can you tell me in detail of how you came to know that you have high blood pressure and what you have been doing about it since then? Probe: who diagnosed, what medications were given, whether he/she sought other treatment.

3. Now, can you tell me about any difficulties you faced in getting your treatment at [mention place]. Probe on physical and social factors: access, availability of medicines, affordability, what did the health personnel advice.

4. So, once you obtained your medicines, can you tell me how you ensure that you follow the instructions given? Please describe the difficulties you have faced. Probe: regularity, timing, preventing factors

5. Can you please tell me who supports you to take your treatment at home and how they support you? Probe: family support, friends or any other support

As you know, there are other factors that might affect your high blood pressure

6. Could you please tell me what do you know about other factors that will increase or decrease your blood pressure? Probe: [If they do not start – prompt by taking one example-] lifestyle factors

Probe for capability (Knowledge) of patients: factors that increase blood pressure [high salt and fat intake, and lack of physical activity, smoking, alcohol]

7. In your opinion, what changes in these are needed for improving blood pressure control?? Probe: Taking an example that they say that needs to be changed and ask for e.g. so you say smoking habits has to be changed, can you describe to me what efforts you have taken to change smoking habits.

8. As you mentioned these obstacles you faced, can you tell me how you have or tried to overcome them? Motivation (lack of interest, lack of discipline, previous experience, memory), Capacity (intensifies feelings of personal insufficiency, self-efficacy, physical problems). Probe: Intention and plans made

9. Now, I like to discuss with you how you get information about your condition or health in general? Can you tell me who you go to and whose opinions matter most regards to information about your illness or other health issues? Probe: Health workers, family, friends, mass media.

10. Let's summarise some of the key points from our discussion. Is there anything else?

11. Do you want to share anything which I missed to discuss?

II. IDI guidelines (For health care workers)

1. We would like to find out from you about what you think are difficulties that patients with high blood pressure face in obtaining treatment for their high blood pressure? Can you tell us with examples, what they face and your views of why they face these obstacles and difficulties?

Probe: do you know of any possible ways they can overcome the difficulties for example, in obtaining regular treatment.

2. So, once patients with high blood pressure start taking their medication, what prevents them or what difficulties do, they face taking the medicines regularly? Please describe in detail the challenges they face. Probe: forgetting, not taking the appropriate dosage etc

3. In your understanding, can you please tell me, what are the supports that patient should have, to take their treatment at home? Probe: family support, friends or any other support

4. In your understanding, are there any difficulties patient faces in obtaining treatment at [mention place]. Probe on physical and social factors: affordability of treatment, availability

of health workers, and medicine, a busy schedule of health workers, patients and provider's communication

As you know, other factors affect the blood pressure of the patients

5. Could you please tell me what additional information you provide to patients to manage their blood pressure other than treatment? Probe: [If they do not start – prompt by taking one example-] lifestyle factors that increase blood pressure [high salt and fat intake, and lack of physical activity, smoking, alcoholism]

6. In your understanding, what kinds of obstacles do patients face in following recommended lifestyle change?

Probe: Motivation (lack of interest, lack of discipline, previous experience, memory), Capacity (intensifies feelings of personal insufficiency, self-efficacy, physical problems).

7. Can you tell me what advice you have provided to them to overcome these obstacles?

8. Now, I like to ask you, in your understanding, how do these patients obtain information about their condition or health in general? Can you tell me whose opinions matter most to patients regards to information about their illness or other health issues? Probe: Health workers, family, friends, mass media.

10. Let's summarize some of the key points from our discussion. Is there anything else?

11. Do you want to share anything which I missed to discuss?

III. FGD guidelines (with hypertensive patients)

Let's start by going around the circle and having each person introduce her/himself.

(Members of the research team should also introduce themselves and describe each of their roles.)

1. Can you tell me in brief one by one about how you came to know that you have high blood pressure and what you have been doing about it since then? Probe: who diagnosed, what medications were given, whether he/she sought other treatment.
2. Now, can you tell me about any difficulties you faced in obtaining your treatment at a Primary Health Centre /Health post or from private practitioners. Probe on physical and social factors: access, availability of medicines, affordability, what did the health personnel advice.
3. So, once you obtain your medicines, can you describe the difficulties you have faced in taking your medications as instructed. Probe: regularity, timing, preventing factors

[notice persons who are not sharing views and probe them as well]

4. Can you please tell me who supports you to take your treatment at home and how they support you? Probe: family support, friends or any other support

As you know, other factors affect your high blood pressure

5. Could you please tell me what you know about other factors that will increase or decrease your blood pressure? Probe: [If they do not start – prompt by taking one

example-] lifestyle factors. Probe for capability (Knowledge) of patients: factors that increase blood pressure [high salt, high fat intake, and lack of physical activity, smoking, alcohol]

6. In your opinion, what changes are needed in your behaviour for improving blood pressure control and what obstacles have you faced?

7. You have mentioned several obstacles. Now can we take them one by one and find out how you have tried to overcome them? Motivation (lack of interest, lack of discipline, previous experience, memory), Capacity (intensifies feelings of personal insufficiency, self-efficacy, physical problems). Probe for Intention and plans made.

8. Now, I like to discuss with you how you get information about your condition or health in general? Can you tell me who you go to and whose opinions matter most regards to information about your illness or other health issues? Probe: Health workers, family, friends, mass media.

9. Let's summarize some of the key points from our discussion. Is there anything else?

10. Do you want to share anything which I missed to discuss?

Chapter 4: Acceptability of a mHealth intervention for hypertension management in a Low and Middle-Income Country setting: A formative qualitative study among patients and healthcare providers

Link to thesis

This chapter presents the formative qualitative study findings on the acceptability of the text messaging mHealth intervention in Nepal. This study informed the Phase II TEXT4BP (Chapters 5, 6) content, format, and frequency of the intervention.

This paper is under review in the BMJ Open and presented in this chapter as a submitted paper based on the BMJ Open format.

Bhandari B*, Schutte A, Jayasuriya R, Vaidya A, Subedi M, Narasimhan P. The potential of a mHealth intervention for hypertension management in a Low and Middle Income Country setting: A formative qualitative study. BMJ Open. [submitted 30th April 2021]

Abstract

Background: Understanding contextual needs and preferences is important for a successful design and effective outcome of an mHealth intervention.

Objectives: This formative study aimed to explore the perspectives of patients and providers on the acceptability of mHealth (text message) and elicit preferred features of mHealth intervention for hypertension management in Nepal.

Design: A qualitative study was conducted using in-depth interviews (IDIs) and focus group discussions (FGDs) guided by the Technology Acceptance Model (TAM).

Setting: The study was conducted at primary healthcare facilities and at a tertiary level referral hospital in Kathmandu, Nepal to represent perspectives of people at different levels of healthcare.

Participants: A total of 61 participants: patients with hypertension (n=41), their family members (n=5), healthcare providers (n=11) and key informants (n=4) were included. We purposively recruited patients with hypertension aged 30 to 70 who attended the selected healthcare facilities to obtain maximum variation based on their age, sex, and literacy.

Results: The study found that respondents perceived usefulness of the mobile phone text message interventions as an acceptable platform that can reinforce behaviour changes. Participants also identified that it could provide reliable information from the health centre and can be delivered in-confidence. User friendliness and delivery of content in local language were identified as advantages under perceived ease of use. Implementation challenges were expressed as digital illiteracy and contextual technical constraints, and solutions were proposed. Participants preferred text messages containing comprehensive contextual content delivered at regular intervals.

Conclusions: We found that a simple mHealth intervention such as text messaging was of value for hypertension management in this LMIC setting. However, meticulous planning must address

the needs of a diverse range of participants to ensure the intervention is acceptable to illiterate and older groups as well.

Keywords: Text messaging, SMS, High blood pressure, Mobile health, Adherence, TAM Model

Introduction

Hypertension, a major cardiovascular disease (CVD) risk factor, is an emerging public health challenge particularly affecting low and middle-income countries (LMICs).[1,2] Although highly effective and affordable medications are widely available, a major challenge in LMICs remains abysmal hypertension control of less than 50%.[3] Nepal is no exception to this, with 57% patients remained undiagnosed in community due to asymptomatic nature of the hypertension.[4] In addition, among those who are diagnosed, only 35-45% of the hypertensive patients have controlled blood pressure,[5,6] leading to high mortality and morbidity.[7]

The Global Burden of Disease Study 2019 has recommended that countries invest in cost-effective public health interventions to improve blood pressure control and prevent premature deaths from hypertension and consequent CVD.[8] Globally, a wide range of non-pharmacological interventions are implemented to improve blood pressure control, such as self-monitoring of blood pressure,[9] educational interventions focused on patients,[10] health professional led care (nurse, pharmacist, community health workers);[11] as well as appointment reminders.[12] However, delivery of these interventions is hindered by inadequate communication between patients and providers,[13] primarily due to a poor clinician to patient ratio in low resource settings.[14]

Mobile health or mHealth uses mobile devices such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices to support medical or public health interventions.[15] In low resource settings, mobile phones are a promising tool to improve healthcare access and coverage.[16,17] It offers a simple and effective mode of communication, enabling the patient to self-manage hypertension through tailored feedback.[18,19] Included in self-management, a text message is an appropriate mode to guide behaviour interventions.[20] Although simple, mobile phones have many advantages in low-resource settings or remote areas with limited internet access.[20,21]

The Nepal Telecom Authority (NTA) has reported an estimated 38.21 million mobile services users in Nepal.[22] Despite this penetration of mobile services to the population, only a few pilot projects have used it for nutrition counselling and maternal and child health services[23,24] and only handful initiatives for non-communicable disease (NCD) management targeting community health workers.[25] There is immense potential to use mobile services to bridge the communication gap between providers and patients for hypertension management in Nepal. However, it is essential to understand its acceptability by target populations, and country-specific needs to develop a mHealth intervention to get its desired outcomes.[26] This formative study aimed to explore different stakeholder's perceptions on the use of mHealth (text messages) to capture multiple level perspectives guided by the TAM model[27] and elicit their preferred features of mHealth intervention (text messages) for hypertension management in Nepal.

Methods

Qualitative research was conducted to explore the perspectives of the study participants on the potential use of mHealth (text message) intervention for patients with hypertension. This study was conducted at primary healthcare facilities (one Primary Healthcare centre and five Health Posts) of Kageswori Manahara municipality and at a Tertiary level referral Hospital in Kathmandu, Nepal (Kathmandu Medical College and Teaching Hospital), to explore the perspective of people of different healthcare levels.

Theoretical model informing the study: Our study used the TAM model developed by Davis[27] as an overarching model to guide the analysis to assess the acceptability of the proposed mHealth intervention (Figure 4.1). This model considered the two main beliefs: perceived usefulness and perceived ease of use as the main factors for an individual's acceptance of the technology. Perceived usefulness is when users believe that using a technology will enhance their job performance and perceived ease of use is a user's belief that a technology is free of effort which is influenced by external factors. [27] We explored mainly these factors in our study. The TAM model considers that there is a strong relationship between a person's intention to use and actual use of technology.[28] This model is valid, robust and has been widely used in understanding human behaviour in acceptance of technology.[28-32] We have used this model for informing our analysis considering its applicability based on our objectives .

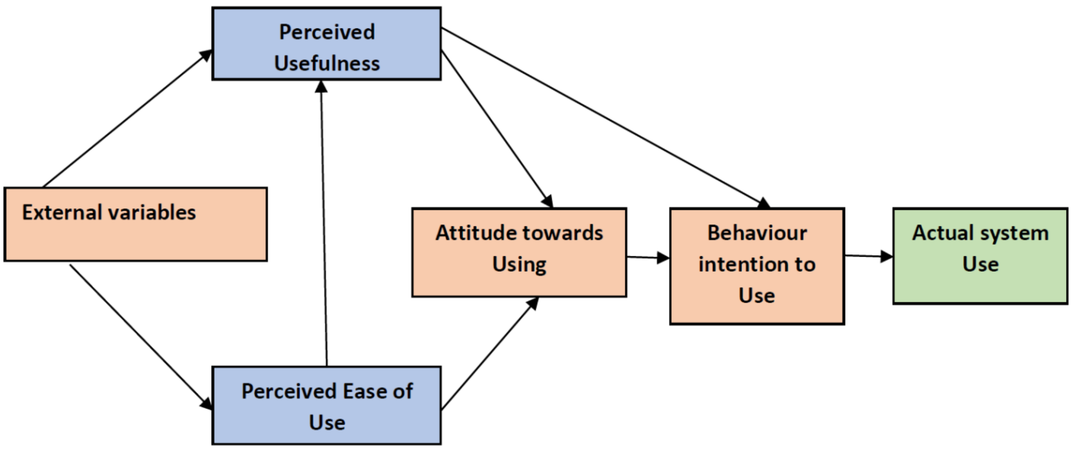

Figure 4.1: Technology Acceptance Model

Source: Davis, 1989[27]

Study populations and recruitment

We included patients with hypertension aged 30 to 70 who attended the selected healthcare facilities from March to July 2018. We excluded patients with complicated hypertension with severe multimorbidity requiring immediate care at tertiary level hospitals, which would limit their ability to participate in the study. Participants with severe mental and physical disabilities and pregnant/postpartum women were excluded from the study. However, we included participants with comorbidities who were not serious. We have included the different groups of patients (based on age, sex, literacy), their family members, healthcare providers (HCWs) from both levels of care, and key informants (KI) to capture the multiple perspectives for validating the data through data source triangulation.[33] Perspectives from patients and family members helped in understanding patient-community level perspectives whereas KI and HCWs perspectives provided an opportunity to understand the system level factors for the contextual design of the mHealth intervention. The details of the study participants and the recruitment process has been described previously[13] and presented briefly in Supplementary file 1.

Data Collection Methods

We collected data using in-depth interviews (IDIs) and focus group discussions (FGD) methods to ensure rigor through methodological triangulation.[33] IDIs provide an opportunity to explore rich personal experiences and perspectives on the topic.[34] However, FGD elicit data from the group of participants where they could hear each other perspectives and comments which they may not have expressed in the IDIs.[35] IDIs and FGDs were conducted using a semi-structured interview guide. The interview guide contained the questions mainly on perspectives on using the mHealth, its advantages, challenges and their preference on the contents, frequency of the intervention. (Supplementary file:2). While taking the consent, participants were explained about details about the objectives of the study, conceptual mHealth intervention (TEXT4BP), and about interviewer. The first author BB (female, PhD fellow), a native language speaker trained in qualitative research methods, conducted all the IDIs in the Nepali language in a suitable private place (OPD of health facilities or privately at the home of the participants without the presence of family members). Interview observation notes for non-verbal cues and audio recordings captured the interview data, which lasted for about 35 to 60 minutes. A total of 25

IDIs among hypertensive patients, five IDIs among family members, 11 IDIs among healthcare providers, and four IDIs among key informants were conducted. Two Focus Group Discussions (FGD) were also conducted using the FGDs guides among 16 (8 participants in each FGD) diverse hypertensive patients at a private OPD room with no additional person present at the tertiary level. The FGDs were facilitated by the first author in the Nepali language, audio recorded and each FGD lasted for 60 to 90 minutes. We decided the number of participants for FGDs based on the standard recommendations for FGDs and patient-availability.[36] The number of IDIs was decided based on the number of diverse group representation (by age, sex, literacy) till the saturation of information achieved at both levels of healthcare. To decide on the saturation of information, the interviewer prepared the summary after each interview to look for any new information coming from IDIs. (Table 4.1)

Table 4.1: Total number of study participants for IDIs and FGDs included from the Primary and Tertiary level.

Participant group	**Primary healthcare level (PL)**	**Tertiary healthcare level (TL)**	**Total**
Patients with hypertension	13 - IDIs	12-IDIs	25
Patients with hypertension	NA	2 FGD (8 in each) *	16
Healthcare provider	<u>5- IDIs</u> Medical Officer- 1 Health Assistant- 1 Community Health Assistant – 1 Axillary Nurse midwife - 1	<u>6 -IDIs</u> Cardiologist -3 Physician- 1 Medical officer- 1 Staff Nurse -1	11
Family members of patients with hypertension	3 -IDIs	2- IDIs	5

Key informants	4- IDIs NCDs policy maker -1 NCDs program focal person at DoHs, MoHP-2 NCDs researcher 1	4
		Total 61

Note: *Due to low patient flow at Primary healthcare level, FGDs could only be conducted at the Tertiary level.

DoHs MOHP= Department of Health Services, Ministry of Health and Population

Data Analysis

All audio recorded FGDs and IDIs with the research participants were transcribed in the local language (Nepali) by the first author and a qualified transcriber. The transcripts were checked against the audio recordings for ensuring accuracy, and pseudonyms were applied to de-identify participants. The transcripts and observation notes were translated into English by the researcher and a qualified translator. Translation reliability and accuracy was checked in a random sample of transcripts by back-translation of the transcripts to compare with the original script in local language by the first author (BB). Transcripts were not shared with the participants, however, the interviewer summarised the main information at the end of the interview to obtain participant validation.[37] NVivo 12 software[38] was used for data management. The first author coded all the transcripts. Data analysis was informed by the TAM model and overarching aim of the study. This study utilised this model to understand the perceived usefulness, perceived ease of use and perceived challenges of using the text messages intervention. We followed the thematic analysis process proposed by Braun and Clarke.[39] It includes familiarising with the transcribed data by reading and re-reading, generating the codes, searching and reviewing the theme, defining and naming the theme and finalising the analysis. The codes and themes were discussed with the co-author (PN) and agreed upon between investigators (BB and PN). The sub- themes generated from the transcripts were mapped under the overarching theme (I-III) of the TAM model and other themes (V-VI) generated based on the objectives of the study as presented in the result section. We followed the Consolidated Criteria for Reporting Qualitative Studies (COREQ) 32-item checklist[40] to ensure reporting consistency. (Supplementary file 3).

Patient and public involvement

This research was conducted without patient or public involvement. Participants were not invited to comment on the study design or contribute to the research write up and dissemination.

Ethics Approval: Ethics approval for the study was obtained from the Human Research Ethics Committee of the University of New South Wales, Australia (Ref no: HC17753) and Nepal Health Research Council (Reg no 21/2018). Informed consent was taken from all the study participants.

Results

Most of the hypertensive participants (29%) were between the age of 50-60 years with mean age of 48 years, female (51%), literate (65%) and employed (70%). Of them, 88% had been diagnosed more than one year prior to the study, with 34% more than 5 years. (Table: 4.2)

Table 4.2: Sociodemographic profile of the study participants of IDIs and FGDs (hypertensive patients)

Characteristics	Categories	Hypertensive patients (N=41)	
		Frequency	Percentage
Age (years)	30-40	10	24.4
	40-50	11	26.8
	50-60	12	29.3
	60-70	8	19.5

	Mean age ± SD	48.17± 10.78	
Sex	Female	21	51.2
	Male	20	48.8
Literate	Yes	27	65.8
	No	14	34.2
Employment	Yes	29	70.7
	No	12	29.3
Duration of diagnosis of hypertension	Less than a year	5	12.2
	1-5 years	22	53.6
	More than five years	14	34.2

Note: details of the study other participants (family members, HCWs and KI) are presented previously.[13]

Our study revealed three broad themes (I-III) on acceptability under the TAM model and other two themes (IV-V) as suggested solutions and preferred features of the mHealth intervention. All the themes, sub themes of study and supporting verbatim are presented in Table 4.3.

<u>Themes mapped under TAM Model</u>

I. Perceived usefulness

The main subthemes under perceived usefulness of TAM model are as follows:

Acceptable and require less resources: Study participants reported that a simple text message would be acceptable in the study settings due to the ubiquity of mobile phones. Participants expressed that mobile phone are popular. They also expressed their interest and readiness to participate in such a program.

"If you send us SMS, we are ready to use this." (P03: 50-55 Y,F, TL)

Healthcare workers (HCWs) also confirmed that mobile phones are widely accessible, even in rural areas. Some stated that getting messages on their mobile phone would be very handy and save time to travel to the health centre in getting information about the disease and its treatment. The key informants examined the mHealth intervention from a program perspective. They identified such an intervention might require less resources as it can be sent to many people at the same time (bulk SMS) with limited investment.

Reinforce behaviour change: HCWs expressed that text messages could act as a reminder to take medication on time and reinforce recommended behaviour changes such as physical activity.

Participants stated that such an intervention might meet their unmet needs to receive specific information to reinforce behaviour change such as how much salt is recommended for blood pressure control.

> *"If specific information (such as this much salt is allowed) will be sent for us, definitely it would help for changing our habits."* (FGD 02: 50-55 Y, F, TL)

Can provide reliable information: Some participants reported that they can search for unlimited information from the internet on their mobile by themselves. However, the authenticity and relevance of those messages could not be determined. They requested information from a "reliable and trustworthy" provider, referring to HCWs.

HCWs reinforced this request and stated that it should be adequately linked with the health system to ensure that messages will be accepted and trusted by participants, that may motivate the intended behaviour change.

Deliver information privately: Participants stated that text messages have the advantage of delivering personalised information on their mobile privately. They valued personal text messages sent on their mobile as others cannot know their hypertension status. This was the case with younger patients, who did not want their illness divulged to people they associate with. Overall, there was no reported difference in usefulness based on the gender and level of healthcare. However, the advantage of getting messages privately was expressed by younger participants, not by the older age groups.

Table 4.3: Themes and subthemes generated on the perception of using a mHealth (Text message) intervention.

Themes Based on TAM Model on acceptability	Subthemes	Supporting verbatim
Perceived usefulness	Acceptable and require less resources	These days, mobile(phone) is widely available and easy to use for many people. If anything comes in the mobile from a reliable source, it might have some good effect. (P021: M, 40-45 Y, PL) It is also a cost-effective program. We can send one SMS to millions of people in a short period. It will increase coverage among the patients and will be more effective. (KII02)
	Reinforce behaviour change	"The patients should at least be notified on their mobile phones to take their medicine on time. Then, the patient would realise and be motivated to follow that." (HCW 02, PL)
	Can provide reliable information	"If messages are sent by you and others like you (health professional), I will happily accept it thinking that doctor with whom I meet at the hospital .... sent this message." (P013: 45-50 Y, PL)
	Deliver information privately	"If I get information on my mobile, then it might help to improve my blood pressure. If I go to the health centre, there would be lots of people ... I feel shame to say myself ill in front of other people. I have not shared with friends, as well." (P014: 35-40 Y, M, TL)
Perceived ease of use	User friendly	I think it will work and be feasible because majority of the people own mobile phone, can very easily see the information in mobile without any difficulties and there is no need to have expensive smartphone for simple SMS. (P20: M, 50-55Y, PL)
	Local language	The SMS language should be simple and easy to understand for us. Nepali is the most common language out here and people can easily read that. (P015: 30-35Y, M, TL)

Perceived challenges – external factors	Mobile phone illiteracy	We cannot read, so how can we know what is being sent in mobile; we will not understand whatever things come into our mobile….is not it? (FGD01; 60-65Y, F, TL)
	Technical constraints	"No. No. How can we manage those mobile services? It will be challenging to implement. It needs a considerable amount of budget, though the concept is excellent." (HCW 03: PL)
Themes under other objectives of study	**Sub - themes**	**Supporting verbatim**
Perceived solutions for overcoming the challenges	System-level preparedness	The hospital must also have a record of the detailed list of OPD patients diagnosed with hypertension. Proper record-keeping is essential. (HCW 09: TL) "For such project, we need some mobile centres/department, or some technical manpower then only we can implement it." (KII 03)
	Alternatives strategies for illiterate	"These days though mother/father is illiterate, there will be son, daughter and grandchildren who are educated. If we could send the message to the family member of the illiterate patients, they will get the information. (HCW 07: PL)
Preferred features of the mHealth intervention	Comprehensive contextual contents	Is BP controlled after taking bitter herbs (chirauto) only or should we go for acupuncture or not..some people say that there is a person who press in the hand and pressure will be fine, so should we follow that or not ?– it should be send in messages. (P08: 50-60 Y F, PL) It should include all the information regarding what type of diet should we take and what should be avoided. Like messages regarding patient should take less salty and oily food. [P012: 45-50 Y, F, PL]
	Reasonable frequency and timing of messages	"I feel like if it can be sent once or twice a week, then it will be kept in touch also. If we send them daily, then they might delete it. (laughs)." (HCW 05, TL)

II. Perceived ease of use:

User friendly: The participants expressed that the text messages can be a simple and easy intervention that do not require advanced technical skills to operate. Participants preferred receiving messages in a simple, clear, and concise format. They further added that if SMS is designed in an understandable format, it can be effective in the study setting:

It will be effective. These days, even the lay man (najjanne), can use simple messaging. (P10: 45-50Y, F, TL)

Local language: Study participants expressed that it would be easy to read and understand if the messages are sent in the Nepali language. If designed in local language, people with low literacy can also utilize it for behaviour modification.

> *Yes, she (patient) could read it if it is sent in Nepali. If sent in English, even I cannot read it. But we both can read in Nepali. (FM03 of 40-45Y, F, PL)*

The ease of use was expressed mostly by the literate group of participants. Older participants and illiterate participants suggested to design simple text in local language.

III. Perceived Challenges - External factors

Many participants also identified obstacles to implementing mHealth interventions in the study settings:

Mobile phone illiteracy: Participants raised concerns about general literacy and digital literacy of patients in reading the SMS even though it is sent in the local (Nepali) language. They reported that it could be difficult for those who have low digital literacy skills, for example, who do not know how to open, read, or send a text message.

Further, an older participant expressed that " *No, I only know how to call. I have a simple mobile. I do not know how to open and read the messages.*" *(P017: 65-70Y, M, PL)*

HCWs added that such a program could be more effective in urban areas and most accessible to the young generation. The participants expressed that age and illiteracy can influence the ability to read text messages.

Technical constraints: HCWs were cautious, highlighting the need for resources to implement such program in Nepal. They expressed concern about resources such as the technical workforce and funding requirement for software development and SMS delivery, including commitment from the authorised bodies in the hospital. Some HCWs also raised the issue of health system preparedness to implement such programs due to cost and shortage of technical workforce.

Many HCWs identified challenges, such as not having an appropriate recording system of hypertensive patient's details in the hospitals to locate/ trace them in the community. They expressed that such intervention would be almost impossible in public hospitals where doctors have a high workload, limiting their ability to record the patients' details, such as their phone number. One HCW expressed that "There is not even a good record-keeping system here in our hospital, and no one is going to record as we don't have time." (HCW 08: TL)

The system-level technical challenges were expressed by both level of healthcare; mostly by the HCWs and KI. No such issues were reported by the hypertensive patients.

Themes based on other objectives of the study

IV. **Perceived solutions**

In the context of resource constraints, participants recommended some solutions to have the desired outcome of text messages intervention:

System-level preparedness: HCWs emphasised a proper record-keeping system, which would help in tracing the hypertensive patients to send SMS messages.

However, they emphasised the need for government commitments for such programs, such as establishing a separate department to monitor the program.

Key informants highlighted the need for system-level preparedness by extensive planning, budgeting, and mobile phone text messaging software development. They expressed that multi-sectoral collaboration and commitments are needed to implement the mHealth program effectively.

Alternative strategies for illiterate groups

Participants suggested including a family member of the illiterate patients when sending messages. They highlighted every household should have at least one literate person. Even the family members were ready to support their parents.

They expressed *"For Illiterate people like my mother, it has to be sent to the member of the family like me. As a son, I must take care of her" (FM 02 of 60-65 Y, F, PL).* Furthermore, video/voice messages, symbolic pictures or cartoons were recommended by HCWs for the illiterate groups.

> *I think the video is more effective than a text message as it has both audio/visual features. (P014: 35-40Y, M, TL)*

However, some participants raised concerns about the family member's relationship with patient and their availability and the feasibility of using video message in a resource-constrained setting like Nepal. Especially these concerns were raised at primary levels where smartphones, internet and MMS facilities are limited and less available.

V. Preferred features of the mHealth (text message) intervention

In each IDI and FGD, answers to the questions on the need and preference of participants to inform the content and delivery of mHealth intervention were analysed:

Comprehensive contextual contents: Participants expressed various misconceptions prevalent in the study setting regarding hypertension and its treatment. Participants preferred getting context-specific messages targeting those misconception on hypertension treatment such as use of locally available herbs: aloe vera juice, bitter juice (Chirauto), barley sprout juice (Jamara) etc. Similarly, they preferred including messages targeting the foods prepared during festivals in Nepal which are high in fat and salt content.

> *Patients says that "yesterday I attended a festival. After eating high salt food and meat, I am getting headache, so I came here for check-up." So, I think you should send information about diet as well. (HCW 04: TL)*

For lifestyle modification, some of the patients expressed that it would be good to receive information about physical activity and culturally appropriate dietary factors. "What kinds of exercise should be done, how much.... amount…. duration…. Time." KI also added that patients should get all the messages on pharmacological and non-pharmacological measures for controlling their blood pressure. Overall, content preferences included information about hypertension and its treatment, dietary factors (local foods), medication, side effects, physical activities, and reminder for medication.

Reasonable frequency and timing of text messages: They also stated that the text messages should be delivered with reasonable frequency and timing. Study participants preferred receiving 2-3 reminders messages per week for taking medication or about specific behaviours.

Overall, participants agreed that daily messages would be too often and monthly would be insufficient.

If you send in the interval of 2-3 days, then then we might see that. (P018: 40-45 Y: M, PL)

Most of them preferred messages to be delivered in the morning or evening. Participants mentioned that if the timing of the message matched with the time of taking their medicine, then it would be more effective "Usually people take medicine in the morning so, that would be a good time." (P05:45-50, F, PL) Another participant also added. “for women….in the evening time would be good as we will be busy in household works during morning.” (FGD 05: 30-35 Y; F, TL) Overall content preferences were not different based on the gender, age, and level of care. However, female participants expressed a greater preference to receive messages in the evening time.

Discussion

This study explored the perspectives of patients and providers on the acceptability of mHealth (mobile phone text messages) intervention for patients with hypertension in Nepal. Overall, participants were receptive towards such text message intervention with some contextual recommendation. This study found that simple mobile phone text messages could be useful in this setting due to the ubiquitous use of mobile phones. Studies from the primary level[26] and rural parts of India[40] have reported similar findings as mHealth being a ubiquitous and acceptable tool for managing cardiovascular diseases and supporting healthcare. Key informants involved in implementing the national NCD program and policy in Nepal identified the low-resource requirements of SMS messages as potentially useful for such interventions. The WHO's Global Observatory for eHealth (GOe) also stated SMS as an easy method to send a brief message at a low cost.[15] Text messages can be sent in bulk to multiple users simultaneously, are cheap, and do not require advanced skills.[16] However, cost effectiveness analysis is an area for future research in this setting.

Our study found behaviour reinforcement/modification as another potential use of mHealth. In chronic diseases such as hypertension, where medication should be taken daily, SMS reminders can increase medication adherence.[42,43] Additionally, WHO GOe stated that SMS was the preferred method for treatment compliance measures worldwide.[15] Non-disclosure issues due to the stigma attached to hypertension was reported, especially by young people in Nepal in an earlier study.[13] The importance of receiving messages privately on mobile was stressed by our respondents, it has not been reported for NCD previously, but these were mostly reported in studies of HIV/AIDS.[44] Overall, there was a consensus of the value of text messaging in getting information privately (in confidence) to hypertensive patients by all the stakeholder groups. However, our study participants did not mention concerns with data security, an important factor while designing a mHealth intervention.

Our participants perceived text message intervention as easy to operate and not requiring advanced technical skills. They preferred to have messages in the local Nepali language for the ease of use for broader groups. We were also able to identify implementation challenges that were similar to other resource-limited settings as well as unique to the setting. Difficulty in reading text messages (even in the local language), a language and literacy barrier including digital literacy in reading the text messages were reported in this study, similar to South Indian studies.[26, 44] In Nepal, though mobile phone penetration is high, digital literacy is only reported as 31%.[45] In this context, alternative solutions identified by stakeholders was inclusion of family members of illiterate/older groups and sending video or symbolic messages.

While there was enthusiasm to use mHealth, HCWs and KI expressed concerns about the lack of resources and technical issues that could be an impediment. A key concern was that implementing a new mHealth (SMS) system in the hospital might require extra technical manpower for software development generating a need for a separate technical department. The immaturity of health information systems in hospitals and gaps in recording essential information was identified. Similar issues have been reported from rural India as a barrier to the continuity of care and follow up with hypertensive patients.[46] These findings were corroborated in other studies in Kenya[47] and Bangladesh.[48] The WHO has also stated that unclear mHealth policy and underdeveloped infrastructure are the most common barriers in adopting mHealth in LMICs settings.[15] In our study, it was explicitly stated that a reliable and peer-reviewed source of information is required. A SMS originating from a public or private health centre will be trusted by individuals as they would be considered reliable. It is therefore, imperative to establish trustworthiness of the information for the desired behaviour modification.[49] The key recommendation was to have government commitment and multisectoral collaboration and coordination with the health system to address the structural barriers to use advanced technology. These aspects should be carefully considered while designing the mHealth intervention for its sustainability.

Implications for mHealth design and future research

This study supported the evidence that mHealth could be acceptable in LMIC settings, if designed based on the local context and needs.[50,51] Our study participants highlighted their interest in getting messages clarifying the misconceptions regarding the use of local herbs for treatment of high blood pressure and targeting cultural food practices. The findings of this formative research informed the contextual contents of our next phase TEXT4BP intervention that would be tested using a randomised controlled trial design.[52] Information on the contents of the intervention, frequency, and timing of the intervention may be of value to a similar resource-limited setting. In Nepal, there are very few studies on mHealth, this study could broaden the horizon for use of mHealth in the management of hypertension. In today's context of the need for evidence-based use of modern technology in health service delivery, as stressed in Nepal Health Sector Strategy 2015-2020,[53] the findings from this study are crucial in designing evidence-based mHealth interventions in the context of Nepal. Future research should explore how best to implement culturally developed mHealth intervention in the regular healthcare system to increase the adoption.

Strength and limitations of the study

One of the strengths of the study is that efforts were taken to ensure the trustworthiness[37] of data by ensuring credibility by adopting appropriate and different methods for data collection (IDIs and FGDs); by including a different cadre of participants (patients, their family, health workers, key informants) from different sites (primary and tertiary level). The researcher (BB) obtained participant validation at the end of the interview by summarising the main points to ensure the respondent's perspective.[54] In addition, we have used the TAM model to inform our analysis. We have presented the steps in the analysis and showed that we generated the themes and subthemes with discussion. However, some limitations were that we had analysed data from different sources and methods together, which might not fulfil all the criteria of triangulation and used purposive sampling, which may have created a selection bias. However, all reasonable efforts were made to ensure the diversity of participants. Furthermore, the transferability of the findings is limited as this study was conducted in urban and semi-urban parts of the country, which may not completely represent the views of people from geographically disadvantaged and remote areas of LMICs.

Conclusions

This study found that participants were receptive towards a simple mHealth intervention such as SMS notifications. Overall, there was a consensus of the value of a text messaging solution to hypertension management by all stakeholder groups. However, meticulous planning must include a diverse range of participants to ensure the intervention is acceptable to a wide range of participants including illiterate and older groups. Similar formative study approaches can be used to inform contextual interventions in other LMIC settings.

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Author contributions

All authors contributed to the conception of research design, acquisition, and data interpretation. BB conducted the fieldwork and wrote the first version of this manuscript. BB and PN participated in the analysis of the data. All the authors BB, AES, RJ, AV, MS and PN were involved in the manuscript drafting, revision, and finalisation. All authors read and approved the final version of the manuscript.

Competing interest

No financial or any other competing interests exist

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Patient consent for publication: Obtained

Data sharing statement: The data for this research consists of audio recordings of interviews, interview transcripts. The researchers have access to this data. All data is stored securely on password-protected and encrypted computers. Participants have not given their permission for data sharing outside the research group. Thus, no additional data is available.

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Supplementary files

Process of participants recruitment

Healthcare providers at both levels distributed a study flyer containing information about the study to the eligible participants at OPD. When an interested participant initiated the contact, the researcher screened them for eligibility and selected purposively after informed consent based on their age, sex, literacy status to capture diverse perspectives. Similarly, study participants were asked to nominate family members after obtaining consent to be contacted by the research team. Healthcare workers from the selected study site were also approached for the interview by the researchers. We also invited key informants (policymakers, researchers, and program implementors) working in Non-Communicable Diseases (NCDs) management based on the recommendation from the local research team.

Definition of the variables

Acceptability: We have used the acceptability approach as defined by Schade and Schlage et.al[1] as "a prospective judgement of measures to be introduced in the future where the target group will not yet experience the new measures".

Literacy: The ability to read and write. We have asked either they could read and write or not.

Employment: The state of having paid work. We have asked whether they were engaged in any paid income work or not.

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1 Schade J, Schlag B. Acceptability of urban transport pricing strategies. Transportation Research Part F: Traffic Psychology and Behaviour. 2003 Mar 1;6(1):45-61.

Definition of the Healthcare Providers

Cardiologist: Medical doctor who had MBBS, MD and DM cardiology degree working in public hospital/medical college at tertiary centre

Physician: Internal medicine physician who had MBBS and MD in internal medicine working in a public medical college at tertiary centre

Medical officer: Medical doctor with MBBS degree, who provides services to the hypertensive patients in both primary and tertiary level.

Health Assistant (HA) and community health assistant (CMA): Non physician health workers (HA- 3 Year certificate level formal education, CMA- diploma level 18-month formal training) who are posted in the government primary healthcare centre and health post and provide OPD service to hypertensive patients in those centres.

Staff nurse/ANM: Health personnel with nursing education (staff nurse- certificate level 3-year nursing education, ANM- diploma level 18-month nursing training) they involve in providing counselling to the hypertensive patients.

Abbreviation of the verbatim of the participants

PL: Primary level

TL: Tertiary level

F: female

M: male

Y: years

Supplementary file: 2

I. **In-depth Interview guides**

1.Icebreakera.How are you doing?

b. What kinds of work are you doing these days?

2.Could you please share your experience of using mobile phone? Probe: How, when, for what purpose etc

3.What do you know about use of mobile health in management of high blood pressure?

4.Could you please share your opinion on using mobile phone for management of high blood pressure? Probe: what, how

5.Have you heard, or have you been told that you can get health messages through mobile phone?

6.What is your opinion about it? What is your perspective on potential of mobile health service in management of hypertension in Nepal? Probe: what, how, example

7.What could the potential advantages of using mobile health in Nepal?

8.What could be the challenges in using mHealth in Nepal for the management of hypertension?

9.What can be done to overcome the challenges for successful outcome?

10.What kinds of mobile health services you would like to get/use?

11.What should be the contents, timing, and frequency of such mHealth services?

12.Do you want to share anything which I missed to discuss?

13.Let's summarise some of the key points from our discussion. Is there anything else?

III. FGD guides

Let's start by going around the circle and having each person introduce her/himself.

(Members of the research team should also introduce themselves and describe each of their roles.)

1. Icebreaker a. How are you doing?

b. What kinds of work are you doing these days?

2. Could you please share your experience of using mobile phone? Probe: How, when, for what purpose etc

3. What do you know about use of mobile health in management of high blood pressure?

4. Could you please share your opinion on using mobile phone for management of high blood pressure? Probe: what, how

5. Have you heard, or have you been told that you can get health messages through mobile phone?

6. What is your opinion about it? What is your perspective on potential of mobile health service in management of hypertension in Nepal? Probe: what, how, example

7. What could the potential advantages of using mobile health in Nepal?

8. What could be the challenges in using mHealth in Nepal for the management of hypertension?

9. What can be done to overcome the challenges for successful outcome?

10. What kinds of mobile health services you would like to get/use?

11. What should be the contents, timing, and frequency of such mHealth services?

12. Do you want to share anything which I missed to discuss?

13. Let us summarise some of the key points from our discussion. Is there anything else

Chapter 5: 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

Link to thesis

This chapter presents the methods of TEXT4BP intervention development and delivery informed by formative studies discussed in the Chapter 3 and 4.

I have registered this protocol in the Australia and New Zealand clinical trial registry: ACTRN12619001213134

I have published this protocol paper in the BMJ Open. It is presented in this chapter according to the published reformatted version.

https://bmjopen.bmj.com/content/bmjopen/10/9/e040799.full.pdf

Open access Protocol

BMJ Open

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

Buna Bhandari ,[1,2] Padmanesan Narasimhan ,[1] Abhinav Vaidya ,[3] Rohan Jayasuriya [1]

Abstract

Introduction

Uncontrolled blood pressure is one of the main risk factors for cardiovascular disease and death in Low 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 message intervention, "TEXT4BP", developed based on behaviour 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 three months, visiting a tertiary health care facility in Kathmandu, Nepal. A nested qualitative study will assess the acceptability of the SMS intervention. The intervention group will receive text messages containing information on hypertension, diet, medication, and physical activity three times a week for three months. The control group will receive standard care. At baseline and three 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 the study

- This study uses SMS 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 COM-B theoretical framework for behaviour 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 and middle-income countries (LMICs).[1, 2] Hypertension is the highest risk factor for cardiovascular disease, of which ischemic heart disease (IHD) and stroke are the first and fifth leading causes of death worldwide. [3] In Asia, the prevalence of hypertension 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 Disease (NCDs), such as hypertension, 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 (DALY) (7.6%) in Nepal.[6]

Despite available information for the effective treatment of hypertension, 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 socio-economic groups.[10] In Nepal, controlled blood pressure among hypertensive patients varies by geographic 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 hypertension 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, mobile health (mHealth) has emerged as an efficient strategy to reach wider audiences to effect behaviour change.[22] Systematic reviews have shown the value of Short Message Service (SMS) in promoting lifestyle change for chronic diseases, including hypertension[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 behaviour 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 (SPIRIT),[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 text messaging intervention (TEXT4BP) compared to standard care for three 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 5.1).**

Study Populations

Participants' eligibility criteria

Patients aged 18-69 years with a clinical diagnosis of hypertension and currently receiving blood pressure-lowering medication for more than three 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 hypertension. In Nepal, treatment for hypertension is not provided in all primary level health care facilities (PHCCs, HPs), 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 Template for Intervention Description and Replication (TIDieR) [29] guidelines have been used to describe the intervention.

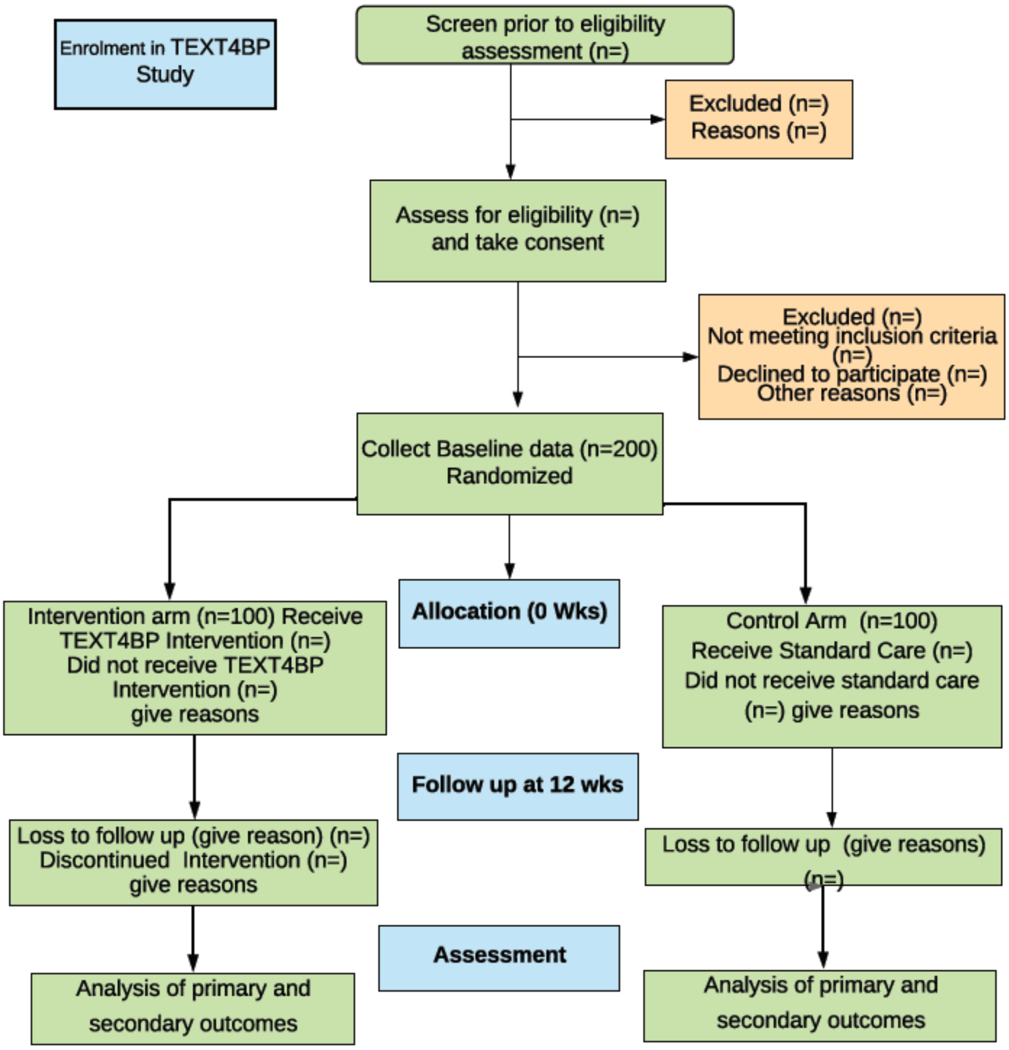

Figure 5.1: Pilot and feasibility RCT CONSORT flow diagram of the TEXT4BP study

CONSORT, Consolidated Standards of Reporting Trials, RCT, Randomised Controlled Trial; TEXT4BP, messaging intervention for blood pressure control

Intervention development

The development of the intervention followed a theory-based approach after eliciting barriers and facilitators for treatment and control of hypertension among a similar population to the target group for the trial. [20] Using a qualitative study of people with hypertension, their family members and health care 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. COM-B (Capability, Opportunity, Motivation, Behaviour) 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 Behaviour Change Wheel (BCW). Then we linked the identified barriers with the intervention functions of the BCW. To systematically address enablers and barriers, the content of the SMS intervention was developed using relevant behaviour change techniques (BCTs).[32] 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 (for example, 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 (e.g., incentivization**).** Examples of the link between barriers and facilitators, BCTs and text messages is given in **Supplement 2.**

The text messages will be translated into Nepali language (Nepali) 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 5.2.**

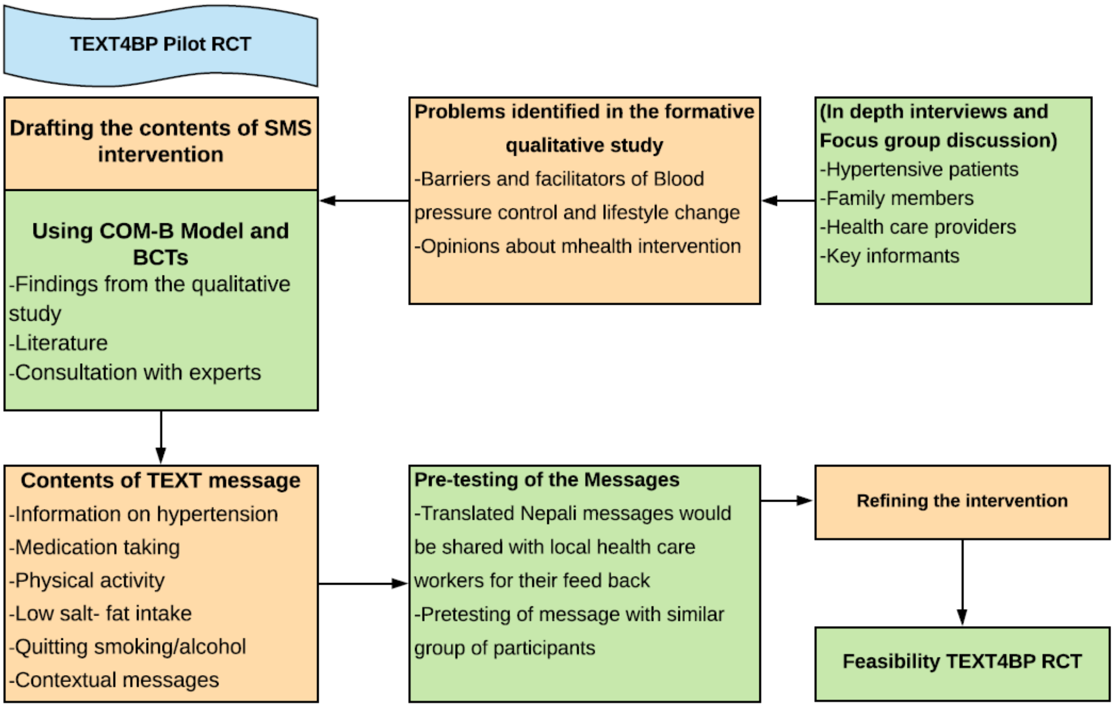

Figure 5.2: Process of TEXT4BP intervention development

COM-B, Capability, Opportunity, motivation, behaviour; RCT, randomised controlled trial; SMS, short message service; TEXT4BP, messaging intervention for blood pressure control

TEXT4BP Intervention

Participants with hypertension in the intervention group will receive mobile phone text messages in Nepali containing information on hypertension 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 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 three 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 three months), they will be provided pamphlets containing information about hypertension and required behaviour modifications.

Study outcomes

Baseline measures

The baseline data collection tools contain questions on i) sociodemographic factors, medical and family history ii) Lifestyle factors: dietary salt consumption based on the WHO STEPS survey questionnaire,[33] Hill- Bone compliance to High Blood Pressure therapy scale,[34] Medication adherence self-efficacy scale, [35] and knowledge and perception of hypertension questionnaire. Time points of measurement and follow up measures are presented in Table 5.1.

Validity and reliability of the tools

All of the measures will be translated to Nepali following accepted standard procedures given by WHO [36] 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 ESC/ESH guidelines [37] for the office blood pressure measurement. Before taking the measurements, participants will be asked to sit comfortably and rest for 5 minutes 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 RCT studies.[38] Whitehead et al.,[38] 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.[39] This is a parameter we would ascertain from this feasibility study to power the planned definitive study.

Table 5.1: 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.

Randomisation, sequence generation and allocation concealment:

Simple randomisation technique will be used for allocation.[42] 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 1-200. After the random number sequence is produced, the numbers indicating the group allocation (i.e. 1 column numbers for the control group and 2 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.[43] 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 (2002)[44] for the allocation concealment to prevent selection bias.

The probability of unequal group sizes using this method of randomization diminishes with large sample sizes (of 200 and over).[45] 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 5.1.** Details of physical measures are given above.

Follow Up data collection

Follow up data collection will be conducted three 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.[40, 41] In-depth interview with intervention group participants (5-6) 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 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 chi-square test and report on any associations with attrition rates. This 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[40, 41] 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 Pty Ltd, London, UK, and US).

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 health care 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 de-identified 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 Behaviour Change techniques. 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 socio-demographic and geographic 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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Author's Contributions

All authors contributed to the preparation of research design, data management, and data interpretation. BB wrote the first version of this manuscript. All the authors BB, RJ, PN, AV were involved in the revision and finalization of the manuscript. All authors read and approved the final version of the manuscript.

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The authors declare that they have no competing interests

Consent for publication

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Supplement 1

Example of development of TEXT4BP text messages based on the formative qualitative study findings using Behaviour change techniques

Barriers /facilitators	Linking with BCTs	Content of text message
Literacy of hypertension and its treatment	Shaping knowledge Health consequences	Do you know? You may have no symptoms and still have high blood pressure. Remember to take your medicine regularly. Do you know? Uncontrolled Blood pressure which is above 140/90 puts you in danger of having complications. Remember to check your BP regularly.
Beliefs about consequences of diseases **Faith in traditional medicine/ local herbs**	Threat Negative reinforcement Shaping knowledge	Uncontrolled High blood pressure can lead to heart attack, paralysis, vision problems and kidney failure so take your medicine regularly. Do not only rely on local remedies like bitter things to control your blood pressure. There are no other supplements to blood pressure medication. You must take medicine if your doctor prescribed it.
Non-adherence **Forgetting to take medicine**	Reinforcement Shaping knowledge/ Emotional consequences Prompts /Cues Habit formation	Are you taking your medicine regularly? Remember! NEVER change your medication or stop taking your medication unless your doctor tells you to. If you are not sure you really need your blood pressure medicine, ask your doctor to explain the reasons why it was prescribed. Try putting your pillbox or bottles near something you see every day, like your toothbrush to help remember to take your blood pressure medication! Do you know? you can set up an alarm on your mobile phone to remind you to take medications

Resistance in behaviour modification/ unhealthy habits	Shaping knowledge Self-monitoring of behaviour Goal setting	Did you know? Smoking, drinking alcohol, eating unhealthy food (high salt and high fat food), little exercise and being mentally stressed puts you in danger of high blood pressure. **Salt intake:** Foods high in sodium(salt) can increase your blood pressure. Try to limit your sodium intake to 5g/day, including what is in and what is added to food. **Physical activity:** Moderate physical activity of 30 minutes can make your blood pressure medications work more efficiently and reduce your blood pressure. Try a 30-minute brisk walk or three 10-minute walks Did you exercise this week? Aim at exercising 30 minutes/day at least five times a week.

Chapter 6: Effectiveness and Acceptability of a Mobile Phone Text Messaging Intervention to Improve Blood Pressure Control (TEXT4BP) Among Patients with Hypertension in Nepal: A Feasibility Randomised Controlled Trial.

Link to thesis

This chapter presents the findings based on the overarching aim of this thesis. Developed TEXT4BP Intervention as discussed in Chapter 5 was implemented and evaluated which is presented in this chapter.

This paper is under review in the Global Heart Journal and presented in this chapter as a submitted version based on the Global Heart format.

Bhandari B*, Narasimhan P, Vaidya A, Jayasuriya R, Schutte AE. Effectiveness and Acceptability of a Mobile Phone Text Messaging Intervention to Improve Blood Pressure Control (TEXT4BP) Among Patients with Hypertension in Nepal: A Feasibility Randomised Controlled Trial. Global Heart. [Submitted 30th July 2021]

Abstract

Background: Uncontrolled blood pressure (BP) is the leading cause of preventable deaths in low- and middle-income countries. mHealth interventions, such as mobile phone text messaging, is a promising tool to improve BP control, but research on feasibility and effectiveness in resource-limited settings remains limited.

Objective: This feasibility study assessed the effectiveness and acceptability of a mobile phone text messaging intervention (TEXT4BP) to improve BP control and treatment adherence among patients with hypertension in Nepal.

Methods: The TEXT4BP study was a two-arm, parallel-group, unblinded, randomised controlled pilot trial that included 200 participants (1:1) (mean age: 50.5 years, 44.5% women) with hypertension at a tertiary referral hospital in Kathmandu, Nepal. Patients in the intervention arm (n=100) received text messages three times per week for three months. The control arm (n=100) received standard care. The COM-B model informed contextual co-designed text messages. Primary outcomes were change in BP and medication adherence at three months. Secondary outcomes included BP control, medication adherence self-efficacy and knowledge of hypertension. A nested qualitative study assessed the acceptability of the intervention.

Results: At three months the intervention group had greater reductions in systolic and diastolic BP vs usual care [-7.09/-5.86 ($p \leq 0.003$) vs -0.77/-1.35 ($p \geq 0.28$) mmHg] [adjusted difference: systolic β= -6.50 (95% CI, -12.6; -0.33) and diastolic BP β= -4.60 (95% CI, -8.16; -1.04)], coupled with a greater proportion achieving target BP (70% vs 48%, $p=0.006$). The intervention arm showed an improvement in compliance to antihypertensive therapy ($p<0.001$), medication adherence ($p<0.001$), medication adherence self-efficacy ($p=0.023$) and knowledge on hypertension and its treatment ($p=0.013$). Participants expressed a high rate of acceptability and desire to continue the TEXT4BP intervention.

Conclusion: The TEXT4BP study provides promising evidence that text messaging intervention is feasible, acceptable, and effective to improve BP control in low-resource settings.

Trial registration: anzctr.org.au Identifier ACTRN12619001213134

Keywords: Mobile health, SMS, Adherence**,** mHealth, Blood pressure

Introduction

The burden of hypertension is escalating globally, especially in low- and middle-income countries (LMICs) in South-East Asia and Sub-Saharan Africa.[1, 2] Uncontrolled blood pressure (BP) among patients diagnosed with hypertension is a significant challenge,[3] leading to high rates of morbidity and mortality largely due to stroke and ischemic heart disease.[4] Nepal is a LMIC in South Asia with an estimated population of 29 million people. It has an overall pooled prevalence of hypertension of 28.5% in 2021.[5] However, around half of patients in Nepal diagnosed with hypertension have uncontrolled BP,[5, 6] significantly contributing to mortality rates and the burden of the disease.[7] Major contributors to uncontrolled BP are poor adherence to antihypertensive medication,[8] unhealthy diet (high salt, low fruit and vegetable intake)[9] and physical inactivity.[10] This has been confirmed by earlier work that we and others have done in Nepal.[11, 12]

The 2020 International Society of Hypertension Guidelines recommends a treatment target of <130/80mmHg for patients younger than 65 years and strongly encourages all BP control efforts.[13] Patient-focused strategies for improving BP control require a systematic approach that should include adequate support for behaviour modification and improved knowledge.[14] In the context of low clinician-to-patient ratios to deliver intensive interventions in LMICs, novel alternatives need to be considered.

Although LMICs face many financial and health system challenges, the rapid uptake and availability of mobile phones provides excellent opportunities for a host of interventions as they are widely integrated into daily life, also in Nepal.[15] Mobile technologies have great potential to deliver healthcare messages effectively and offer a promising tool in resource-limited settings.[16] Previous studies have reported favourable outcomes in using text messages (SMS) in managing hypertension, namely promoting lifestyle change,[17] improving medication adherence,[18,19] and managing cardiovascular risk factors.[20,21] However, these studies are mostly confined to high-income countries that differ substantially from LMICs.

The potential of mobile phones in the management of hypertension has yet to be evaluated in Nepal. Our formative work in Nepal[22, 23] found health workers and patients with hypertension to be highly receptive towards mobile phone interventions, such as messaging to reinforce the value of medication adherence (based on theories of behaviour modification). We therefore assessed the effectiveness and acceptability of a text message intervention to improve BP control (TEXT4BP) and treatment adherence among patients with hypertension attending a tertiary hospital in Nepal.

Methods

Study design and setting: This pilot study was conducted using a two-arm parallel-group unblinded randomised controlled trial among patients with diagnosed hypertension. We also used a nested qualitative design to assess the acceptability of the TEXT4BP intervention among the intervention arms. This study was conducted in the Cardiology and Medicine Outpatient Department of the Kathmandu Medical College and Teaching Hospital (KMCTH), Nepal. The methods and design have been described previously.[24]

Sample size: The sample size was based on recommendations for determining the sample size for a pilot randomised control trial.[25] For the main trial to have 90% power, two-sided alpha of 0.5 and standardised effect size to be small (0.1), a pilot trial with a sample size of 75 patients per treatment arm (1:1) was recommended. We estimated the attrition rate to be 30%, and therefore included 100 participants in each arm.

Study population and recruitments: We included patients diagnosed with hypertension aged 18-69 years and prescribed for antihypertensive medication for at least three months. Eligibility criteria included that participant had a mobile phone and were able to read text messages by themselves or with their family's help. We excluded patients with severe physical or mental illness, which would reduce their ability to participate in the study. Pregnant and post-partum women were also excluded from the study. All eligible patients were invited to the study by a relevant health professional (cardiologist, physician, nurse) who provided information about the study using a leaflet. Those who showed interest were asked to contact the research team directly for participation. Once the interested participants-initiated contact, the researchers made an appointment, described the study, obtained written informed consent, and carried out a baseline data collection. Randomisation was done after baseline data collection.

Randomisation and allocation: We used a simple randomisation technique[26] and allocated participants using an opaque sealed envelope[27] in the intervention or control arm. This sealed envelope method is one of the methods suggested by Schulz and Grimes[28] for the allocation concealment to prevent allocation bias.

TEXT4BP intervention procedure (described in detail previously):[24] Intervention development and delivery were informed by formative qualitative studies,[22, 23] and the COM-B model of the behaviour change wheel and behaviour change techniques (BCTs).[29] The intervention arm received mobile phone text messages containing (a) general patient educational information (hypertension and its treatment, complications, signs and symptoms, medication, common side effects and consequences of non-adherence, physical activity, diet low in salt, low fat and some cultural messages) and (b) reminders for taking medication. (c) Smoking- and alcohol-related messages were tailored according to each patient. Text messages were sent three times per week in the morning (9-10 am) for three months, with the average length of the text message being 160 characters (see Supplementary File 1: Sample of the intervention text messages). We engaged a company (Aakash SMS: https://aakashsms.com/) to deliver the text messages which use the Nepal Telecom and N Cell telecom providers.

'Usual care': The control group received standard care. Patients with hypertension receives a prescription of medicine and advice for follow-up in Nepal. At the end of the study, we provided all control participants with a pamphlet containing educational information on hypertension and recommended modification of lifestyle and health behaviours.

Data collection methods: Baseline (0 weeks) and follow-up (12 weeks) data collection were conducted using a tablet-based KOBO tool box (https://www.kobotoolbox.org), containing questions of sociodemographic characteristics, family and medical history, and lifestyle factors: dietary salt consumption, physical activity, smoking status, and alcohol intake based on the World Health Organisation STEPWISE (WHO STEPs) survey,[30] the Hill Bone Compliance to High BP Therapy Scale,[31] Medication adherence self-efficacy scale[32] and a researcher-developed structured questionnaire on the knowledge of hypertension and its treatment.

The Hill Bone compliance scale[31] is used to measure adherence to antihypertensive therapy. It consists of 14 items: nine items on medication, three items on salt intake and two items on appointment keeping. Each item is scored on a response of 1-4, where a lower score indicates higher adherence to antihypertensive therapy. In the current study, the reliability coefficient Cronbach's alpha of the total Hill Bone compliance scale was 0.87 at baseline and 0.92 at follow-up. The medication adherence self-efficacy tool had 13 items, where the score ranged from 1-4, with a higher score indicating better medication adherence self-efficacy. Cronbach's alpha of the medication adherence self-efficacy tool's reliability coefficient was 0.98 at baseline and 0.97 at the follow-up. During follow-up, participants in the text message intervention group were also asked about the acceptability of the intervention using the Marshfield usability survey tool.[33] The tool contains 13 items, and each item has a 1-4 response. We also conducted in-depth qualitative interviews among five intervention arm participants, selected purposively based on their age, gender, and literacy level. All the study tools were pretested, and necessary modification was done before the actual data collection.

Physical measurements: BP, height, weight, waist, and hip circumference were measured by a trained research assistant (clinically trained registered nurse) following a standard protocol. Brachial BP was measured with the participant in the sitting position using an Oscillometric BP monitor (Kenz BPM OS-30, Suzuken Pvt. Ltd, Japan) following the guidelines of the European Society of Hypertension.[34] Patients were rested for 5 min, and three systolic and diastolic readings were measured 1-2 min apart, and the mean of the last two readings was used. A digital scale and height stadiometer were used for the weight and height measurement respectively. Waist and hip circumference were measured using a constant tension measuring tape using standard procedures.

Outcomes: The primary outcomes of the study were change in the systolic and diastolic BP, and medication adherence score from baseline to follow-up. The secondary outcomes were changes in BP control, medication adherence self-efficacy score and knowledge score of hypertension. Acceptability of the intervention was also one of the secondary outcomes of the study.

Statistical analyses: All analyses were done in SPSS version 26 (IBM Corp, NY/USA) using the intention to treat analysis approach. Baseline and follow-up sociodemographic information and outcomes were compared using the Chi-square test for categorical data and independent sample t-tests for continuous data. We analysed the three-month primary outcomes using a linear mixed model for repeated measures, which included data available on all randomised patients attending the follow-up visit at three months. This method has the advantage of implicitly accounting for missing data at the random mechanism using maximum likelihood. We also included an interaction term between the time and randomised group to assess possible differences of treatment effects (text message intervention vs usual care) per time points.

Additionally, we adjusted the model for other covariates though there were no differences between the groups at baseline. As a measure of the intervention effect, the estimated mean difference (β) between groups alongside 95% confidence intervals (CIs) and two-sided p values were reported, and statistical significance was set at $p<0.05$. Histograms and scatterplots of residuals and the predicted value suggested a good model fit. Further, a sensitivity analysis[35] was conducted using multiple imputations to create 20 imputed datasets of the missing values at follow-up. Univariate and multivariate general linear model analysis was performed to determine the robustness of the findings. In-group comparisons were conducted using the paired t-test. Qualitative interviews were transcribed, and line-by-line inductive coding was completed. Analysis was facilitated with NVivo software V.12 (QSR International, London, UK and USA).

Patient and public involvement

Formative studies[22, 23] informed our intervention through input from patients with hypertension, health care providers and key informants. However, participants were not invited to comment on the study design or contribute to research results and dissemination.

Ethics and dissemination

This study was approved by 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). All participants provided written informed consent.

Results

A total of 268 patients with hypertension were screened and assessed for eligibility (see CONSORT flow diagram in Figure 6.1). Of these, 45 did not meet the inclusion criteria, and 23 declined to participate. Thus 200 participants were included in the TEXT4BP trial after study procedures were explained in detail and written informed consent was obtained. None of the recruited participants refused to receive the intervention or withdrew their consent during the study. Over the 12 weeks of follow-up, the retention rate was 77%. We compared the sociodemographic variables between those completing the study and those lost to follow-up separately for intervention and control arm and found no differences in both arms (all p≥0.15, see Supplementary file 2: STable 1).

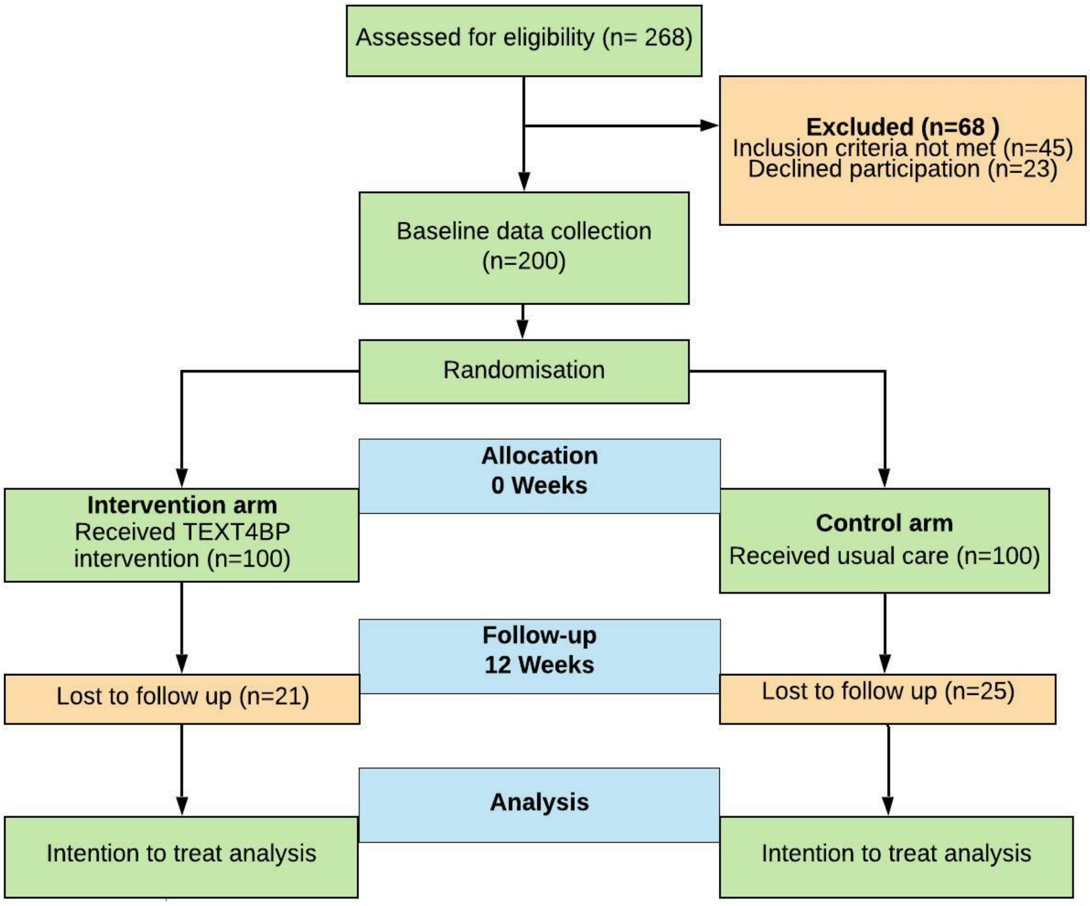

Figure 6.1: CONSORT flow diagram of the TEXT4BP Study

Baseline characteristics of the study participants

The intervention and control groups had a similar distribution in terms of age (with more than 50% of the participants between 46-60 years), sex, literacy, marital status, and religion (Table 6.1). All socioeconomic, blood pressure, and behavioural characteristics were comparable ($p \geq 0.20$) between the intervention and control arm, except for the Hill Bone salt-related score, which was slightly higher in the intervention arm ($p=0.043$).

Effects of the intervention

Blood pressure: We found a significant decrease in systolic ($p=0.003$) and diastolic BP ($p<0.001$) in the intervention arm only, at follow-up compared to baseline (Figure 6.2).

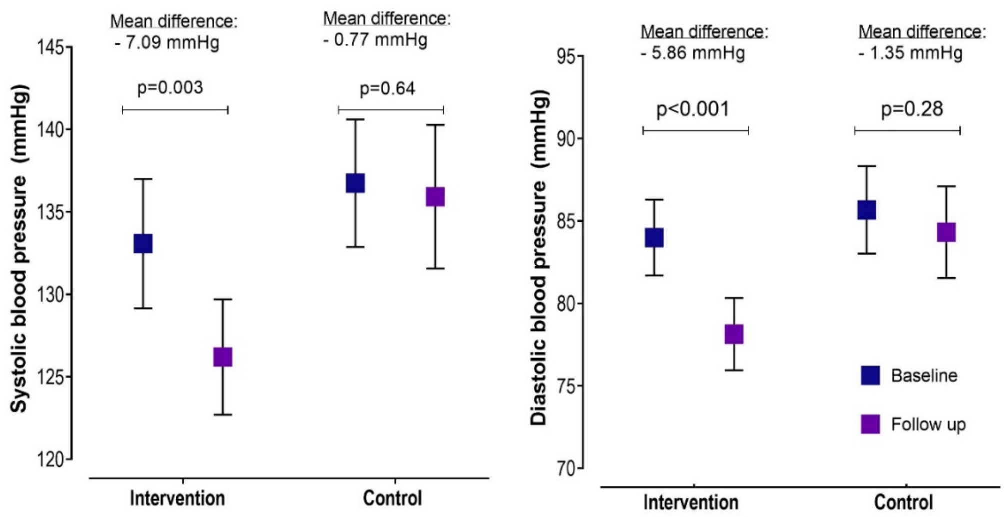

Figure 6.2: Change in systolic and diastolic blood pressure from baseline to follow-up in the text message intervention and control groups (paired test result)

Table 6.1: Comparison of baseline sociodemographic and outcome measures in the intervention and control arm

Characteristics	Category	Intervention arm N=100	Control arm N=100	P value
Age (years)	18 – 45	32	23	0.28[a]
	46 – 60	57	61	
	61– 69	11	16	
	Mean ± SD	49.2 ± 9.78	51.7 ± 9.21	0.071
Sex, n	Female	42	47	0.48 [a]
Literacy status,+ n	Literate	82	72	0.091 [a]
Ethnicity*, n	Upper caste groups	63	60	0.34 [a]
	Relative advantages and disadvantages Janajatis	29	36	
	Others**	8	4	
Marital status, n	Married	88	92	0.35 [a]
Employment, n	Employed	53	55	0.77 [a]
Religion, n	Hindu	92	91	0.80 [a]
	Others	8	9	
Systolic BP (mmHg)	Mean ± SD	134±19.5	137±25.3	0.38 [b]
Diastolic BP (mmHg)	Mean ± SD	84±11.6	86±13.4	0.35 [b]
BP control (<140/90 mmHg)	N (%)	60	54	0.39 [a]
Duration of hypertension (years)	Mean ± SD	5.40 ± 6.02	6.50±6.18	0.20[a]
Antihypertensive agents used	One	73	74	0.87 [a]
	More than one	27	26	
Other comorbidities***	Yes	56	62	0.39 [a]
Hill Bone Compliance score				
Total score (56)	Mean ± SD	25.9± 6.10	25.5 ± 6.13	0.61 [b]
- Medication related score (36)	Mean ± SD	14.6 ± 4.77	14.0 ± 5.07	0.43 [b]
- Salt related score (12)	Mean ± SD	7.06 ±1.36	7.02 ± 1.31	0.043 [b]
- Appointment related score (8)	Mean ± SD	4.35 ± 0.98	4.50 ± 0.97	0.28 [b]
Medication adherence self-efficacy score	Mean ± SD	36.6±7.87	36.6± 9.68	0.95 [b]
Knowledge of hypertension score	Mean ± SD	17.5±3.75	17.3± 3.92	0.66 [b]

*Note: Number and percentage are the same as the denominator is 100 for each. [a]p value of Chi-square test, [b] p-value of the t-test *caste classification card used in STEPS survey Nepal is used for ethnicity division with six caste category.[54] ** others = (Dalit, disadvantaged non-Dalit Terai caste groups, religious minorities) *** other comorbidities: Diabetes, COPD, Arthritis, etc., +Literate: Ability to read and write.*

At follow-up, systolic (p=0.001) and diastolic BP (p <0.001) were significantly lower in the intervention arm when compared to the control arm (Table 6.2). The intervention arm had a greater reduction in systolic (β=-6.36, p=0.043) and diastolic (β=-4.51, p=0.013) BP at follow-up than those in the control arm. These BP reductions remained significant after adjusting for age, sex, education, marital status, occupation, religion, smoking status, and alcohol intake (Table 6.2).

BP control (<140/90 mm of Hg) improved by 10% in the intervention arm, but this was not observed in the control arm (-6.00%) with a substantial difference of 70% vs 48% control (p=0.006) at follow-up **(Figure 6.3)**

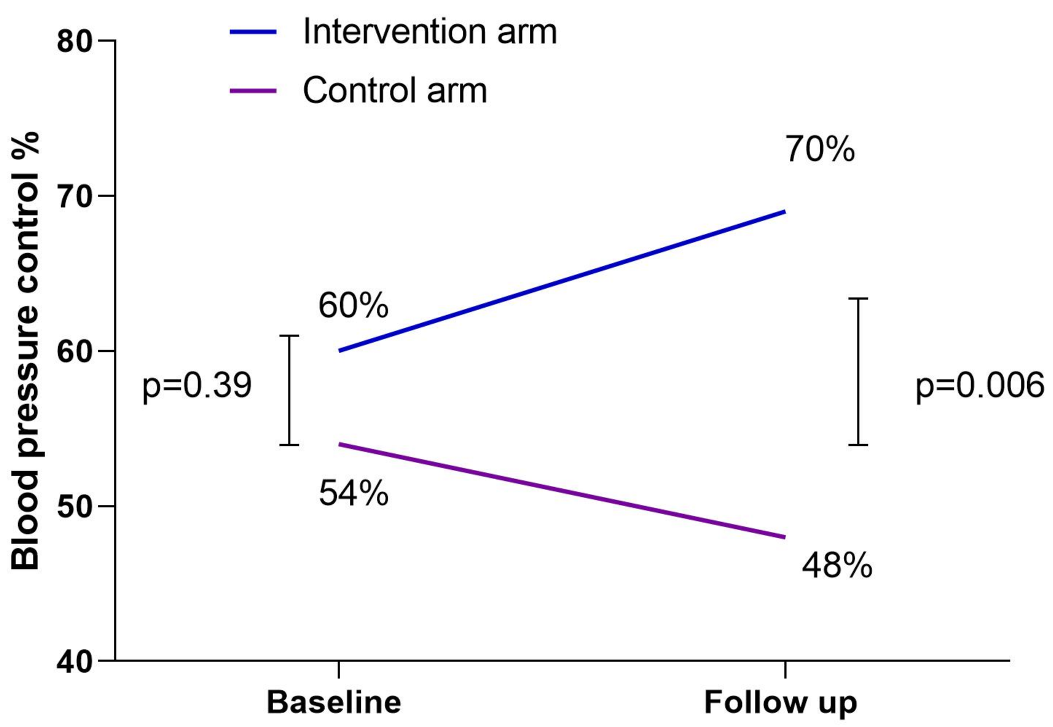

Figure 6.3: Blood pressure control at baseline and follow-up in the text message intervention and control groups

Table 6.2: Effectiveness of the TEXT4BP intervention among the intervention group compared to the control group

Outcome variable	Intervention (12 weeks) M (SD)	Control (12 weeks) M (SD)	P value [a]	Time*Group[b] Model 1		Time*Group[b] Model 2	
				B (95% CI)	P value	B (95% CI)	P value
Systolic BP	126 ± 15.6	136 ± 18.9	0.001	-6.36 (-12.5, -0.19)	0.043	-6.50 (-12.6, - 0.33)	0.039
Diastolic BP	78.2 ± 9.8	84.3 ± 11.6	<0.001	-4.51 (-8.06, -0.97)	0.013	-4.60 (-8.16, -1.04)	0.011
Hill Bone Compliance to High BP Therapy Scale							
Total Hill Bone score	18.4 ± 2.55	22.5 ± 8.13	<0.001	-4.57 (-7.07, -2.07)	<0.001	-4.48 (-6.97, -1.99)	<0.001
- Medication compliance score	10.1 ± 1.58	12.5 ± 5.76	0.001	-3.01 (- 4.92, -1.10)	0.002	-2.94 (-4.84, -1.03)	0.003
- Salt related score	5.47 ±1.36	6.59 ± 1.56	<0.001	-1.18 (-1.75, -0.62)	<0.001	-1.18 (-1.75, -0.62)	<0.001
- Appointment related score	2.91 ± 1.02	3.43 ± 1.48	0.013	-0.38 (-0.82, 0.058)	0.95	-0.38 (-0.82, 0.66)	0.091
Medication adherence self-efficacy score	50.6 ± 2.01	46.7 ± 9.74	0.001	3.94 (0.55, 7.33)	0.023	3.86 (0.49, 7.23)	0.025
Knowledge of hypertension	20.7 ± 2.39	18.5 ± 4.68	<0.001	1.81 (0.39, 3.24)	0.013	1.73 (0.32, 3.15)	0.016

Note: M (SD)= Mean (Standard Deviation); [a] = t-test; CI = Confidence interval
[b]=Results are presented as mean differences with the 95% CI at follow up (12 weeks) calculated using Mixed effect models with baseline value and control group as reference categories.
Model 1: Unadjusted; Model 2: adjusted for age, sex, education, marital status, occupation, religion, smoking, alcohol intake.

Hill Bone compliance score: In-group analysis showed a decrease in the Hill Bone medication compliance score only in the intervention arm ($p<0.001$) at follow up, with a lower score reflecting increased medication adherence (Figure 6.4). At follow-up, we found a significantly lower total Hill Bone score ($p <0.001$) in the intervention arm compared to the control arm. The total Hill Bone compliance score ($\beta= -4.57$, $p<0.001$), medication-related score ($\beta= -3.01$, $p<0.001$), and salt related score ($\beta= -1.18$, $p<0.001$) showed greater reductions among the intervention arm at follow-up compared to the control arm and remained significant also after adjustment of other covariates. However, there was no change in the Hill Bone appointment-related score (Table 6.2).

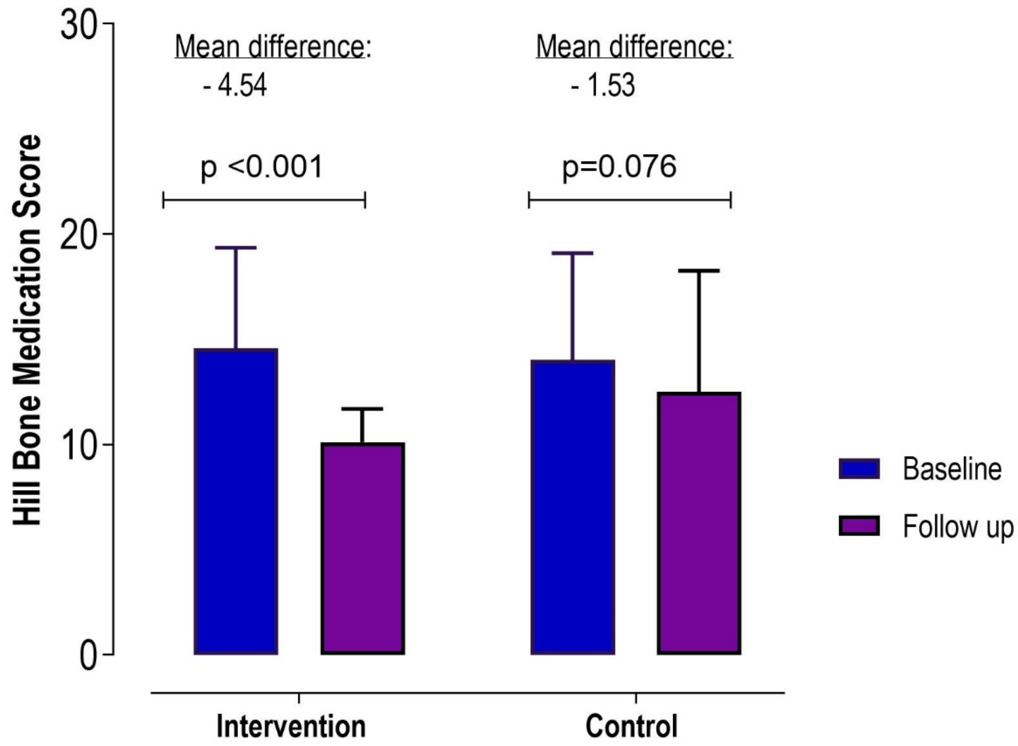

Figure 6.4: Change in Hill Bone medication compliance-related score from baseline to follow-up in the text message intervention group compared to the control group (paired test result)

Medication adherence self-efficacy: The score improved more among the intervention arm (β=3.94, p=0.023) than the control arm at follow-up before and after adjustment for covariates (Table 6.2).

Knowledge Score: The total knowledge of hypertension score (β=1.81, p=0.013) improved slightly among the intervention arm at follow-up compared to the control arm, also after adjustment (Table 6.2).

Sensitivity Analyses: We also used multiple imputations to impute missing values at follow-up and performed general linear univariate and multivariate analyses using the imputed data (Supplementary File: Stable 2). These analyses corroborate the findings in Table 6.2 regarding the effectiveness of the intervention**.**

Acceptability of the intervention

At follow-up, most of the participants in the intervention arm responded that they found the text messaging useful (89%), culturally appropriate (90%), and age-appropriate (90%), and would recommend text messages to other patients with hypertension (89%) (Table 6.3). Similarly, most responded that the intervention had a positive impact on their BP (86%), impacted on eating a low salt, low-fat diet (87%), positively impacted knowledge on hypertension (89%) and had a positive impact on their physical activity (73%). However, three-quarter (74%) responded that the intervention had not impacted the frequency of monitoring their BP (Table 6.3).

Table 6.3: Responses on the acceptability of the TEXT4BP intervention

(n=79)

Do you think those text messages were	**Yes** **N (%)**	**No** **N (%)**
Useful, n	70 (89)	9 (11)
Culturally appropriate, n	71 (90)	8(10)
Age appropriate, n	71 (90)	8(10)
Would you recommend messages to others, n	70 (89)	9 (11)
Do you think those text message has had a positive impact on your		
Overall BP, n	68 (86)	11 (14)
Diet or eating low salt and fat diet, n	69 (87)	10 (13)
Physical activity patterns, n	58 (73)	21 (27)
Knowledge of hypertension, n	70 (89)	9 (11)
Frequency of monitoring BP, n	21 (22)	58 (78)

We used a Marshfield questionnaire to assess the intervention's usability among the study participants. More than half (58%) of the participants strongly agreed that the SMS was easy to use (mean 4.46) and were confident in reading the message (mean 4.31). Similarly, 65% of participants strongly agreed that they could trust the message content (mean 4.63), and 61% wanted to receive the message again. Almost all responses had a mean score of more than four, where the highest mean was 4.63, indicating they were satisfied with the SMS system. The lowest mean score was 3.96, indicating that it was not as satisfying as talking to a real person (Supplementary File 2: STable 3).

The findings of the qualitative interviews were aligned with the Marshfield questionnaire. Participants found the intervention acceptable, informative, and useful in supporting their behaviour modification. Participants found the format, frequency, and content of the messages very acceptable. Some of the participant feedback included: 'It is simple…It's in understandable form' (P001), and 'I really felt good to receive text messages because I got to know about unknown things like - we should not take this food; we should carry medicine while travelling etc. I feel like I am receiving necessary information. It is good' (P003).

Participants also expressed that message related to preferred food during festival times were very helpful in controlling the high salt and high-fat foods. Some participants shared that they felt that someone was caring about their health when they received the messages. Some participants also expressed that text messages reminded them to take and buy medicine on time: '*it worked as a reminder to me'* (P004). Some also expressed their desire to continue the program. However, illiterate participants expressed difficulties in reading the messages. The family member was supposed to read the text message for them, but this deemed to be problematic in some cases due to the unavailability of the family member, e.g. '*The problem is; my son was occupied with work. Due to his job, he wasn't able to meet me and read message for me'* (P005). Participants suggested the use of voice messaging to overcome the challenges of illiteracy.

Discussion

This is the first randomised controlled trial to our knowledge which used the text messaging mHealth for the management of hypertension in Nepal. Our study found a culturally acceptable mobile phone text messaging intervention to be effective in reducing systolic and diastolic BP and improving BP control when compared to usual care in an LMIC, Nepal. The study demonstrated improved adherence to antihypertensive medication, including medication adherence self-efficacy, and a modest improvement in knowledge regarding hypertension among participants receiving text messages. We found that the intervention was highly acceptable to participants, and participants expressed a desire for the continuation of the program. Collectively, our study demonstrates that mHealth can be a viable and practical approach in LMICs and has the potential to be integrated into the wider health system. This is in line with the Nepal Health Sector Strategy 2015-2020[36] which stressed the importance of evidence-based use of modern technology in health services and information delivery in Nepal. Our findings should be confirmed in a large, randomised trial across multiple settings with long-term follow-up to demonstrate cost-effectiveness.

In LMICs, the use of simple text messages can contribute to bridging the gap in health care access especially in populations of ethnic minorities.[37,38] Our findings are encouraging and corroborates a systematic review and meta-analysis (Text2preventCVD) that showed a greater improvement of SBP −4.13 mm Hg, and DBP −1.11 mm Hg in studies using text messages.[39] However, all included trials did not focus on patients with hypertension. Another recent systematic review and meta-analysis that focused on 24 randomised trials using mHealth interventions among hypertensive patients provided evidence of a greater reduction of both SBP −3.78 mmHg and DBP −1.57 mmHg among the mHealth intervention groups.[40] However, most of these studies (22) were from HICs and only 10 studies used text messages as an intervention; the other studies used interventions based on apps and other types of mHealth. The STAR Trial conducted in South Africa[41] among patients with hypertension reported a small change in SBP (-2.2 mm Hg) at 12 months compared to our study (-6.36 mmHg) assessed at 3 months. Although we were not able to report on the long-term effectiveness of the intervention in our study, a previous systematic review reported no difference on the effect of the text messaging interventions based on duration.[42]

The mechanism of effectiveness in improvement in BP might be through greater patient engagement in self-care through text messages by continuation of care beyond the hospital setting.[43] This mechanism may have filled the continuity-in-care gap between health workers and patients in low resource settings by providing acceptable information to adopt a healthy lifestyle.[44] Additionally, messages informed by the theoretical model have the advantage of catering for the needs of and ensuring better engagement with patients[45] rather than only transferring knowledge.[46] Our theory-informed intervention resulted in better patient engagement and motivation for behaviour change leading to effectiveness of the intervention in our study.

Medication non-adherence is one of the major predictors of uncontrolled BP among patients with hypertension.[47] Text messages act as reminders to reinforce daily taking of medication[17] and address the issue of forgetfulness which is identified as one of the barriers for medication adherence.[48] Additionally, higher self-efficacy is associated with better initiation and engagement with self-care behaviours such as medication adherence, physical activity, and dietary changes among patients with hypertension.[49,50] Similar improvements of medication adherence were reported in previous systematic reviews of patients with chronic disease[42] and among patients with hypertension[51] using text message interventions. However, most of the included studies were from high-income countries. It is well established that the level of education and employment, dietary habits and preferences, lifestyle behaviours and a general understanding on the risks of raised BP[23] are substantially different in LMICs, and thus findings from high income countries cannot be directly translated to low resource settings.

There is very little evidence on the acceptability of text message interventions in the self-management of long-term illness.[51] Our study addressed this gap by providing evidence that a contextual co-designed mHealth intervention can be acceptable, useful, and informative in low resource settings. Participants acknowledged their interest in continuation of the program beyond the follow-up time. In the Text2PreventCVD systematic review most studies reported useful and moderate to high levels of satisfaction with a text-messaging programme.[39] One study reported that young participants may be more ready to accept text messaging interventions,[52] where others reported a decline in the interest of the participants over time.[53] Also in our study, there was a hesitancy in acceptance of the intervention among illiterate participants who found it difficult to read the text messages. Further studies are recommended to determine the long-term acceptability of our mHealth intervention.

Our study provides clear evidence on the effectiveness and acceptability of text messaging interventions in patients with hypertension in Nepal, despite the study coinciding with a festival season in Nepal (Dashain and Tihar) where high fat, high salt diets and excessive alcohol use are considered celebrated foods. The effectiveness of the messages in our study may be due to the impact of theory driven co-designed contextual text messages (including the impact of festive food and local herbs) through formative studies which was acknowledged by the study participants. Furthermore, in times of COVID 19, integration of mHealth interventions for the management of chronic illness in healthcare settings has become more relevant than ever.

Strengths and limitations

Our intervention development followed a vigorous co-designed method, informed by the COM-B behaviour change model[29] and evidence of formative studies[22,23]which ensured the robustness of our intervention. We have previously described the details of the intervention and delivery[24] that can be replicated. By using randomisation, we reduced selection and allocation bias. There are also limitations which need to be considered. Our pilot study was not powered to detect the observed difference of BP between groups though our sample size decision was based on the standard recommendation for the pilot RCT.[25] We used self-reported measures for assessing medication adherence which may have overestimated adherence. However, we used the validated Hill Bone tool with high reliability to overcome this limitation. This trial was not blinded, but we minimised potential bias by conducting group-allocation after the completion of baseline data collection. We minimised measurement bias at follow-up by advising the study participants not to disclose their allocation until measuring their outcomes at follow up. This was a small-scale intervention conducted at a tertiary referral-level hospital, thus generalisability of our findings to remote areas is unclear.

Conclusion

Our TEXT4BP randomised controlled trial has demonstrated that a contextual co-designed text messaging intervention informed by the behaviour change model to reduce BP and improve control in low resource settings is feasible, acceptable, and effective. Large-scale controlled trials building on our findings are recommended to evaluate the implementation of text message interventions in broader communities in LMICs to determine the sustainability of the effectiveness and acceptability.

Data Accessibility Statements

Data associated with this paper is available upon submitted request to the corresponding author.

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Author contributions

All authors contributed to the conception of research design, acquisition, and data interpretation. BB conducted the fieldwork and wrote the first version of this manuscript. BB analysed the data with the contribution of AES. All the authors BB, PN, RJ, AV and AES were involved in the manuscript drafting, revision, and finalisation. All authors read and approved the final version of the manuscript.

Competing interest

No financial or any other competing interests exist.

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Supplementary files

Barriers /facilitators	Linking with BCTs	Content of text message
Capability barriers Literacy of hypertension and its treatment	Shaping knowledge Health consequences	Do you know? You may have no symptoms and still have high blood pressure. Remember to take your medicine regularly. Do you know? Uncontrolled Blood pressure which is above 140/90 puts you in danger of having complications. Remember to check your BP regularly.
Motivation barriers/facilitators Beliefs about consequences of diseases Faith in traditional medicine/ local herbs	Threat Negative reinforcement Shaping knowledge	Uncontrolled High blood pressure can lead to heart attack, paralysis, vision problems and kidney failure so take your medicine regularly. Do not only rely on local remedies like bitter things to control your blood pressure. There are no other supplements to blood pressure medication. You must take medicine if your doctor prescribed it.
Capability/Opportunity/motivation/ barriers Non-adherence Forgetting to take medicine	Reinforcement Shaping knowledge/ Emotional consequences Prompts /Cues Habit formation	Are you taking your medicine regularly? Remember! NEVER change your medication or stop taking your medication unless your doctor tells you to. If you are not sure you really need your blood pressure medicine, ask your doctor to explain the reasons why it was prescribed. Try putting your pillbox or bottles near something you see every day, like your toothbrush to help remember to take your blood pressure medication! Do you know? you can set up an alarm on your mobile phone to remind you to take medications

<u>Opportunity/motivation barriers</u>	Shaping knowledge	Did you know? Smoking, drinking alcohol, eating unhealthy food (high salt and high fat food), little exercise and being mentally stressed puts you in danger of high blood pressure.
unhealthy dietary habits (cultural practices)	Self-monitoring of behaviour	Did you exercise this week? Aim at exercising 30 minutes/day at least five times a week.
Resistance in behaviour modification/	Goal setting	**Salt intake:** Food high in sodium(salt) can increase your blood pressure. Try to limit your sodium intake to 5g/day, including what is in and what is added to food.
Stigma and Non-disclosure	Shaping knowledge	**Festive food:** Happy Dashain/Happy Tihar (Nepali festival name which was during intervention). Please remember to enjoy the festival limiting food with high salt and high fat which will affect your blood pressure.
	Reinforcement	**Physical activity:** Moderate physical activity of 30 minutes can make your blood pressure medications work more efficiently and reduce your blood pressure. Try a 30-minute brisk walk or three 10-minute walks
		Don't feel ashamed in disclosing your high blood pressure status. Please disclosure yours and encourage other to disclose for the timely diagnosis and seek treatment to prevent the complications.
		Don't worry! If you have high blood pressure, it does not mean you are ill or weak. If you can keep the blood pressure under control (<140/90) then it will not harm you.

Supplementary tables STable 1: Comparison of demographic profile of completers and loss to follow-up of intervention and control arm

Characteristics	**Category**	**Intervention arm**			**Control arm**		
		Completers N = 79 (%)	Loss to follow up N= 21 (%)	P value	Completers N=75 (%)	Loss to follow up N= 25 (%)	p value
Age	Mean ± SD	49.2 ± 10.1	49.2 ± 8.5	0.99	51.2 ± 9.3	53.1 ± 8.8	0.38
Sex	Male	46 (58.2)	11 (52.4)	0.63	38 (50.7)	16 (49.3)	0.23
Literacy status	Literate	65 (76.2)	16 (82.3)	0.52	53 (70.7)	20 (80.0)	0.36
Ethnicity	Upper caste groups	49 (62)	13 (61.9)	0.95	42 (56)	19 (76)	0.18
	Advantages/disadvantages Janajatis	24 (30.4)	6 (28.6)		30 (40)	5 (20)	
	Others	6 (7.6)	2 (9.5)		3 (4)	1 (4)	
Marital status	Currently married	69 (87.3)	19 (90.5)	0.69	69 (89.3)	25 (100)	0.08
Occupation	Employed	41 (51.9)	11 (52.3)	0.69	42 (56.0)	14 (56.0)	1.00
Religion	Hindu	72(91.1)	20 (95.2)	0.53	67(89.3)	24 (96)	0.31

STable 2: Effectiveness of TEXT4BP intervention among the intervention arm compared to control arm using data based on multiple imputation

Outcome variable	Regression coefficient* Model 1		Regression coefficient* Model 2	
	β (95% CI)	**p value**	**β (95% CI)**	**p value**
Systolic blood pressure	-8.56 (-12. 97, -4.14)	<0.001	-8.4 (-12.9, - 3.9)	<0.001
Diastolic blood pressure	- 5.40 (-8.35, -2.45)	<0.001	-5.28 (-8.33, -2.23)	0.001
Hill Bone compliance scale Total score	-4 (-6.15, -1.84)	<0.001	-4.29 (-6.48, -2.11)	<0.001
- Medication related score	-2.40 (- 3.89, -0.91)	0.002	-2.56 (- 4.07, -1.05)	0.001
- Salt related score	-1.12 (-1.63, -0.58)	<0.001	-1.05 (-1.59, -0.51)	<0.001
- Appointment related score	-0.45 (-0.88, 0.03)	0.37	-0.50 (-0.94, -0.06)	0.024
Medication adherence self-efficacy	3.01 (1.23, 4.79)	0.001	3.20 (1.39, 5.01)	0.001
Knowledge of hypertension	1.58 (0.62, 2.54)	0.001	1.50 (0.53, 2.46)	0.002

** General linear univariate and multivariate model of imputed data Model 1: Unadjusted model,*

Model 2: Adjusted model for age, sex, education, marital status, occupation, religion, smoking status, alcohol intake, BMI.

STable 3: Responses on the Marshfield usability of the intervention questionnaire

Questions	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	Mean ± SD
I thought SMS system was easy to use	58 (73.4)	9 (11.4)	7 (8.9)	1 (1.3)	4 (5.1)	4.46±1.06
I felt very confident reading SMS	58 (73.4)	5 (6.3)	7 (8.9)	1 (1.3)	8 (10.1)	4.31±1.30
I needed to learn a lot of things before I could get going with SMS*	6 (7.6)	5 (6.3)	9 (11.4)	2 (2.5)	57 (72.2)	4.25±1.31
I felt that I needed someone's help to be able to read the SMS*	8 (10.1)	7 (8.9)	7 (8.9)	4 (5.1)	53 (67.1)	4.10±1.42
I found SMS to be complex*	5 (6.3)	3 (3.8)	8 (10.1)	2 (2.5)	61 (77.2)	4.40±1.20
Using the system of SMS did not take much time	61 (77.2)	5 (6.3)	7 (8.9)	2 (2.5)	4 (5.1)	4.48±1.09
I could always trust the SMS to work	65 (82.3)	3 (3.8)	8 (10.1)	2 (2.5)	1 (1.3)	4.63±0.86
My privacy was protected when I used the SMS system	59 (74.7)	3 (3.8)	8 (10.1)	1 (1.3)	8 (10.1)	4.31±1.31
Using SMS service was as satisfying as talking to a real person	42 (53.2)	12(15.2)	10 (12.7)	10 (12.7)	5 (6.3)	3.96±1.32
In general, I was satisfied with the system of SMS	59 (74.7)	12(15.2)	7 (8.9)	0	1 (1.3)	4.62±0.75
I think I would like to receive such SMS again	61 (77.2)	4 (5.1)	13(16.5)	1 (1.3)	0	4.58±0.81
The system of SMS could help me better manage my health and medical needs	54 (68.4)	13(16.5)	8 (10.1)	4 (5.1)	0	4.48±0.87
I could be more involved in my care by using the SMS service system	56 (70.9)	11(13.9)	9(11.4)	2 (2.5)	1 (1.3)	4.50±0.88

*Reverse coding

Chapter 7: Discussion, Future Recommendations and Conclusion

7.1 Introduction

This chapter discusses and summarises the findings of this PhD thesis and demonstrates how the findings address the overarching research aims and objectives of the thesis. I have synthesized the findings and implications from the Phase I (qualitative formative studies - Chapter 3 and Chapter 4); and Phase II (methods - Chapter 5 and results - Chapters 6 of the quantitative component) parts of my research. The contribution of the findings of this thesis in relevance to the existing body of knowledge and future directions in terms of research, practice, and policy are also provided, along with a discussion of the strengths and limitations of the studies. Finally, I provide brief conclusions based on the findings.

As outlined in Figure 7.1, the first aim of this thesis was to explore the perspectives of the different stakeholders on the facilitators and barriers for the treatment and control of blood pressure among patients with hypertension in Nepal based on the gaps identified in the literature review (Chapter 2). The findings presented in Chapter 3 provided a detailed insight into the different capabilities, motivations/opportunities, barriers, and facilitators faced by patients with hypertension. This study established an empirical need for implementing contextual interventions to address the identified gap in Nepal and guided the intervention development in Phase II of the research.

Secondly, this research aimed to understand the acceptability of a text messaging mHealth intervention to get more insight into its potential use in Phase II. The findings guided by the

Technology Acceptance Model (TAM) provided an insight into the perceived usefulness, ease of use, and implementation challenges and proposed recommendations to overcome the identified challenges. These findings are presented in Chapter 4 of this thesis, and were incorporated to design and implement the interventions in Phase I.

The findings provided clear evidence that a text messaging mHealth approach is a potential platform to deliver interventions for patients with hypertension. I co-designed an mHealth intervention using only text messages, considering the limited penetration of smartphones in Nepal, and considering the digital literacy required to operate advanced app-based programs (highlighted in the formative study - Chapter 4). In Chapters 5 and 6, I discussed the development, implementation, and evaluation of the mHealth based study, acronym being TEXT4BP (TEXT message intervention For improving Blood Pressure control).

Finally, the overarching aim of my PhD thesis was to assess the effectiveness and acceptability of the TEXT4BP intervention in improving blood pressure control among patients with hypertension in Nepal. The findings of the TEXT4BP feasibility study, discussed in detail in Chapter 6, answered the overarching aim of this thesis.

The key findings of both Phases of the study (I and II) are summarised and discussed in the next section, followed by the strengths and limitations of the studies and their implications for future research and policies.

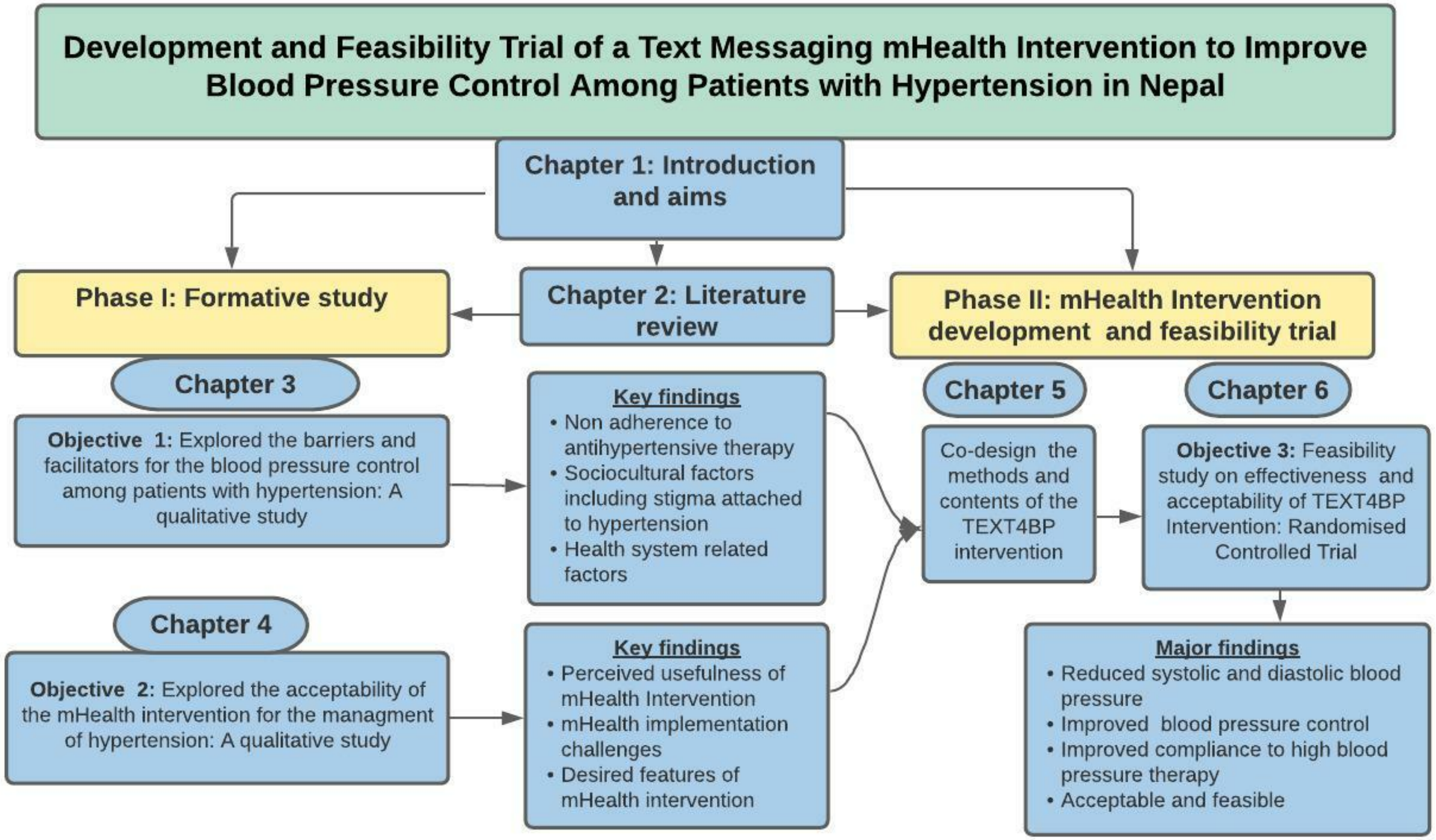

Figure 7.1: Summary of studies undertaken in Phase I and Phase II presented in this thesis

7.2 Phase I - Formative study

7.2.1 Barriers and facilitators for the treatment and control of blood pressure

Uncontrolled blood pressure is a major therapeutic challenge among patients with hypertension globally. This is especially the case in LMICs such as Nepal.[1] The first empirical contribution of this thesis is that it systematically provided evidence for individual, social, and system-level barriers and facilitators as presented in Chapter 3 (Published in BMC Public Health Journal).[2] The use of the COM-B model[3] of the Behaviour Change Wheel (BCW) as the overarching framework had the advantage of understanding the individual's internal and external factors and provided guidance in choosing the appropriate intervention to address the identified issues. The key barriers to blood pressure control identified in this study were: (i) Non-adherence to antihypertensive therapy; (ii) Sociocultural factors, including stigma attached to hypertension; (iii) Health system-related barriers. These barriers are discussed below.

i. Non-adherence to antihypertensive therapy

Non-adherence to antihypertensive therapy is a significant contributor to poor blood pressure control. According to the WHO, adherence to therapy is "the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider".[4] This study reported medication adherence barriers under several themes, classified using the components of the COM-B model. A systematic review by Dhar L and colleagues in 2017 [5] on studies from LMIC settings and studies of Nepal reported high rates (around 50%) of non-adherence to antihypertensive therapy.[6, 7] In our study, forgetfulness, fear of side effects, and medicine addiction contributed to non-adherence to antihypertensive therapy. In addition, motivational barriers such as a strong belief and trust in locally available herbs and bitter substances led to switching/not starting the allopathic medication.

Inadequate knowledge and misconceptions about disease and treatment were also explored as barriers to treatment and lifestyle modification. Similar capability barriers such as inadequate knowledge were reported in previous systematic reviews[8, 9] and other studies from Nepal.[7, 10] However, many reported misconceptions such as "hypertension is an old age disease"; "Medicine should be taken only after their fifties", and "power of body can control hypertension" were novel findings in this study. Misconceptions might be due to a low health literacy of hypertension which, as reported by Shrestha et al. among more than half of their study participants (52%, n=164) in the eastern part of Nepal in 2016.[11] Such misconceptions would also interfere in the timely diagnosis of hypertension and in adapting the recommended behaviours to achieve target blood pressure among patients with hypertension.[8]

ii. **Sociocultural factors, including stigma**

The study uncovered the stigma associated with hypertension as a barrier in this setting which were largely ignored from previous studies conducted in Nepal.[7,10] Non-disclosure of disease was associated with fear of exclusion in a social gathering, difficulties in getting married, and fear of job loss as patients with hypertension were considered incapable and weak. These concerns were expressed mainly by young, unmarried participants. Stigma was documented as a barrier to healthcare seeking and treatment adherence in other diseases such as lung cancer,[12] and reported barriers for hypertension management in Eiteria, an African setting.[13] Furthermore, the current study explored socio-cultural barriers such as practice of social drinking and a high preference for salty-fatty foods. Contextual interventions incorporating cultural aspects were critical to addressing these barriers.

iii. Health System-related factors

The system-level physical opportunity barriers explored in the study were (i) accessibility of health care services, (ii) affordability/availability of antihypertensive medications, (iii) poor communication between patients and providers, (iv) lack of skilled health workers to diagnose and treat hypertension, especially at the primary health care level. The high workload of healthcare workers, scarce human resources, and lack of counselling for treatment contributed to poor doctor-patient relationships leading to mistrust in treatment. These findings are consistent with previous studies from Nepal where they have highlighted the lack of human health resources, poor communication of health care providers and affordability issues for the treatment of hypertension.[7, 9, 10] However, those studies did not specifically explore the barriers in primary and secondary levels of health care. The role of health care providers in increasing health literacy, improving adherence to antihypertensive therapy, and behaviour modification are well established.[14, 15]

The current study also identified facilitators to encourage better management of hypertension, including the perceived threat of the disease, family and peer support, and self-reminders to take medication. These facilitators need to be enhanced by sensitizing patients about the complications of hypertension and involving the family members in supporting the self-care of patients. The contextual design of the intervention was crucial to overcome these identified barriers. Based on the Behaviour Change Wheel (BCW),[3] different intervention functions such as education, enablement, persuasion, reinforcement, environmental modelling can address these issues as discussed in-detail in Chapter 3.[3] In the context of human resource constraints, easily available mediums such as mobile phones can bridge this gap in the LMIC setting for intervention delivery.[16] To my knowledge, there were no studies exploring the feasibility and acceptability of mHealth to improve the management of hypertension in Nepal. Therefore, I explored the acceptability of a mHealth intervention, with the results discussed in Chapter 4 and briefly synthesized in the following section.

7.2.2 Potential of a mHealth intervention to improve hypertension management

The mHealth interventions usually fail due to a lack of understanding of contextual needs.[17] Therefore, it is imperative to understand contextual needs and challenges for successful design and implementation of the mHealth intervention to get its desired outcome.[18] The main contribution of the findings informed by technology acceptance model of Chapter 4 (Under Review, BMJ Open, July 2021) [19] are discussed below:

i. Perceived usefulness of mHealth interventions

Our study reported a consensus of different stakeholders regarding the perceived benefits of a text messaging mHealth intervention. The ubiquitous use of mobile phones is evidenced by a penetration rate of over 100% in Nepal.[20] The rate is higher than the estimated total population size, and could be due to the use of more than one SIM card per person. Previous meta-analysis by Thakkar et al., and a study based in South Africa by Bobrow et al. reported the usefulness of mHealth for behaviour reinforcement and as a reminder for medication adherence.[16, 21] The WHO Global Observatory Group stated in their 2011 report that Short Message Services (SMS) was the preferred method for treatment compliance and an easy way of sending a brief message at a low cost. [22] The cost effectiveness benefit was highlighted by a previous systematic review by Beratarrechea and colleagues among studies from developing countries.[23] In a similar vein, the current study reported that mHealth could be an acceptable tool for behaviour reinforcement. The key informants of my study (involved implementing the NCD management program in Nepal) also perceived that a text message intervention could be cost-effective as it can be sent to many people in bulk at the same time and rate of SMS is also cheap (0.0018 USD/SMS). In addition, participants perceived such an intervention could deliver the message privately, which may address stigma and non-disclosure barriers discussed in Chapter 3.

ii. mHealth implementation challenges

Our study highlighted many implementation challenges including literacy as a key issue. Language and literacy barriers in reading the text messages were also raised by studies from South India conducted by Sydney et al. (2012) and Smith et al. (2015).[24, 25] Our study recommended involving a family member or using other video or voice messages to address these challenges. However, the use of voice/video might not be feasible in more isolated, resource-limited settings such as Nepal due to poor access to internet and smartphones.

This study also reported technical and system-level issues such as an improper recording system of patient details in hospitals and under-resourcing in the healthy system as an implementation challenge to mHealth. The WHO Global Observatory Group reported issues such as operating cost, lack of knowledge of mHealth applications and outcomes, unclear policies, and underdeveloped infrastructure as the most common barriers in adopting mHealth in LMICs.[22] Similar technical and operational challenges in using mHealth in LMICs,[26] and a poorly-resourced health information system were reported by Lall and colleagues (2019) in rural India as a barrier to the continuity of care and follow up of patients with hypertension.[27] The usability issues of cost, information carrying capacity, language and literacy in using mHealth were also reported in the studies from Bangladesh[28] and Kenya.[29] Therefore, for successful design and for the scaling up of mHealth interventions, these challenges need to be considered and all the stakeholders should be engaged with.[30]

iii. Desired features of mHealth intervention

Participants in this study expressed their interest to use technology for hypertension management. They also expressed their desired modalities of the mHealth intervention. These are provided in Figure 7.2. It is essential that the participant's preference and need be considered while designing a mHealth intervention for its sustainability. Based on the experience in Nepal, we recommend that multisectoral collaboration and commitment from government are required to address structural barriers to using advanced technology to manage hypertension. These include inadequate recording of details of patients in hospitals, lack of technical manpower/department. Despite these challenges, our study found that a text messaging mHealth intervention could be feasible and acceptable in the context of Nepal. However, meticulous planning should include diverse participants, such as illiterate and the elderly group. The findings of this formative research informed the Phase II TEXT4BP study (Chapter 5 and 6), discussed in the following section.

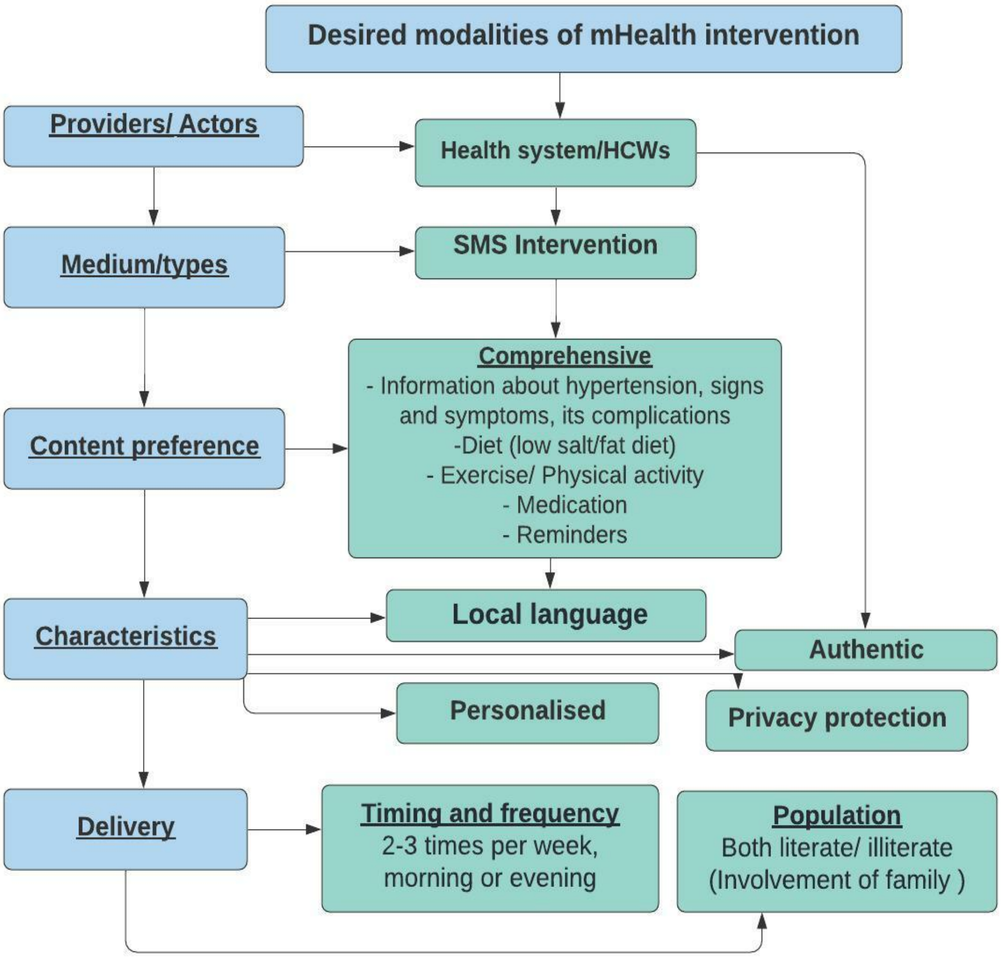

Figure 7.2: Desired features of a mHealth intervention

7.3 Phase II – Development and evaluation of mHealth intervention

As discussed in Chapter 2, in a setting with a limited healthcare workforce, finding an alternative solution to complement the health service and information delivery was a critical strategy. Phase II of this project aimed to co-design and evaluate a mHealth intervention that would cater to the needs of a wide range of patients with hypertension for self-management of their blood pressure by taking medicine on time, alongside diet and exercise as recommended. The co-design of the mHealth intervention involves the assessment of user knowledge and needs to inform the intervention focus, content and technology, prototype development and pilot testing as reported in a systematic review by Eyles H, et.al.[31] I assessed the background knowledge and evidence, user needs to inform the focus and type of intervention through literature and Phase I formative studies (fig 2). Following this, I developed the content of the TEXT4BP intervention text messages based on the need of participants and the behaviour change techniques.[3, 32] The messages were pre-tested and revised based on the feedback from participants and local health care workers. The intervention development process and the study protocol were described in detail in Chapter 5 (published in BMJ Open).[33]

The TEXT4BP intervention was a well-structured, simple text messaging mHealth intervention evaluated using a robust randomized controlled trial design with nested qualitative interviews. The findings of the TEXT4BP study indicated that the intervention was feasible, effective, and acceptable in the study setting, which is discussed in Chapter 6 in detail and synthesized below:

i. **Feasibility of TEXT4BP intervention**

I recruited the required number of study participants (n=200) within the stipulated time, despite the study coinciding with Nepal's greatest festival (Dashain and Tihar). Only 8.5% (n=23) screened participants refused to participate in the study due to various reasons such as not being interested and having a lack of time required for data collection. However, none of the recruited participants refused to receive the intervention or withdrew their consent during the study. The COVID-19 lockdown in March 2020 hampered follow-up data collection in Nepal, which posed unprecedented challenges for individuals and their livelihoods. Despite these disruptions, the retention rate at three months of follow-up was 77% (N=154), which is encouraging in LMIC settings. Hence, this study suggested that such an intervention is feasible in resource-constrained settings like Nepal, although a cost-effectiveness analysis was beyond the scope of this study.

ii. **Effectiveness of the TEXT4BP intervention**

The TEXT4BP study was effective as it resulted in a greater reduction of SBP [β= -6.50 (-12.6; -0.33)] and DBP [β= -4.60 (-8.16; -1.04)] in the intervention arm compared to the control at three months of follow up, and after adjusting for potential confounders. Overall blood pressure control also saw a greater improvement among the intervention arm (10% vs -6%, p=0.006), as discussed in detail in Chapter 6 (Submitted to Global Heart Journal, July 2021). The effectiveness of the intervention demonstrated in this study corroborates previous systematic reviews and meta-analysis conducted by Li R et.al.[34, 35] Both reviews reported a more significant reduction of the SBP and DBP among the intervention group. However, those reviews included studies mainly from HICs, not all included studies in Islam et.al review targeted interventions to patients with hypertension,[35] and not all studies used text messages as intervention (mostly app-based) in the review by Li R and colleagues.[34]

In addition, the TEXT4BP intervention improved the compliance to antihypertensive therapy, medication adherence self-efficacy, and knowledge of diseases – a crucial predictor for blood pressure control. In contrast to this study, a recently published systematic review and meta-analysis by Khoong et.al (including 15 studies using text messaging and 12 studies using mHealth applications), reported a significant reduction of SBP in the intervention arm, but did not report a significant difference in the reduction of SBP between the intervention and control arms.[36] This might be due to only half of the included studies in this review using a theoretical model to inform their intervention. Our intervention was informed by theory to address patient needs that ensured better engagement,[37,38] and was contextually co-designed.[31] Those contextual messages would have acted as a reinforcement for taking medicines on time, improved physical activity, and encourage a low salt diet as participants highly acknowledged the impact of these contextualised text messages. The value and effectiveness of the co-designed mHealth intervention were highlighted by previous studies on the development of text messages for healthy lifestyles for teens[39] and mHealth for obesity management on young adults.[40]

iii. **Acceptability of the TEXT4BP intervention**

The acceptability of a mHealth intervention plays a vital role in getting the desired effect. There is limited evidence on the acceptability of text messages for the self-management of chronic diseases.[41] This study reported that the TEXT4BP intervention was acceptable as participants (more than 80%) reported they were satisfied with the content, frequency and timing of the intervention. Participants also expressed a desire for continuity of the intervention. This is an original contribution to understandings of mHealth interventions in LMICs. Participants perceived the intervention as simple, easy, and valuable for reinforcing their behaviour change and experienced the intervention as culturally appropriate. Our findings corroborated the findings reported in a systematic review by Khoong et.al, 2021 where most of the studies reported a high level of satisfaction, perceived usefulness and ease of use.[36] However, some of the included studies in this review reported high level of satisfaction and use at initial stage, but declining interest and use with long-term use.[36, 42] Therefore the long-term acceptability of our intervention needs further research. In addition, some challenges were reported by participants, such as the busyness of the family member while involving them in reading the text messages for the elderly/illiterate group.

To conclude, the encouraging evidence of this feasibility study recommends the future large-scale experimentation of this TEXT4BP intervention using a sufficiently powered randomized controlled trial design. A large-scale trial would provide robust evidence on long-term effectiveness and acceptability, including cost-effectiveness to integrate such an intervention into routine health care practice.

7.4 Strengths and limitations

7.4.1 Formative qualitative study (Phase I)

The primary strength of this formative qualitative study lies in its methodology. Different approaches were used to ensure the trustworthiness of the data.[43] Two different data collection methods were employed, namely in-depth interviews (IDIs) and focus group discussions (FGDs), to triangulate the study's findings.[44] IDIs provided an opportunity to understand the in-depth personal experiences and perspectives on the mHealth intervention.[45] In addition, FGD prompted participants to share experiences while hearing each other's perspectives and to make additional comments which they may not have expressed in the IDIs.[46] Similarly, the maximum variation (in terms of age, sex, area of residence, education, duration of disease etc.) method of purposive sampling[47] was used to ensure the heterogenicity of the participants and information that added to the credibility of the findings. Furthermore, different stakeholders such as patients with hypertension, their family members, health care providers, and key informants were included in the study to explore holistic understanding from multiple sources. Perspectives from patients and family members helped in understanding patient-community level perspectives whereas key informants and healthcare workers' perspectives provided opportunities to understand system-level factors for the contextual design of the mHealth intervention.

Likewise, participants from both the primary and tertiary levels of health care were involved in representing the diverse perspectives of different healthcare levels. Notably, the method and analysis of the first objective (barriers and facilitators) were guided by the COM-B model that provided an opportunity to systematically understand the patients' internal and external barriers and facilitators as discussed in Chapter 3. Additionally, methods and analyses of the acceptability of the mHealth intervention of the prospective users was informed by the TAM model (discussed in Chapter 4), that systematically helped to understand the perceived usefulness and challenges in implementing mHealth in the study setting. As a native of Nepal, I conducted all of the interviews; having an in-depth understanding of the health system and settings allowed me to gather richer data by forming rapport and trust with the study participants.

Some limitations of the methods need to be considered while evaluating the findings of this study. Firstly, although I have endeavoured to triangulate the study findings using different methods and sources of data collection, data were analysed together, which might not have fulfilled all of the criteria of data triangulation.[44] Secondly, being a native interviewer had many advantages, which I mentioned as a strength. At the same time, participants might have assumed that I shared an awareness of all of the issues prevalent in the study setting, and therefore may not have expressed the complete set of barriers. Similarly, some healthcare workers might have provided an ideal answer after being familiar with my professional background. To overcome this, I tried to probe more to gather their neutral perspectives.

Thirdly, recruiting participants for interviews from primary and tertiary health care facilities may have led participants to give a socially-desirable answer regarding using the health services.[48]

Fourthly, our study might not capture the barriers faced by the patients at the community level who were not seeking health services, as there is reported evidence that around one fifth of the total population of Nepal prefer to go to traditional healers as their first point of contact before seeking modern care health services.[49] Finally, this study was conducted in urban and semi-urban parts of the capital city of Nepal. I chose the primary and tertiary health care facilities within the geographically accessible locations due to resource constraints. Thus, the study might not represent the barriers faced by patients with hypertension living in geographically disadvantaged areas of the country. Moreover, the acceptability of mHealth in those remote areas could be different.

7.4.2 TEXT4BP study (Phase II)

To our knowledge, the TEXT4BP was the first study conducted using a text messaging mHealth tool among patients with hypertension in Nepal. The intervention development followed a rigorous co-design process informed by the formative studies and theoretical framework. Therefore, this intervention addressed the contextual needs and preferences of the participants. The content, timing, and frequency of intervention delivery were also informed by the formative studies, leading to high acceptability of the intervention among participants. In addition, this study used a robust randomized controlled trial design[50] using the sealed envelope method[51] to implement the intervention, limiting selection and allocation bias of the study. Further, this study comprised both illiterate and elderly groups, leading to a broader intervention coverage.

Several limitations of the study also need to be considered. Firstly, the sample size of this feasibility study was not powered. However, we have followed the standard recommendation to determine the sample size for pilot RCTs (n=200).[52] Secondly, this was an unblinded trial that could have led to some measurement bias from the interviewer. However, randomization was done only after baseline data collection. In addition, participants were instructed not to reveal their allocation status until assessing the outcome measures at the follow-up to limit measurement bias. Thirdly, I have used the self-reporting method to assess the medication adherence due to resource constraints that may have overestimated the adherence to antihypertensive therapy. It would have been best to perform biological testing along with self-report to determine medication adherence reliably.[53] I employed the Hill Bone Compliance to antihypertensive therapy scale with high reliability to limit overestimation, though evaluation of the psychometric properties of the tool was out of the scope of our study.

Fourth, participants received tailored the messages only for smoking and alcohol intake, but not for all content. Therefore, tailored messages, especially reminders customised with medication time, could address psychological needs and preferences leading to more effective change and maintenance of behaviour.[54] Fifth, the trial duration was short term, only for three months, so this study could not determine the long-term effectiveness and acceptability of the intervention. Finally, I conducted this study among the patients visiting a single tertiary referral level hospital in Kathmandu, thus the findings require confirmation at other hospitals and primary healthcare settings. The generalisability of the findings to a remote, geographically disadvantaged part of the country is not clear.

7.5 Future recommendations

7.5.1 Future research directions

There are multiple areas of future research that have emerged from this thesis. Based on the promising findings of the TEXT4BP pilot study, a large-scale double/triple-blinded randomized controlled trial is recommended for future research to limit the measurement and analysis bias. In addition to including a blinded component, a follow up study for at least one year to assess the long-term effectiveness and acceptability of the intervention and its translation into regular health care practice may offer further insights that this study could not provide. A longer-term study involving a larger participant pool would provide more data to establish the effectiveness and acceptability of such an intervention on a broader scale, involving as multi-institute, rural-urban and primary-tertiary level comparisons to generalise the findings to all levels. Another area of future research could be feasibility of the other advanced mHealth technologies such as app-based interventions or video/voice messages in LMIC settings. While scaling up the TEXT4BP program to evaluate on a large scale, the following aspects should be considered:

1. Cost-effectiveness analyses of the intervention.
2. A more-inclusive alternative for illiterate/elderly groups such as utilizing voice or pictorial/video messages.
3. More robust measures of medication adherence, such as biological measures.
4. Evaluating the psychometric properties of the self-reported tool of medication adherence.
5. Tailored messages to the individual matching their medication timing and other behaviours.

In addition, some of the barriers reported in the first qualitative study, such as the stigma and non-disclosure, and sociocultural factors associated with the dietary practices, need further exploration. Community-based interventions can be designed and evaluated to target these sociocultural and stigma-related barriers specifically.

7.5.2 Implications for practice and control of hypertension

The findings of this thesis have some practical implications for improving blood pressure control among patients with hypertension in Nepal. The first qualitative study provided evidence of numerous system-level barriers, including poor communication between healthcare providers and patients. There is a need to strengthen the trust relationship between patients and providers. To address these identified gaps in the Phase I, adequate counselling from the health care provider could be a helpful strategy. Our findings can be used as a reference by a health organization to train health care workers about counselling and its importance for better treatment adherence.[55]

In addition, key organizations such as local government bodies, along with the primary health care facilities, can use our study findings to design the awareness programs for non-communicable disease management at community level. These programs could be education to the local religious leader, patients, their family members, and other influencing community people about hypertension and the importance of behaviour modification to overcome the stigma and other sociocultural barriers.

Finally, in the context of limited human resources, a regular text messaging system into regular practice could be used for information based on the findings of the TEXT4BP study. Text messages could provide an opportunity to disseminate the information and remind the patient beyond the health care settings to engage in self-management of blood pressure control.

7.5.3 Policy implications

The findings from my research have implications for the NCD health policy in Nepal, although the prime focus of this thesis was not on health policy. As discussed in Chapter 2, in line with the National health policy,[56] the Multisectoral Action Plan (2014-2020) on the prevention and control of NCDs was developed in 2014 in Nepal. The Plan has set the target to reduce mortality due to cardiovascular diseases by 25 % and to reduce the overall prevalence of high blood pressure by 25 % among ten other targets.[57] In this context, the findings of this thesis stressed the need and relevance of implementing and updating those NCD policies into practice.

Although Nepal's national health policy focused on universal health coverage, antihypertensive medicines were not freely available at the health facilities, as discussed in Chapter 3. In addition, health system/structure strengthening is one of the key focus areas of the Multisectoral Action Plan (2014-2020) for the prevention and control of NCDs in Nepal. Yet, primary health care facilities struggle with a lack of skilled health care workers, diagnostic and treatment facilities for hypertension management, and are forced to refer patients to the tertiary level which, in turn, were overwhelmed by an under-resourced health workforce. Therefore, strategic endorsement of those policies at the practice level to manage NCDs, especially hypertension, is a prime policy-level recommendation based on Phase I of this thesis.

In addition, Phase II of this thesis generated novel evidence that a simple text messaging mHealth intervention can be a feasible and effective tool to address the issue of uncontrolled blood pressure. These findings can be used as a reference by policymakers to develop the evidence-based use of mHealth to manage hypertension in Nepal, as stressed in the Nepal Health Sector Strategy 2015-2020.[58] The Regional NCD Action Plan of Nepal focuses on evidence-based research; however, there is a need to prioritise mHealth-based research for the management of hypertension. Prioritisation of mHealth research could support the cost-effectiveness and long-term effectiveness evaluation of mHealth intervention (TEXT4BP) at a large scale and can provide evidence to scale up the initiative into the regular health care delivery, if found to be cost-effective.

Although Nepal has drafted the National e-Health strategy 2017,[59] there is a need to formulate a clearer mHealth policy and strategy to guide future mHealth research and implementation into regular health care practice.

Foreseeing these policy level possibilities, I aim to disseminate the findings of this thesis as a policy pitch in the national level forum, especially to the concerned stakeholders of the Nepal

Ministry of Health and Population to serve as testimony that a mHealth intervention can be envisaged into clinical and public health practice in Nepal.

7.6 Conclusions

This PhD thesis demonstrates the feasibility of using a text messaging mHealth intervention for hypertension management in Nepal. Firstly, the evidence-based co-design of an mHealth intervention is novel in the context of Nepal. Previous studies conducted in Nepal are mostly cross-sectional, primarily focusing on the prevalence, awareness, and treatment of hypertension. In this context, this study has broadened the horizon of research for hypertension management.

Secondly, findings from the Phase I formative study provide a detailed understanding of the different individual, community and system-level barriers and facilitators for hypertension management in Nepal. These findings corroborate the existence of different system-level issues such as affordability, availability, and accessibility as barriers similar to other LMIC settings. In addition, this thesis explored different contextual barriers related to dietary practices shaped by sociocultural factors, misconceptions and stigma, and non-disclosure issues related to the disease.

Thirdly, co-design is an emerging concept in mHealth interventions. This thesis presented an mHealth intervention co-design process informed by a theoretical model and conducted using a formative research approach. The study demonstrated that the text messaging intervention was well-received by all stakeholders, including patients and their families.

Finally, Phase II of this thesis presented evidence highlighting the mHealth intervention as a feasible, effective, and acceptable tool for improving treatment adherence and blood pressure control among patients with hypertension.

In conclusion, this PhD thesis has generated novel evidence and added new knowledge for evaluating an mHealth program in Nepal and recommend further large-scale studies to assess its long-term impact, cost-effectiveness, and sustainability. The study has also highlighted the value and process of the contextual co-designed mHealth intervention and can be referenced for similar studies in LMIC settings.

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List of Appendices

Appendix 1: Main key words – used for the literature search

I have used the following main key words in the different databases (PubMed/Medline, Embase, CHINAL, and Google Scholar). Major key words used for the literature review included:

- Non communicable diseases, cardiovascular diseases, ischemic heart disease
- Prevalence of hypertension, And Nepal
- Risk factors of hypertension (obesity, overweight, smoking, alcohol, physical activity/inactivity, dietary factors, salt, fatty diet, fruits and vegetable intake, high cholesterol), And Nepal
- Complications of hypertension, coronary artery disease, chronic kidney disease, retinopathy, stroke, And Nepal
- Treatment and control of hypertension, awareness, treatment, control, And Nepal
- Barriers and facilitators, treatment and control of hypertension, And Nepal
- Adherence to antihypertensive medication, And Nepal
- Pharmacological intervention, non-pharmacological intervention
- mobile health, mHealth for hypertension, Text message /SMS intervention, And Nepal
- Acceptability, effectiveness, co-design, And mHealth and hypertension
- Health system of Nepal, guidelines for management of hypertension, And Nepal
- Different behavioural model/theory/framework,
- Health belief Model
- Transtheoretical Model, Social cognitive theory, Theory of Planned behaviour
- Behaviour changes wheel, COM-B, And hypertension,
- TAM Model, And hypertension

Appendix 2: Conference Abstract

APHA 2020 VIRTUAL
Annual Meeting and Expo • Oct. 24-28
Creating the Healthiest Nation: Preventing Violence

3012.0 - Cultural validation and evaluation of psychometric properties of hill bone medication compliance sub scale for patients with hypertension in Nepal

Download

Tuesday, October 27, 2020

1:30 AM - 1:45 AM

Session: Epidemiology/Biostatistics Oral Session (SA)

Program: APHA Student Assembly

Abstract

Introduction: The Hill-Bone compliance to high blood pressure Therapy Scale (HBTS) developed in the US has been tested for use in other settings with mixed results. We utilised a cohort of patients enrolled in an intervention trial to test its validity and reliability, the first such study in Nepal.

Methods: The original HBTS instrument was translated into Nepali, using accepted methods and administered to 200 patients with diagnosed hypertension recruited from a tertiary level facility in Kathmandu. We carried out factorial validity of the medication compliance sub scale, starting with the original 9 item HBTS using Confirmatory Factor Analysis (CFA). Composite reliability for congeneric measures were also tested.

Results: A six item scale with acceptable goodness of fit criteria on CFA, Chi square 14.93 (df = 11, p = 0.06), CFI=0.99, IFI=0.99 and RMSEA =0.042 was obtained. Composite reliability for congeneric measures were shown with all standard factor loadings at 0.6 or above and correlated item-total correlations with value >0.5 indicated good internal consistency. The Cronbach's alpha of the six items was 0.90 and ICC 0.6. We tested the scale for its ability to predict patients under control of their high blood pressure. The six-item scale was found to have sensitivity of 69% and specificity of 29%.

Conclusion: A valid and reliable measure of medication compliance for hypertension patients in Nepalese context was found using six items of the HBTS. This has value to test change in compliance to medication. However, the predictive validity of the scale requires further testing.

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Learning Areas

Chronic disease management and prevention Epidemiology

Keyword(s)

Hypertension, Chronic Disease Management and Care

Appendix 3: Data collection tools of TEXT4BP study

Section: 1 Demographic information (from STEPS tool)

STEP I. Demographic information			
Demographic information			
Question		**Response**	**Code**
11	Sex (record male female as observed)	Male 1 Female 2	C1
13	How old are you?	Years └─┴─┘	C3
14	In total, how many years have you spent in school or full-time study (excluding pre-school)?	Years └─┴─┘	C4
15	What is the **highest level of education** you have completed?	No formal schooling 1 Less than primary school 2 Primary school completed 3 Secondary school completed 4 Higher secondary (10+2)/ PCL completed 5 Bachelor's degree completed 6 Post graduate degree 7 Refused 88	C5
16	What is your **ethnic background**? (USE CASTE CLASSIFICATION CARD)	Dalit 1 Disadvantaged Janajatis 2 Disadvantaged non-Dalit Terai caste groups 3 Religious minorities 4 Relatively advantaged Janajatis 5 Upper caste groups 6 Refused 88	C6

Demographic information continued			
Question		Response	Code
17	What is your **marital status**?	Never married 1 Currently married 2 Separated 3 Divorced 4 Widowed 5 Cohabitating 6 Refused 88	C7
18	Which of the following best describes your **main work** status over the past 12 months?	Government employee 1 Non-government employee 2 Self-employed 3 Non-paid 4 Student 5 Homemaker 6 Retired 7 Unemployed (able to work) 8 Unemployed (unable to work) 9 Refused 88	C8
19	How many people older than 15 years, including yourself, live in your household?	Number of people └─┴─┘	C9
20	Taking **the past year**, can you tell me what the average earnings per month of the household have been?	≤Quintile Q1 More than Q1≤ Q2 More than Q2≤ Q3 More than Q2≤ Q3 More than Q3≤ Q4 More than Q4 Don't know Refused 88	C10b

Section 2 Medical and family history of hypertension

CORE: History of Raised Blood Pressure

Question	Response	Code
Does anyone in your first degree relative have hypertension?	Yes 1 No 2 Don't know 77	H0
Have you ever had your blood pressure measured by a doctor or other health worker?	Yes 1 No 2 If No, go to H6 No 2 If No, go to H6	H1
When were you first diagnosed by the doctor or health worker?	____ days ago, Or ____ months ago, Or ____ years ago,	H2a
Have you been prescribed medication for your hypertension?	Yes 1 No 2 If No, go to H4	H2c
In the past two weeks, have you taken any drugs (medication) for raised blood pressure prescribed by a doctor or other health worker?	Yes 1 No 2 If No, go to H4	H3
Have you ever seen a traditional healer for raised blood pressure or hypertension?	Yes 1 No 2	H4
Are you currently taking any herbal or traditional remedy for your raised blood pressure?	Yes 1 No 2	H5
Do you have any of the following diseases	Diabetes COPD High cholesterol Other	H6

Section 3 Knowledge and perception on Hypertension

Single choice unless indicated *Indicates reverse coding

Question	Response	Code
vledge on Hypertension	Single choice unless mentioned otherwise	
What does the term hypertension mean?	High blood pressure 1 High level stress/tension 2 Nervous condition 3 High blood sugar 4 Overactivity 5 Don't know 77 Refused 88	K1
How dangerous is hypertension to your health?	Extremely dangerous 1 Dangerous 2 Moderately dangerous 3 Slightly dangerous 4 Not at all dangerous 5 Don't know 77 Refused 88	K2
HBP always has symptoms	Yes 1 No 2 Don't know 77 Refused 88	K3
The following are symptoms of hypertension	a. Headache Yes 1 No 2 b. Sweating Yes 1 No 2 c. Vision problem Yes 1 No 2	K4

	d. Stomach ache Yes 1 No 2* e. Shortness of breath Yes 1 No 2	
Would lowering high blood pressure improve a person's health?	Yes 1 No 2 Don't know 77 Refused 88	K5
What should top normal blood pressure level be?	150 1 140 2 120 3 Don't know 77 Refused 88	K6
What should bottom normal blood pressure level be?	100 1 90 2 80 3 Don't know 77 Refused 88	K7
Does control of blood pressure reduce the likelihood of getting other disease?	Yes 1 No 2 Don't know 77 Refused 88	K8
If left untreated, hypertension cause:	a. Premature death Yes 1 No 2 b. Heart attack Yes 1 No 2 c. Stroke Yes 1 No 2 d. Cancer Yes 1 No 2* e. Kidney disease Yes 1 No 2	K9
Knowledge of risk factors		
Which of the following actions may prevent a person from getting high blood pressure?	Weight loss in the overweight Yes1 No 2 Quit smoking Yes 1 No 2 Increase exercise Yes 1 No 2 Drink alcohol Yes 1 No 2* Eat less fat in meals Yes 1 No 2 Eat less salt in meals Yes 1 No 2 Eat more fruit & vegetable Yes 1 No 2	K10
Perception on Hypertension		
How serious of a personal health concern do you think blood pressure is?	Extremely serious concern 1 Serious concern 2 Moderately serious concern 3 Slightly serious concern 4 Not at all serious 5 Don't know 77 Refused 88	K11
High blood pressure (hypertension) is a life-long disease	Strongly agree 1 Agree 2 Neither agree nor disagree 3 Disagree 4 Strongly disagree 5 Don't know 77 Refused 88	K11a

High blood pressure (hypertension) is something you can cure	Strongly agree 1 Agree 2 Neither agree nor disagree 3 Disagree 4 Strongly disagree 5 Don't know 77 Refused 88	K12
High blood pressure (hypertension) is something you can control	Strongly agree 1 Agree 2 Neither agree nor disagree 3 Disagree 4 Strongly disagree 5 Don't know 77 Refused 88	K12a
Changing lifestyle can help to lower your blood pressure?	Strongly agree 1 Agree 2 Neither agree nor disagree 3 Disagree 4 Strongly disagree 5 Don't know 77 Refused 88	K13
High blood pressure is an unavoidable part of aging	Strongly agree 1 Agree 2 Neither agree nor disagree 3 Disagree 4 Strongly disagree 5 Don't know 77 Refused 88	K14
Beliefs on treatment		
How important do you think taking medicine is to keeping blood pressure under control?	Extremely important 1 Important 2 Moderately important 3 Slightly important 4 Not important 5 Don't know 77 Refused 88	K15
Drugs for increased blood pressure must be taken every day.	Strongly agree 1 Agree 2 Neither agree nor disagree 3 Disagree 4 Strongly disagree 5 Don't know 77 Refused 88	K16
Individuals with increased blood pressure must take their medication only when they feel ill*	Strongly agree 1 Agree 2 Neither agree nor disagree 3 Disagree 4 Strongly disagree 5 Don't know 77 Refused 88	K17
Individuals with increased blood pressure must take their medication throughout their life.	Strongly agree 1 Agree 2 Neither agree nor disagree 3 Disagree 4 Strongly disagree 5 Don't know 77 Refused 88	K18
If the medication for increased blood pressure can control blood pressure, there is no need to change lifestyles. *	Strongly agree 1 Agree 2 Neither agree nor disagree 3 Disagree 4 Strongly disagree 5	K19

	Don't know 77 Refused 88	
If individuals with increased blood pressure change their lifestyles, there is no need for treatment. *	Strongly agree 1 Agree 2 Neither agree nor disagree 3 Disagree 4 Strongly disagree 5 Don't know 77 Refused 88	K20
Individuals with increased blood pressure can eat salty foods if they take their drugs regularly. *	Strongly agree 1 Agree 2 Neither agree nor disagree 3 Disagree 4 Strongly disagree 5 Don't know 77 Refused 88	K21

Tobacco use			
Now I am going to ask you some questions about tobacco use.			
Question		**Response**	**Code**
20	Do you **currently** smoke any **tobacco** prod- ucts, such as cigarettes, cigars, pipes, bidis, hukahs or tamakhus? (USE SHOWCARD)	Yes 1 No 2 If No, go to T8	T1
21	Do you currently smoke tobacco products **daily**?	Yes 1 No 2	T2
22	How old were you when you **first started?** smoking?	Age (years) └┴┘ If known, go to T5a/T5aw Don't know 77	T3
23	Do you remember how long ago it was?(RECORD ONLY 1, NOT ALL 3) Don't know 77	In Years └┴┘ If known, go to T5a/T5aw OR in months └┴┘ If known, go to T5a/T5aw OR in weeks └┴┘	T4a T4b T4c
24	On average, **how many** of the following products do you smoke **each day/week?** (IF LESS THAN DAILY, RECORD WEEKLY) (RECORD FOR EACH TYPE, USE SHOWCARD) Don't know 7777	DAILY↓ WEEKLY↓ Manufactured cigarettes └┴┴┴┘ └┴┴┴┘ Hand-rolled cigarettes └┴┴┴┘ └┴┴┴┘ Pipes full of tobacco └┴┴┴┘ └┴┴┴┘ Cigars, cheroots, cigarillos └┴┴┴┘ └┴┴┴┘ Other └┴┴┴┘ └┴┴┴┘ If other, go to T5other, else go to T6 Other (please specify): └┴┴┴┴┴┘	T5a/T5aw T5b/T5bw T5c/T5cw T5d/T5dw T5e/T5ew T5other/ T5otherw

25	During the past 12 months, have you tried to **stop smoking**?	Yes 1 No 2	T6
26	During any visit to a doctor or other health worker in the past 12 months, were you advised to quit smoking tobacco?	Yes 1 If T2=Yes, go to T12; if T2=No, go to T9 No 2 If T2=Yes, go to T12; if T2=No, go to T9 No visit during the past 12 months 3 If T2=Yes, go to T12; if T2=No, go to T9	T7
27	In the past, did you **ever smoke** any to- bacco products? (USE SHOWCARD)	Yes 1 No 2 If No, go to T12	T8
28	In the past, did you, **ever** smoke **daily**?	Yes 1 If T1=Yes, go to T12, else go to T10 No 2 If T1=Yes, go to T12, else go to T10	T9

Tobacco use continued

Question		Response	Code
31	Do you **currently use** any **smoke- less tobacco** products such as [snuff, chewing tobacco, nasal snuff, khaini, surti, gutka]? (USE SHOWCARD)	Yes 1 No 2 If no, go to T15	T12
32	Do you **currently use smokeless tobacco** products **daily?**	Yes 1 No 2 If no, go to T14aw	T13
33	On average, how many **times a day/ week** do you use …. (IF LESS THAN DAILY, RECORD WEEKLY) (RECORD FOR EACH TYPE, USE SHOWCARD) Don't know 7777	DAILY↓ WEEKLY↓ Snuff, by mouth └┴┴┴┘ └┴┴┴┘ Snuff, by nose └┴┴┴┘ └┴┴┴┘ Chewing tobacco └┴┴┴┘ └┴┴┴┘ Betel └┴┴┴┘ └┴┴┴┘ Other └┴┴┴┘ └┴┴┴┘ If other, go to T14other, if T13=No, go to T16, else go to T17 Other (please specify): └┴┴┴┴┴┴┘ If T13=No, go to T16, else go to T17	T14a/T14aw T14b/T14bw T14c/T14cw T14d/ T14dw T14e/T14ew T14other/ T14 otherw
37	During the past 7 days, on how many days did someone smoke in closed areas **in your workplace** (in the build- ing, in a work area or a specific office) when you were present?	Number of days └┴┘ Don't know or don't work in a closed area 77	T18

Alcohol consumption			
The next questions ask about the consumption of alcohol.			
Question		**Response**	**Code**
38	Have you **ever** consumed an alcoholic drink such as beer, wine, spirits, fermented cider or [jaad, raksi, tungba? (USE SHOWCARD)	Yes 1 No 2 If no, go to D1	A1a
39	Have you consumed an alcoholic drink within the **past 12 months**?	Yes 1 No 2 If no, go to D1	A1b
40	During the past 12 months, **how frequently** have you had at least one alcoholic drink? (READ RESPONSES, USE SHOWCARD)	Daily 1 5–6 days per week 2 1–4 days per week 3 1–3 days per month 4 Less than once a month 5	A2
41	Have you consumed an alcoholic drink within the **past 30 days**?	Yes 1 No 2 If no, go to D1	A3
42	During the past 30 days, on how many **occasions** did you have at least one alcoholic drink?	Number └─┴─┘ Don't know 77	A4
43	During the past 30 days, when you drank alcohol, **on aver- age**, how many **standard alcoholic drinks** did you have during one drinking occasion? (USE SHOWCARD)	Number └─┴─┘ Don't know 77	A5
44	During the past 30 days, what was the **largest number** of standard alcoholic drinks you had on a single occasion, counting all types of alcoholic drinks together?	Largest number └─┴─┘ Don't Know 77	A6
45	During the past 30 days, how many times did you have for **men**: **five or more** for **women**: **four or more** standard alcoholic drinks in a single drinking occasion?	Number of times └─┴─┘ Don't know 77	A7

46	During the past 30 days, when you consumed an alcoholic drink, how often was it with meals? Please do not count snacks.	Usually with meals 1 Sometimes with meals 2 Rarely with meals 3 Never with meals 4	A8
47	During each of the **past 7 days**, how many standard alco- holic drinks did you have each day? (USE SHOWCARD) Don't know 77	Monday └─┴─┘	A9a
		Tuesday └─┴─┘	A9b
		Wednesday └─┴─┘	A9c
		Thursday └─┴─┘	A9d
		Friday └─┴─┘	A9e
		Saturday └─┴─┘	A9f
		Sunday └─┴─┘	A9g

Diet			
The next questions ask about the fruit and vegetables that you usually eat. I have a nutrition card here that shows you some examples of local fruit and vegetables. Each picture represents the size of a serving. As you answer these questions please think of a typical week in the last year.			
Question		**Response**	**Code**
48	In a typical week, on how many days do you **eat fruit**? (USE SHOWCARD)	Number of days Don't know └┴┘ If Zero days, go to D3 77	D1
49	How many **servings** of fruit do you eat on **one** of those days? (USE SHOWCARD)	Number of servings └┴┘ Don't know 77	D2
50	In a typical week, on how many days do you **eat vegetables**? (USE SHOWCARD)	Number of days Don't know └┴┘ If Zero days, go to D5 77	D3
51	How many **servings** of vegetables do you eat on one of those days? (USE SHOWCARD)	Number of servings └┴┘ Don't know 77	D4
52	What type of oil or fat is most often used for meal preparation in your household? (USE SHOWCARD) (SELECT ONLY ONE)	Mustard oil 1 Refined vegetable oil 2 Lard or suet 3 Butter or ghee 4 Noodles oil 5 Other 6 If other, go to D5 other 7 None in particular 8 None used 77 Don't know Other (Please Specify) ………………………………….	D5 D5 other
53	On average, how many meals per week do you eat that were not prepared at a home? By meal, I mean breakfast, lunch and dinner.	Number └┴┘ Don't know 77	D6
54	How much of the oil/ghee identified in D5 does your household consume?(Fill only one option) 1 deuwa (1 chauthai) = 125ml; 5 muthi = 250ml, 1 mana = 500ml 1 litre = 1000 ml	millilitres in a day └┴┴┴┘ millilitres in a week └┴┴┴┘ millilitres in a month └┴┴┴┘ Don't Know 77	X1
55	How many people of following age groups live in your household? (Record for all the options applicable)	Less than 3 years └┴┘	X2a
		3 to 5 year └┴┘	X2b
		5 to 7 year └┴┘	X2c
		7 to 9 years └┴┘	X2d
		9 to 12 years └┴┘	X2e
		12 to 21 years └┴┘	X2f
		More than 21 years └┴┘	X2g
Dietary salt			

The next questions ask about your knowledge, attitudes and behaviour towards dietary salt. Dietary salt includes ordinary table salt, unrefined salt such as sea salt, iodised salt and salty sauces such as soya sauce or fish sauce. The following questions are on adding salt to food right before you eat it, how food is prepared in your home, eating processed foods that are high in salt such as chau chau, Lays chips, Kurkure, salty biscuits, canned fish, dry meat, titaura, preserved pickle, bhujia, mixtures, papad etc. and on controlling your salt intake. Please answer the questions even if you consider yourself to eat a diet low in salt.

Question		Response		Code
56	How often do you **add salt** to your food before you eat it or as you are eating it? (SELECT ONLY ONE)	Always Often Sometimes Rarely Never Don't know	1 2 3 4 5 77	DS1
57	How often is **salt added** in cooking or preparing foods in your household?	Always Often Sometimes Rarely Never Don't know	1 2 3 4 5 77	DS2
58	How often do you eat **processed food high in salt**, such as chau chau, Lays, Kurkure, salty biscuits, canned fish, dry meat, titaura, preserved pickle, bhujia, mixtures, papad etc.? (USE SHOWCARD)	Always Often Sometimes Rarely Never Don't know	1 2 3 4 5 77	DS3
59	**How much salt** do you think you consume?	Far too much Too much Just the right amount Too little Far too little Don't know	1 2 3 4 5 77	DS4
60	Do you think that too much salt in your diet could cause a serious **health problem**?	Yes No Don't know	1 2 77	DS5
61	How important to you is **lowering the salt** in your diet?	Very important Somewhat important Not at all important Don't know	1 2 3 77	DS6

Dietary salt continued			
Question		**Response**	**Code**
62	Do you do any of the following on a regular basis to **control your salt intake**? (RECORD FOR EACH)		
	Avoid/minimise consumption of processed foods	Yes 1 No 2	DS7a
	Look at the salt or sodium labels on food	Yes 1 No 2	DS7b
	Eat meals without adding salt at the table	Yes 1 No 2	DS7c
	Buy low salt/sodium alternatives	Yes 1 No 2	DS7d
	Cook meals without adding salt	Yes 1 No 2	DS7e
	Use spices other than salt when cooking	Yes 1 No 2	DS7f
	Avoid eating out	Yes 1 No 2	DS7g
	Other	Yes 1 If Yes, go to DS7other No 2	DS7h
	Other (please specify)	└┴┴┴┴┴┴┘	DS7other
63	Which type of salt do you use?	Crystal Salt 1 Powdered Salt without logo 2 Powdered salt with two children logo 3 Others 4 (If others go to X3 other Others (Please Specify) └┴┴┴┴┘	X3 X3 Other
64	How much salt does your family? consume?(Fill only one option) 1 pathi crystal salt = 3,000 mg 1 mana crystal salt = 375 mg 1packet powdered salt = 1,000 mg	milligrams in a day └┴┴┴┘ milligrams in a week └┴┴┴┘ milligrams in a month └┴┴┴┘ Don't know 77	X4

Physical activity			
Next, I am going to ask you about the time you spend doing different types of physical activity in a typical week. Please answer these questions even if you do not consider yourself to be a physically active person. Think first about the time you spend doing work. Think of work as the things that you have to do such as paid or unpaid work, study or training, household chores, harvesting food and crops, fishing or hunting for food, seeking employment, walking uphill or downhill for routine work. In answering the following questions 'vigorous-intensity activities' are activities that require hard physical effort and cause large increases in breathing or heart rate, 'moderate-intensity activities' are activities that require moderate physical effort and cause small increases in breathing or heart rate.			
Question		**Response**	**Code**
Work			
79	Does your work involve vigorous-intensity activity that causes large increases in breathing or heart rate [carrying or lifting heavy loads, digging or construction work] for at least 10 minutes continu- ously? (USE SHOWCARD)	Yes 1 No 2 If no, go to P4	P1
80	In a typical week, on how many days do you do Vigorous-intensity activities as part of your work?	Number of days └┘	P2
81	How much time do you spend doing vigorous- intensity activities at work on a typical day?	Hours: minutes └┴┘ hrs : └┴┘ mins	P3 (a-b)
82	Does your work involve moderate-intensity activity that causes small increases in breathing or heart rate [brisk walking, carrying light loads, manual washing clothes, mopping of floor, gardening at home] for at least 10 minutes continuously? [INSERT EXAMPLES] (USE SHOWCARD)	Yes 1 No 2 If no, go to P 7	P4
83	In a typical week, on how many days do you do moderate-intensity activities as part of your work?	Number of days └┘	P5
84	How much time do you spend doing moderate- intensity activities at work on a typical day?	Hours: minutes └┴┘ hrs : └┴┘ mins	P6 (a-b)
Travel to and from places			
The next questions exclude the physical activities at work that you have already mentioned. Now I would like to ask you about the usual way you travel to and from places. For example, to work, for shopping, to market, to place of worship.			
85	Do you walk or use a bicycle (pedal cycle) for at least 10 minutes continuously to get to and from places?	Yes 1 No 2 If no, go to P 10	P7
86	In a typical week, on how many days do you walk or bicycle for at least 10 minutes continuously to get to and from places?	Number of days └┘	P8

87	How much time do you spend walking or bicycling? for travel on a typical day?	Hours: minutes └┴┘ : └┴┘ hrs mins	P9 (a-b)

Physical activity continued			
Question		Response	Code
Recreational activity			
The next questions exclude the work and transport activities that you have already mentioned. Now I would like to ask you about sports, fitness and recreational activities (leisure) like cycling, swimming, volleyball, badminton, yoga.			
88	Do you do any vigorous-intensity sports, fitness or recreational (leisure) activities that cause large increases in breathing or heart rate [running or football] for at least 10 minutes continuously? (USE SHOWCARD)	Yes 1 No 2 If no, go to P 13	P10
89	In a typical week, on how many days do you do vigorous-intensity sports, fitness or recreational (leisure) activities?	Number of days └┘	P11
90	How much time do you spend doing vigorous- intensity sports, fitness or recreational activities on a typical day?	Hours: minutes └┴┘ : └┴┘ hrs mins	P12 (a-b)
91	Do you do any moderate-intensity sports, fitness or recreational (leisure) activities that cause a small increase in breathing or heart rate [brisk walking, cycling, swimming, volleyball, badminton, yoga] for at least 10 minutes continuously? [INSERT EXAMPLES] (USE SHOWCARD)	Yes 1 No 2 If no, go to P16	P13
92	In a typical week, on how many days do you do moderate-intensity sports, fitness or recreational (leisure) activities?	Number of days └┘	P14
93	How much time do you spend doing moderate- intensity sports, fitness or recreational (leisure) activities on a typical day?	Hours: minutes └┴┘ : └┴┘ hrs mins	P15 (a-b)

Sedentary behaviour				
The following question is about sitting or reclining at work, at home, getting to and from places, or with friends including time spent sitting at a desk, sitting with friends, travelling in car or bus, reading, playing cards or watching television, but does not include time spent sleeping. [INSERT EXAMPLES] (USE SHOWCARD)				
94	How much time do you usually spend sitting or recline- ing on a typical day?	Hours: minutes	└┴┘ : └┴┘ hrs mins	P16 (a-b)

Section 5: Treatment of high blood pressure

105	Are you currently receiving any of the following treatments/advice for high blood pressure prescribed by a doctor or other health worker?		
	Drugs (medication) that you have taken in the past two weeks	Yes 1 If yes go to the H6 No 2	H3a
	Advice to reduce salt intake	Yes 1 No 2	H3b
	Advice or treatment to lose weight	Yes 1 No 2	H3c
	Advice or treatment to stop smoking	Yes 1 No 2	H3d
	Advice to start or do more exercise	Yes 1 No 2	H3e
106	Have you ever seen a traditional healer for raised blood pres- sure or hypertension?	Yes 1 No 2	H4
107	Are you currently taking any herbal or traditional remedy for your raised blood pressures?	Yes 1 No 2	H5
Medication history and Adherence related Questions			
108	**How many antihypertensive medications are you taking currently?**	One 1 Two 2 More than two 3	H6

Section 6: The Hill-Bone Compliance to High Blood Pressure Therapy Scale

No. Item Response: 1. All of the time 2. Most of the time		**Responses***			
		1	**2**	**3**	**4**
1	How often do you forget to take your HBP medicine?				
2	How often do you decide NOT to take your HBP medicine?				
3	How often do you eat salty food?				
4	How often do you add salt to your food before you eat it?				
5	How often do you eat fast food?				
6	How often do you make the next appointment before you leave the doctor's office?*				
7	How often do you miss scheduled appointments?				
8	How often do you forget to get prescriptions filled?				
9	How often do you run out of HBP pills?				
10	How often do you skip your HBP medicine before you go to the doctor?				
11	How often do you miss taking your HBP pills when you feel better?				
12	How often do you miss taking your HBP pills when you feel sick?				
13	How often do you take someone else's HBP pills?				
14	How often do you miss taking your HBP pills when you are careless				

***Responses 1-All the time, 2- Most of the time, 3- Some of the time, 4= Never**

Section 7: Medication Adherence Self- Efficacy Questionnaire

S. N	**Items (situations)**	**Responses**			
How confident are you that you can take your blood pressure medications		1	2	3	4
1.	When you are busy at home				
2.	When there is no one to remind you				
3.	When you worry about taking them for the rest of your life				
4.	When you do not have any symptoms				
5.	When you are with family members				
6.	When you are in a public place				
7.	When the time to take them is between your meals				
8.	When you are traveling				
9.	When you take them more than once a day				
10.	When you have other medications to take				
11.	When you feel well				
12.	If they make you want to urinate while away from home				
How confident are you that you can carry out the following tasks					
13.	Make taking your medications part of your routine				

Responses 1-Not at all sure, 2- A Little sure , 3- Fairly Sure , 4= Extremely Sure

Section 8: Mobile phone text message usability survey (Marshfield usability Survey)

Marshfield usability survey statements		**Responses***				
		1	**2**	**3**	**4**	**5**
1	I thought the system was easy to use					
2	I felt very confident using the system					
3	I needed to learn a lot of things before I could get going with the system					
4	I felt that I needed someone's help to be able to use the system					
5	I found the system to be complex					
6	Using the system did not take much time					
7	I could always trust the system to work					
8	My privacy was protected when I used the system					
9	Using the system was as satisfying as talking to a real person					
10	It was easy to learn to use the system					
11	In general, I was satisfied with the system					
12	I think most people could learn to use the system very quickly					
13	I think I would like to use the system again					
14	The system could help me better manage my health and medical needs					
15	I could be more involved in my care by using the system					
16	The system could help me monitor my medical condition					

(1=Strongly Disagree; 2=Disagree; 3=Neither Agree nor Disagree; 4=Agree; 5=Strongly Agree)

Section 9: Physical Measurements (from STEPS tools)

STEP II. Physical measurements			
CORE: Height and weight			
Question		**Response**	**Code**
114	Interviewer ID	└┴┴┘	M1
115	Device IDs for height and weight	Height └┴┘ Weight └┴┘	M2a M2b
116	Height	in centimetres (cm) └┴┴┘.└┘	M3
117	Weight If too large for scale 666.6	in kilograms (kg) └┴┴┘.└┘	M4
CORE: Waist			
119	Device ID for waist	└┴┘	M6
120	Waist circumference	in Centimetres (cm) └┴┴┘.└┘	M7
CORE: Blood pressure			
121	Interviewer ID	└┴┴┘	M8
122	Device ID for blood pressure	└┴┘	M9
123	Cuff size used	Small 1 Medium 2 Large 3	M10
124	Reading 1	Systolic (mmHg) └┴┴┘ Diastolic (mmHg) └┴┴┘	M11a M11b
125	Reading 2	Systolic (mmHg) └┴┴┘ Diastolic (mmHg) └┴┴┘	M12a M12b
126	Reading 3	Systolic (mmHg) └┴┴┘ Diastolic (mmHg) └┴┴┘	M13a M13b
127	During the past two weeks, have you been treated for raised blood pressure with drugs (medication) prescribed by a doctor or other health worker?	Yes 1 No 2	M14

Hip circumference				
128	Hip circumference	in centimetres (cm)	└┴┴┘.└┘	M15
129	Waist circumference	in centimetres (cm)		

Appendix 4: Ethics approval letter for study I from UNSW

UNSW SYDNEY

15-Dec-2017

Dear Associate Professor Anura Jayasuriya,

Project Title	Understanding the perceived facilitators and barriers for treatment and control of high blood pressure among patients with hypertension in Nepal.
HC No	HC17753
Re	HC17753 Notification of Ethics Approval
Approval Period	15-Dec-2017 - 14-Dec-2022

Thank you for submitting the above research project to the **HREC Executive** for ethical review. This project was considered by the **HREC Executive** at its meeting on **14-Dec-2017**.

I am pleased to advise you that the **HREC Executive** has granted ethical approval of this research project. The following condition(s) must be met before data collection commences:

Conditions of Approval:
N/A

Conditions of Approval - All Projects:

- The Chief Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Chief Investigator will seek approval from the **HREC Executive** for any modifications to the protocol or other project documents.
- The Chief Investigator will notify the **HREC Executive** immediately of any protocol deviation or adverse events or safety events related to the project.
- The Chief Investigator will report to the **HREC Executive** annually in the specified format and notify the **HREC Executive** when the project is completed at all sites.
- The Chief Investigator will notify the **HREC Executive** if the project is discontinued before the expected completion date, with reasons provided.
- The Chief Investigator will notify the **HREC Executive** of his or her inability to continue as Coordinating Chief Investigator including the name of and contact information for a replacement.

The **HREC Executive** Terms of Reference, Standard Operating Procedures, membership and standard forms are available from https://research.unsw.edu.au/research-ethics-and-compliance-support-recs.

If you would like any assistance, or further information, please contact the ethics office on:
P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385 7007
E: humanethics@unsw.edu.au

Appendix 5: Ethics approval letter for study I from NHRC

NEPAL HEALTH RESEARCH COUNCIL ESTD. 1991

Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.: 1836

22 February 2018

Ms. Buna Bhandari Bhattarai
Principal Investigator,
University of New South Wales, Australia

Subject: Approval of research proposal entitled **Exploring perceived facilitators and barriers for treatment and control of high blood pressure among hypertensive patients of selected area of Kathmandu, Nepal.**

Dear Ms. Bhattarai,

It is my pleasure to inform you that the above-mentioned proposal submitted on **10 January 2018** (**Reg.no. 21/2018** please use this Reg. No. during further correspondence) has been approved by NHRC Ethical Review Board on **21 February 2018.**

As per NHRC rules and regulations, the investigator has to strictly follow the protocol stipulated in the proposal. Any change in objective(s), problem statement, research question or hypothesis, methodology, implementation procedure, data management and budget that may be necessary in course of the implementation of the research proposal can only be made so and implemented after prior approval from this council. Thus, it is compulsory to submit the detail of such changes intended or desired with justification prior to actual change in the protocol before the expiration date of this approval. Expiration date of this study is **February 2021.**

If the researcher requires transfer of the bio samples to other countries, the investigator should apply to the NHRC for the permission. The researchers will not be allowed to ship any raw/crude human biomaterial outside the country; only extracted and amplified samples can be taken to labs outside of Nepal for further study, as per the protocol submitted and approved by the NHRC. The remaining samples of the lab should be destroyed as per standard operating procedure, the process documented, and the NHRC informed.

Further, the researchers are directed to strictly abide by the National Ethical Guidelines published by NHRC during the implementation of their research proposal **and submit progress report in between and full or summary report upon completion.**

As per your research proposal, the total research amount is **NRs. 2,00,000.00** and accordingly the processing fee amount to **NRs 10,000.00.** It is acknowledged that the above-mentioned processing fee has been received at NHRC.

If you have any queries, please feel free to contact the Ethical Review M & E section of NHRC.

Thanking you.

Appendix 6: Ethics approval letter for study II from UNSW

UNSW
SYDNEY

15-Jul-2019

Dear A/Prof Rohan Jayasuriya,

Project Title	Feasibility study on the Effectiveness and Acceptability of Mobile Phone Text Messaging Intervention for Improving Treatment Adherence and Lifestyle Modification for Blood Pressure Control among Hypertensive Patients in Nepal: A Pilot Randomized Control Trial
HC No	HC190357
Re	HC190357 Notification of Ethics Approval
Approval Period	15-Jul-2019 - 14-Jul-2024

Thank you for submitting the above research project to the **HREC Executive** for ethical review. This project was considered by the **HREC Executive** at its meeting on **11-Jul-2019**.

I am pleased to advise you that the **HREC Executive** has granted ethical approval of this research project. The following condition(s) must be met before data collection commences:

Conditions of Approval:
N/A

Conditions of Approval - All Projects:

- The Chief Investigator will immediately report anything that might warrant review of ethical approval of the project.
- The Chief Investigator will seek approval from the **HREC Executive** for any modifications to the protocol or other project documents.
- The Chief Investigator will notify the **HREC Executive** immediately of any protocol deviation or adverse events or safety events related to the project.
- The Chief Investigator will report to the **HREC Executive** annually in the specified format and notify the **HREC Executive** when the project is completed at all sites.
- The Chief Investigator will notify the **HREC Executive** if the project is discontinued before the expected completion date, with reasons provided.
- The Chief Investigator will notify the **HREC Executive** of his or her inability to continue as Coordinating Chief Investigator including the name of and contact information for a replacement.

The **HREC Executive** Terms of Reference, Standard Operating Procedures, membership and standard forms are available from https://research.unsw.edu.au/research-ethics-and-compliance-support-recs.

If you would like any assistance, or further information, please contact the ethics office on:
P: +61 2 9385 6222, + 61 2 9385 7257 or + 61 2 9385 7007

Appendix 7: Ethics approval letter for study II from NHRC

Government of Nepal

Nepal Health Research Council (NHRC)

Estd. 1991

Ref. No.: 587

4 September 2019

Ms. Buna Bhandari Bhattarai
Principal Investigator
The University of New South Wales
Australia

Ref: **Approval of thesis proposal** entitled **Feasibility study on Effectiveness and Acceptability of Mobile Phone Text Messaging Intervention for Improving Treatment Adherence and Lifestyle Modification for Blood Pressure Control among Hypertensive Patients of Kathmandu, Nepal: A Pilot Randomized Control Trial**

Dear Ms. Bhattarai,

It is my pleasure to inform you that the above-mentioned proposal submitted on **15 May 2019** **(Reg. no. 302/2019)** please use this Reg. No. during further correspondence) has been approved by Nepal Health Research Council (NHRC) Ethical Review Board on **24 July 2019**.

As per NHRC rules and regulations, the investigator has to strictly follow the protocol stipulated in the proposal. Any change in objective(s), problem statement, research question or hypothesis, methodology, implementation procedure, data management and budget that may be necessary in course of the implementation of the research proposal can only be made so and implemented after prior approval from this council. Thus, it is compulsory to submit the detail of such changes intended or desired with justification prior to actual change in the protocol. Expiration date of this proposal is **December 2021.**

If the researcher requires transfer of the bio samples to other countries, the investigator should apply to the NHRC for the permission. The researchers will not be allowed to ship any raw/crude human biomaterial outside the country; only extracted and amplified samples can be taken to labs outside of Nepal for further study, as per the protocol submitted and approved by the NHRC. The remaining samples of the lab should be destroyed as per standard operating procedure, the process documented, and the NHRC informed.

Further, the researchers are directed to strictly abide by the National Ethical Guidelines published by NHRC during the implementation of their project proposal and **submit progress report in between and full or summary report upon completion.**

As per your thesis proposal, the total research amount is **Rs 8,00,000** and accordingly the processing fee amounts to **Rs 10,000.** It is acknowledged that the above-mentioned processing fee has been received at NHRC.

If you have any questions, please contact the Ethical Review M & E Section at NHRC.

Thanking you,

Appendix 8: Ethics approval letter for study II from KMCTH

Kathmandu Medical College Public Ltd.
Institutional Review Committee (IRC)
Sinamangal
(Affiliated to Ethical Review Board, Nepal Health Research Council)

Ref.:030520192

Date: 3rd May, 2019

Chairperson
Prof. Dr. Sunil Kumar Joshi

Member Secretary
Dr. Deepak Regmi

Members
Prof. Dr. Chanda Karki
Prof. Dr. Hemang Dixit
Prof. Dr. Manindra R. Baral
Prof. Dr. Ramesh K. Adhikari
Prof. Dr. Mathura KC
Dr. Naresh Manandhar
Dr. Pratibha Manandhar

To whom it may concern

This is to inform that Ms. Buna Bhandari has been granted ethical approval for the study on **"Feasibility study on the Effectiveness and Usability of Mobile Phone Text Messaging Intervention for Improving Treatment Adherence and Lifestyle Modification for Blood Pressure Control among Hypertensive Patients in Nepal"** by the KMC IRC meeting held on 3rd May, 2019

Appendix 9: Participant information sheet and consent form study I- Qualitative study

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Understand perceived facilitators and barriers for treatment and control of blood pressure among hypertensive patients

1. What is the research study about?

You are invited to take part in this research study. The research study aims to understand the perceived facilitators and barriers to treatment and control of blood pressure among hypertensive patients of Nepal. Findings from this study will be used to develop a program that will help people with high blood pressure improve their control of the condition. You have been invited because you have been diagnosed to have hypertension and have attended a Primary Health Care centre, a Health Post or a private medical practitioner to obtain treatment for high blood pressure and you agreed to be contacted for this study. In some cases, you may have seen the advertisement about the project and contacted us about the study.

2. Who is conducting this research?

The study is being carried out by the following researchers:
Name of Chief Investigator: Associate Professor Rohan Jayasuriya
Name of Co-Investigator: Dr Padmanesan Narasimhan
Student investigator: Buna Bhandari Bhattarai
From the School of Public Health and Community Medicine, Faculty of Medicine
University of New South Wales, Sydney, Australia
Name of Co-Investigator: Associate Professor Abhinav Vaidya
Kathmandu Medical College, Kathmandu, Nepal

Research Funder: This research is not funded.

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part. The research study is looking recruit people who meet the following criteria:

- Patients age 30 -70years
- Already diagnosed as having hypertension.

Exclusion criteria: Patient with complicated high blood pressure and serious multi morbidity requiring treatment/care at secondary level hospitals. Participants with severe mental and physical disability and pregnant women

4. Do I have to take part in this research study?

Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage.

If you decide you want to take part in the research study, you will be asked to:

- Read the information carefully (ask questions if necessary);
- Sign and return the consent form if you decide to participate in the study;
- Take a copy of this form with you to keep.

5. What does participation in this research require, and are there any risks involved?

Participation in an in-depth interview

If you decide to take part in the research study, you will be asked to participate in a face to face in-depth interview. You will be asked questions about your perceptions of barriers and facilitators to treatment and control of blood pressure, barriers to lifestyle modification such as dietary habits, smoking, and alcohol consumption; physical activity, types of medication and adherence; barriers encountered in obtaining care at the health-care facility**.** It should take approximately 45 to 60 mins to complete.

To ensure, we collect the responses accurately, we seek your permission to digitally record the interview using as audiotape.

If you would like to participate but do not wish to be recorded, you will need to discuss the options for your participation with the research team

We don't expect the questions to cause any harm or discomfort, however if you experience feelings of distress as a result of participation in this study you can let the research team know and they will provide you with assistance. If they feel that you require professional care you will be referred to the relevant staff at the Primary Health Care centre.

6. What are the possible benefits to participation?

We hope to use information we get from this research study to develop a program that may benefit others who are having problem of high blood pressure in Nepal.

7. What will happen to information about me?

By signing the consent form, you consent to the research team collecting and using information about you for the research study. Your data will be kept for a minimum of 7 years after the project's completion. The data will be stored in the password protected computer belonging to the researcher. These files will later be transferred to a password protected computer at the school (SPHCM) allocated to the student researcher and then transferred to secure storage at the University of New South Wales, Australia.

Researchers at UNSW are required to store their any aggregated data in the UNSW data repository, this is a system called ResData. Once the aggregated data is deposited into this repository, it will be retained in this system permanently. It will, however, be retained in a format where your identity will not be known.

Your information will only be used for planning the second study and the intervention program and for thesis writing, scientific publication and presentation in de-identified form only.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a compliant about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the **UNSW Privacy Management Plan**.

8. How and when will I find out what the results of the research study are?

The research team intend to publish and/or report the results of the research study in a variety of ways. All information published will be done in a way that will not identify you.

If you would like to receive a copy of the results you can let the research team know by adding your email or postal address within the consent form. We will only use these details to send you the results of the research.

9. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document. Alternatively, you can contact the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with the Kathmandu Medical College, Kathmandu and the UNSW Sydney School of Public Health and Community Medicine.

If you decide to leave the research study, the researchers will not collect additional information from you. Any identifiable information about you will be withdrawn from the research project.

The research team will destroy any information about you that was collected during your participation in the study.

10. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact Details

Name	Buna Bhandari Bhattarai
Position	Phd Student
Telephone	
Email	buna.bhandaribhattarai@student.unsw.edu.au

Support Services Contact Details

If at any stage during the study you become distressed or require additional support from someone not involved in the research please call:

Name/Organisation	Primary Health Care Center (site to be filled in at recruitment0
Position	Medical Officer
Telephone	To be filled in at recruitment
Email	

What if I have a complaint or any concerns about the research study?

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact

Position	Associate Professor at Kathmandu Medical College
Telephone	
Email	
HC Reference Number	[INSERT HC reference number]

The UNSW Human Ethics Coordinator:

Complaints Contact

Position	UNSW Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	[INSERT HC reference number]

Consent Form – Participant providing own consent

Declaration by the participant

☐ I understand I am being asked to provide consent to participate in this research study;

☐ I have read the Participant Information Sheet or someone has read it to me in a language that I understand;

☐ I understand the purposes, study tasks and risks of the research described in the study;

☐ I understand that the research team will audio record the interviews; I agree to be recorded for this purpose.

☐ I provide my consent for the information collected about me to be used for the purpose of this research study only.

☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received;

☐ I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;

☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only;

Name: ____________________________________

Address: __________________________________

Email Address: _____________________________

☐ I understand that I will be given a signed copy of this document to keep;

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Declaration by Researcher*

☐ I have given a verbal explanation of the research study, its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

[+]An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.
Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with Kathmandu Medical College, Kathmandu and The University of New South Wales, Australia. In withdrawing my consent I would like any information which I have provided for the purpose of this research study withdrawn. I understand that the information collected about me during my participation in the focus group cannot be withdrawn given the nature of the focus group.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	
Email:	
Phone:	
Postal Address:	

Appendix 10: Participant information sheet and verbal consent form study I

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Understand perceived facilitators and barriers for treatment and control of blood pressure among hypertensive patients

VERBAL CONSENT SCRIPT

1. Introduction

I am Buna Bhandari Bhattarai, PhD student at University of New South Wales, Australia. I am conducting this interview as a part of a study undertaken by The University of New South Wales, Australia and Kathmandu Medical College, Kathmandu, Nepal. The main purpose of the study is to understand the perceived facilitators and barriers to treatment and control of high blood pressure among patients with high blood pressure in Nepal.

2. Invitation

I would like to invite you to participate in this research study. Before we go any further I need to let you know that participation in this research study is voluntary. If you do not want to take part, you do not have to. Are you happy for me to provide you with further information on the research study?

- ☐ If no, thank the participant for their time and end the consent process.
- ☐ If yes, proceed with the following information.

3. Description of participation

If you decide to take part in the research study, you will be asked to participate in a face to face in-depth interview. You will be asked questions about your perceptions of barriers and facilitators to treatment and control of high blood pressure and in obtaining services for your condition; barriers to lifestyle modification such as dietary habits, smoking, alcohol consumption and physical activity. We will also ask you about support you get from others including your family to manage these changes**.** The interview should take approximately 45 to 60 mins to complete.

To ensure, we collect the responses accurately, we seek your permission to digitally record the interview using an audiotape.

If you would like to participate but do not wish to be recorded, you will need to discuss the options for your participation with the research team.

We don't expect the questions to cause any harm or discomfort, however if you experience feelings of distress as a result of participation in this study you can let the research team know and they will provide you with assistance. If they feel that you require professional care you will be referred to the relevant staff at the Primary Health Care centre.

4. Data storage and use

By providing verbal consent, you consent to the research team collecting and using information about you for the research study. Your data will be kept for a minimum of 7 years after the project's completion. The data will be stored in the password protected computer belonging to the researcher. These files will later be transferred to a password protected computer at the school (SPHCM) allocated to the student researcher and then transferred to secure storage at the University of New South Wales, Australia.

Your information will only be used for planning the second study and the intervention program and for thesis writing, scientific publication and presentation in de-identified form only.

5. Withdrawal from the research

If you decide to leave the research study, we will not collect additional information from you. Any identifiable information about you will be withdrawn from the research project. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Australia and with the Kathmandu Medical college, Kathmandu Nepal.

6. Questions

Do you have any questions in regards to the information that I have provided?

- ☐ If yes, answer any questions the participant may have
- ☐ If no, continue to collect consent.

If you would like, I will send you an email/letter containing the details of the person for you to contact if you have any questions or complaints about the research study.

7. Consent

Now that I have explained what your involvement in the research study requires, are you happy to provide your consent to participate in the study?

- ☐ If no, thank the participant for their time and end the consent process.
- ☐ If yes, ensure you record the time and date the verbal consent was collected from the participant. Furthermore, you will need to ask the participant if:
    - o they would like a copy of the participant information sheet sent to them;
    - o They are happy to be audio recorded (if applicable to the study).

Appendix 11: Participant information sheet and consent form study II

School of Public Health and Community Medicine	UNSW SYDNEY
PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM Feasibility study on the Effectiveness and Acceptability of Mobile Phone Text Messaging Intervention for Improving Treatment Adherence and Lifestyle Modification for Blood Pressure Control among Hypertensive Patients in Nepal: A Pilot Randomized Control Trial	

1. What is the research study about?

You are invited to take part in this research study. The research study aims to assess the effectiveness and acceptability of mobile phone text message intervention for improving treatment adherence and lifestyle modification for blood pressure control among hypertensive patients of Nepal. You have been invited because you responded to study advertisement flyer and met the inclusion criteria of this research study.

2. Who is conducting this research?

The study is being carried out by the following researchers:

Name of Chief Investigator: Associate Professor Rohan Jayasuriya
Name of Co-Investigator: Dr Padmanesan Narasimhan
Student investigator: Buna Bhandari Bhattarai
From the School of Public Health and Community Medicine, Faculty of Medicine
University of New South Wales, Sydney, Australia
Name of Co-Investigator: Professor Abhinav Vaidya
Department of Community Medicine, Kathmandu Medical College, Kathmandu, Nepal
Research Funder: This research is not funded.

3. Inclusion/Exclusion Criteria

Before you decide to participate in this research study, we need to ensure that it is ok for you to take part. The research study is looking to recruit people who meet the following criteria:

Inclusion criteria

1. Participants with hypertension (clinical diagnosis of hypertension and currently receiving blood pressure lowering medication at least for three month) between the ages of 18-69 years of age living in the selected area.
2. Participants who or whose family have a mobile phone and able to read a text message by themselves or with the help of family members.
3. Participants who are likely to be in the study area during the period of intervention.

Exclusion criteria as assessed by consulting physician and researchers

1. Those who have severe mental illness or cognitive impairment or any physical disability.
2. Participants who have serious illness needed immediate care.
3. Those who are pregnant or post-partum.
4. Those residing in hospitals, prisons, nursing homes and other institutions

5. Those unable or unwilling to give informed consent

4. Do I have to take part in this research study?

Participation in this research study is voluntary. If you do not want to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage. If you decide, you want to take part in the research study, you will be asked to:

- Read the information carefully (ask questions if necessary);
- Sign and return the consent form if you decide to participate in the study;
- Take a copy of this form with you to keep.

5. What does participation in this research require, and are there any risks involved?

If you decide to take part in the research study, you will be asked to participate in a face to face Interview and we will measure your blood pressure, weight, height, waist and hip circumference at the start of the study and during follow up at 12 weeks (3 months) of participation in the study.

If you decide to take part in the research study, we will ask you to complete a survey administered on tablet computers by the researchers. The questionnaire will ask you questions about your sociodemographic characteristics, medical and family history of hypertension, your lifestyle practices on smoking, physical activity, alcohol consumption, and diet; knowledge and perception of hypertension, treatment of hypertension and adherence to antihypertensive treatment questionnaire.

After the questions, the interviewer will then obtain your physical measurements of height, weight, blood pressure, waist and hip circumferences. It should take approximately 50 – 60 minutes to complete.

There will be two groups in the study. Intervention arm will receive the text messages regarding taking medication, lifestyle changes like taking low salt and fat diet, reduction/quitting of smoking and information about hypertension and its treatment thrice a week for three months in mobile number which you will provide to the research team. You can opt out any time during the study if you do not wish to continue. You'll be provided the mobile number of the researcher where you can inform if you do not wish to further get the text messages and be part of the study.

Control arm will be provided usual care. At the end of the study (after three months), they will get the pamphlets containing information about hypertension and required behaviour modification. You will be randomly allocated to either in intervention or control arm.

Then, after three months of follow up again you will be asked similar questions as baseline and physical measurement will be taken similarly.

We don't expect this questionnaire to cause any harm or discomfort, however, if you experience feelings of distress as a result of participation in this study then you can let the research team know and they will provide you with assistance; or you can also request to stop the survey.

6. What are the possible benefits to participation?

We cannot and do not guarantee or promise that you will receive any other benefits from this study. We hope to use information, we get from this research study to benefit for the development of the program to improve treatment adherence and blood pressure control of hypertensive patients in the future. There are no costs associated with participating in this research study, nor will you be paid.

7. What will happen to information about me?

By signing the consent form you consent to the research team collecting and using information about you for the research study. Your data will be kept for a minimum of 7 years after the project's completion. We will store information about you in a password protected computer belonging to the researcher. These files will later be transferred to a password protected computer at the school (SPHCM) allocated to the student researcher and then transferred to UNSW OneDrive secure storage at the University of New South Wales, Australia.

Your information will only be used for thesis writing, scientific publication and presentation in de-identified form only.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP

Act. Further information on how the University protects personal information is available in the **UNSW Privacy Management Plan**.

8. How and when will I find out what the results of the research study are?

The research team intend to publish and/ report the results of the research study in a variety of ways. All information published will be done in a way that will not identify you. If you would like to receive a copy of the results, you can let the research team know by including your details in the space provided in the consent form.

9. What if I want to withdraw from the research study?

If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document. Alternatively, you can ring the research team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney and the Kathmandu Medical College and teaching Hospital, Kathmandu. If you decide to leave the research study, the researchers will not collect additional information from you. Any identifiable information about you will be withdrawn from the research project. The research team will destroy any information about you that was collected during your participation in the study.

10. What should I do if I have further questions about my involvement in the research study?

The person you may need to contact will depend on the nature of your query. If you require further information regarding this study or if you have any problems which may be related to your involvement in the study, you can contact the following member/s of the research team:

Research Team Contact Details

Name	Buna Bhandari Bhattarai
Position	Student Investigator
Telephone	
Email	buna.bhandaribhattarai@student.unsw.edu.au

Support Services Contact Details

If at any stage during the study, you become distressed or require additional support from someone not involved in the research please call:

Name/Organisation	Kathmandu Medical College and Teaching Hospital
Position	Counseller
Telephone	To be filled in at recruitment
Email	To be filled in at recruitment

What if I have a complaint or any concerns about the research study?

If you have a complaint regarding any aspect of the study or the way it is being conducted, please contact the UNSW Human Ethics Coordinator:

Complaints Contact

Position	UNSW Human Research Ethics Coordinator
Telephone	
Email	humanethics@unsw.edu.au
HC Reference Number	

Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this research study;
- ☐ I have read the Participant Information Sheet, or someone has read it to me in a language that I understand;
- ☐ I understand the purposes, study tasks and risks of the research described in the study;
- ☐ I provide my consent for the information collected about me to be used for the purpose of this research study only.
- ☐ I have had an opportunity to ask questions and I am satisfied with the answers I have received;

☐ I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study and withdrawal will not affect my relationship with any of the named organisations and/or research team members;

☐ I would like to receive a copy of the study results via email or post, I have provided my details below and ask that they be used for this purpose only;

Name: ______________________________________

Address: ____________________________________

Email Address: _______________________________

☐ I understand that I will be given a signed copy of this document to keep;

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

Declaration by Researcher*

☐ I have given a verbal explanation of the research study; its study activities and risks and I believe that the participant has understood that explanation.

Researcher Signature*

Name of Researcher (please print)	
Signature of Researcher	
Date	

[+]An appropriately qualified member of the research team must provide the explanation of, and information concerning the research study.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this research study described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales and Kathmandu Medical Collège and Teaching Hospital. In withdrawing my consent, I would like any information which I have provided for the purpose of this research study withdrawn.

Participant Signature

Name of Participant (please print)	
Signature of Research Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	
Email:	
Phone:	
Postal Address:	