Using apps to support the self-management of hypertension in Saudi Arabia

by

Tourkiah Alessa

A thesis submitted to the University of Sheffield in partial fulfillment of the requirements for the degree of Doctor of Philosophy

The University of Sheffield

Faculty of Medicine, Dentistry and Health

School of Health and Related Research

March 2021

PhD Project Supervisors

Professor Luc de Witte

Professor Mark Hawley

Declaration

I, Tourkiah Alessa, hereby declare that no part or whole of the work referred to in this thesis has been submitted to any University or institution of learning other than the University of Sheffield, for the purpose of the awarding of an academic degree or any qualification of that sort. This thesis is submitted in the form of the **Publication Format Thesis** which allows the thesis to be composed of academic publications, alongside with the traditional thesis sections. Three published papers, of which I am the first author, are included in my PhD thesis, in Chapters 3, 4 and 6. These were originally published in the Journal of Medical Internet research (JMIR) mHealth and uHealth. This work is under the terms of Creative Commons Attribution 4.0 license which permits me to include/use these published articles in my thesis.

Acknowledgements

I am grateful to God for the strength granted to me during my PhD. I would also like to extend my thanks to all those who have supported and helped me throughout my doctoral research. First, I thank my supervisors, Professor Luc de Witte and Professor Mark Hawley for providing an intellectually stimulating environment to work in and for providing the foundation for me to grow as a PhD student and an independent researcher. I will forever be grateful to you both for guiding me through this project with your long experience and extensive knowledge and for showing confidence in me to complete this work. Luc, your limitless academic and emotional support and guidance has been a big source of great help, reassurance and encouragement, particularly in those times where I found the project most demanding and stressful! I could not complete this project without your guidance. Mark, your support and your attention to detail has been a tremendous benefit to me, helping me to stay alert and think through issues with greater clarity, as well as your limitless guidance in all areas of the PhD. Together you have been a wonderful, encouraging and attentive supervisory team.

Secondly, I wish to acknowledge the generosity of my employer King Saud University (KSU) for funding my research, and all the support provided by the Saudi Cultural Bureau staff. I would also like to thank the Cora Health development team for their generous cooperation in translating this app into Arabic. And, of course, my appreciation goes to all of the participants who took part in the qualitative and mixed method studies and who provided essential data for the project.

I am also grateful to other academics in ScHARR at the Univesity of Sheffield for their support and advice, Prof. Alicia O'Cathain, Dr. Richard Cooper, Dr. Emma Hock and Dr. Kate Fryer, and Dr Kiera Bartlettof the University of Manchester.

I am also grateful to the co-authors of my published PhD studies for their time, effort, and to my PhD colleagues for sharing ideas and being there for support and friendship – the PhD was much less lonely because of you all.

Most importantly, many thanks for my lovely mom, Modi, who has provided me with much emotional support, inspiration, advice and prayer; I am incredibly lucky to have you as a mum. Many thanks for my great father, Ali, who has always supported and encouraged me to pursue my education, and who pushed me to return to the UK to finalize my PhD even after his heart attack. I know you both missed me a lot, as I did, while I have been living away during this study time.

To my dear husband, Musaad and my wonderful princess Ranya, thank you. You have been a rock throughout my studies, always encouraging me and believing in me, within all the difficulties in my tough and long journey; when I had not time for you. I couldn't have done this without you.

I also want to acknowledge the unlimited moral support of my lovely sisters, Dr. Nourah, Mrs. Nada and Eng. Ghaida, who were always there to cheer me up throughout this project. I am thankful to all of you. Likewise, to my lovely brothers, Mr. Abdullah, Mr. Hamad, Eng. Nasser and Captine. Mohammed. I am lucky to have such wonderful siblings! Thank you for all of your support.

I wish to end by dedicating this thesis to my parents, to share with you this achievement, in recognition of all the love and encouragement you have shown me.

Abbreviations

BP: blood pressure

SBP: systolic blood pressure

DBP: diastolic blood pressure

mHealth: mobile health

App: application

HCP: health care professional/provider

MRC: Medical Research Council

BCT: behavior change technique

BCTTv1: behavior change technique taxonomy v1

TDF: theoretical domain framework

RCT: randomized controlled trial

FDA: US Food and Drug Administration

CE: European Union Conformite Europeene

UCD: User-centered design

MOH: Ministry of Health

NHS: National Health Service

Table of Contents

List of Figures

List of Tables

List of appendices

Abstract

Background: Hypertension is a chronic condition that affects one billion adults globally will affect an estimated 1.56 billion by 2025. Its prevalence in Saudi Arabia is particularly high and is the main risk factor for death. Hypertension can be greatly improved by effective self-management. Smartphone apps offer potential solutions to aid self-management, and their availability has hugely increased recent years. An increasing number of studies have advocated their use in clinical settings. This increase in commercial hypertension apps, and the growing enthusiasm for their use in patient care urgently necessitates research to identify those that are most suited to facilitating the self-management of hypertension in Saudi Arabia.

Purpose: The aim of this PhD research was to review available apps for the self-management of hypertension based on their effectiveness, privacy and security, and their theoretical underpinning, to identify the most suitable apps for use in the Saudi context, and to evaluate the usability and acceptance of the most suitable app among Saudi patients.

Methods: This PhD consists of four studies. A systematic review explored the usability and effectiveness of apps in supporting self-management of hypertension (Study 1). An app store review was carried out to review available hypertension self-management apps in the most common app stores, and identify their functionalities, privacy and security characteristics, and theoretical backgrounds (Study 2). A systematic selection approach was used to identify the most suitable, effective and secure apps, which were then explored via a qualitative study to identify the most suitable app for the Saudi context (Study 3). Finally, a mixed methods study amongst Saudi hypertension sufferers evaluated the acceptance and usability of the selected app in both a real-life context and a controlled setting (Study 4).

Results: Study 1 identified apps with the potential to be effective in supporting hypertension self-management, and found that apps are more likely to be effective if they have more comprehensive functionalities. Study 2 found 186 such apps, but few of them (n=30) are likely to be effective, and most of them did not meet current standards of privacy and security, and were lacking a sound theoretical bases. In Study 3, the systematic selection approach, identified 5 apps that are likely to be effective, and that have adequate privacy and security measures. These 5 apps were assessed in a qualitative study with patients and doctors, who identified three apps as more suitable, with Cora health app rated highest in participants' ratings. Study 4 found that the Cora health app can be acceptable and usable in the self-management of hypertension, but there are some issues that could be improved.

Conclusion: This PhD study demonstrates that the selected app is usable and acceptable in the self-management of hypertension and has the potential to be effective. Future research would be required to assess the app's effectiveness in a larger study with longer follow up periods.

Dissemination

Publication of thesis Chapters

Chapter 3

Alessa T, Abdi S, Hawley MS, & de Witte L. Mobile Apps to Support the Self-Management of Hypertension: Systematic Review of Effectiveness, Usability, and User Satisfaction. Journal of Medical Internet Research mHealth and uHealth. 2018; 6(7), e10723.

Chapter 4

Alessa T, Hawley MS, Hock ES, de Witte L. Smartphone Apps to Support Self-Management of Hypertension: Review and Content Analysis. Journal of Medical Internet Research mHealth and uHealth, 2019;7(5): e13645

Chapter 6

Alessa T, Hawley MS, Alsulamy N, de Witte L. Using a commercially available app for self-management of hypertension: Acceptance and usability study in Saudi Arabia. Journal of Medical Internet Research mHealth and uHealth. 2021; 9(2):e24177. doi: 10.2196/24177.

<u>Chapter 5</u>
Alessa T, Hawley MS, de Witte L. Identification of the most suitable app for self-management of hypertension for use in Saudi Arabia. Journal of Medical Internet Research mHealth and uHealth

Other Publications

Alsulamy N, Lee A, Thokala P, **Alessa** T. What Influences the Implementation of Shared Decision Making: An Umbrella Review. Patient Educ Couns. 2020 Aug: S0738-3991(20)30436-5.

Alsulamy N, Lee A, Thokala P, **Alessa** T. Factors Influencing the Implementation of Shared Decision Making in The Eastern Mediterranean Region: A Systematic Review. Patient Educ Couns. 2021Mar.

Littler BKM, **Alessa** T, Dimitri P, Smith C, de Witte L. Reducing negative emotions in children using social robots: systematic review. Arch Dis Child. 2021 Mar. doi: 10.1136/archdischild-2020-320721.

International and national Conference presentation

<u>Chapter 5</u>

Alessa T, Hawley MS, de Witte L. Smartphones Apps to Support the Self-Management of Hypertension: identification of the most suitable apps at 15th AAATE Conference GLOBAL CHALLENGES IN ASSISTIVE TECHNOLOGY Bologna (IT), 27-30 August 2019.

Alessa T, Hawley MS, de Witte L. Patient and doctor attitudes towards, and acceptance of, the use of hypertension apps in Saudi Arabia at ICHIHIM 2020: XIV. International Conference on Health Informatics and Health Information Management London 21-22 May 2020.

Alessa T, Hawley MS, de Witte L. Smartphones Apps to Support the Self-Management of Hypertension: identification of the most suitable apps. Sheffield Institute for International Development Postgraduate Research Conference. 2019

Alessa T, Hawley MS, de Witte L. Patient and doctor attitudes towards, and acceptance of, the use of hypertension apps in Saudi Arabia. Sheffield Institute for International Development Postgraduate Research Conference. 2020

<u>Chapter 3</u>

Alessa T, Abdi S, Hawley MS, de Witte L. Mobile Apps to Support the Self-Management of Hypertension: Systematic Review of Effectiveness, Usability, and User Satisfaction. Sheffield Institute for International Development Postgraduate Research Conference. 2018.

Blogs

Smartphones apps to support the self-management of hypertension: effectiveness and user satisfaction. Available at: https://blogs.ucl.ac.uk/cbc-digi-hub-blog/2018/10/10/smartphones-apps-to-support-the-

Smartphone Apps to Support Self-Management of Hypertension: Review and Content Analysis Available at: http://www.catch.org.uk/news-articles/smartphone-apps-to-support-self-management-of-hypertension-review-and-content-analysis/

Chapter 1 Introduction

In this chapter, the general overview of the project is presented, followed by the structure of the thesis.

1.1 Introduction

There has been an exponential increase in the prevalence of hypertension globally and it has almost reached an epidemic scale (1). Hypertension is a long-term condition requiring ongoing healthcare and if it is not properly controlled, it can cause organ damage leading to complications such as renal and cardiovascular diseases causing protracted morbidity and premature mortality. Thus, hypertension has high human and economic cost (1-3).

Self-management of hypertension could be an effective way to manage hypertension and prevent serious complications arising from the condition, by engaging patients in their health through monitoring their health status, complying with treatment recommendations and making corresponding healthcare decisions (4-5). At the same time, self-management offers a way to reduce pressure on healthcare services by encouraging patient to monitor their own health.

Advances in technology in recent years have greatly increased the general population's access to self-management tools, including mobile health (mHealth) interventions intended to help patients self-manage hypertension and enhance their health outcomes. The growth in the use of smartphones combined with healthcare apps could play a key role in self-management, something that is evidenced by the explosion of available hypertension apps on app stores in recent years (6-7). Smartphone apps are considered an effective tool to support the self-management of hypertension and lower BP, especially in developed countries (8,9). However, the increasing range of commercially available blood pressure (BP) apps has created a pressing need for research to distinguish apps that really have the potential to be effective in helping people to manage their BP.

Despite the increasing use of smartphones and health apps in Saudi Arabia and the increasing prevalence of hypertension, there are no studies that address the use of smartphone apps to support the self-management of hypertension in Saudi Arabia. Saudi Arabia is also a unique context in term of its religion, language, primary care system, and lifestyle of its citizens and as such requires its own studies into the use of such interventions (these contextual factors are considered further in section 2.5.2). Therefore, it is imperative to identify and evaluate health apps that can be used efficiently and effectively in the Saudi context.

The aim of this PhD research was to review available apps for the self-management of hypertension based on their effectiveness, privacy and security, and their theoretical underpinning, before identifying the most suitable apps for use in the Saudi context, and evaluating the usability and acceptance of the most suitable app among Saudi patients. To achieve this aim, the following objectives were identified (more details are provided in section 2.7):

1. To synthesise the available evidence about app usability, end-user satisfaction, and the effectiveness of apps in terms of lowering BP.
2. To identify and describe available apps that can support the self-management of hypertension and identify their functionalities, levels of privacy and security, and theoretical backgrounds.
3. To determine the most suitable hypertension self-management apps that meet the criteria of effectiveness, theoretical backgrounds, and privacy and security.
4. To identify the most suitable apps for the Saudi context by exploring Saudi patients' and doctors' experiences in self-management of hypertension, and their attitudes towards the app(s) identified.
5. To translate the most suitable app into the Arabic language through co-operation with the selected app's developers.
6. To assess the usability and acceptance of the selected app in real-life and controlled settings.

The first stage of the research was to report on current theories about self-management to inform the research (presented in Chapter 2). Four studies were then undertaken (see also Figure 1.1)

A systematic literature review was conducted (**Study 1, Chapter 3**) synthesising evidence about the effectiveness of apps to support self-management, user satisfaction with these apps, as well as their usability (objective 1). This was the first study to investigate this specific topic and has been published in JMIR mHealth and uHealth (10)

Next, we conducted an app store review (**Study 2**, **Chapter 4**). This described and analysed the available apps in the most common app stores that can be used to support the self-management of hypertension (objective 2). This study analysed the apps' functionalities, identified their theoretical basis, and assessed their privacy and security. This study has been published in JMIR mHealth and uHealth (7).

To select the most suitable app, a two-part study was conducted (**Study 3, Chapter 5**). The first phase used a systematic selection approach (Section 5.1) to guide the selection process of the most suitable apps from among those identified in Study 2 (objective 3). This selection was based on 3 criteria: effectiveness, theoretical background, and privacy and security. The second phase was an exploratory qualitative study among Saudi end-users (Section 5.2) by means of semi-structured interviews with doctors and focus groups with patients. The data from this study were analysed to select the most suitable app for use in the Saudi context (objective 4). The developer of the selected app was then approached to collaborate on translating the app into Arabic (objective 5). This study has been submitted to the Journal Patient Education and Counselling.

Finally, the selected app was evaluated using a mixed-method approach (**Study 4, Chapter 6**). Its usability and acceptance were assessed among patients by means of a usability test and a usability and acceptance study in real life in Saudi Arabia (thus achieving objective 6, and completing the overall aim of the research). This study has been published in JMIR mHealth and uHealth (11).

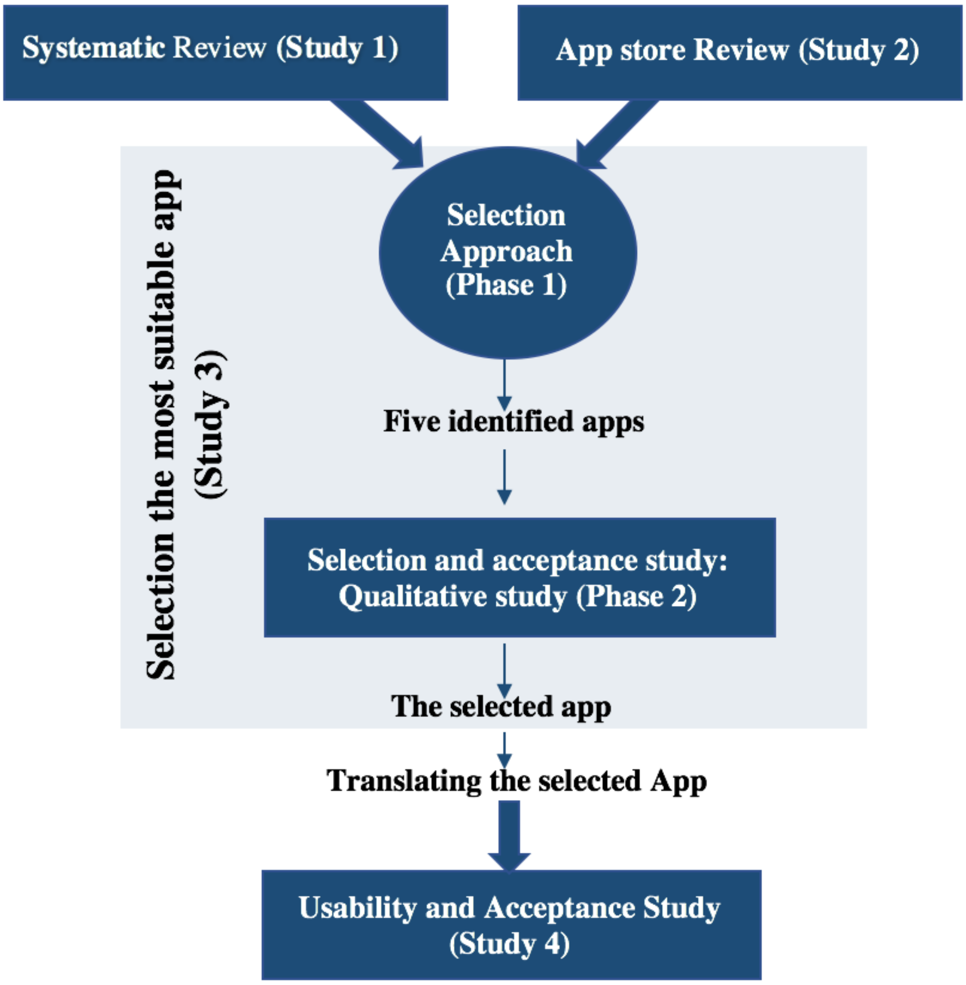


Figure 1.1: Outline of the project's Studies

1.2 Methodology

As presented above, this thesis explored various kinds of questions that were required to be answered via different approaches. A pragmatic approach therefore was adopted in this research, i.e. the design that is most suited and appropriate to answering the research question was chosen instead of any one underlying philosophical viewpoint (12-15). Pragmatism is not committed to one belief or reality, in contrast to other positions e.g. postpostivism and interpretivism (13). This pragmatic approach permits multiple methodologies or methods to be utilised to solve the complex research problem (i.e. multi-faceted questions), as in this project, in greater detail than using a single approach (12-14). As a number of different methodologies were adopted, instead of offering an explanation and a rationale for each in a single chapter focused on methodology, descriptions and rationales for their use in each study are discussed in Chapters 3, 4, 5 and 6

Since the research questions and approaches answering them are so distinct, using either quantitative or qualitative research alone would also result in failure to address all of the research questions satisfactorily (13). Quantitative research (e.g. experimental studies), typically seeks to determine or verify causation with a large sample of participants and to generalise findings, whereas qualitative research can obtain more detailed descriptions of participants' views and experiences (12,13,15,16). Whilst both types of research were essential to answer some of the research questions, neither would have been capable of answering all of them sufficiently in isolation.

Likewise, there is no justification for combining and integrating the findings at any stage: the research questions are so different that to combine the data would be unhelpful. Therefore, a mixed-methods approach, in which qualitative and quantitative data is integrated (12), has not been used as an overarching methodology, because it would undermine the aims and objectives of the research. In study 4, a mixed-method design was adopted only to assess the usability and acceptance of the selected app.

1.3 Structure of the thesis

This thesis comprises seven chapters.

Chapter 1 Introduction (presented above). This gives the general overview of the research, the overall methodological approach of the PhD, and the structure of the thesis.

Chapter 2 Background This chapter introduces the classification and global prevalence of hypertension, as well as its prevalence in Saudi Arabia. It also summarises existing literature on the concept of self-management, self-management of hypertension in particular, and self-management theories. It discusses the concepts of mHealth and the significance of mHealth technology in Saudi Arabia. This chapter ends by presenting the research questions, the overall aim and objectives of the research, and describes the significance of the project as a whole.

Chapter 3 Systematic review study This chapter presents the systematic review (Study 1), which synthesised current evidence regarding the effectiveness of apps in lowering BP, their usability, and patients' acceptance of them.

Chapter 4 App review study This chapter presents the app store review (Study 2) undertaken to review all the available hypertension apps on the most popular platforms (iPhone and Android), to investigate their main functionalities and assess their privacy and security, and their theoretical underpinning.

Chapter 5 App selection and acceptance study This chapter presents a two-phase approach for the selection of the most suitable app within the Saudi context (Study 3). The first phase presents the systematic selection approach conducted to select the most suitable (effective and secure) apps. The second phase presents the qualitative study undertaken to explore the acceptance and attitudes of patients and doctors towards the suitable hypertension self-management apps identified in the systematic approach, with the aim of selecting the most suitable app.

Chapter 6 Usability and acceptance Study This chapter presents the mixed method study (Study 4) done to evaluate the usability and acceptance of the selected app among Saudi hypertension patients in both real-life and controlled settings.

Chapter 7 General discussion This chapter presents the discussion of the PhD findings in general, starting with the main findings, reflection on the main findings, its limitations and strengths, recommendations for further research, and conclusion

1.4 References

1. Kannel WB. Risk stratification in hypertension: new insights from the Framingham Study. Am J Hypertens. 2000 Jan [cited March 2018];13(1 Pt 2):3S-10S. doi: 10.1016/s0895-7061(99)00252-6.
2. Jones NR, McCormack T, Constanti M, McManus RJ. Diagnosis and management of hypertension in adults: NICE guideline update 2019. Br J Gen Pract. 2020 Jan pcited 2018 Jan] 30;70(691):90-91. doi: 10.3399/bjgp20X708053.
3. Lovic D, Narayan P, Pittaras A, Faselis C, Doumas M, Kokkinos P. Left Ventricular Hypertrophy in Athletes and Hypertensive Patients. The Journal of Clinical Hypertension (Greenwich, Conn.). 2017 Mar [Cited Mar 2020] 19(4): 413-17.
4. Bosworth HB, Powers BJ, Oddone EZ. Patient self-management support: novel strategies in hypertension and heart disease. Cardiol Clin. 2010 pcited 2018 Mar];28(4):655-663. doi:10.1016/j.ccl.2010.07.003
5. Ryan P, Sawin KJ. The Individual and Family Self-Management Theory: background and perspectives on context, process, and outcomes. Nurs Outlook. 2009 Jul-Aug [cited 2018 Jan];57(4):217-225.e6. doi: 10.1016/j.outlook.2008.10.004.
6. Kumar N, Khunger M, Gupta A, Garg N. A content analysis of smartphone-based applications for hypertension management. J Am Soc Hypertens. 2015 Feb [cited 2018 Jan];9(2):130-6. doi: 10.1016/j.jash.2014.12.001
7. Alessa T, Hawley MS, Hock ES, de Witte L. Smartphone Apps to Support Self-Management of Hypertension: Review and Content Analysis. JMIR Mhealth Uhealth 2019 [cited 2020 Jan];7(5):e13645. doi: 10.2196/13645
8. Parati G, Torlasco C, Omboni S, Pellegrini D. Smartphone Applications for Hypertension Management: a Potential Game-Changer That Needs More Control. Curr Hypertens Rep. 2017 Jun [cited 2018 Mar];19(6):48. doi: 10.1007/s11906-017-0743-0.
9. Rehman H, Kamal AK, Morris PB, Sayani S, Merchant AT, Virani SS. Mobile Health (mHealth) Technology for the Management of Hypertension and Hyperlipidemia: Slow Start but Loads of Potential. Curr Atheroscler Rep. 2017 Mar[cited 2018 Feb];19(3):12. doi: 10.1007/s11883-017-0649-y.
10. Alessa T, Abdi S, Hawley MS, de Witte L. Mobile Apps to Support the Self-Management of Hypertension: Systematic Review of Effectiveness, Usability, and User Satisfaction. JMIR Mhealth Uhealth 2018 [cited 2018 Aug];6(7):e10723. doi: 10.2196/10723
11. Alessa T, S Hawley M, Alsulamy N, de Witte L. Using a Commercially Available App for the Self-Management of Hypertension: Acceptance and Usability Study in Saudi Arabia. JMIR Mhealth Uhealth 2021 [cited 2021 Feb];9(2):e24177. doi: 10.2196/24177
12. Creswell JW, Plano Clark VL. Designing and Conducting Mixed Methods Research. SAGE Publications Ltd. SAGE Publications, lnc.; 2018.
13. Creswell JW, Creswell D. Research Design Qualitative, Quantitative & Mixed Methods Approaches. SAGE Publications Ltd. SAGE Publications, lnc.; 2017.
14. Seale, C. Quality in qualitative research. Qualitative Inquiry. 1999 pcited 2018 Mar]; 5, 465-478. doi: 10.1177/107780049900500402
15. Pope C, Mays N. Qualitative research in health care. Florida: John Wiley & Sons; 2008
16. Bryman A. Social research methods. 4th ed. New York: Oxford University Press; 2012.

Chapter 2 Background

This chapter provides the background for the PhD topic and the significance of the research. It begins by introducing the classification and global prevalence of hypertension, as well as its prevalence in Saudi Arabia. It also summarises existing literature on the concept of self-management, self-management of hypertension in particular, and self-management theories. It discusses the concepts of mHealth and the significance of mHealth technology in Saudi Arabia. This chapter ends by presenting the research questions, and overall aim and objectives of the research, as well describing the significance of the project as a whole.

2.1 Classification and Prevalence of Hypertension

The United States Joint National Committee for Detection, Evaluation and Treatment of High BP (HBP) (1) and the National Institute for Health and Care Excellence in the UK (2) recommend that the normal systolic Blood pressure (SBP) should be less than 120 mmHg and the Diastolic Blood Pressure (DBP) should be less than 80 mmHg. Hypertension is diagnosed when high SBP (≥140 mmHg) or DBP (≥90 mmHg) are recorded at two or more consecutive visits to a doctor (Table 2.1). Numerous methods of resting BP classification can assist in the identification of individuals at risk of high BP and can also facilitate therapeutic treatment. According to NICE criteria, hypertension is classified into stages, the most common of which are stages 1 and 2 (1-3).

Table 2.1 Classification of BP

BP Classification	SBP (mmHg)	DBP (mmHg)
Normal	<120	and <80
Prehypertension	120–139	or 80–89
Stage 1 Hypertension	140–159	or 90–99
Stage 2 Hypertension	160-179	or 100-109
Severe (Stage 3) Hypertension	≥180	or ≥110

According to the World Health Organization, hypertension is a major cause of premature death on a global scale (4). In 1975, as many as 594 million adults were reported to have high BP, with the figure increasing to 1.13 billion by 2015, mainly in nations with low or middle incomes (5). The World Heart Federation (2013) estimates that by 2025, a total of 1.56 billion adults will have hypertension (5, 6).

An extensive research of the prevalence of HBP in Saudi Arabia indicated an overall rate of 26.1%, a rate of 22.4% in the rural population, and a perceptibly higher rate of 27.9% in the urban population. These rates are generally regarded as high (7). A study conducted in 2013 showed that 27.2% of Saudi people over the age of 30 had been diagnosed with hypertension, while 41% of those over the age of 15 were borderline hypertensive (8). The Ministry of Health (MOH) in Saudi Arabia revealed the tendency for BP to increase as individuals get older; within the 55–64-year age bracket, the rate reaches 51.2%, while in people over the age of 65, the figure approaches 70% (9).

The Global Burden of Disease study has found that hypertension is one of the foremost death-risk elements in Saudi Arabia, so it is a serious issue in the country (8). Another crucial factor is that a significant fraction of people with hypertension remain undiagnosed, meaning many individuals are unaware they have the condition, and considerable efforts are made by the Saudi government to motivate the population to undergo basic health appraisals annually. Additionally, many Saudi national surveys have indicated that despite the high prevalence of hypertension, it is poorly controlled among people (7, 8, 10). For instance, a national survey reported that almost 72% of patients were on hypertension medication, but 55% of them still had uncontrolled BP levels. This leads to an increased risk of developing complications and a high economic cost (8). Another study indicated that 60% of people with hypertension, who followed and attended primary healthcare centres, have uncontrolled BP (11). Saudi Arabia has a clear problem with hypertension, primarily because of a relative lack of control of BP. Thus, progress in the development of innovative strategies for BP control is essential.

2.2 Complications of Hypertension

Epidemiological studies have demonstrated that hypertension can be a risk element for a number of diseases, including heart failure, stroke, coronary and peripheral arterial diseases and renal disease (12, 13). Furthermore, hypertension is a risk element for every clinical manifestation of atherosclerosis (1).

Hypertension can cause structural and functional changes within the heart. Such changes can involve atherosclerotic coronary artery disease, cardiac arrhythmias, diastolic dysfunction, left ventricular hypertrophy, cardiac remodelling and microvascular disease (13). Recently conducted clinical trials revealed that left ventricular hypertrophy can recede and the possibility of cardiovascular disease can be decreased when SBP is controlled, the target being below 130 mmHg as opposed to 140 mmHg (14). Furthermore, evidence suggests that when BP is decreased, coronary heart disease and deaths caused by ischemic heart disease can be successfully decreased (15-17). It has been established by such research that BP decrease is significant in the prevention of heart illnesses.

Hypertension is the major element of risk for strokes. Furthermore, it results in a growing risk of dementia and cognitive impairment (18). Epidemiological studies have shown that it is three times more likely for individual with hypertension to experience a stroke than a person whose BP is normal (18). A meta-analysis (16) that explored the association between 843 subsequent strokes and BP level showed that a decrease of SBP of 20 mmHg or 10 mmHg DBP was linked with a decline in death from ischemic heart disease and stroke by about one half. These results confirm the significance of BP control in decreasing the likelihood of a stroke.

According to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (19) in the USA, HBP is the second major cause of kidney failure. Furthermore, from 2010–2013, high BP led to a 7.7% increase in the kidney failure rate. Damage to small blood vessels from hypertension is regarded as one reason for kidney failure. Consequently, it is crucial to control BP to help prevent kidney disease.

2.3 Self-Management

The term self-management, coined in the mid-1960s, was established and used with the aim of highlighting the active engagement of people with long-term conditions in their treatment (20,21). The nature of chronic disease management requires the application of a positive and dynamic technique to help patients with chronic conditions to move from a passive, powerless role, to an active, effective role (22). Although there is currently no agreed definition of self-management (23, 21), self-management can usefully be defined as the proactive management of patients in in their own symptoms, lifestyle changes, physical and psychosocial impacts and treatment (23, 24). Optimal self-management enables individuals to monitor their diseases, as well as to use strategies (e.g. behavioural and cognitive) to maintain a good quality of life (25). In self-management, a continuous and dynamic process of self-regulation is achieved by the patient through a productive partnership with the healthcare-provider. The concept of self-management is often interchangeably used with self-care. But self-care describes more general ways for individuals to live healthy lives by undertaking preventative strategies to promote and maintain their health (26).

Lorig and Holman (22) suggest that the main self-management processes/skills include decision-making, problem solving, collaboration with healthcare providers, resource utilisation and taking action. Schulman-Green et al. (25) indicated that accounts of self-management derive from the point-of-view of people with long-term illness. These include (1) focusing on the need of chronic illnesses, like learning, taking responsibility of healthcare need and carrying out health behaviours and tasks, (2) activating resources, including psychological and healthcare recourses, and (3) coping with long-term illness, e.g. how they include management of their illness in their daily routine.

To achieve effective self-management, it is essential to educate people to help them gain an awareness of responsibility over their conditions (27, 28), since patients with chronic diseases need to learn ways of managing their illness. To do so, they need to have an attitude towards their illness that is conducive to its treatment, as well as the necessary behaviors and skills to control the impact of the illness and manage aspects of treatment such as physical exercise and medication (23, 25). Shared decision-making about treatment is a basic requirement (22). Thereby, it is important that patients have a good understanding and knowledge of their condition, including how to manage it and access support services. This will make the patient more likely to engage with the self-management of their condition and increase their confidence in managing it (28). For almost all chronic diseases it is important that patients adopt a healthier lifestyle, or at least a lifestyle that reduces risk factors (28). Social support is also essential to facilitate the adoption of these self-management activities for these patients (29).

2.3.1 Hypertension Self-Management

Hypertension self-management encompasses an array of activities or behaviours that people with hypertension perform to manage their condition and promote their own health (1, 30, 31). Hypertension has recently been recognised more as a lifestyle disease. The risk factors of hypertension such as smoking, obesity, excessive alcohol intake, sedentary lifestyle and unhealthy dietary habits significantly contribute to development of hypertension, and changes aimed at improving lifestyle can have a profound effect in controlling hypertension (1,2). Self-management has become an effective approach to managing hypertension, and it helps prevent subsequent serious and long-term complications involving hypertension because it enables people with hypertension to engage in their own healthcare. Patients with hypertension should have essential information and skills (e.g problem solving) to understand their condition, become aware of challenges in its management, and create a strategy or plan for finding a solution, which results in the development of patient self-efficacy and confidence (26, 30).

Efficient self-management of hypertension includes the self-monitoring of BP and its symptoms; understanding when BP level and its symptoms are a problem, which enables the patient to gauge BP responses to health behaviour, as well as taking appropriate action (e.g. adjusting treatments and adopting recommended healthy lifestyles including a good diet, physical activity, and stress management) (2, 30, 32). In self-managing hypertension, a healthcare team is usually involved, with which the patient can collaborate to set targets for BP, frequency of BP readings, and other strategies. This collaboration provides negotiation and agreement of goals through problem identification, action planning and shared decision making to control BP properly (30, 33, 34).

2.3.2 Challenges of Self-Management of Hypertension

Studies of self-management of hypertension often identify the following challenges for people with hypertension: poor access to community resources, a lack of knowledge about hypertension, competing health priorities, and non-compliance with hypertension medication (35, 36). A more recent meta-review found that patients face a number of barriers when attempting to self-manage and control their BP, including stress and anxiety, busy lifestyle, forgetting, cost, and lack of family support (37). Other studies have identified challenges specific to Saudi Arabia (7, 8, 10, 38-40), which include: 1) a lack of knowledge and poor education and awareness about managing hypertension; 2) a lack of education and training centres to support patients in managing their condition; 3) a limited number of qualified specialists and nurses; 4) widespread obesity and a widespread lack of physical activity due to a sedentary lifestyle; 5) a high prevalence of smoking; 6) an unhealthy diet compared with other Eastern societies; 7) poor compliance with medication. Since this phase of the PhD was completed, additional research has found more evidence of barriers facing Saudi hypertension sufferers. Al Hadlaq et al (41) found that lack of motivation, forgetting, and busy lifestyle are barriers that affect Saudi patients' effective self-management of their hypertension, factors which were already identified in our qualitative study (Chapter 6).

Self-management programs can help to mitigate these challenges by giving patients a more active role in their health, increasing their self-confidence, motivation and efficacy. This can be fulfilled by means of collaboration between patients and professionals to establish realistic goals, build knowledge, and conduct self-monitoring activities, leading to taking appropriate actions (30, 33).

2.4 Self-management and behaviour change theories

Self-management is a complex task that requires changes in behaviour on different levels and in different domains (21, 32). Patients need support to realise this and that is why many self-management interventions have been and are being developed. These interventions are mostly based on behaviour change theories. The following subsections discuss the most frequently used theories and how these will be used in our study of apps to support self-management of people with hypertension.

2.4.1 The Health Belief Model (HBM)

The Health Belief Model (HBM), a socio-psychological model, predicts: 1) whether individuals will accept or reject healthcare treatments that will prevent more serious conditions developing in the future; and 2) whether the individuals will engage in self-managing their condition through conducting activities and adopting health behaviour (42). This model theorises that the beliefs people hold concerning whether or not they are at risk of contracting diseases, as well as how they view the benefits of acting to manage or avoid diseases, impacts how ready they are to make positive changes with regards to their health (42). Its emphasis is on how people perceive illnesses. The model utilises a number of concepts to anticipate why people will alter their behavior to prevent future ill health, take tests to establish if they have an illness, and take action to control illnesses (42). The concepts are presented in Figure 2.1.

1. **Perceived susceptibility**: how an individual perceives the likelihood of becoming ill
2. **Perceived severity**: the extent an individual sees a health condition as serious and likely to entail negative consequences
3. **Perceived benefits**: the belief that adopting new behaviours will bring about positive change
4. **Perceived barriers**: the environmental factors individuals believe might diminish their ability to effect healthy change
5. **Cues to action**: environmental factors which may promote/encourage the uptake of health-boosting behaviours
6. **Self-efficacy**: how confident an individual is that they will be able to alter their behavior.

Figure 2.1: Description of HBM concepts.

The model suggests that patients view towards their illness and the ways in which they could make positive changes to how they manage their illness impact the extent to which they perform positively (42) (see Figure 2.2). It is worth noting that a stimulus is also believed to be necessary to initiate self-management behaviours.

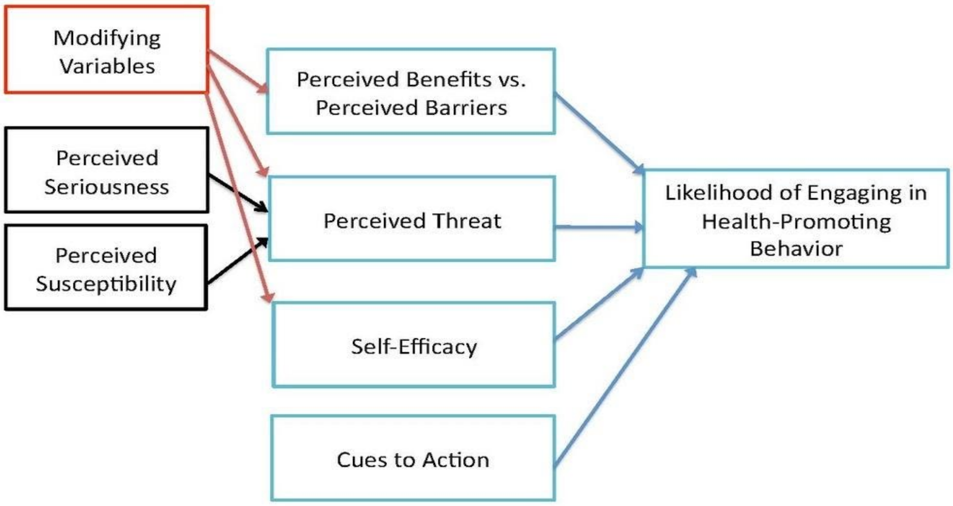


Figure 2.2 Health Belief Model (HBM), adopted from (43) under the terms of the GNU Free Documentation License, Version 1.2.

The HBM is an extensively utilised and well-tested explanatory model for anticipating self-management behaviours. For more than twenty years, patients' attitude towards their own chronic condition have been assessed using the HBM (44). The HBM has also been utilised to inform useful interventions regarding health-related behaviours by aiming at different parts of the model's main constructs. Recent studies have shown that the HBM has been used successfully in educational programs to improve self-management of chronic conditions including hypertension (44, 45). The HBM has several benefits: it can be implemented easily and it enables research into the creation of novel prevention methods in healthcare. It can also be used to predict a number of behaviours concerning health/treatment. More generally, the model gives an insight into the complexity of health behaviour (42).

However, Jones et al (47) suggests that there is no strong evidence to suggest that utilising the HBM to inform interventions is beneficial: a systematic review that assessed healthcare adherence in the prevention and management of chronic illnesses showed that there was no relationship between HBM-use and the success of interventions. There are two possible explanations for this. First, the HBM components outlined in this model are not clearly defined, which could undermine its applicability (48). Second, it has been found that most research based on the HBM has only integrated specific components of it, and has therefore not piloted the model in completion (44). The results of a meta-analysis of 18 studies intended to assess whether the HBM could predict behaviour longitudinally showed that 'Perceived benefits' and 'Perceived barriers' most consistently predicted self-management behavior, but some of its predictors are weak (44). A possible answer to this criticism is that susceptibility and severity indirectly influence behavior, meaning such behaviours are mediated by the perception of threat (49).

Although the HBM is widely used in self-management of chronic diseases and there is some evidence of its effectiveness, it neglects factors other than psychological factors; e.g. economic and environmental factors, both of which could impact health and self-management behaviour. It also does not assess the effect of social norms or peer opinion/influence.

2.4.2 The theory of reasoned action/planned behaviour (TBP)

The Theory of Planned Behaviour (TBP) was designed as part of an effort to strongly link behaviour and attitude (42). TBP is an elaboration of the theory of reasoned action (TRA), which was provided by Icek Aizen (42), to improve on the predictive power of the TRA by including perceived behavioural control.

According to the TBP, how a person behaves is decided by their intention to engage in a certain behaviour or enact that behavior (e.g. self-management activities of his/her condition). The theory emphasises that to engage in self-management of chronic diseases, it is necessary to alter attitudes toward self-management activities and behaviors. For example, by presenting likely outcomes of self-management activity and behaviour with a person to change how they perceive that self-management behaviour (e.g. consuming less salt meals and regularly taking medication will result in controlling BP level), or by discussing social norms with them, and thus reminding them of how their peers might perceive their activities. Lastly, addressing perceived behavioural control with them, to help them to feel more positively about their ability to self-manage their condition and effect behavioural change (42).

Unlike the TRA, the TBP addresses environmental and structural factors; it also considers why individuals choose behaviours. The most significant way in which TBP differs from the HBM is that it emphasises social norms in its assessments, viewing it as a vital variable in analysing and understanding behaviour. However, the theory also has flaws and limitations. For example, it does not account for the variables of fear or mood. These are potentially significant variables, and it is reasonable to think that a theory of behaviour that does not take them into account is going to be limited. It is also worth noting that behavioural intention does not consistently result in self-management activities and behaviours because other variables can affect these activities as well, such as economic or environmental factors (42).

It has been found that models such as the TRA/TBP are able to predict intention relatively accurately. However, it should be noted that medium-large alterations in intention sometimes solely brings about small-medium alterations in behaviour regarding self-management for people who have chronic diseases (50, 51). This gives weight to the view that behaviour alteration is a process involving two stages: the motivational stage (the upshot of which is an intention to act in a certain way), and the volitional stage (in which the behaviour occurs in the way it was planned) (52). People tend to move from the motivational stage to the volitional stage via an alteration of mindset, which is brought about by a consideration of the options available, as well as their probable outcomes. By contrast, the defining feature of the volitional stage is plan formulation (52). It is reasonable to argue that the TRA and the TBP offer effective models of the motivational stage to be applied to self-management of chronic disease; however, they do not aid the identification of factors that may be important to the volitional stage (53).

2.4.3 Social Cognitive Theory (SCT)

It is increasingly common for Social Cognitive Theory to be used to aid the self-management of chronic diseases. The social learning theory was developed by Bandura, in 1977, in response to studies in psychology which investigated the behaviour of children. The theory offered an explanation of how children's behaviour develops, for example how they alter their behaviour by modelling it on caregivers and peers and also through reinforcement (i.e. if the behaviour is praised or punished). This theory was refined by Bandura in 1986 and renamed the Social Cognitive Theory (SCT) (54).

The SCT indicates that interpersonal factors in one's environment are important for understanding and predicting an individual's self-management behaviours. The theory emphasises the importance of the interaction between the individual, their actions, their cognition, and their environment (55). For instance, SCT states that adopting a good self-management behaviour is most likely to occur in a social context where there is an ongoing interaction between a person's cognitions, actions and environment. This contrasts with other theories such as TTM and TBP, which focus on the individual's intentions (42).

The central concepts of SCT used to encourage self-management via intervention are: self-efficacy; outcome expectation; environmental determinants of behavior; observational learning; and self-regulation (42, 55). The term 'outcome expectation' refers to an individual's beliefs concerning how likely it is that certain outcomes will occur if they choose or perform a certain behaviour. So, for example, a patient with hypertension might expect to have sufficient control of their BP if they manage their diet properly. Having an outcome expectation is not sufficient to bring about changes in self-management behaviour, however. Bandura theorizes that the explanation for this is that some patients lack 'efficacy expectancy'. The definition of 'self-efficacy' is an individual's own estimation and judgments of their capacity to enact a particular self-management behaviour (55). Stated simply, self-efficacy is the person's level of confidence that they can complete a given action or task. In this way, efficacy expectancy enables the cultivation of new self-management practices. The notion of self-efficacy provides an explanation of why some patients with hypertension may fail to adopt self-management behaviours, e.g. eating healthily, even though they are aware of the positive outcomes of such behaviours.

Bandura (55) suggests that the extent to which a person is capable of learning from their experiences, and changing their behaviour in response to what they have experienced, is highly dependent on their self-efficacy. Self-efficacy varies from person to person. Many factors can impact a patient's likelihood of successfully self-managing their chronic diseases and their behavioural change, including: how difficult the new behaviour is (magnitude); the lessons they have, or have not, learned from previous experience (generality); and the degree of expectation of the patient (strength).

From this perspective we can expect the outcome of a patient's attempts to improve their self-efficacy to depend on the following: their ability to conceptualise their environment (symbolizing capability); their ability to know when they or others are likely to engage in certain behaviours (forethought capability); their ability to learn lessons from the experiences of others (vicarious capability); their ability to change how much they self-regulate, as well as their own standards (self-regulatory capability); and, finally, their ability to reflect upon their own situation (self-reflective capability) (55). Patients with high self-efficacy are far more likely to be successful in their attempts to self-manage their condition; those who have relatively little self-efficacy will find it more difficult to manage their condition. Therefore, a task for healthcare professionals is to help develop self-efficacy in patients.

It is argued in SCT that a patient's environment is an important factor in determining whether self-management will be successful. 'Observational learning' can be understood as the process of modelling one's behaviour on someone else's behaviour, e.g. a caregiver or a peer. It is important that one's environment offers incentives for developing new behaviour – these incentives might be rewards, but they might also be punishments. It is also beneficial if an individual's environment facilitates their changes in behaviour (42), e.g. by providing novel resources or structures that make them easier to perform.

In order to self-regulate an individual with hypertension will need to self-monitor BP, set goals for optimal level of BP, receive feedback on their measurement and performance, decide on rewards, self-instruct, and enlist social support. Bandura (55) indicated that there is some overlap between self-regulation and increasing self-efficacy with a view to self-managing chronic diseases.

Healthcare providers who work in the field of hypertension should ensure that they provide information effectively, i.e. in a way that enables individuals to alter their actions, and thus improve their health. Furthermore, they should consider the following observation (54, 55): how people feel, e.g. how motivated they feel, and how they behave, are usually a response to what they believe, rather than a response to facts. This insight can be used to guide approaches to patients with hypertension, as well as other diseases.

2.4.4 The trans-theoretical model (TTM)

The transtheoretical model (TTM) was created by Prochaska and DiClemente. It was designed to integrate different theories of self-management and behaviour change, for example TBP and self-efficacy, into one framework that is relatively simple to use (42). The TTM model is different to the theories mentioned above in that it is stage-based. The model includes 5 phases of readiness: pre-contemplation, contemplation, preparation, action and maintenance (42). The stage of pre-contemplation is when positive change to one's (self-management) behaviour is not being considered, and will not be for the next 6 months. The stage of contemplation is when a person is starting to consider changing their behaviour, but is not yet prepared to enact any behavioural change for the next six months. The preparation stage is when a person is both ready to change behaviour, and intending to do so within a month. The stage of action is when an individual has been carrying out a new behaviour for up to the past 6 months. The stage of maintenance is achieved when a new behaviour has been maintained for 6 months (42) (See Figure 2.3.)

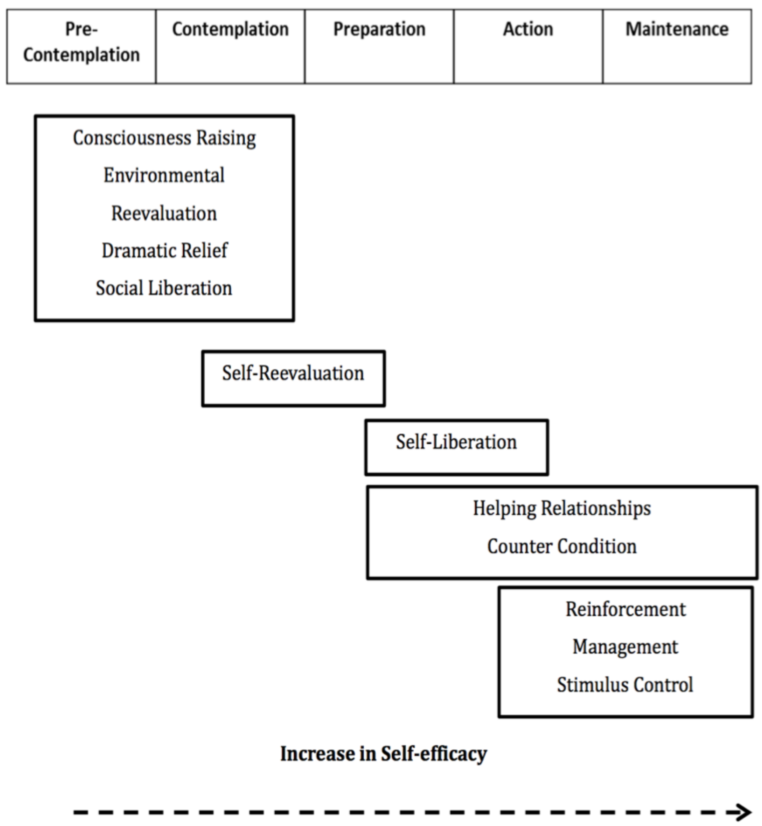


Figure 2.3 The Trans-Theoretical Model and Process of Change'. Adopted with permission from (42).

The model aims to encourage changes in patients' self-management activities. It seeks to achieve this by tailoring the intervention to the stage of readiness that the individuals are currently in, and their motivation to adopt new behaviours. It is common for the stage that the individual is in to change during the processes of self-management and behaviour modification. In between each state and associated set of activities, patients will change their environment and experience, with a view to modifying behaviours, beliefs, cognitions, feelings and relationships. According to this model it is vital that the readiness of each patient to move from one stage to another is assessed, to effectively support behaviour change (42).

Arafat et al (56) found through systematic reviews that interventions informed by TTM are effective in encouraging exercise and healthier diets as well as lowering HbA1c levels in people with diabetes. In the case of hypertension, the TTM has been successfully used in multiple self-management interventions: interventions based on the TTM resulted in reduction in BP, heart attack and stroke events amongst people with hypertension. TTM has also been found to enhance medication adherence amongst people with hypertension as well as patients receiving medication to lower lipids (57).

TTM is one of the most popular theoretical models in research on self-management and behaviour change. However, the model is not without criticism. Its predictive value is limited, because the activity change determinants and validated staging algorithms are not included in the TTM (58). Another criticism is that it is often only partly used; in a review of 24 uses of TTM in physical activity interventions, only 7 utilised TTM in its entirety (i.e. using all four of its dimensions: Self-efficacy, Stages of Change, Processes of Change and Decisional Balance) to enhance the intervention (59). It has been suggested by Hutchison et al (59) that elements of TTM must be used together to understand behaviour change and support self-management; a fuller intervention that does not reduce TTM to stages is suggested to be more beneficial.

It appears that using interventions informed by all constructs of TTM in supporting self-management and behaviour change could play a key role in improving engagement in self-management activities, changing behaviours and improving health outcomes. This is especially the case when all elements of TTM are used together to understand behaviour change. However, the emphasis that the TTM places on individual motivation is challenged by the idea that other social factors, including gender, age, wealth, and environment, also influence self-management behaviour. It is also unclear how long individuals need to be in each stage (60).

2.4.5 Technology Acceptance Model (TAM)

Various theories describe the process by which people either accept or reject new technologies and the factors that might contribute. One of the most commonly cited ones is the Technology Acceptance Model (TAM). The TAM devised by Davis on 1989 (128) is a model that seeks to explain individuals' intentions to use and accept a new technology. The model aims to describe what factors influence people's intentions to use new technologies. The model borrows from and adapts the TRA to deal explicitly with the use of technology, positing that individuals' perceptions of a technology's ease of use and usefulness together shape an individual's attitudes toward that technology, and their intention to use it. The TAM is widely used, and has been shown to be 'robust and valid' (129), at least within the setting for which it was designed, i.e. office technology uptake. There is also support for the model within healthcare technology (130).

The TAM has been greatly expanded since its original inception, resulting in TAM2 and TAM3, as well as strongly influencing the development of the Unified Theory of Acceptance and Use of Technology (UTAUT), which incorporates the TAM concepts of perceived usefulness and ease of use (renamed as performance and effort expectancy).

Chau and Hu (131) found that TAM had an explanatory power of 42% when investigating decisions by healthcare professionals to accept a new technology. As Abbasi et al (132) point out, the model fails to explain the remaining variance in behavioural intention. Since the TAM derives in part from the TRA, it is also subject to some of the same issues affecting this earlier model, including a lack of clarity in how developers of interventions should incorporate aspects of the model (133), and the criticism that intentions do not always lead to actions (134, 135).

2.4.6 The Mobile App Rating Scale (MARS)

The Mobile App Rating Scale (MARS) is the one of the most commonly used tools to assess/rate the quality of mHealth apps (136). It aims to provide a means to assess a range of app quality indicators relating to functionality, engagement, information quality, aesthetics and subjective app quality. These indicators were derived from previous research, but sought to bring them together under a single framework (136). The MARS offers a way to measure the quality of apps that is simple and easy to implement with minimal training, and provides reliable, objective and widely applicable assessments of the quality of apps (137). The model produces a mean score, as well as subscale scores for each indicator, which can be used to weigh up the pros and cons of a given app.

Although the MARS is easy to use, it has been criticised for being too generic, and omitting other important elements, such as users' prior attitudes, knowledge, and intentions, all of which may affect the development of a health behaviour (138). The MARS also omits other essential items, such as privacy and security (138, 136). It has also been found to produce low scores for apps that have been subjected to rigorous scientific testing, suggesting that it may be biased towards well-designed apps, even if there is no evidence base to support their effectiveness (139).

2.4.7 Discussion

The theories that have been discussed in this section are the most commonly used in behaviour change interventions for self-management. Each theory has its strengths and weaknesses. They share attributes with each other, but also have unique elements (42, 55).

The Medical Research Council (MRC) 2008 provides guidance concerning the development and evaluation of complex interventions. It is suggested that theory should be used at every stage of designing an intervention, and in its implementation and evaluation (61). Using theory helps researchers understand why and how an intervention is working (successful) or not working (unsuccessful). However, the MRC does not specify or advise on how to choose and apply theories; this is perhaps because using behaviour change theories is a complicated matter (42, 62). For example, there are many theories that are possibly applicable, all of which have component variables (Johnston and Dixon 2008). There is also no consensus on which theories are the most powerful to support the development of interventions, and some theories share concepts but use different terms (62-66). Lastly, authors often do not accurately describe how they have transformed theoretical insights into practical strategies, and therefore their work cannot be easily used to design interventions (66).
In addition to these issues arising from the theories themselves, the use of theories in interventions also has a number of associated problems. For example, often when a theory is cited in reports it is unclear in what way it informed the design of the intervention. Also, descriptions of interventions commonly lack sufficient detail for them to be replicated (62, 63, 65, 67-69).

There has been an effort in recent years to increase the parsimony of theories concerning self-management and behavioural change, with a view to bringing about a reduction in duplication, and therefore to render theories more useful with regards to developing interventions (67). Lippke and Ziegelmann (63) indicate that a theory-based intervention is important for successful self-management and behaviour change, but argue that focusing on one theory when designing an intervention may not lead to the development of the most effective interventions, whereas it is clearly necessary in the development of health-theory work. They therefore suggest that intervention developers should consider employing strategies drawn from behaviour change theories that may not be derived from a single theory (63).

Doshi et al. (70) suggest a way of breaking down theories into 20 strategies; what they offer can be considered a theoretical tool. It is known as the Behavioural Theory Content Survey (BTS). Broadly stated, this tool offers a way of analysing which theories contribute to interventions. BTS assesses elements of the four key models for behaviour change discussed before: (1) SCT, (2) TPB, (3) HBM, and (4) TTM. These strategies are present in more than one theory, which is why they are listed individually. Each strategy is given a mark out of 5, therefore the maximum score is 100. Despite being available since 2003, this tool is used comparatively little in the development of healthcare intervention.

More recently, Abraham and Michie (71) created a taxonomy of behaviour change techniques (BCTs). Examples of BCTs include: 'promote self-monitoring ' and 'prompt specific goal setting'. These BCTs are viewed as the ‘active ingredients’ in an intervention. The aim of Abraham and Michie’s work was to offer a detailed explanation of how interventions are designed and put into practice (delivered). They therefore attempted to understand what elements of an intervention are effective - which is a difficult task owing to the complexity of interventions. The elements that Abraham and Michie identify as effective include self-monitoring, promoting goal-setting and review, and providing feedback.

It would also be necessary to decide whether one BCT alone has an effect, as opposed to collections of BCTs combining to create an effect (71). This point notwithstanding, it appears possible to comprehend of how certain elements may be useful for some individuals in certain situations; this understanding could be utilised to develop new interventions (64).

A more comprehensive and extensive BCT Taxonomy v1 (BCTTv1) has been developed (2013). This taxonomy consists of 93 BCTs organised into 16 groups. It has been widely utilised to code interventions in behaviour change and self-management of chronic diseases (72-75). This taxonomy will be used in this project to identify BCTs of the apps’ content (69) (See Chapter 4). The process of linking BCTs with theory will increase understanding of their functional associations, and therefore how their underlying mechanisms are indicated by their outcomes (effects). This process will increase understanding of the most effective ways to use BCTs. However, Cane et al. (76) and Hobbes et al. (77) have suggested that attempting to group them with constructs or theories is impractical, due to the large amount of BCTs in this taxonomy, and theories that would need to be analysed.

An alternative approach is offered by Cane et al. (78) and also by Cane et al. (76) who argue BCTs can be grouped and linked with theoretical constructs, e.g. the Theoretical Domains Framework (TDF). The TDF was developed through interdisciplinary collaboration: 18 theoretical psychologists, 16 healthcare service researchers, and 30 psychologists worked together to create it. It was derived from 33 theories and is ‘an integrative framework of behaviour change theories’. Michie et al (79) argue that the TDF can be consistently grouped with the BCTs. In this project, the BCTs of the apps (see above) will be linked with 14 theoretical constructs (i.e. mechanisms of action), to investigate these mechanisms of action underpinning the apps, as presented in Chapter 4.

In 2011, a review reported that there are 19 frameworks that attempt to help intervention developers to create interventions that are informed by theories regarding self-management. The review also stated that none of the frameworks were linked to a specific theory and were not sufficiently coherent or complete (62). Responding to these assessments of existing frameworks, Michie et al (62) presented an alternative method for developing behaviour change interventions. Their alternative approach is informed by a ‘wheel structure' which incorporates aspects of the 19 studies, plus a main theory of behaviour (see Figure 2.4) In the centre of the wheel are a collection of sources of behaviour that can be focussed on and altered through an intervention. The section surrounding the centre details the different approaches relevant to developing interventions. In the outer section of the wheel various 'policy categories' are presented. Policy categories should be understood as ways that interventions could be implemented (62). Michie et al (62) created the 'Behaviour Change Wheel' to help identify the smallest amount of components that can be used to increase understanding of performance of a 'target behaviour', which would then be included in a framework for developing and designing interventions. This was done so that developers could make more informed decisions, based on an understanding of all the available options.

The 'Capability, Opportunity, Motivation and Behaviour' ('COM-B') model is the central model of behaviour (62, 80). Six variables are discussed in this model: 1) psychological capability, 2) physical capability, 3) automatic motivation, 4) reflective motivation, 5) social opportunity, and 6) physical opportunity (62, 80). It is possible to be more specific about the six variables listed above by linking COM-B to TDF, as presented in yellow in Figure 2.4 (78,79). Both the sources of self-management behaviour and the needs (e.g. Opportunity) can be established, targeted, and altered.

The standard use of the Behaviour Change Wheel is to work from the centre (sources of behaviour) to the outer circle, e.g. intervention functions. This process can then be used to link to potential BCTs. In the case of this research, BCTs are identified first, and then linked to TDF mechanisms of action, to understand the theoretical underpinnings of the apps.

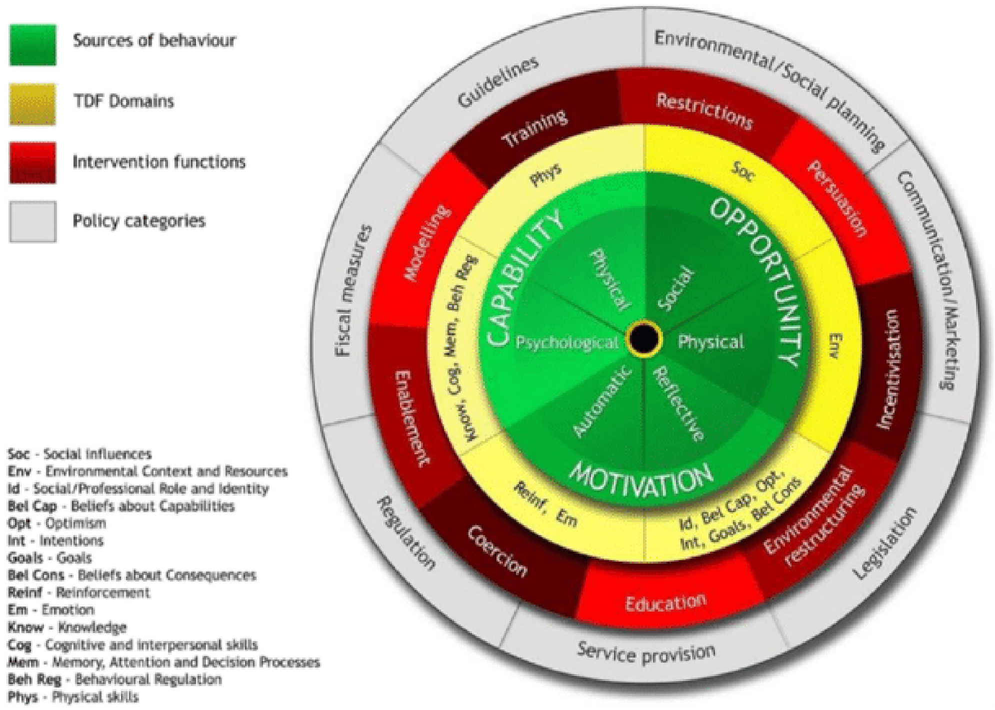


Figure2.4 Behaviour Change Wheel (BCW)' and 'TDF domains'. Adopted with permission from (62, 80).

2.5 Mobile Health (mHealth)

E-health is a concept dating back to 1999 that explains the role of electronic processes, technology and communication in supporting healthcare. It involves a group of systems or services central to healthcare information technology (81). The emergence of mHealth, which is a sub-type of eHealth, was brought about by two factors: 1) the significant growth of mobile technologies and 2) improvements in mobile applications ('apps') that are designed to address medical problems (81).

mHealth can be defined as the implementation and use of a digital health intervention, typically utilising wireless devices, e.g. mobile phones and tablets, to provide medical services and information (82, 83). mHealth encompasses the utilization of these devices in the collection of patient health information, for example by checking patients' vital signs in real-time, providing healthcare information to practitioners, patients and researchers, and delivering healthcare via mobile telemedicine (82, 84). It has been revealed that the number of mobile phone users (subscriptions) now is around five billion and commercial wireless signals were used by around 85% of people in the world (127). The penetration and growth of mobile phone networks in many parts of the developing world allows increasingly high data transmission speeds along with cheaper and more powerful handsets that can transform access to healthcare information and services, and their management and their delivery.

The popularity of mHealth has risen as a beneficial method in enhancing peoples' health outcomes (85-87). Utilising mHealth to manage and control chronic disease has been extensively researched. These studies have used mobile phones to improve health outcomes by voice or short message services (SMS). Systematic reviews assessing mobile phone text and voice message interventions to offer healthcare and promote disease management found significant improvements in healthcare outcomes and care processes for providers and patients (85, 88). Several RCTs have also examined the use of mobile phone calls or text-messages in supporting the self-management of hypertension and have found significant improvements in healthcare outcomes including SBP and DBP (89, 90). However, the utility of mobile phones in self-management is largely restricted to communication between the patient and healthcare professionals through SMS or phone calls, which do not offer much in terms of actual participation of the patient in managing their health (91). Mobile phones offer fewer opportunities for patient participation in health management compared to smartphones. The scenario has shifted to more active involvement of the patients themselves with the advent of affordable smartphones in the market (91, 92).

The prevalence of smartphone technology is continuing to increase around the world (82). In 2020, 6.95 billion people were estimated to be using smartphones (93). This number was projected to increase to be 7.41 billion by 2024. These smartphone platforms are becoming more computationally powerful, user-friendly, and readily available. At the same time, increasingly complex mobile apps have been developed, which offer greater portability. Corresponding with the rapid increase in the use smartphones has been a significant increase in health apps, more than 100,000 of which are used, by millions of people (73, 82). A survey also showed that more than half (52%) of smartphone users make use of at least on mHealth app, and this percentage is anticipated to increase in the next years (92). Additionally, the number of health apps downloaded has rapidly increased: in 2013 it was 1.7 billion, and in 2016 it was 3.2 billion (94). This would suggest people's willingness and tendency to manage their health through apps. Since 2008, these apps have been readily available via distribution platforms, known as 'app stores' (84). It is possible for users to install these applications to run on smartphones and modern tablets.

It has been suggested in studies that using apps is an effective solution for managing and controlling chronic diseases and supporting self-management (95). Apps offer simple and new strategies and solutions to record, store and present data, and so on (96, 97). Birkhoff and Smeltzer (98) suggest that smartphone apps may improve patient care by allowing them to feel empowered and more in control of chronic conditions. Other studies have suggested that apps are more accessible and provide better visualisations for people compared with older technologies such as the web, which may lead to better understanding among patients (99-101). Many participants in these studies viewed mHealth apps as useful tools to improve their knowledge and management of their conditions, but they also revealed some important issues with these apps, such as the desire for designs to be more tailored to individual needs, prohibitive costs, and concerns regarding effectiveness and privacy and security (102).

It has been argued that smartphone interventions based on apps have good potential as a tool for controlling hypertension, due to their easy inputting of data, often automatically via wireless devices, and the ease with which they can be integrated with existing technology, and provide reminders to patients, e.g. to take medication (92, 96). A review of available hypertension apps on the two most frequently used smartphone platforms revealed that there are many available apps for patients with hypertension and significant numbers of patients tend to use them (103). The majority of these apps are aimed at supporting sufferers of hypertension in their self-management by making available tailored information, self-monitoring activities, feedback, and reminders (103). Several studies in self-management of hypertension advocate using apps as an optimal and accessible solution in managing hypertension through engaging patients in managing their own health (91, 92), and several studies have found that apps have the potential to be effective (104-106).

However, despite the promise that mHealth apps appear to offer, there are concerns regarding the quality of apps that are available (107-109). The app market is not regulated in the way that medical devices are, for instance. App developers are usually not experts on health, nor are experts typically involved in app development (110). Few researchers release their apps commercially due to the prohibitive resources required, including the costs of programming, design expertise and the requirement to provide ongoing support (110, 111). It is therefore important to develop ways to distinguish the effectiveness of commercially available apps, the adequacy of their security and privacy measures, as well as their usability and acceptance among end users.

2.5.1 mHealth in Saudi Arabia

The mobile market in developing states has been recognised as the most rapidly growing economic sector, with 5.3 billion mobile users worldwide in 2010, 70% of whom were from developing countries (81, 112). Saudi Arabia has experienced a remarkable expansion in the area of technology and communication. According to Albabtain et al (112), Saudi Arabia is recognised to be one of the leading mobile markets in the Middle East. There were an estimated 3.19 million smartphone users in Saudi Arabia in 2021, with this number estimated to rise to 36.2 million by 2025 (140). Saudi Arabia has the highest mobile penetration rate, with approximately 186%, compared with the developed nations average of 116% and the developing nations average of 73% (112). mHealth seems to be an increasingly important part of Saudi Arabia's healthcare system; a recent survey measuring the usage and prevalence of smartphone applications among patients indicated that 92% of the participants (Saudi patients with mental health issues) used mobile apps to control and manage their health (113). Moreover, the MOH in Saudi Arabia has smartphone health applications (e.g. for booking appointments) that are available for Saudi people on the main smartphone platforms (114). The importance of mHealth to the Saudi healthcare system seems to have rapidly increased further, during Covid-19, when many Saudi health apps were lunched to support patients in tracking coronavirus exposure and infection, and to provide health and quarantine advice to Saudi residents (114).

It appears that Saudi people are already experienced with smartphones and health apps, but there is no data substantiating their usage in managing hypertension. According to Albabtain et al (112) Aljuraiban (115) and Jusoh (94), in Saudi Arabia, mHealth apps can be the most available, accessible and useful way to combat and prevent health problems and to manage chronic diseases. This would suggest that healthcare apps are likely to be an effective and helpful tool to facilitate the self-management of hypertension in Saudi Arabia.

2.5.2 Saudi Arabia Context

Saudi Arabia is among the biggest nations in the Middle East, situated on the Arabian Peninsula. Its predominant industry is oil and gas extraction. Since the discovery of crude oil in Saudi Arabia in 1938, profits from its extraction have facilitated rapid economic development and social change (141, 142), with knock-on impacts on the lives and lifestyles of its citizens (141, 142). This has included an increase in lifestyle diseases, including hypertension, which is estimated to affect 27.7% of the adult Saudi population (7, 8). The prevalence of hypertension in Saudi Arabia is particularly high and is the main risk factor for death (7-9). There has also been a significant increase in the use of smartphones and health apps in this context (112, 113, 115).

Hypertension and other chronic diseases present issues for the MOH (8). Hypertension sufferers are generally treated within primary-care centers and clinics at hospitals. However, as with other conditions requiring specialist treatment, they are commonly referred to specialist treatment facilities or surgical centres, in this case for hypertension and other cardiovascular disorders (143).

Islam is the main and official religion of Saudi Arabia, and Saudi culture is profoundly shaped by these beliefs. Islam encourages certain healthy lifestyle practices, such as eating in moderation, taking regular exercise, and refraining from consuming alcohol, drugs and tobacco (144). However, in practice many unhealthy behaviours are common among Saudis, including poor diet, resulting in obesity, as well as smoking, and living relatively sedentary lifestyles (145). These lifestyle factors have led to a rapid increase of hypertension, and a need to promote patients' engagement in self-managing their disease to avoid health complications (23,41, 145).

2.5.2 Why use smartphone apps for self-managing of hypertension in Saudi Arabia?

The problems associated with self-management of hypertension in Saudi Arabia are characterised by lack of engagement with the condition, for example: (1) poor adherence to prescribed medication (116-118), (2) failing to adopt a healthy lifestyle (41), (3) lacking awareness and/or understanding of the condition and its risk factors (119-121). Smartphone apps have the potential to mitigate all of these problems. As outlined above, it has been shown that smartphone apps, through offering goal setting that requires negotiation in a partnership between patients and their health professionals, feedback about BP measurements to promote self-management, reminders, e.g. to take medication and measure BP, and information about the condition to promote self-management, can support self-management and help to control BP. These apps therefore have the potential to increase patients' awareness of their condition, and to engage them in self-regulation of their condition, thereby increasing their self-confidence and allowing them to participate with their physician in decision-making (92, 122, 12).

2.6 Significance of research

Despite the increasing prevalence of hypertension globally, and the increase in commercially available self-management apps, there was previously little to no evidence as to the potential effectiveness, usability and security and privacy of these apps. Since the shortcomings in these apps might lead to significant concerns as to their potential benefit, and may even present a risk to users (73), there was an urgent need to investigate the effectiveness of these apps, the levels of security and privacy that they offered, and their usability and acceptance among users. This research begins to address this lack of evidence.

As outlined above, hypertension is the main risk factor for death in Saudi Arabia. Different cultures are likely to have their own specific needs and expectations surrounding the use of mHealth apps (102, 125), so it is essential that research identifies the most suitable apps for a particular cultural context, and examines their potential usability within that context. Despite these factors, no previous studies have explored the potential of hypertension self-management apps in the context of Saudi Arabia, or the other Gulf States (126). This research fills this gap in existing scholarship by reviewing available apps for the self-management of hypertension, identifying the most suitable apps for the Saudi context, and assessing the usability and acceptance of the most suitable app among Saudi patients.

2.7 Aims and Objectives

The overall aim of this PhD research was to review available apps for the self-management of hypertension based on their effectiveness, privacy and security, and their theoretical underpinning, to identify the most suitable apps for use in the Saudi context, and to evaluate the usability and acceptance of the most suitable app among Saudi patients. To achieve this aim, the objectives are as follows:

1. To synthesise and appraise the available evidence about app usability, end-user satisfaction, and the effectiveness of apps in terms of lowering BP; to identify which functionalities are most effective (Study 1: Systematic review).

2. To identify and describe available apps that can support the self-management of hypertension and identify their functionalities, levels of privacy and security, and theoretical backgrounds. (Study 2: App stores review)

3. To determine the most suitable hypertension self-management apps that meet the criteria of effectiveness, theoretical backgrounds, and privacy and security (Study 3 Phase 1).

4. To identify the most suitable app for the Saudi context by exploring Saudi patients' and doctors' experiences in self-management of hypertension, and their attitudes towards the app(s) identified in the systematic approach above (Study 3 Phase 2).

5. To translate the most suitable app into the Arabic language through co-operation with the selected app's developers.

6. To assess the usability and acceptance of the selected app in real life and controlled settings. (Study 4)

2.8 Research questions

Q1. What evidence is there in the literature about the effectiveness of apps to lower BP, their usability and user satisfaction and what are the characteristics/functionalities of effective apps? (Study 1: systematic review)

Q2. What apps are available that support the self-management of hypertension and what are their characteristics and theoretical backgrounds? (Study 2: App stores review)

Q3. To what extent do these available apps meet the criteria of effectiveness, theoretical underpinning, and privacy and security to support the self-management of hypertension? (Study 3 Phase 1)

Q4. Of those apps identified as most suitable, which are the most suitable for use within the Saudi context? (Study3 phase 2)

- What are people with hypertension and doctors’ attitudes towards, and their acceptance of these apps in the self-management of hypertension?

Q5. How usable is the most suitable app and to what extent do users accept it? (Study 4)

2.9 References

1. Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL Jr et al. National Heart, Lung, and Blood Institute Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure; National High Blood Pressure Education Program Coordinating Committee. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. JAMA. 2003 May 21;289(19):2560-72. doi: 10.1001/jama.289.19.2560
2. Jones NR, McCormack T, Constanti M, McManus RJ. Diagnosis and management of hypertension in adults: NICE guideline update 2019. Br J Gen Pract. 2020 Jan [cited Jan 2018];70(691):90-91. doi: 10.3399/bjgp20X708053.
3. Saudi Hypertension Guidelines 2018. SHAMS. Saudi Hypertension Management Society (SHAMS); Feb 2018. 4th edition. Available from: https://shms.wildapricot.org/page-1561572/5727953
4. Raised blood pressure. WHO; 2015. [Cited Aug 2018]. Available from: http://www.who.int/gho/ncd/risk_factors/blood_pressure_prevalence_text/en/
5. Zhou B, Di Cesare M, Danaei G, Cowan, Melanie J et al. Worldwide trends in blood pressure from 1975 to 2015: a pooled analysis of 1479 population-based measurement studies with 19·1 million participants. The Lancet. 2017 [cited March 2019]; 389(10064), 37–55. doi: http://dx.doi.org/10.1016/S0140-6736(16)31919-5
6. Joffres M, Falaschetti E, Gillespie C, Robitaille C, Loustalot F, Poulter N, McAlister FA, Johansen H, Baclic O, Campbell N. Hypertension prevalence, awareness, treatment and control in national surveys from England, the USA and Canada, and correlation with stroke and ischaemic heart disease mortality: a cross-sectional study. BMJ Open. 2013 Aug [cited 2018 Aug];3(8): e003423. doi: 10.1136/bmjopen-2013-003423.
7. Al-Nozha MM, Abdullah M, Arafah MR, Khalil MZ, Khan NB, Al-Mazrou YY, et al. Hypertension in Saudi Arabia. Saudi Med J. 2007 Jan [cited Aug 2018];28(1):77-84. Available from: https://pubmed.ncbi.nlm.nih.gov/17206295/
8. El Bcheraoui C, Memish ZA, Tuffaha M, Daoud F, Robinson M, Jaber S, Mikhitarian S, Al Saeedi M, AlMazroa MA, Mokdad AH, Al Rabeeah AA. Hypertension and its associated risk factors in the kingdom of saudi arabia, 2013: a national survey. Int J Hypertens. 2014 [cited Jan 2019] ;2014:564679. doi: 10.1155/2014/564679.
9. Health Days 2017 - World Hypertension Day. Riyadh: Ministry of Health (MHO); 2017. [cited 2018 Jan]. Available from: https://www.moh.gov.sa/en/HealthAwareness/healthDay/2017/Pages/HealthDay-2017-05-17.aspx
10. Saeed AA, Al-Hamdan NA, Bahnassy AA, Abdalla AM, Abbas MAF. Abuzaid LZ. Prevalence, Awareness, Treatment, and Control of Hypertension among Saudi Adult Population: A National Survey. International Journal of Hypertension. 2011 [cited 2020 Aug]; (2011): 174135-8. doi: https://doi.org/10.4061/2011/174135
11. Al-Tuwijri AA, Al-Rukban MO. Hypertension control and co-morbidities in primary health care centers in Riyadh. Ann Saudi Med. 2006 Jul-Aug [cited 2019 Jul];26(4):266-71. doi: 10.5144/0256-4947.2006.266.
12. Kannel WB. Risk stratification in hypertension: new insights from the Framingham Study. Am J Hypertens. 2000 Jan [cited March 2018];13(1 Pt 2):3S-10S. doi: 10.1016/s0895-7061(99)00252-6.
13. Lovic D, Narayan P, Pittaras A, Faselis C, Doumas M, Kokkinos P. Left Ventricular Hypertrophy in Athletes and Hypertensive Patients. The Journal of Clinical Hypertension (Greenwich, Conn.). 2017 Mar [Cited 2020 Mar] 19(4): 413-17.
14. Verdecchia P, Staessen JA, Angeli F, de Simone G, Achilli A, Ganau A, et al. Usual versus tight control of systolic blood pressure in non-diabetic patients with hypertension (Cardio-Sis): an open-label

randomised trial. Lancet. 2009 Aug [cited 2018 Mar];374(9689):525-33. doi: 10.1016/S0140-6736(09)61340-4.

15. Collins R, Peto R, MacMahon S, Hebert P, Fiebach NH, Eberlein KA, et al. Blood pressure, stroke, and coronary heart disease. Part 2, Short-term reductions in blood pressure: overview of randomised drug trials in their epidemiological context. Lancet. 1990 Apr [cited 2018 Mar];335(8693):827-38. doi: 10.1016/0140-6736(90)90944-z.

16. Lewington S, Clarke R, Qizilbash N, Peto R, Collins R; Prospective Studies Collaboration. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. Lancet. 2002 Dec [cited 2018 Mar];360(9349):1903-13. doi: 10.1016/s0140-6736(02)11911-8.

17. Ettehad D, Emdin CA, Kiran A, Anderson SG, Callender T, Emberson J, et al. Blood pressure lowering for prevention of cardiovascular disease and death: a systematic review and meta-analysis. Lancet. 2016 Mar [cited 2018 Mar];387(10022):957-967. doi: 10.1016/S0140-6736(15)01225-8.

18. Johansson BB. Hypertension mechanisms causing stroke. Clin Exp Pharmacol Physiol. 1999 Jul [cited 2018 Mar];26(7):563-5. doi: 10.1046/j.1440-1681.1999.03081.x.

19. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). United State: NIDDK; 2020 Mar. Available from: https://www.niddk.nih.gov/health-information/kidney-disease/high-blood-pressure

20. Balduino Ade F, Mantovani Mde F, Lacerda MR, Meier MJ. Análise conceitual de autogestão do indivíduo hipertenso [Conceptual self-management analysis of hypertensive individuals]. Rev Gaucha Enferm. 2013 Dec [cited 2018 Mar];34(4):37-44. Portuguese. doi: 10.1590/s1983-14472013000400005. PMID: 25080698.

21. Grady PA, Gough LL. Self-management: a comprehensive approach to management of chronic conditions. Am J Public Health. 2014 Aug [cited 2018 Feb];104(8):e25-31. doi: 10.2105/AJPH.2014.302041.

22. Lorig KR, Holman H. Self-management education: history, definition, outcomes, and mechanisms. Ann Behav Med. 2003 Aug [cited 2018 Feb];26(1):1-7. doi: 10.1207/S15324796ABM2601_01.

23. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Educ Couns. 2002 Oct-Nov [cited 2018 Feb];48(2):177-87. doi: 10.1016/s0738-3991(02)00032-0.

24. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. JAMA. 2002 Nov 20;288(19):2469-75. doi: 10.1001/jama.288.19.2469.

25. Schulman-Green D, Jaser S, Martin F, Alonzo A, Grey M, McCorkle R, Redeker NS, Reynolds N, Whittemore R. Processes of self-management in chronic illness. J Nurs Scholarsh. 2012 Jun [cited 2018 Feb];44(2):136-44. doi: 10.1111/j.1547-5069.2012.01444.x.

26. Richardson J, Loyola-Sanchez A, Sinclair S, Harris J, Letts L, MacIntyre NJ, Wilkins S, Burgos-Martinez G, Wishart L, McBay C, Martin Ginis K. Self-management interventions for chronic disease: a systematic scoping review. Clin Rehabil. 2014 Nov [cited 2018 Feb];28(11):1067-77. doi: 10.1177/0269215514532478.

27. Embrey N. Self-management education in multiple sclerosis services. Nurs Times. 2005 Aug [cited 2018 Mar];101(34):34-6.

28. Corrie C, Finch A. Expert patients. London, Reform. 2015 Feb [cited 2018 Mar]. Available from: https://www.basw.co.uk/system/files/resources/basw_114654-4_0.pdf

29. Whitehead L, Jacob E, Towell A, Abu-Qamar M, Cole-Heath A. The role of the family in supporting the self-management of chronic conditions: A qualitative systematic review. J Clin Nurs. 2018 Jan;27(1-2):22-30. doi: 10.1111/jocn.13775.

30. Bosworth HB, Powers BJ, Oddone EZ. Patient self-management support: novel strategies in

hypertension and heart disease. Cardiol Clin. 2010 pcited 2018 Mar];28(4):655-663. doi:10.1016/j.ccl.2010.07.003

31. National Clinical Guideline Centre (UK). Hypertension: The Clinical Management of Primary Hypertension in Adults: Update of Clinical Guidelines 18 and 34 [Online]. London: Royal College of Physicians (UK); 2011 Aug [cited 2018 Mar]. Available from https://pubmed.ncbi.nlm.nih.gov/22855971/

32. Dye CJ, Williams JE, Evatt JH. Improving hypertension self-management with community health coaches. Health Promot Pract. 2015 Mar;16(2):271-81. doi: 10.1177/1524839914533797. Epub 2014 May 16. PMID: 24837989.

33. Bosworth HB, Olsen MK, Grubber JM, et al. Two self-management interventions to improve hypertension control: a randomized trial. Ann Intern Med. 2009 [cited 2018 Mar];151(10):687-695. doi:10.7326/0003-4819-151-10-200911170-00148

34. McKinstry B, Hanley J, Heaney D, McCloughan L, Elton R, Webb DJ. Impact on hypertension control of a patient-held guideline: a randomised controlled trial. Br J Gen Pract. 2006 Nov [cited 2018 Mar];56(532):842-847.

35. Flynn SJ, Ameling JM, Hill-Briggs F, Wolff JL, Bone LR, Levine DM et al. Facilitators and barriers to hypertension self-management in urban African Americans: perspectives of patients and family members. Patient Prefer Adherence. 2013 Aug pcited 2018 Mar];7:741-9. doi: 10.2147/PPA.S46517.

36. Khezri, R Ravanipour M, Jahanpour F, Barekat M, Hosseini S. Empowerment in the self-management of hypertension: challenges from the perspective of Iranian elderly patients. Journal of Research & Health. 2017 Dec [cited 2018 Mar]; 7(1), 603–613.

37. Shahaj O, Denneny D, Schwappach A, Pearce G, Epiphaniou E, Parke HL et al. Supporting self-management for people with hypertension: a meta-review of quantitative and qualitative systematic reviews. J Hypertens. 2019 Feb [cited 2019 Jan];37(2):264-279. doi: 10.1097/HJH.0000000000001867.

38. Aldiab A, Shubair MM, Al-Zahrani JM, Aldossari KK, Al-Ghamdi S, Househ M, et al.. Prevalence of hypertension and prehypertension and its associated cardioembolic risk factors; a population based cross-sectional study in Alkharj, Saudi Arabia. BMC Public Health. 2018 Nov [cited 2019 Jan];18(1):1327. doi: 10.1186/s12889-018-6216-9.

39. Moradi-Lakeh M, El Bcheraoui C, Tuffaha M, Daoud F, Al Saeedi M, Basulaiman M, et al. The health of Saudi youths: current challenges and future opportunities. BMC Fam Pract. 2016 Mar [cited 2019 Jan];17:26. doi: 10.1186/s12875-016-0425-z.

40. Khayyat SM, Khayyat SM, Hyat Alhazmi RS, Mohamed MM, Abdul Hadi M. Predictors of Medication Adherence and Blood Pressure Control among Saudi Hypertensive Patients Attending Primary Care Clinics: A Cross-Sectional Study. PLoS One. 2017 Jan [cited 2018 Feb];12(1):e0171255. doi: 10.1371/journal.pone.0171255.

41. AlHadlaq RK, Swarelzahab MM, AlSaad SZ, AlHadlaq AK, Almasari SM, Alsuwayt SS, Alomari NA. Factors affecting self-management of hypertensive patients attending family medicine clinics in Riyadh, Saudi Arabia. J Family Med Prim Care. 2019 Dec [cited 2020 Jan];8(12):4003-4009. doi: 0.4103/jfmpc.jfmpc_752_19.

42. Glanz K, Rimer BK, Viswanath K. Health Behavior and Health Education: Theory, Research and Practice (4th Edition). San Francisco, CA, USA: John Wiley & Sons, Inc; 2008

43. Laurenhan. The Health Belief Model. [digital image]; 2013 Nov. Available from: https://en.wikipedia.org/wiki/File:The_Health_Belief_Model.pdf

44. Carpenter CJ. A meta-analysis of the effectiveness of health belief model variables in predicting behavior. Health Commun. 2010 Dec [cited 2018 Mar];25(8):661-9. doi: 10.1080/10410236.2010.521906.

45. Jalilian F, Motlagh FZ, Solhi M, Gharibnavaz H. Effectiveness of self-management promotion

educational program among diabetic patients based on health belief model. J Educ Health Promot. 2014 Feb [cited 2018 Mar]; 3:14. doi: 10.4103/2277-9531.127580

46. Shabibi P, Zavareh MSA, Sayehmiri K, Qorbani M, Safari O, Rastegarimehr B, Mansourian M. Effect of educational intervention based on the Health Belief Model on promoting self-care behaviors of type-2 diabetes patients. Electron Physician. 2017 Dec [cited 2018 Mar];9(12):5960-5968. doi: 10.19082/5960.

47. Jones CJ, Smith H, Llewellyn C. Evaluating the effectiveness of health belief model interventions in improving adherence: a systematic review. Health Psychol Rev. 2014 [cited 2018 Mar];8(3):253-69. doi: 10.1080/17437199.2013.802623.

48. Wang Y, Fadhil A, Lange J, Reiterer H. Towards a Holistic Approach to Designing Theory-based Mobile Health Interventions. Cornell University: New York; 2017.

49. Janz NK, Becker MH. The Health Belief Model: a decade later. Health Educ Q. 1984 Spring;11(1):1-47. doi: 10.1177/109019818401100101.

50. Webb TL, Sheeran P. Does changing behavioral intentions engender behavior change? A meta-analysis of the experimental evidence. Psychol Bull. 2006 Mar;132(2):249-68. doi: 10.1037/0033-2909.132.2.249.

51. Richardson J, Loyola-Sanchez A, Sinclair S, Harris J, Letts L, MacIntyre NJ, Wilkins S, Burgos-Martinez G, Wishart L, McBay C, Martin Ginis K. Self-management interventions for chronic disease: a systematic scoping review. Clin Rehabil. 2014 Nov [cited 2018 Mar];28(11):1067-77. doi: 10.1177/0269215514532478.

52. Heckhausen, H., Gollwitzer, P.M. Thought contents and cognitive functioning in motivational versus volitional states of mind. Motiv Emot. 1987 Jun [cited 2018 Mar]; 11, 101–120 (1987).doi: https://doi.org/10.1007/BF00992338

53. Michie S, Johnston M, Francis J, Hardeman W, Eccles M. From Theory to Intervention: Mapping Theoretically Derived Behavioural Determinants to Behaviour Change Techniques. Applied Psychology 2008 Jul [cited 2018 Mar];57(4): 660-80. doi: https://doi.org/10.1111/j.1464-0597.2008.00341.x

54. Bandura A. Social foundations of thought and action: A social cognitive theory. Englewood Cliffs, NJ: Prentice-Hall; 1986

55. Bandura A. Health promotion by social cognitive means. Health Educ Behav. 2004 Apr [cited 2018 Mar];31(2):143-64. doi: 10.1177/1090198104263660.

56. Arafat Y, Mohamed Ibrahim MI, Awaisu, A. Using the Transtheoretical Model to Enhance Self-Management Activities in Type 2 Diabetic Patients: A Systematic Review. Value in Health. 2016 May [cited 2018 Mar];18(7), A617. doi: https://doi.org/10.1016/j.jval.2015.09.2152

57. Johnson SS, Driskell MM, Johnson JL, Prochaska JM, Zwick W, Prochaska JO. Efficacy of a transtheoretical model-based expert system for antihypertensive adherence. Dis Manag. 2006 Oct;9(5):291-301. doi: 10.1089/dis.2006.9.291.

58. Adams J, White M. Why don't stage-based activity promotion interventions work? Health Educ Res. 2005 Apr [cited 2018 Mar];20(2):237-43. doi: 10.1093/her/cyg105.

59. Hutchison AJ, Breckon JD, Johnston LH. Physical activity behavior change interventions based on the transtheoretical model: a systematic review. Health Educ Behav. 2009 Oct [cited 2018 Mar];36(5):829-45. doi: 10.1177/1090198108318491.

60. West R. Time for a change: putting the Transtheoretical (Stages of Change) Model to rest. Addiction. 2005 Aug;100(8):1036-9. doi: 10.1111/j.1360-0443.2005.01139.x.

61. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M; Medical Research Council Guidance. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008 Sep [cited 2018 Mar];337:a1655. doi: 10.1136/bmj.a1655.

62. Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci. 2011 Apr 23; 6:42. doi: 10.1186/1748-5908-6-42.

63. Lippke S, Zielgelmann JP. Theory-based health behavior change: Developing, testing, and applying theories for evidence-based interventions. Applied Psychology: An international review. 2008 Jul [cited 2018 Jul]; 57(4):698 - 716. Available from: doi: 10.1111/j.1464- 0597.2008.00339.

64. Michie S, Johnston M, Francis J, Hardeman W, Eccles M. From Theory to Intervention: Mapping Theoretically Derived Behavioural Determinants to Behaviour Change Techniques. Applied Psychology. 2008 [cited 2018 Jul]; 57(4):660-668. doi: 10.1111/j.1464-0597.2008.00341.x

65. Michie S, Carey RN, Johnston M, Rothman AJ, de Bruin M, Kelly MP, Connell LE. From Theory-Inspired to Theory-Based Interventions: A Protocol for Developing and Testing a Methodology for Linking Behaviour Change Techniques to Theoretical Mechanisms of Action. Ann Behav Med. 2018 May [cited Jul 2018];52(6):501-512. doi: 10.1007/s12160-016-9816-6.

66. Hardeman, W, Johnston M, Johnston D, Bonetti D, Wareham N, Kinmonth, AL. Application of the Theory of Planned Behaviour in Behaviour Change Interventions: A Systematic Review. Psychology & Health. 2002 [cited 2018 Mar]; 17(2), 123-158.

67. Hagger MS. Theoretical integration in health psychology: Unifying ideas and complementary explanations. British Journal of Health Psychology. 2009 May [cited 2018 Mar];14(2): 189-194. doi: 10.1348/135910708x397034

68. Michie S, Fixsen D, Grimshaw JM, Eccles, MP. Specifying and reporting complex behaviour change interventions: the need for a scientific method. Implementation Sci. 2009 [cited 2018 Mar];4, 40. doi: https://doi.org/10.1186/1748-5908-4-40

69. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W et al. The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. Annals of Behavioral Medicine. 2013 Aug [cited 2018 Mar];1-15. doi: 10.1007/s12160-013-9486-6

70. Doshi A, Patrick K, Sallis JF, Calfas K. Evaluation of physical activity web sites for use of behavior change theories. Ann Behav Med. 2003 Spring;25(2):105-11. doi: 10.1207/S15324796ABM2502_06.

71. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. Health Psychol. 2008 May [cited 2018 Apr];27(3):379-87. doi: 10.1037/0278-6133.27.3.379.

72. McBain H, Shipley M, Newman S. The impact of self-monitoring in chronic illness on healthcare utilisation: a systematic review of reviews. BMC Health Serv Res. 2015 Dec [cited 2018 Mar] 18;15:565. doi: 10.1186/s12913-015-1221-5. PMID: 26684011;

73. Edwards EA, Lumsden J, Rivas C, Steed L, Edwards LA, Thiyagarajan A et al. Gamification for health promotion: systematic review of behaviour change techniques in smartphone apps. BMJ Open. 2016 Oct [cited 2018 Mar];6(10):e012447. doi: 10.1136/bmjopen-2016-012447.

74. Heron N, Kee F, Donnelly M, Cardwell C, Tully MA, Cupples ME. Behaviour change techniques in home-based cardiac rehabilitation: a systematic review. Br J Gen Pract. 2016 Oct [cited 2018 Jul];66(651):e747-57. doi: 10.3399/bjgp16X686617.

75. Morrissey EC, Corbett TK, Walsh JC, Molloy GJ. Behavior Change Techniques in Apps for Medication Adherence: A Content Analysis. Am J Prev Med. 2016 May;50(5):e143-e146. doi: 10.1016/j.amepre.2015.09.034.

76. Cane J, Richardson M, Johnston M, Ladha R, Michie S. From lists of behaviour change techniques (BCTs) to structured hierarchies: comparison of two methods of developing a hierarchy of BCTs. Br J Health Psychol. 2015 Feb;20(1):130-50. doi: 10.1111/bjhp.12102.

77. Hobbs L, Campbell R, Hildon Z, Michie, S. Behaviour change theories across Psychology, Sociology, Anthropology and Economics: A Systematic Review. Psychology and Health. 2011 [cited 2018 Jun];026(Suppl. 1), 31.

78. Cane J, O'Connor D, Michie S. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implement Sci. 2012 Apr [cited 2018 Mar];7:37. doi: 10.1186/1748-5908-7-37.
79. Michie S, Carey RN, Johnston M, Rothman AJ, de Bruin M, Kelly MP, Connell LE. From Theory-Inspired to Theory-Based Interventions: A Protocol for Developing and Testing a Methodology for Linking Behaviour Change Techniques to Theoretical Mechanisms of Action. Ann Behav Med. 2018 May 18;52(6):501-512. doi: 10.1007/s12160-016-9816-6.
80. Michie, S., Atkins, L., & West, R. (2014). The behaviour change wheel: A guide to designing interventions. Surrey, UK: Silverback Publishing.
81. MHealth new Horizen for health through mobile technologies: Based on the findings of the second global survey on eHealth. WHO;2011. Available from: https://www.who.int/goe/publications/goe_mhealth_web.pdf
82. Istepanian RSH, Woodward B. M-health: fundamentals and applications. Hoboken: John Wiley & Sons; 2017.
83. Whittaker R. Issues in mHealth: findings from key informant interviews. J Med Internet Res. 2012 Oct [cited 2019 Jan];14(5):e129. doi: 10.2196/jmir.1989.
84. Eren H, Webster JG. The e-medicine, e-health, m-health, telemedicine, and telehealth handbook. Volume II, Telehealth and mobile health. 1st ed. Florida: CRC Press; 2016
85. Krishna S, Boren SA, Balas EA. Healthcare via cell phones: a systematic review. Telemed J E Health. 2009 Apr [cited 2018 Mar];15(3):231-40. doi: 10.1089/tmj.
86. Buhi ER, Trudnak TE, Martinasek MP, Oberne AB, Fuhrmann HJ, McDermott RJ. Mobile phone-based behavioural interventions for health: A systematic review. Health Education Journal. 2013 Jul [cited 2018 Mar];72(5), 564–583. Available from: doi: http://doi.org/10.1177/0017896912452071
87. Marcolino MS, Oliveira JAQ, D'Agostino M, Ribeiro AL, Alkmim MBM, Novillo-Ortiz D. The Impact of mHealth Interventions: Systematic Review of Systematic Reviews. JMIR Mhealth Uhealth 2018 Jan [cited 2018 Jul] ;6(1):e23. doi: 10.2196/mhealth.8873
88. de Jongh T, Gurol-Urganci I, Vodopivec-Jamsek V, Car J, Atun R. Mobile phone messaging for facilitating self-management of long-term illnesses. Cochrane Database Syst Rev. 2012 Dec [cited 2018 Jul];12(12):CD007459. doi: 10.1002/14651858.CD007459.pub2
89. Yoo HJ, Park MS, Kim TN, Yang SJ, Cho GJ, Hwang TG, Baik SH, Choi DS, Park GH, Choi KM. A Ubiquitous Chronic Disease Care system using cellular phones and the internet. Diabet Med. 2009 Jun pcited 2018 Jul];26(6):628-35. doi: 10.1111/j.1464-5491.2009.02732.x.
90. Orsama AL, Lähteenmäki J, Harno K. Active assistance technology reduces glycosylated hemoglobin and weight in individuals with type 2 diabetes: results of a theory-based randomized trial. Diab Technol Therapeut 2013 [cited 2018 Mar]; 15:662–669. doi: 10.1089/dia.2013.0056
91. Goldberg EM, Levy PD. New Approaches to Evaluating and Monitoring Blood Pressure. Curr Hypertens Rep. 2016 Jun [cited 2018 Mar];18(6):49. doi: 10.1007/s11906-016-0650-9.
92. Parati G, Torlasco C, Omboni S, Pellegrini D. Smartphone Applications for Hypertension Management: a Potential Game-Changer That Needs More Control. Curr Hypertens Rep. 2017 Jun [cited 2018 Mar];19(6):48. doi: 10.1007/s11906-017-0743-0.
93. S. O'Dea. Forecast number of mobile users worldwide 2020-2024; 2020 [cited 2021 May]. Available from https://www.statista.com/statistics/218984/number-of-global-mobile-users-since-2010/
94. Survey on Trend , Opportunities and Challenges of mHealth Apps. 2017 [cite 2018 Mar];11(6), 73– 85. doi: http://doi.org/10.3991/ijim.v11i6.7265
95. Whitehead L, Seaton P. The Effectiveness of Self-Management Mobile Phone and Tablet Apps in

Long-term Condition Management: A Systematic Review. J Med Internet Res. 2016 May [cited 2018 Mar];18(5):e97. doi: 10.2196/jmir.4883. PMID: 27185295;

96. Omboni S. Connected Health in Hypertension Management. Front Cardiovasc Med. 2019 Jun [cited 2020 Nov]; 6:76. doi: 10.3389/fcvm.2019.00076.

97. Fadilah SZ, Susanti IA, Setyorini DY, Pradipta RO. Effectiveness of Mobile-Based Health Interventions for the Management of Hypertensive Patients: A Systematic Review [Online]. Jurnal Ners 2020 April [cited 2020 November];15(2) 238-245. doi: http://dx.doi.org/10.20473/jn.v15i2.19022

98. Birkhoff SD, Smeltzer SC. Perceptions of Smartphone User-Centered Mobile Health Tracking Apps Across Various Chronic Illness Populations: An Integrative Review. J Nurs Scholarsh. 2017 Jul [cited 2018 Jul];49(4):371-378. doi: 10.1111/jnu.12298.

99. Bonoto BC, de Araújo VE, Godói IP, de Lemos LL, Godman B, Bennie M, Diniz LM, Junior AA. Efficacy of Mobile Apps to Support the Care of Patients With Diabetes Mellitus: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. JMIR Mhealth Uhealth. 2017 Mar [cited Mar 2018];5(3):e4. doi: 10.2196/mhealth.6309.

100. Tinschert P, Jakob R, Barata F, Kramer JN, Kowatsch T. The Potential of Mobile Apps for Improving Asthma Self-Management: A Review of Publicly Available and Well-Adopted Asthma Apps. JMIR Mhealth Uhealth. 2017 Aug [cited 2018 Jul];5(8):e113. doi: 10.2196/mhealth.7177.

101. Fu H, McMahon SK, Gross CR, Adam TJ, Wyman JF. Usability and clinical efficacy of diabetes mobile applications for adults with type 2 diabetes: a systematic review. Diabetes research and clinical practice. 2017 [cited 2018 Mar]; 131, 70-8

102. Vo V, Auroy L, Sarradon-Eck A. Patients' Perceptions of mHealth Apps: Meta-Ethnographic Review of Qualitative Studies. JMIR Mhealth Uhealth. 2019 Jul [cited 2020 Sep] 10;7(7):e13817. doi: 10.2196/13817.

103. Kumar N, Khunger M, Gupta A, Garg N. A content analysis of smartphone-based applications for hypertension management. J Am Soc Hypertens. 2015 Feb [cited 2018 Jan];9(2):130-6. doi: 10.1016/j.jash.2014.12.001

104. Logan AG. Transforming hypertension management using mobile health technology for telemonitoring and self-care support [online]. Can J Cardiol. 2013 May [cited 2020 Aug];29(5):579–85. doi: 10.1016/j.cjca.2013.02.024

105. Hallberg I, Ranerup A, Kjellgren K. Supporting the self-management of hypertension: Patients' experiences of using a mobile phone-based system. J Hum Hypertens. 2016 Feb [cited 2018 Jan];30(2):141-6. doi: 10.1038/jhh.2015.37. Epub 2015 Apr 23.

106. Santo K, Redfern J. The Potential of mHealth Applications in Improving Resistant Hypertension Self-Assessment, Treatment and Control [Onlline]. Curr Hypertens Rep. 2019 Oct [cited 2020 November];21(10):81. doi: 10.1007/s11906-019-0986-z.

107. Bondaronek P, Alkhaldi G, Slee A, Hamilton FL, Murray E. Quality of Publicly Available Physical Activity Apps: Review and Content Analysis. JMIR Mhealth Uhealth. 2018 Mar [cited 2018 Mar];6(3):e53. doi: 10.2196/mhealth.9069.

108. Alexander JC, Joshi GP. Smartphone applications for chronic pain management: a critical appraisal [online]. J Pain Res. 2016 Sep [cite 2020 Aug]; 26;9:731-734. doi: 10.2147/JPR.S119966.

109. Boudreaux ED, Waring ME, Hayes RB, Sadasivam RS, Mullen S, Pagoto S. Evaluating and selecting mobile health apps: strategies for healthcare providers and healthcare organizations. Transl Behav Med. 2014 Dec [cited 2019 Jan];4(4):363-71. doi: 10.1007/s13142-014-0293-9.

110. Jake-Schoffman DE, Silfee VJ, Waring ME, Boudreaux ED, Sadasivam RS, Mullen SP, Carey JL, Hayes RB, Ding EY, Bennett GG, Pagoto SL Methods for Evaluating the Content, Usability, and Efficacy of Commercial Mobile Health Apps.JMIR Mhealth Uhealth 2017 Dec [cited 2019 Mar];5(12):e190

doi: 10.2196/mhealth.8758

111. Turner-McGrievy GM, Hales SB, Schoffman DE, Valafar H, Brazendale K, Weaver RG, Beets MW, Wirth MD, Shivappa N, Mandes T, Hébert JR, Wilcox S, Hester A, McGrievy MJ. Choosing between responsive-design websites versus mobile apps for your mobile behavioral intervention: presenting four case studies [online]. Transl Behav Med. 2017 Jun [cited 2020 Aug];7(2):224-232. doi: 10.1007/s13142-016-0448-y

112. Albabtain AF, AlMulhim DA, Yunus F, Househ MS. The Role of Mobile Health in the Developing World: A Review of Current Knowledge and Future Trends [online]. Journal of Selected Areas in Health Informatics. 2014 Feb [cited Oct 2017];4(2):10–15.

113. Atallah N, Khalifa M, El Metwally A, Househ M. The prevalence and usage of mobile health applications among mental health patients in Saudi Arabia. Comput Methods Programs Biomed. 2018 Mar [cited 2018 Feb]; 156:163-168. doi: 10.1016/j.cmpb.2017.12.002.

114. Apps for Smartphones. Saudi Arabia: Ministry of Health (MOH); 2017 [2020]. Available from https://www.moh.gov.sa/en/Support/Pages/MobileApp.aspx

115. Aljuraiban GS. Use of Weight-Management Mobile Phone Apps in Saudi Arabia: A Web-Based Survey. JMIR Mhealth Uhealth. 2019 Feb 22;7(2):e12692. doi: 10.2196/12692. PMID: 30794205.

116. Al-Tuwijri AA, Al-Rukban MO. Hypertension control and co-morbidities in primary health care centers in Riyadh. Ann Saudi Med. 2006 Jul-Aug [cited Jan 2018;26(4):266-71. doi: 10.5144/0256-4947.2006.266.

117. Khayyat SM, Khayyat SM, Hyat Alhazmi RS, Mohamed MM, Abdul Hadi M. Predictors of Medication Adherence and Blood Pressure Control among Saudi Hypertensive Patients Attending Primary Care Clinics: A Cross-Sectional Study. PLoS One. 2017 Jan pcited 2018 Jan];12(1):e0171255. doi: 10.1371/journal.pone.0171255.

118. Alqarni AM., Hammad AS, Alhejail M, Alatawi AA, Alrashedi M, Alenezi MF et al. Assessment of Adherence to Hypertension Medications and Awareness of Hypertension Medications among People with Hypertension in Tabuk. *The Egyptian* Journal of Hospital Medicine*. 2018; 70*, 1365-1370. DOI:10.12816/0044650

119. Elbashir B, Al-dkheel M, Aldakheel H, Aruwished N, Alodayani N. Hypertension in Saudi Arabia: Assessing Life Style and Attitudes. International Journal of Translational Medical Research and Public Health. 2020 [cited Nov 2020];4(1), 23–29. doi: https://doi.org/10.21106/ijtmrph.112

120. Al Duraihim H, Alghamdi G, AlNemer M, Abdulaal AE, Al Sayyari A. Blood pressure control, lifestyle and disease awareness of Saudi hypertensive patients. Saudi J Kidney Dis Transpl. 2019 Jan-Feb;30(1):33-38.

121. Bakhsh LA, Adas AA, Murad MA, Nourah RM, Hanbazazah SA, Aljahdali AA, Alshareef RJ. Awareness and Knowledge on Hypertension and its SelfCare Practices Among Hypertensive Patients in Saudi Arabia. Ann. Int. Med. Den. Res. 2017 Aug [cited 2018 Jan]; 3(5):ME58-ME62. doi: 10.21276/aimdr.2017.3.5.ME13

122. Or C, Tao D. A 3-Month Randomized Controlled Pilot Trial of a Patient-Centered, Computer-Based Self-Monitoring System for the Care of Type 2 Diabetes Mellitus and Hypertension. J Med Syst 2016 Apr; [cited 2017 apr];40(4):81. doi: 10.1007/s10916-016-0437-1.

123. Logan AG, Irvine MJ, McIsaac WJ, Tisler A, Rossos PG, Easty A, et al. Effect of home blood pressure telemonitoring with self-care support on uncontrolled systolic hypertension in diabetics. Hypertension 2012 Jul [cited 2018 Jan];60(1):51-57. doi: 10.1161/HYPERTENSIONAHA.111.188409

124. Alessa T, Hawley MS, Hock ES, de Witte L. Smartphone Apps to Support Self-Management of Hypertension: Review and Content Analysis. JMIR Mhealth Uhealth 2019 [cited 2020 Jan];7(5):e13645. doi: 10.2196/13645

125. Clemmensen T, Hertzum M, Hornbæk K, Shi Q, Yammiyavar, P. Cultural cognition in usability

evaluation. Interacting with Computers. 2009 [cited 2019 Jan]; 21(3), 212-220.

126. Alessa T, Abdi S, Hawley MS, de Witte L. Mobile Apps to Support the Self-Management of Hypertension: Systematic Review of Effectiveness, Usability, and User Satisfaction. JMIR Mhealth Uhealth 2018 [cited 2018 Aug];6(7):e10723. doi: 10.2196/10723
127. Abdulla, M and Smaeel. Providing Information through Smart Platforms: An Applied Study on Academic Libraries in Saudi Universities. Journal of Education Society and Behavioural Science 2019 [cited 2021 May]. doi: 10.9734/jesbs/2019/v30i430134

128. Davis F, Bagozzi R P, Warshaw, PR. User acceptance of computer technology: A comparison of two theoretical models.. Management Science 1989 [cited 2021 May];35(8), 982-1003. doi: 10.1287/mnsc.35.8.982

129. King, WR, He J. A meta-analysis of the technology acceptance model. Information and Management 2006 [cited 2021 May] 43, 740-755. doi: 10.1016/j.im.2006.05.003

130. Holden RJ, Karsh B. The technology acceptace model: Its past and its future in health care. Journal of Biomedical Informatics 2010 [cited 2021 May]; 43(1), 159-189. doi: 10.1016/j.jbi.2009.07.002

131. Chau, PYK, & Hu PJ. Examining a Model of Information Technology Acceptance by Individual Professionals: An Exploratory Study. Journal of Management Information Systems, 2002 [cited 2021 May] 18(4), 191-229.

132. Abbasi, MS, Chandio, FH, Soomro, AF, & Shah F. Social influence, voluntariness, experience and the internet acceptance: An extension of technology acceptance model within a south-Asian country context. Journal of Enterprise Information Management 2011 [cited 2021 May]; 24(1), 30-52.

133. Hardeman W, Johnston M, Johnston D, Bonetti D, Wareham N, & Kinmouth A L. Application of the theory of planned behaviour in behaviour change interventions: A systematic review. Psychology & Health 2002 [cited 2021 May]; 17(2), 123-158. doi: 10.1080/08870440290013644a.

134. Webb TL. Sheeran. Does changing behavioral intentions engender behavior change? A meta-analysis of the experimental evidence. Psychological Bulletin,2006 [cited 2021 May]; 132(2), 249-268. doi: 10.1037/0033-2909.132.2.249

135. Rahimi B, Nadri H, Lotfnezhad Afshar H, Timpka T. A Systematic Review of the Technology Acceptance Model in Health Informatics. Appl Clin Inform. 2018 [cited 2021 May] ;9(3):604-634. doi:10.1055/s-0038-166809

136. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR Mhealth Uhealth. 2015 pcited 2021 Jun];3(1):e27. Published 2015 Mar 11. doi:10.2196/mhealth.3422

137. Terhorst Y, Philippi P, Sander LB, Schultchen D, Paganini S, Bardus M, . . . Messner E. Validation of the Mobile Application Rating Scale (MARS). PloS One 2020 [cited 2020 jun]; 15(11), E0241480.

138. Llorens-Vernet P, Miró J. Standards for Mobile Health–Related Apps: Systematic Review and Development of a Guide. JMIR Mhealth Uhealth 2020 Mar [cited 2020 Sep];8(3):e13057. doi: 10.2196/13057

139. Salazar A, de Sola H, Failde I, Moral-Munoz JA Measuring the Quality of Mobile Apps for the Management of Pain: Systematic Search and Evaluation Using the Mobile App Rating Scale. JMIR
140. Statista Research Department. Number of mobile phone internet users in Saudi Arabia from 2015 to 2025; 2020 [cited 2021 May]. Available from: https://www.statista.com/statistics/558821/number-of-mobile-internet-user-in-saudi-arabia/

141. Almutairi KM. Culture and language differences as a barrier to provision of quality care by the health workforce in Saudi Arabia. Saudi Med J 2015 [cited 2021 May]; 2, 36(4), 425-431.

142. Al-Yousuf M, Akerele T, Al-Mazrou Y. Organization of the Saudi health system. East Mediterr Health J 2002[cited 2021 May]; 8(4-5), 645-653.

143. Gailey S, Bruckner TA, Lin TK. et al. A needs-based methodology to project physicians and nurses to 2030: the case of the Kingdom of Saudi Arabia. Hum Resour Health 2021 [cited 2021 May]; 19, 55 (2021). https://doi.org/10.1186/s12960-021-00597-w

144. Rassool GH. The crescent and Islam: Healing, nursing and the spiritual dimension. Some considerations toward an understanding of the Islamic perspectives on caring. Journal of Advanced Nursing 2000 [cited 2021 May];, 32(6), 1476-1484.

145. Alasqah I, Mahmud I, East L, & Usher K. Patterns of physical activity and dietary habits among adolescents in Saudi Arabia: A systematic review. International Journal of Health Sciences 2021 [cited 2021 May], 15(2), 39–48.

Chapter 3 Study 1: Mobile Apps to Support the Self-Management of Hypertension: Systematic Review of Effectiveness, Usability, and User Satisfaction

Published as: Alessa T, Abdi S, Hawley MS, de Witte L. Mobile Apps to Support the Self-Management of Hypertension: Systematic Review of Effectiveness, Usability, and User Satisfaction. JMIR Mhealth Uhealth. 2018 Jul 23;6(7). doi: 10.2196/10723

This chapter presents a systematic review synthesising the existing scientific evidence as to the effectiveness and usability of apps for hypertension self-management and user satisfaction. The review also investigates the functionalities of the apps to identify which combinations are most likely to be effective. The results from this investigation form the basis of the subsequent app store review, presented in the next chapter.

Abstract

Background: Hypertension is a chronic disease that is considered to be a public health problem and requires efforts by patients to manage themselves. The global growth in the use of mobile phones and tablets has been accompanied by the increased use of health apps. Many of these apps support the self-management of hypertension and, therefore, they have the potential benefits of lowering blood pressure. Despite this, there is currently a lack of evidence for their effectiveness, usability, and patient satisfaction with their use.

Objective: A systematic review was conducted to assess the effectiveness of apps in lowering blood pressure, as well as their usability and patients' satisfaction with their use.

Methods: We conducted searches in the following databases: MEDLINE (OVID), EMBASE (OVID), PsycINFO (OVID), CINAHL, the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library), IEEE Xplore ASSIAN, Google Scholar and the main Arabic databases Al Manhal, AskZad, and Mandumah. We looked for studies that used apps in the self-management of hypertension from 2008-2016. We also checked the reference lists of the review papers and all the primary studies for additional references.

Results: A total of 21 studies with a total of 3112 participants were included in the review. Of the 14 studies that assessed the effectiveness of the apps in lowering blood pressure, 10 (71.4%) studies (6 RCTs and 4 nonrandomized studies) reported that using the apps led to significant decreases in blood pressure and seemed to be effective in the self-management of hypertension. Of these 10, only 2 (20%) RCTs and 3 (30%) nonrandomized studies had a low–moderate risk of bias. The results of this review are inconclusive regarding which combinations of functionalities would be most effective in lowering blood pressure because of variation in the studies' quality, but the data suggest that apps incorporating more comprehensive functionalities are likely to be more effective. In all the studies that assessed the usability of the apps and users' acceptance of them, all the apps seemed to be accepted and easy to use.

Conclusions: Most of the studies reported that apps might be effective in lowering blood pressure and are accepted by users. However, these findings should be interpreted with caution, as most of the studies had a high risk of bias. More well-designed, large-scale studies are required to evaluate the real effect of using apps in lowering blood pressure and to identify the most effective functionality combinations for lowering blood pressure.

KEYWORDS mobile phone; mobile application; mobile app; self-management; hypertension; blood pressure

3.1 Introduction

Hypertension, in which the blood pressure (BP) in the arteries is raised, is one of the most common chronic diseases in adults. Patients can be diagnosed with hypertension when their systolic blood pressure (SBP) and diastolic blood pressure (DBP) are above 140/90 mm Hg, respectively (1). Hypertension has been recognized as a major risk factor for many diseases, such as renal failure, heart disease, and stroke (1). Despite the effect of lowering BP on reducing the risk of renal and cardiovascular disease, most people with hypertension poorly control their BP (2). Therefore, it is important to encourage patients' involvement in controlling their BP.

Self-management is considered an important element of chronic care management (3). Self-management demands an active role of patients in managing their symptoms, treatment, psychosocial and physical effects, and changing lifestyle (4-6). Achieving an optimum level of self-management behavior is difficult and requires considerable effort from patients. Mobile health technology (mHealth), defined as the use of mobile devices to deliver health care (7), has the potential to facilitate and optimize patients' self-management (8-11). This can be performed by integrating health care with everyday life by delivering and collecting health information and services in a convenient, accessible, and interactive mode (12,13). The use of the new generation of these mobile devices, including mobile phone and tablets, has increased rapidly in recent years, and it is estimated that by 2018 mobile phones will be used by one-third of the global population (14). Mobile phones have become an important platform to deliver health to patients through health apps. The rapid growth in the use of these devices has been accompanied by a huge expansion in health and health-related behavior apps, and more than 100,000 of these are used by millions of people (14,15). Many health apps are targeted to support people with hypertension in their self-management by offering self-monitoring activities, reminders, tailored information, and feedback (16,17).

To the best of our knowledge, despite the potential benefits of apps for people with hypertension and the increased use of these apps, a synthesis of studies on their effectiveness in this population has not been conducted. This systematic review will synthesize the existing evidence on the effectiveness of apps in lowering BP, as well as their usability and patients' satisfaction with their use.

3.2 Methods

A systematic review was conducted and reported per the PRISMA statement for systematic reviews (18,19).

3.2.1 Eligibility Criteria

The inclusion criteria were dependent on PICOS (18) as described below:

Population

The population was people with hypertension (18 years of age and over) and health care professionals (HCPs) supporting people with hypertension in their self-management in any care setting, without limitations on the participants' gender, age or socio-demographic characteristics. Studies about people with chronic illness including hypertension as one of their inclusion criteria were also included.

Intervention

The intervention was a mobile phone or a tablet app that collects data, provides feedback, connects with HCPs or informs about hypertension to support the self-management tasks of hypertension. These tasks include self-monitoring of BP and other biometrics, healthy eating and drinking, being physically active, maintaining a healthy weight, adhering to medication, and managing stress and coping (1). The app should also enable interactions between the user and the device via a set of interfaces (eg, a visual user interface). Studies in which a health app was the only method of delivery or in which it was a component of a blended intervention were also included.

Comparator

The comparator was either usual care or any other control intervention. Articles with no comparison were also included.

Outcomes

The outcomes of studies that were considered are: levels of BP, SBP, and DBP, as well as usability, attitudes, and satisfaction with mobile apps.

3.2.2 Study Designs

The eligible study designs were all quantitative, qualitative, and mixed-method studies that explore the self-management of hypertension using apps. Pilot studies were included because they might enable us to understand the status of apps.

Data Sources and Search Methods

The electronic databases EMBASE (OVID), MEDLINE (OVID), PsycINFO (OVID), the Cochrane Central Register of Controlled Trials (CENTRAL, The Cochrane Library), CINAH, ASSIAN, and IEEE Xplore were searched, as was Google Scholar. Hand searching through the reference lists of included studies and systematic reviews was also conducted to find more related studies. These databases were searched using the concepts of hypertension, mobile apps, telemonitoring, and self-management (see

Appendix 2 for the MEDLINE search strategy). The search strategy was limited to English research published from 2008, when the first app store was launched, (12) to June 25, 2017.

3.2.3 Exclusion Criteria

Studies were excluded based on the criteria in Textbox 1. Conference abstracts, protocols, commentaries or editorials or studies not in English or Arabic were not included.

Study Selection

Reference management software (Endnote) was utilized to collect results from databases, and to de-duplicate articles. Two reviewers (TA and SA) independently scanned titles against the eligibility criteria and in a second phase the abstracts of selected titles. Cohen kappa was calculated to determine the agreement between the reviewers for each step of selecting titles and abstracts.

Textbox 1. Exclusion criteria.

They were not aimed at hypertension or studies focusing only on primary prevention of hypertension or hypertension during pregnancy.

They examined interventions accessed by a personal digital assistant, desktop computer, laptop, netbook

They examined interventions accessed by a mobile phone or traditional tablet that did not permit participants to download or use any app from the app store.

They solely used messaging including short message service (SMS) text messaging, multimedia messaging service (MMS), websites, calls, emails or Web-based apps.

A mobile device was used to transmit information provided by a blood pressure monitoring device to care providers or clinicians, but in which there was no interaction with the user.

They describe only the technological development of a mobile system.

Titles and in the second phase abstracts received 2 points if they met the criteria, zero if not and 1 point when there was doubt. If the sum of reviewer scores for a title was 2 or more, the study was included for the next phase. Otherwise, it was excluded. Two reviewers separately reviewed the full articles when the total scores for the abstract equaled 2 points or more. Any disagreements were resolved through a discussion with other researchers (LdW and MSH).

3.2.4 Data Extraction and Quality Assessment

Two reviewers independently (TA and SA) extracted data and assessed the quality of the included studies. Any disagreement was resolved through a discussion with other researchers (LdW and MSH) until consensus was reached.

Data were extracted using a standardized form, which was piloted by the reviewers. The Cochrane Collaboration's Risk of Bias Tool was utilized to assess randomized controlled trials (RCTs) (20). Nonrandomized quantitative studies were evaluated using 3 tools provided by the US National Institute of Health (NIH), March 2014 version: 1 for observational studies, 1 for controlled studies, and 1 for pre-post studies without control group (21). The Critical Appraisal Skills Programme (CASP) was utilized for the quality assessment of qualitative studies (22).

3.2.5 Data Synthesis and Analysis

An overview of the basic characteristics of the studies, including the intervention, population, and outcome, was summarized in a table. Data were not combined because of differences in the designs of the studies. A narrative synthesis was conducted instead (18,23). All research findings were classified according to review objectives.

3.3 Results

3.3.1 Summary of Search Results

The review steps are summarized in Figure 3.1. Searching the electronic databases yielded a total of 6302 titles. After all duplicates were removed, 5676 records remained for title screening. Cohen kappa for agreement between the 2 reviewers was 0.72. Subsequently, the 2 reviewers (TA and SA) assessed the remaining 1968 abstracts; Cohen kappa for agreement between them in that step was 0.83. Of these, 569 went forward for full-text assessment, supplemented by 3 studies identified from reference tracking. A total of 548 papers were excluded at full-text screening, as they did not meet the criteria relating to the participants or interventions, or they were conference abstracts, editorials, or protocols. This led to a selection of 24 publications. Only 21of these were included in this review, as 2 publications were a subset analysis of a previous publication, and 1 publication was about a part of the sample of a larger study described in another publication.

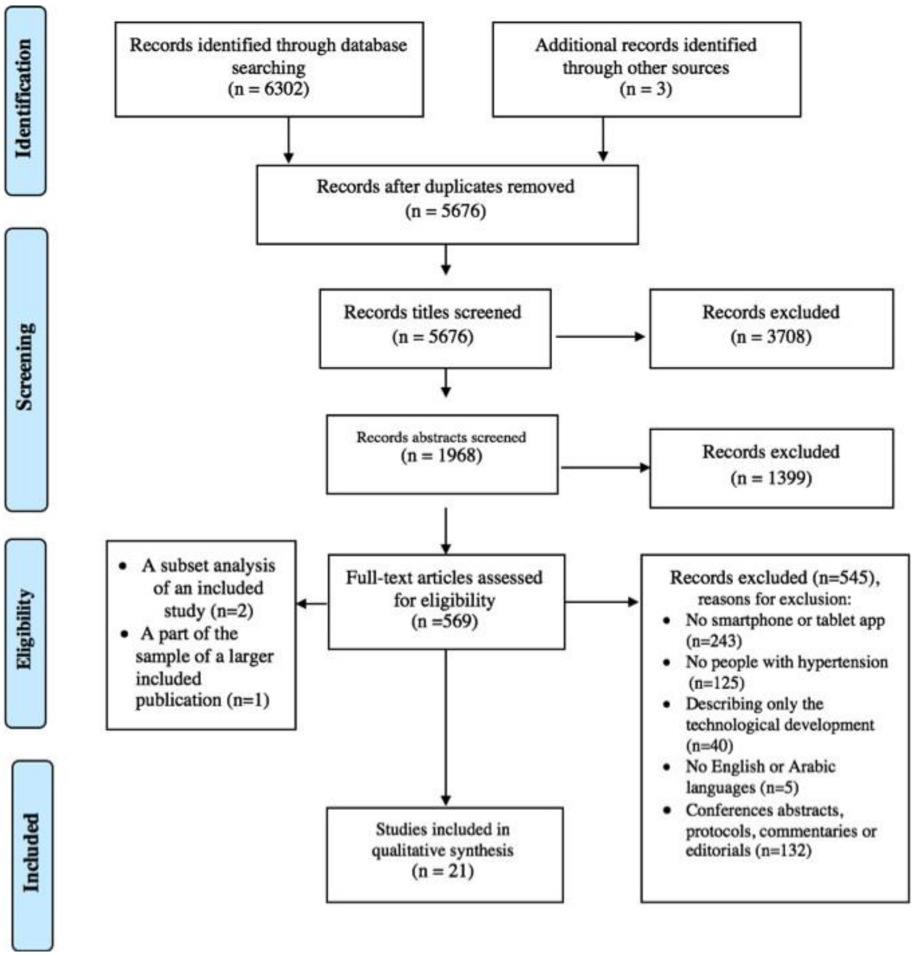


Figure 3.1 PRISMA flow diagram.

3.3.2 Study Characteristics

There were 21 studies included in this review. The publication year of the studies ranged from 2012 to 2017 (see Appendix 1). Most studies (11/21, 52%) were conducted in the US (24-32) and Canada [33,34], while 7 (33.3%) were carried out in European countries, including France (35), Sweden (36-38), Spain (39,40) and Italy (41). The remaining 3 (14.3%) studies were conducted in China (42,43) and South Korea (44).

Of the 21 studies, 9 (43%) were randomized controlled trials (RCTs) (24,25,27,28,30,33-35,42),10 (48%) were nonrandomized studies (26,29,31,32,37,39-41,43,44), and 2 (10%) were qualitative studies (36,38). Fourteen (14/21, 67%) studies reported on the apps' effectiveness in controlling BP. Of these studies, 4 (27%) also assessed user satisfaction and experience with the apps (27,30,31,39). The remaining 7 (33%) studies that did not report efficacy focused on user satisfaction with and attitudes towards the apps and their usability (26,32,36,38,40,43,44). The study duration ranged from 1-12 months. The studies included a range of 19 to 1012 participants, with a total of 3112 participants.

Participants' mean age ranged from 42.4 (27) to 69.5 (42) years of age. The population groups of the studies included individuals with hypertension (24-30,32,36-39,41-44), metabolic syndrome risk factors (34), obstructive sleep apnea with high cardiovascular risk (35), and overweight individuals (31). Of the 21 included studies, 5 (24%) reported to having used behavioral theories, such as self-determination theory (24,26,27), motivational interviewing (30) and theory of planned behavior (43) to underpin and guide the intervention methods and the development of the technology. The other studies did not report using behavioral theories. However, an investigation of the apps' functionalities identified recognizable elements of behavioral strategies.

All the included studies focused on supporting self-management of hypertension. Nine (43%) of the included studies were aimed to enhance self-management without involving clinicians to monitor patients remotely (29,33,35-38,42-44). The other 11 (52%) studies mainly involved clinicians or other HCPs remotely monitoring patient data and health status (24-28,30-32,39-41), while the remaining study involved the researcher remotely monitoring patient data and alerting physicians if needed (34,36). In these 11 (52%) studies involving HCPs, the HCPs provided feedback, including a medication plan or adjustments (24-27,39,41), regular online coaching consultation, (31) instructions (28,30), or communication with patients (40,42) (see Appendix 1).

3.3.3 Intervention Characteristics

In most studies, an app was supplemented with other interventions, such as a website (28,36-39,41), voice telephone messages (33), exercise prescription (34), a nasal mask and an auto-titrating machine (35), an electronic medication tray, email, SMS, or phone call (24-27), and education provided by a nurse (28). The control group in the controlled studies had usual care. In some studies, this was combined with the recording of prescribed exercise (34) and the BP measurements (42) in a logbook or with the education provided by a nurse (28).

Functionalities of the Apps

The 21 reviewed studies used 16 apps. Fourteen different apps were used in 14 studies (28-35,39-44), 1 app was used in 3 studies (36-38), and another app was used in the other 4 studies (24-27).

The main functions of the apps can be categorized into the strategies involved: self-monitoring capabilities, goal setting, the reminder and alert component (the use of prompts or cues), automatic feedback educational information, communication with HCPs and stress management. All 16 apps incorporated at least one of these functions. Table 3.1 summarizes the characteristics of the apps and systems.

The 16 apps have some similar characteristics and functionalities. All the apps have self-monitoring capabilities for BP and other health data (medication adherence, physical activity, eating and drinking, weight, sleep, stress, symptoms, medication side effect, and self-reflection answers) (24-44). This enables the user to track their BP and other health data over time in different formats, including graphical and/or tabular formats, and access the summary, raw data and/or analyzed results, the majority of which consisted of the BP, medication adherence, physical activity, eating and drinking, weight, and stress. The second most common functionality was a reminder and alert component that prompts self-monitoring by reminding patients about their medication time, BP measurements, hospital visits or personal goals, or the system alerts another person (eg, health professional) when a medication dose is missed or when the BP is higher than the normal level, a feature included in 13/16 (81%) apps (24-29,31-34,36-42,44).

Table 3.1 Intervention characteristics (identified by a check mark if they were met).

Study	Functionalities Self-monitoring	Use of prompt/cues (reminder and alert)	Educational information	Communication with others	Automatic feedback	Stress management
Anglada-Marti nez et al (39)	✔	✔	✔	✔	✔	—
Bengtsson et al (36)	✔	✔	—	—	✔	—
Bengtsson et al (37)	✔	✔	—	—	✔	—
Hallberg et al (38)	✔	✔	—	—	✔	—
Carrera et al (40)	✔	✔	✔	✔	✔	—
McGillicuddy et al (25)	✔	✔	—	—	✔	—
McGillicuddy et al (26)	✔	✔	—	—	✔	—
Davidson et al (24)	✔	✔	—	—	✔	—
McGillicuddy et al (27)	✔	✔	—	—	✔	—
Bloss et al (28)	✔	✔	✔	✔	✔	—
Patel et al (29)	✔	✔	✔	—	—	—
Or and Tao (42)	✔	✔	✔	—	✔	—
Logan et al (33)	✔	✔	—	—	✔	—
Petrella et al (34)	✔	✔	—	—	—	—
Albini et al (41)	✔	✔	✔	—	—	—
Mao et al (31)	✔	✔	✔	✔	—	—
Moore et al (30)	✔	—	—	✔	✔	—
Mendelson et al (35)	✔	—	✔	—	—	—
Kang et al (44)	✔	✔	✔	—	✔	—
Sun et al (43)	✔	—	—	—	—	—
Banerjee et al (32)	✔	✔	—	✔	✔	✔

Educational information (28,29,31,35,39-42,44) and automatic feedback (24-28,30,32,33,36-40,42,44) were the next most common features. Of 16 apps, 6 (38%) apps provided a tool for the users to communicate with their families and HCPs (28,30-32,39,40) and 1 app (6%) supported stress management (32). Although setting goals is one of the most important techniques in the self-management of hypertension (45), most included studies reported that goals were set through negotiation and discussion between the patients and their HCPs without explicitly mentioning setting them in the app (24-27,29-31,34-38,42).

The most common comprehensive combination of strategies was self-monitoring, educational information, automatic feedback, reminders, and alerts. This combination was found in 5/16 (31%) apps (28,39,40,42,44), 3 of which also provided communication with HCPs (28,39,40), and patients families (28). The second most frequently used combination was self-monitoring and prompt or cue, with the addition of either feedback (24-27,32,33,36-38) or educational information (29,31,41), with 2/7 (29%) apps providing communication with HCPs (31,32). The remaining 4/16 (25%) apps only focused on self-monitoring (30,34,35,43) with either educational information (35), automatic feedback and communication with HCPs (30) or reminders or alerts (34) (see Table 3.2).

Data Input Methods

Most apps (14/16, 88%) used self-monitoring of BP and supported other self-monitoring tasks (24-28,30-38,40-44), while 2 apps (13%) focused solely on self-monitoring of medication compliance (29,39). In 50% (7/14) of the apps, the collected BP readings were transmitted automatically from BP monitoring devices to the app using wireless transmission. In 3 of these 7 apps (42.9%), Bluetooth was employed (24-27,33,34) while for the remaining 4 apps (57%) the transmission method was not described (28,30,35,42). Manual entry of BP data was used in 50% of apps (7/14) (31,32,36-38,40,41,43,44), one of which (14%) also automatically transmitted data (31). Blood glucose readings were also wirelessly transmitted in 3

Table 3.2 Common combinations of app functionalities (N=16).

Common Combination	n (%)
Self-monitoring + automatic feedback + prompt or cue (reminders and alerts) + educational information	5 (31)
Self-monitoring + prompt or cue (reminders and alerts) + automatic feedback	4 (25)
Self-monitoring + prompt or cue (reminders and alerts) + educational information	3 (19)
Self-monitoring + communicate with health professional + automatic feedback	1 (6)
Self-monitoring + prompt or cue (reminder and alerts)	1 (6)
Self-monitoring + educational information	1 (6)
Self-monitoring	1 (6)

of the 16 apps (19%) (28,34,42) and medication data was wirelessly transmitted in 2 of the apps (13%) [24-27,30). There was no description of the technology used. Data was inputted manually in 3 other apps (3/16, 19%) using different formats, such as choosing an option or typing (29,39,44). Other manually inputted data include: weight in 4 apps (25%) (31,32,34,41), number of steps walked in two apps (13%) (31,34), reflective answers representing users' expectations toward their BP readings in one app (43), answers to questions about well-being, side effects, symptoms, and medication in another app (44), and other lifestyle aspects such as smoking, stress, and exercise in 2 apps (32,44).

3.3.4 Quality Appraisal

All 9 RCT studies presented some degree of potential bias when assessed using the Cochrane Collaboration's Risk of Bias Tool. Three of them were of low to moderate risk of bias (fair-good quality) because they met most of the criteria (33,35,42), while the remaining studies were considered to be of high risk of bias (poor quality) (24,25,27,28,30,34) (see Multimedia Appendix 4). Four of the 9 studies (44%) failed to report and apply random sequence generation (24,25,27,28). Seven of the 9 studies (78%) presented a high risk of bias or information was not explicitly provided regarding the blinding of participants, personnel, or the outcome assessor (24,28,30,33-35,42). Five (5/9, 56%) studies had a high risk of bias in other areas, such as small sample size (24,25,27,30,42).

One controlled study presented poor quality because of failure to apply blinding of the outcome assessor and sample size justification (see Appendix 5) Most observational studies (4/7, 57%) were found to be of poor quality because of a high risk of bias or the lack of information concerning the sampling method and selection (32,39,43,44), and failure to clearly report the study aims, design, duration, and outcome measures (32,40), as well as high attrition rate (39,44). The remaining 3 (43%) studies were of fair-good quality (26,31,37) (see Appendix 6). One of the pre-post studies (1/2, 50%) presented poor quality because of selection and attrition bias (39) (see Appendix 7). The two qualitative studies were deemed to be of low risk of bias as they met most of the CASP tool's criteria. However, both seemed to fail to adequately report the saturation of data during data collection and the relationship between researcher and participants (see Appendix 8).

3.3.5 Blood pressure

Fourteen studies (14/21, 67%) reported outcomes related to BP (24,25,27-31,33-35,37,39,41,42). From these, 9 studies (64%) were RCTs (24,25,27,28,30,33,34,35,42), and 5 (36%) were nonrandomized studies (29,31,37,39,41). Only 2 (14%) of them did not report the effect on DBP (25,31). BP outcomes were presented as mean (25,27,29,39), mean change (24,28,30,33,37), or both (31,34,41,42) (see Appendix 3).

As shown in Table 3.3, 6/9 (67%) studies demonstrated positive effects on BP (24,25,27,30,33,42), whereas 3/9 (33%) studies reported no positive impact on BP (28,34,35). The 6 studies that demonstrated positive effects showed a significant decrease in SBP ($P<.05$). The decrease in the intervention arm ranged from 8.7 to 34.8 mm Hg (24,25,27,30,33,42). Significant decreases in DBP were reported in 2/6 (33%) studies, ranging from 4.9 to 12 mm Hg (24,33). Only 1 of the 6 studies (17%) (30) reported a nonsignificant trend toward greater decrease.

Three out of 9 studies (33%) were of fair-good quality. However, the remaining 6 studies (67%) were of poor quality (see Quality Appraisal section for an in-depth discussion of this). Of the 3 studies that were fair-good quality, only 2 (67%) were positive. Five of the studies (5/14, 36%) are nonrandomized (29,31,37,39,41). Of these, 4 (80%) reported a significant decrease in BP (29,31,37,41). This decline ranged from 5.7 to 10.5 mm Hg and from 4.9 to 6.2 mm Hg for SBP and DBP respectively (see 3.4). Three of the 5 (60%) nonrandomized were of good-fair quality and 2 (40%) of the studies were of poor quality (see Quality Appraisal section).

Of the 6 studies with low-moderate risk of bias, 1 (17%) reported no significant effect on BP (18). Five studies, 2 of which were RCTs (40%) (33,42) that reported positive impacts on BP. Most of these studies (4/5, 80%) used apps with functionalities including self-monitoring as well as reminders and alerts with either automatic feedback (33,37) or educational information (29,31), while 1 RCT used the most comprehensive combination of strategies including self-monitoring, reminders and/or alerts, automatic feedback and educational information (42). Two other studies (2/14, 14%) (28,39) using apps with the same comprehensive combination of functionalities represented a high risk of bias and reported no statistically significant effects of using the app.

Table 3.3 Blood pressure effects and quality of randomized controlled trial (RCT).

RCT study	Follow up point, month	N	Systolic blood pressure Change	Systolic blood pressure Effect	Diastolic blood pressure Change	Diastolic blood pressure Effect
Logan et al (33), mean (SD)						
Intervention						
Over 24 hours	12	55	-8.7(14.7)	Positive[a]	-4.2(9.3)	Positive
During the daytime	12	55	-9.1(15.6)	Positive[a]	-4.6(9.2)	Positive
Control						
Over 24 hours During	12	55	-1.7(12.1)	—	-1.1(6.8)	—
During the daytime	12	55	-1.5(12.2)	—	-1.3(6.6)	—
Or and Tao (42), mean (95% CI)						
Intervention	3	33	–16.7 (–22.8 to –10.7)	Positive	–8.0 (–11.5 to –4.5)	Neutral[b]
Control	3	30	–2.1 (–8.6 to 4.4)	—	–2.1 (–8.6 to 4.4)[c]	—
Mendelson et al (35)						
Intervention	4	54	NR[d]	Neutral	NR	Neutral
Control	4	53	NR	—	NR	—
Davidson et al (24), **mean**						
Intervention	6	33	–34.8	Positive	–12	Positive
Control	6	30	–9.7	—	–4.5	—
McGillicuddy et al (25)**(mm Hg), mean (SE)**						
Intervention	12	9	132.2 (3.7)	Positive	NR	NR
Control	12	9	154.2 (5.7)	—		—
McGillicuddy et al (27) **(mm Hg), mean**						
Intervention	3	9	121.80	Positive	80.70	Neutral
Control	3	10	138.78	—	79.44	—
Moore et al (30), **mean (SD)**						
Intervention	3	20	–26.3 (11.9)	Positive	–13.7 (9.4)	Neutral
Control	3	22	–16.0 (12.1)	—	–8.2 (8.6)	—
Petrella et al (34)						
Intervention	13	75	NR	Neutral	NR	Neutral
Control	13	74	NR	—	NR	—
Bloss et al (28), **mean**						
Intervention	6	65	NR	Neutral	–3.6	Neutral

Control	6	65	NR	—	–6.1	—

[a]The app had significant positive effect on blood pressure,[b]The app had neutral effect on blood pressure.
[c]*P*<.001, [d]NR: not reported.

Table 3.4 Blood pressure effects and quality of nonrandomized studies.

Randomized controlled trial study	Follow up point, month	N	Systolic Blood Pressure Change	Effect	Diastolic Blood Change	Pressure Effect
Bengtsson et al (37), mean (SD)						
Intervention	2	50	–7 (18)	Positive[a]	–4.9 (10)	Positive
Control	2	50	NR[b]	—	NR	—
Patel et al (29) (mm Hg), mean						
Intervention	7	50	135	Positive	85	Positive
Control	7	30	NR	—	NR	—
Mao et al (31), mean (SE)						
Intervention	4	763	–5.96 (1.64)	Positive	NR	NR
Control	4	73	NR	—	NR	—
Albini et al (41), mean (SD)						
Intervention	6	303	–10.5 (6.3)	Positive	–6.2 (3.8)	Positive
Control	6	298	–6.1 (6.9)	—	–3.4 (4.5)	—
Anglada-Martínez et al (39) (mm Hg), mean (SD)						
Intervention	6	42	131.3 (9.8)	Neutral[c]	75.4 (6.7)	Neutral
Control	6	42	130.2 (13.9)	—	79.9 (9.6)	—

[a]The app had significantly positive effect on blood pressure.

[b]NR: not reported.

[c]The app had neutral effect on blood pressure.

The evidence is therefore inconclusive about which of these functionality combinations would be more effective in lowering BP, but it suggests that apps incorporating more comprehensive functionalities are likely to be effective.

4.3.6 Usability, Satisfaction, and Attitudes

Two of the 21 studies (10%) explored the usability of the apps (36,40) and 9 (43%) assessed user satisfaction with and attitudes toward the apps (26,27,30-32,38,39,43,44), 1 of which (1/9, 11%) also evaluate usability among experts (44). All of these 11 studies focused on the patient perspective, whereas 5 of them (46%) also considered the HCPs' perspective (30,36,39,40,44).

Generally, the use of the app was highly accepted by participants in all 9 studies that assessed user satisfaction (26,27,30-32,38,39,43,44). User satisfaction was measured through the participants rating their experience with the app (30,31), administration of satisfaction questionnaires (26,27,32,39,44), or conducting interviews (38,43). The satisfaction rate ranged from 7.2 to 9.8 (30,31,39) for studies using a 10-point satisfaction rating scale, and from 3.1 to 4.8 (27,44) for studies utilizing a 5-point satisfaction rating scale.

The participants reported that the apps were easy to use (27,32,38,39,43), convenient (38,43), helpful in effectively communicating with HCPs (26,27) and in hypertension management (27,38,43,44), including medication adherence and adjustment (26,27,43), and helped increase their active role in care, health awareness, and motivation (30,38,43). Although some participants felt that the apps were useful only for patients with an unstable BP (38,43), elderly patients, patients with polypharmacy or caregivers (39), most patients and HCPs stated that they would continue using the app after the study (30,39,43) and would recommend it to their friends (39). In 3 of the 9 studies (33%) (30,38,43) the participants suggested that the app would be more useful if improvements could be made. These improvements include tailoring the graph according to the participants' preference, for example, coloring graphs, sending motivational messages according to the inputted data (38). It also was suggested to support the self-monitoring of other conditions such as blood glucose (43), include alerts that inform patients if the BP readings are abnormal, and improving the performance of the app by loading faster (30).

One study (1/3, 33%) evaluated the app through conducting heuristic evaluation among technology and health informatics experts, and 2 studies (2/3, 67%) only conducted a usability test of the app amongst users. In the heuristic evaluation, some usability problems were identified. Of the 2 studies that assessed usability among users, 1 used direct observation of the participants (40) and the other used an observation method with specific questions asked to the participants (36). All the participants found both apps easy to use (36,40).

Six studies assessing usability and satisfaction (6/11, 55%) were of poor quality and only 5 of the 11 (46%) presented a low-moderate risk of bias. Generally, the participants seemed satisfied with the apps, they accepted using them in managing their condition and found them easy to use.

3.4 Discussion

Principal Findings

The aim of this systematic review was to synthesize evidence about the effectiveness, acceptance, and usability of using mobile and tablet apps to reduce BP.

This review found studies about 16 apps with similar functionalities. However, they were different in the number of combined functionalities. The majority of the apps used different combinations of functionalities, whereas 1 app had only 1 function (43). In all 9 studies that assessed users' satisfaction, the participants generally seemed to accept using apps to support the self-management of their BP. It also indicates that using the apps seems to be effective in supporting the self-management of hypertension and has the potential to lower BP as this was reported in 10 studies (6 RCTs and 4 nonrandomized studies). It should be noted that, of these, only 2 RCTs (33%) and 3 nonrandomized studies (75%) were of good quality. Due to the variety of study designs and quality the results, there is inconclusive evidence about which of these functionality combinations would be more effective in lowering BP. However, it would appear that apps incorporating more comprehensive functionalities are likely to be effective.

This study found that using apps may help reduce SBP and DBP significantly. Notably, this result was in accordance with other studies using mobile and other similar older technologies (11,46). In 1 meta-analysis, a decrease of 5 mm Hg in DBP or 10 mm Hg in SBP was found to reduce coronary heart disease events by 22% and stroke by 41% (47), as a decrease of 1 mm Hg in SBP leads to a 5% reduction in the risk of stroke (46). The findings of this review are in line with other systematic reviews that involved mobile phone and tablet-based intervention in managing chronic diseases, which showed that the use of apps has the potential to improve health outcomes among those living with chronic diseases (8,10,11,48,49).

The results with regard to acceptance are supported by studies assessing the acceptance and usability of mobile apps in the management of chronic diseases (49,50). A study assessing the usability of a commercially available app for diabetes found a lack of usability for its main target users of elderly diabetics (51). This finding, thereby, highlights the importance of assessing the usability of apps for hypertension and close cooperation and intensive usability tests with the targeted users during the development process of the apps.

In some studies, the apps were used in combination with other platforms, such as a website. The reported effects, therefore, cannot be solely attributed to the apps. The use of apps with automatic feedback without the involvement of clinicians to monitor patients remotely may be effective in controlling BP. Similarly, apps in which HCPs were involved in monitoring patients remotely and providing their feedback or instructions, with either automatic feedback or not, could also have a significant impact on BP. In short, it is possible that both approaches are effective.

The results of this review should be interpreted with caution, as some studies with a high risk of bias (6/9, 67% of RCTs; 6/10, 60% of nonrandomized studies) were included, and methodological issues have been identified in most of the included studies. These issues emerged from potential biases in some RCT studies because of the failure to implement the blinding of subjects and the assessor, lack of concealment and randomization procedures, small sample size, and short study duration. However, the blinding of subjects was impossible across the interventions due to the nature of using apps. Nonrandomized quantitative studies also had limitations, such as their small sample size, short duration, and attrition bias (39). Many of the studies included in this paper were conducted in different health and social care settings, which means that comparisons between them are not straightforward. Consequently, the generalizability of the results of some of these studies is limited. Although evidence of the effectiveness of mHealth is increasing, there is a lack of evidence concerning the sustainability of the findings after the app intervention has ceased. This suggests that further research is warranted to determine long-term benefits and eliminate these limitations.

Strengths and Limitations of this Review

This review has some limitations that should be considered when interpreting the results. First, studies published in languages other than English were not included, which increases the likelihood of relevant research being missed. Moreover, all types of studies were included regardless of their quality as it is often helpful to have more recent findings. However, low-quality studies present more inconclusive data, which affects the results. It was not possible to conduct a meta-analysis due to the study designs heterogeneity; combining results that have been obtained from different types of randomized and nonrandomized studies will not yield useful data. In addition, the inclusion of controlled and non-controlled studies might yield a combination of possibly inconclusive results. Their inclusion may offer a wider body of evidence. Despite these limitations, this study is the first systematic review exploring the effectiveness of using mobile apps in the self-management of hypertension and their acceptance among users. Consequently, it might be a useful roadmap to guide further studies on the use of mobile apps by people with hypertension. The authors developed a comprehensive search strategy and then hand searched the reference lists of each identified full-text articles and systematic review to find potentially relevant studies for inclusion in this systemic review and considered combinations of functionalities that were used in the apps.

Recommendations for Further Study

The methodological quality of studies included in this review was generally low. This indicates that future studies should consider some essential criteria, including a sufficient number of participants and duration time, concealment and randomization procedures, blinding of the assessor, and low attrition rates. Future studies assessing the effectiveness of apps should focus on apps that incorporate more comprehensive functionalities, that are identified in this review as the most promising functionalities for self-management of hypertension, including self-monitoring, reminders and alerts with either automatic feedback or educational information or both. It is important also to assess and understand users' satisfaction wit and acceptance of these apps. A well-designed RCT with multiple arms using apps with different combinations of functionalities to enable identification of the most effective combinations would also be beneficial.

3.5 Conclusion

This systematic review indicates that the use of apps to support the self-management of hypertension are accepted by patients and could assist in lowering and controlling their BP. It would appear that apps incorporating more comprehensive functionalities are likely to be effective. The results should be interpreted with caution, as most of the studies were of high risk of bias. More research is required to identify the effectiveness of using apps in lowering BP and to understand what functionality combinations are effective for lowering BP.

Acknowledgments

We thank all authors for their contribution. TA is a PhD student at Sheffield University, funded by the Saudi Culture Bureau.

Authors' Contributions

TA developed the review protocol and LdW and MSH significantly contributed to the development of the review protocol. TA and SA completed data screening, data extraction, and quality appraisal of relevant studies with disagreements resolved through discussion with other authors (LdW and MSH). TA also drafted the manuscript, LdW and MSH reviewed the manuscript and contributed to subsequent drafts. Authors TA, MSH, and LdW read and approved the final review

3.6References

1. Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, et al. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Hypertension 2003 Dec;42(6):1206-1252. doi: 10.1161/01.HYP.0000107251.49515.c2
2. Chow CK, Teo KK, Rangarajan S, Islam S, Gupta R, Avezum A, et al. Prevalence, awareness, treatment, and control of hypertension in rural and urban communities in high-, middle-, and low-income countries. JAMA 2013 Sep 04;310(9):959-968. doi: 10.1001/jama.2013.184182
3. Ryan P, Sawin KJ. The Individual and Family Self-Management Theory: background and perspectives on context, process, and outcomes. Nurs Outlook 2009;57(4):217-225.e6 doi: 10.1016/j.outlook.2008.10.004
4. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. JAMA 2002 Nov 20;288(19):2469-2475.
5. Grady PA, Gough LL. Self-management: a comprehensive approach to management of chronic conditions. Am J Public Health 2014 Aug;104(8):e25-e31. doi: 10.2105/AJPH.2014.302041
6. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Educ Couns 2002;48(2):177-187.
7. Whittaker R. Issues in mHealth: findings from key informant interviews. J Med Internet Res 2012;14(5):e129 doi: 10.2196/jmir.1989
8. Whitehead L, Seaton P. The Effectiveness of Self-Management Mobile Phone and Tablet Apps in Long-term Condition Management: A Systematic Review. J Med Internet Res 2016;18(5):e97. doi: 10.2196/jmir.4883
9. Logan AG. Transforming hypertension management using mobile health technology for telemonitoring and self-care support. Can J Cardiol 2013 May;29(5):579-585. doi: 10.1016/j.cjca.2013.02.024
10. Bonoto BC, de AVE, Godói IP, de LLLP, Godman B, Bennie M, et al. Efficacy of Mobile Apps to Support the Care of Patients With Diabetes Mellitus: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. JMIR Mhealth Uhealth 2017 Mar 01;5(3):e4. doi: 10.2196/mhealth.6309
11. Liu S, Dunford SD, Leung YW, Brooks D, Thomas SG, Eysenbach G, et al. Reducing blood pressure with Internet-based interventions: a meta-analysis. Can J Cardiol 2013 May;29(5):613-621. doi: 10.1016/j.cjca.2013.02.007.
12. Eren H, Webster J. Telehealth and mobile health. In: CRC Press , editor. CRC Press. Florida USA: CRC Press; 2016:978-971.
13. Majeed-Ariss R, Baildam E, Campbell M, Chieng A, Fallon D, Hall A, et al. Apps and Adolescents: A Systematic Review of Adolescents' Use of Mobile Phone and Tablet Apps That Support Personal Management of Their Chronic or Long-Term Physical Conditions. J Med Internet Res 2015 Dec;17(12):e287 . doi: 10.2196/jmir.5043.
14. Edwards EA, Lumsden J, Rivas C, Steed L, Edwards LA, Thiyagarajan A, et al. Gamification for health promotion: systematic review of behaviour change techniques in smartphone apps. BMJ Open 2016 Oct 04;6(10):e012447. doi: 10.1136/bmjopen-2016-012447.
15. Istepanian R, Woodward B. Preview this item M-Health : Fundamentals and Applications. In: IEEE Press Series on Biomedical Engineering. New Jersey USA: Wiley-IEEE Press; 2016:1119302897.
16. Kumar N, Khunger M, Gupta A, Garg N. A content analysis of smartphone-based applications for hypertension management. J Am Soc Hypertens 2015 Feb;9(2):130-136. doi: 10.1016/j.jash.2014.12.001.
17. Parati G, Torlasco C, Omboni S, Pellegrini D. Smartphone Applications for Hypertension Management: a Potential Game-Changer That Needs More Control. Curr Hypertens Rep 2017 Jun;19(6):48. doi: 10.1007/s11906-017-0743-0.
18. CRD. Systematic reviews: crd's guidance for undertaking reviews in healthcare. York: University of York; 2009. Available from: https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf.
19. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gøtzsche PC, Ioannidis JPA, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. BMJ 2009;339:b2700.
20. Higgins J, Green S. Cochrane handbook for systematic reviews of interventions. Version. Oxford: The Cochrane Collaboration; 2011. Available from: http://handbook-5-1.cochrane.org/
21. National I. National Institutes of Health (NIH). Study quality assessment tools | national heart, lung, and blood institute (nhlbi) Available from:https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools

22. Critical A. Published. 2006. 10 questions to help you make sense of qualitative research Available from: https://hhs.hud.ac.uk/lqsu/ Useful/critap/Qualitative Research Checklist/CASP-Qualitative-Research-Checklist-31.05.13.pdf.
23. Booth A, Sutton A, Papaioannou D. Systematic approaches to a successful literature review. 2nd ed. London, UK: Sage; 2016.
24. Davidson TM, McGillicuddy J, Mueller M, Brunner-Jackson B, Favella A, Anderson A, et al. Evaluation of an mHealth Medication Regimen Self-Management Program for African American and Hispanic Uncontrolled Hypertensives. J Pers Med 2015 Nov 17;5(4):389-405. doi: 10.3390/jpm5040389
25. Pilheu JA. [The lung, macrophages and oxygen radicals]. Medicina (B Aires) 1989;49(1):87-90.
26. McGillicuddy JW, Weiland AK, Frenzel RM, Mueller M, Brunner-Jackson BM, Taber DJ, et al. Patient attitudes toward mobile phone-based health monitoring: questionnaire study among kidney transplant recipients. J Med Internet Res 2013;15(1):e6. doi: 10.2196/jmir.2284.
27. McGillicuddy JW, Gregoski MJ, Weiland AK, Rock RA, Brunner-Jackson BM, Patel SK, et al. Mobile Health Medication Adherence and Blood Pressure Control in Renal Transplant Recipients: A Proof-of-Concept Randomized Controlled Trial. JMIR Res Protoc 2013;2(2):e32. doi: 10.~~2196/resp~~rot.2633
28. Bloss CS, Wineinger NE, Peters M, Boeldt DL, Ariniello L, Kim JY, et al. A prospective randomized trial examining health care utilization in individuals using multiple smartphone-enabled biosensors. PeerJ 2016;4:e1554. doi: 10.7717/peerj.1554
29. Patel S, Jacobus-Kantor L, Marshall L, Ritchie C, Kaplinski M, Khurana PS, et al. Mobilizing your medications: an automated medication reminder application for mobile phones and hypertension medication adherence in a high-risk urban population. J Diabetes Sci Technol 2013 May;7(3):630-639.
30. Moore J, Marshall M, Judge D. Technology-supported apprenticeship in the management of hypertension: a randomized controlled trial. J Clin Outcomes Manag 2014;21(3).
31. Mao AY, Chen C, Magana C, Caballero BK, Olayiwola JN. A Mobile Phone-Based Health Coaching Intervention for Weight Loss and Blood Pressure Reduction in a National Payer Population: A Retrospective Study. JMIR Mhealth Uhealth 2017 Jun 08;5(6):e80. doi: 10.2196/mhealth.7591.
32. Banerjee A, Ramanujan R, Agnihothri S. Mobile Health Monitoring: Development and Implementation of an app in a Diabetes and Hypertension Clinic. Mobile health monitoring; 2016 Presented at: International Conference on System Sciences; 2016; Hawaii p. 3424-3436. doi: 10.1109/HICSS.2016.427
33. Logan AG, Irvine MJ, McIsaac WJ, Tisler A, Rossos PG, Easty A, et al. Effect of home blood pressure telemonitoring with self-care support on uncontrolled systolic hypertension in diabetics. Hypertension 2012 Jul;60(1):51-57. doi: 10.1161/HYPERTENSIONAHA.111.188409.
34. Petrella RJ, Stuckey MI, Shapiro S, Gill DP. Mobile health, exercise and metabolic risk: a randomized controlled trial. BMC Public Health 2014; 14:1082. doi: 10.1186/1471-2458-14-1082
35. Mendelson M, Vivodtzev I, Tamisier R. CPAP treatment supported by telemedicine does not improve blood pressure in high cardiovascular risk osa patients: a randomized, controlled trial. Sleep~~ 2014;37~~(11):a.
36. Bengtsson U, Kjellgren K, Höfer S, Taft C, Ring L. Developing an interactive mobile phone self-report system for self-management of hypertension. Part 2: content validity and usability. Blood Press 2014 Oct;23(5):296-306. doi: 10.3109/08037051.2014.901009
37. Bengtsson U, Kjellgren K, Hallberg I, Lindwall M, Taft C. Improved Blood Pressure Control Using an Interactive Mobile Phone Support System. J Clin Hypertens (Greenwich) 2016 Feb;18(2):101-108. doi: 10.1111/jch.12682] [Medline: 26456490]
38. Hallberg I, Ranerup A, Kjellgren K. Supporting the self-management of hypertension: Patients' experiences of using a mobile phone-based system. J Hum Hypertens 2016 Feb;30(2):141-146. doi: 10.1038/jhh.2015.37
39. Anglada-Martínez H, Martin-Conde M, Rovira-Illamola M, Sotoca-Momblona JM, Sequeira E, Aragunde V, et al. Feasibility and Preliminary Outcomes of a Web and Smartphone-Based Medication Self-Management Platform for Chronically Ill Patients. J Med Syst 2016 Apr;40(4):99. doi: 10.1007/s10916-016-0456-y
40. Carrera A, Pifarré M, Vilaplana J. Bpcontrol. A mobile app to monitor hypertensive patients. Appl Clin Inform 2016;7(4):1120-1134.
41. Albini F, Liu X, Torlasco C. Use of Apps to Improve Drug Adherence in Hypertensive Patients. Drug Adherence in Hypertension and Cardiovascular Protection 2016:517-520.
42. Or C, Tao D. A 3-Month Randomized Controlled Pilot Trial of a Patient-Centered, Computer-Based Self-Monitoring System for the Care of Type 2 Diabetes Mellitus and Hypertension. J Med Syst 2016

Apr;40(4):81. doi: 10.1007/s10916-016-0437-1

43. Sun N, Rau PP, Li Y, Owen T, Thimbleby H. Design and evaluation of a mobile phone-based health intervention for patients with hypertensive condition. Computers in Human Behavior 2016 Oct; 63:98-105. doi: 10.1016/j.chb.2016.05.001.
44. Kang H, Park H. A Mobile App for Hypertension Management Based on Clinical Practice Guidelines: Development and Deployment. JMIR Mhealth Uhealth 2016 Feb 02;4(1):e12
45. Bosworth H, Powers B, Oddone E. Patient Self-Management Support: Novel Strategies in Hypertension and Heart Disease. Cardiol Clin 2010;28(4):655-663.
46. McLean G, Band R, Saunderson K, Hanlon P, Murray E, Little P, et al. Digital interventions to promote self-management in adults with hypertension systematic review and meta-analysis. J Hypertens 2016 Apr;34(4):600-612. doi: 10.1097/HJH.0000000000000859
47. Law MR, Morris JK, Wald NJ. Use of blood pressure lowering drugs in the prevention of cardiovascular disease: meta-analysis of 147 randomised trials in the context of expectations from prospective epidemiological studies. BMJ 2009;338:b1665.
48. Flores MG, Granado-Font E, Ferré-Grau C, Montaña-Carreras X. Mobile Phone Apps to Promote Weight Loss and Increase Physical Activity: A Systematic Review and Meta-Analysis. J Med Internet Res 2015;17(11):e253 doi: 10.2196/jmir.4836
49. Fu H, McMahon SK, Gross CR, Adam TJ, Wyman JF. Usability and clinical efficacy of diabetes mobile applications for adults with type 2 diabetes: A systematic review. Diabetes Res Clin Pract 2017 Sep;131:70-81. doi: 10.1016/j.diabres.2017.06.016
50. Cho M, Sim J, Hwang S. Development of smartphone educational application for patients with coronary artery disease. Healthc Inform Res 2014;20(2):117.
51. Arnhold M, Quade M, Kirch W. Mobile applications for diabetics: a systematic review and expert-based usability evaluation considering the special requirements of diabetes patients age 50 years or older. J Med Internet Res 2014;16(4):a

Chapter 4: Study 2: Smartphone Apps to Support Self-Management of Hypertension: Review and Content Analysis

Published as: Alessa T, Hawley MS, Hock ES, de Witte L. Smartphone Apps to Support Self-Management of Hypertension: Review and Content Analysis. JMIR Mhealth Uhealth 2019;7(5). doi: 10.2196/13645

The previous chapter presented the systematic review of the existing literature on hypertension self-management apps. This chapter presents the review of apps that are available in two of the main app stores and assesses their quality against a number of criteria. The results of this chapter form the starting point for the next step, which is the selection of an app that is most suitable for the Saudi context.

Abstract

Background: Hypertension is a widespread chronic disease, and its effective treatment requires self-management by patients. Health-related apps provide an effective way of supporting hypertension self-management. However, the increasing range and variety of hypertension apps available on the market, owing to the global growth in apps, creates the need for patients and health care professionals to be informed about the effectiveness of these apps and the levels of privacy and security that they provide.

Objective: This study aimed to describe and assess all available apps supporting hypertension self-management in the most popular app stores and investigate their functionalities.

Methods: In January 2018, the UK Apple and Google Play stores were scanned for all free and paid apps supporting hypertension self-management. Apps were included if they were in English, had functionality supporting hypertension self-management, and targeted adult users with hypertension. The included apps were downloaded and their functionalities were investigated. Behavior change techniques (BCTs) linked with the theoretical domain framework (TDF) underpinning potentially effective apps were independently coded by two reviewers. The data privacy and security of the apps were also independently assessed.

Results: A total of 186 hypertension apps that met the inclusion criteria were included in this review. The majority of these apps had only one functionality (n=108), while the remainder offered different combinations of functionalities. A small number of apps had comprehensive functionalities (n=30) that are likely to be more effective in supporting hypertension self-management. Most apps lacked a clear theoretical basis, and 24 BCTs identified in these 30 apps were mapped to 10 TDF mechanisms of actions. On an average, 18.4 BCTs were mapped to 6 TDF mechanisms of actions that may support hypertension self-management behaviors. There was a concerning absence of evidence related to the effectiveness and usability of all 186 apps, and involvement of health care professionals in the app development process was minimal. Most apps did not meet the current standards of data security and privacy.

Conclusions: Despite the widespread accessibility and availability of smartphone apps with a range of combinations of functionalities that can support the self-management of hypertension, only a small number of apps are likely to be effective. Many apps lack security measures as well as a clear theoretical basis and do not provide any evidence concerning their effectiveness and usability. This raises a serious issue, as health professionals and those with hypertension have insufficient information to make decisions on which apps are safe and effective.

KEYWORDS **smartphone apps; mobile apps; self-management; hypertension; blood pressure; mobile applications**

4.1 Introduction

Internationally, hypertension is one of the most common chronic diseases in adults and is considered one of the main risk factors for numerous diseases such as stroke, heart disease, and renal failure (1). It is estimated that around one billion individuals live with hypertension worldwide, and the majority of people are not proficient at controlling their blood pressure (BP) through medication or lifestyle choices, despite the fact that lowering BP decreases the risk of renal and cardiovascular disease (2). Self-management is considered to be among the most effective methods of coping with hypertension, helping individuals with hypertension be more responsible for their own health (3).

The recent emergence of information and communication technologies such as mobile health supports the self-management of chronic conditions (4-7). The increase in smartphone devices over the past decades has been rapid: By 2022, it is predicted that there will be 6.8 billion smartphone users [8]. This rapid increase of smartphone users corresponds with an increase in health apps offering health services and information (9,10).

Many apps have become available for patients with hypertension, and their number is increasing rapidly (11,12). The majority of these smartphone apps are aimed at helping people manage and control their hypertension (11,12), but it is currently unclear to what extent the evidence supports their effectiveness. A recent systematic review of apps aimed at supporting the self-management of hypertension found few studies reporting the effectiveness of apps (13). The majority of the apps in this review were study-specific and are therefore not available commercially in the app stores. The review concluded that apps containing more comprehensive functionalities, defined as three or more functionalities, are more likely to be effective in lowering BP (13) than apps with only one or two functionalities.

Even though many of the apps lacked evidence of theoretical underpinning, an examination of their functionalities revealed recognizable elements of behavioral change strategies (13). Studies have shown that self-management programs are more likely to be effective if they are supported by theory-based interventions (14-16). Theory allows identification of target behavior and strategies of behavioral changes needed to achieve desirable health outcomes. However, research has revealed that many commercial health apps lack theoretical underpinnings and theoretically consistent use of behavior change techniques (BCTs) (17-19). In addition, the majority of health apps lack privacy and security measures that adequately ensure protection of users' data, posing risks to user confidentiality (19,20). This is problematic, as it compromises both the personal data of the user as well as their trust in the app.

These shortcomings might lead to significant concerns about apps having little to no benefit, or even presenting a risk to users (17), highlighting the necessity of providing adequate information about the effectiveness of these apps and the robustness of their privacy and security features for patients and health care professionals. As such, these findings increase the importance of characterizing and investigating potential theoretical mechanisms of action in existing commercial apps with comprehensive functionalities as well as assessing the privacy and security of such apps. A method of investigating potential theoretical mechanisms of action by grouping BCTs with theoretical domain framework (TDF) mechanisms of actions, using the TDF and BCT Taxonomy (v1) (BCTTv1), has been extensively employed to characterize BCTs in health interventions (17,21-23), especially those relating to chronic diseases.

A review by Kumar et al (12) searched for the most downloaded and popular apps in May 2014 and found there are many apps that support the self-management of hypertension by offering self-monitoring activities, feedback, reminders, and tailored information. However, the search was restricted to the 50 most popular apps for every search term (high blood pressure and hypertension) on the two smartphone platforms. As a result, only 200 apps were screened, excluding many apps that might be suitable to support people with hypertension in their self- management. Furthermore, this review excluded smartphone app–based BP-measuring devices, arguing that they lacked accuracy, despite evidence that some of these specific devices used for measuring BP have been found to be accurate (24,25).

This study has reviewed all the available apps, updated our knowledge of new apps related to hypertension, and described their main functionalities as well as functionality combinations. Even though apps have numerous potential benefits and are used by an increasing number of patients, to the best of our knowledge, no previous review has analyzed all available apps; considered functionality combinations; included apps associated with accessory devices; considered the link between BCTs and the TDF mechanisms of action, which underpin the potentially effective apps; and considered privacy and security assessment of the potentially effective apps. The aim of this study was to fill this knowledge gap by addressing these points.

4.2 Methods

5.2.1 Study Design

This study is a content analysis and review of apps supporting hypertension self-management available in the most popular app stores. The *Quality and Risk of Bias Checklist for Studies That Review Smartphone Applications* (26) was utilized to ensure the adequate description of the app review's methods.

App Identification

Overview

In January 2018, an electronic search of apps was undertaken on the app stores of the two major types of smartphones in the United Kingdom—the iPhone (Apple Store) and Android (Google Play). These two platforms were searched because they were the world's most used operating systems in 2017 (27). The terms “hypertension” and “high blood pressure” were separately searched for in both stores. There were no restrictions concerning subcategories like “health and wellness.”

Inclusion and Exclusion Criteria

An app was included based on the following criteria: 1) The description was written in English, and “hypertension” or “high blood pressure” was included in the keywords or the accompanying description. 2) The collected data provided feedback, connected with health care professionals, or informed the patient about hypertension and self-management tasks related to hypertension; such tasks involve the self-monitoring of BP and other health data including healthy diet, exercising, taking medications, maintaining an appropriate weight, and managing stress. 3) The app was aimed at adults, in general, rather than health care providers (HCPs) specifically. Both paid and free apps were considered in the study.

An app was excluded based on one of the following criteria:
1) if it was not targeted at hypertension or if it focused solely on hypertension during pregnancy or primary prevention of hypertension; 2) if it was described in the app store catalogue as a “prank app” because it was not designed for medical purpose, but for entertainment; 3) if it was not designed for general use, for example, if it only provided services offered by particular hospitals or was designed only to be used as part of a specific study; and 4) if it did not run properly or required identification access after downloading the app, such as personal identification or primary care/hospital number.

The researcher selected the basic, completely functional version of an app if it had more than one version, such as high definition, lite, or pro. Apps appearing in both stores were rated independently to account for differences in features supported by various mobile operating systems. If an app appeared in response to searches for both “hypertension” and “high blood pressure” by a platform, it was included once, not twice.

Screening and Selection of Apps

All apps that were identified through the search and met the inclusion criteria based on their title and description were downloaded by the researcher (TA) onto an iPhone 6 (running iPhone operating system, version 11.2.2; iOS, Apple Inc, Cupertino, CA) and Android Samsung Galaxy S7 (running 8.1 software; Seoul, South Korea). The apps were then screened for all exclusion and inclusion criteria. If they met the criteria, the apps were run for 2 days, so that the researcher could investigate all reminders or notifications that appeared. Data on all the included apps were charted.

Data Abstraction

Overview

Abstracted data for all identified apps involved the name of the app, developer, version date, price and functions, available languages, and number of downloads. The involvement of health care professionals (eg, medical/health care professionals and behavior change specialists) was determined based on whether health professionals were involved in the development of the app as well as user involvement, which was included in the description on the app store. Following data abstraction, potentially effective apps (apps that were found to have comprehensive functionalities) were selected and considered for further analysis.

Functionalities

App functionalities were categorized based on the functionalities of hypertension self-management that have been determined in several previous studies about hypertension apps (11-13) and examined for effectiveness in scientific trials (28,29). The functionalities that were considered in this study are self-monitoring, goal setting, reminders, educational information, feedback, stress management, communication with HCPs and others, and export of users' data to others via email.

Apps Considered for Further Analysis

According to Alessa et al (13), apps with comprehensive functionalities are more likely to be effective. Such apps were identified on the basis of the presence of three or more functionalities, including (but not limited to) self-monitoring, reminders, and educational information or automatic feedback. Therefore, of the apps originally identified, apps that were found to have comprehensive functionalities were considered for further analysis. These apps were then analyzed to assess their privacy, security, and theoretical underpinning. This is because theoretical underpinning and privacy as well as security measures are essential criteria for apps to be used in health care (19).

Privacy and Security

Privacy and security were assessed based on the Online Trust Alliance (30) and the recommendations of the Information Commissioner's Office (31). These recommendations consist of seven questions examining the accessibility and availability of the privacy policy, the practices of data sharing and collecting, and data security as interpreted in the privacy and security statement (Table 4.3). These assessment questions and recommendations have also been previously used to assess privacy and security of existing health apps (19). The assessment was conducted by two independent reviewers (TA and EH). Any discrepancies were resolved by discussion with the other researchers (LdW and MSH).

Theoretical Underpinning

To identify the mechanisms of action underpinning the existing apps with comprehensive functionalities, the BCT v1 Taxonomy (BCTTv1) was used to code the content of the app and extract the number of BCTs in each app and the frequency of use of each BCT in the apps. Each BCT was coded with "0" as Absent or "1" as Present (18). The coding was undertaken by the two reviewers. Any disagreements were resolved by discussion with the other researchers. Interrater reliability for the presence or absence of the BCTs was assessed by calculating Cohen kappa for each item.

The present BCTs were then mapped to mechanisms of action of the TDF, based on several previously published expert consensuses linking BCTs to TDFs domains for health interventions, and the agreed judgement (consensus) of the study's researchers (23,32-34). The linking of BCTs to TDF was conducted independently by the two reviewers, and any discrepancies were resolved by discussion with other researchers of the study team. The final results were then agreed upon by the research team.

Additional Aspects

Two additional characteristics/aspects for the selected apps were also described—US Food and Drug Administration (FDA) or European Union Conformite Europeene (CE) approval and their individual user rating.

4.2.2 Statistical Analysis

The number and frequency of BCTs and TDF used in the reviewed apps were summarized as the SD, mean, and median using Microsoft Excel (Microsoft Corp, Redmond, WA). Proportions were also used to summarize the variables, including app functionalities, user ratings, and data privacy and security.

4.3 Results

4.3.1 Summary of Search Results

The study steps are summarized in Figure 4.1. A search of the two app stores yielded a total of 775 apps (495 in Android Google Play Store and 280 in iPhone Apple Store). The titles and descriptions of these apps were screened for eligibility. A total of 564 apps were excluded because they did not meet the specific inclusion criteria. The 211 remaining apps (116 in Google Play and 95 in Apple Store) were considered for further analysis (installed). Subsequently, a total of 25 apps (11 in Google Play and 14 in App Store) were excluded because of registration problems (eg, requiring specific identification access such as hospital or primary care identification) or installation failure. The remaining 186 apps (106 in Google Play and 80 in App Store) were included in the review.

The cost of the apps varied. Over a quarter of the apps (27.9%) cost between £0.59 to £17. Most apps (134/186, 72.1%) were free to download. Of the apps that were free to download, 19 either were trials of the complete app or required subscription fees. All apps (n=186, 100%) were in English, although some also supported other languages such as Chinese, German, and Russian.

4.3.2 General App Characteristics

Of the 186 apps that met the selection criteria, more than half (106/186, 57%) were available through the Android operating system. The remaining apps were available through the iPhone operating system (80/186, 43%). Only 11 apps were found to be available on both platforms (Appendix 9).

The version date of the reviewed apps ranged from February 8, 2012, to February 13, 2018. According to the number of downloads, more than half of the included Android apps (60/106, 57%) had over 500 downloads. Information on the number of downloads was not available for Apple apps.

4.3.3 Apps' Purpose and Functionalities

All apps could be classified according to their functionalities, including stress management, communication with HCPs and others, self-monitoring abilities, reminders, automatic feedback, educational information, and goal setting. Each app had at least one of these functionalities (Appendix 4.1). Table 4.1 summarizes the frequency of functionalities across the included apps. The most common self-management functionality was educational information about hypertension (110/186,59.1%). Educational content varied across apps. Most included basic educational information on high BP or information on diet and food (eg, dietary approaches to stop hypertension). Some apps contained general information on hypertension or alternative treatments. Although the majority of educational material was text-based, several apps contained video and images to depict their content.

The second most common functionality was self-monitoring (99/186, 53.2%), which allows users to monitor their BP and other data over a period of time presented in different forms, including graphs or tables, and to see an overview. The majority of these apps (n=94) aided BP tracking, while some of them also supported the self-monitoring of other data concerning medication, nutrition, physical activity, weight, and emotions. A few apps (n=5) only focused on tracking medication compliance, potassium intake, or sodium intake. Seven of these apps received BP readings automatically from the BP measurement device but do not provide a manual entry function. Of the remaining 84 apps, 73 necessitated manual entry of BP data, and 11 allowed both manual and automatic data transfer. Notably, a few apps (3/186, 1.6%) claimed that they turn the smartphone into a device capable of recording BP data. This was presumably achieved by using a "cuffless technique" in which the user puts a finger over the camera of their smartphone. Despite most of these apps claiming to measure BP, they did not report any evidence of their reliability and validity.

The third most common functionality was the provision of automatic feedback (52/186, 28%). This feedback was provided to users in different ways, either through self-care messages and notifications or by representing data in distinct color codes to inform the user of whether measurements have diverged from the average level.

One-fifth of the apps (39/186, 21%) had a functionality to remind users about BP measurements, their hospital appointments, their medication time(s), and personal goals. Certain apps (10/186, 5.4%) included BP goal setting, and a few also enabled the user to set other goals such as blood glucose levels, weight, and physical activity. A few apps (5/186, 2.7%) provided a tool for communication with others, including

HCPs or friends, through text messaging, chats, or virtual meetings with coaches. Five apps (2.7%) also supported stress management by providing relaxation tips or other therapies.

Around one-fourth of the apps (51/186, 27.4%) allowed users to export their entered data over time directly to others, including physicians, via email and other apps such as “WhatsApp,” thus facilitating patient-physician communication.

As shown in Table 4.2, the majority of the apps (n=108) included only one functionality such as educational information (n=82), self-monitoring (n=25), or stress management (n=1). Almost one-fourth (45/186, 24.1%) of the apps combined two functionalities, while a small number of apps (33/186, 17.8%) included comprehensive functionalities (ie, three or more functionalities). None of the 33 apps included all 8 abstracted functionalities. Thirty of these apps included, among other functionalities, self-monitoring and reminders, with educational information (5/186, 2.7%), automatic feedback (16/186, 8.6%), or both (9/186, 4.8%).

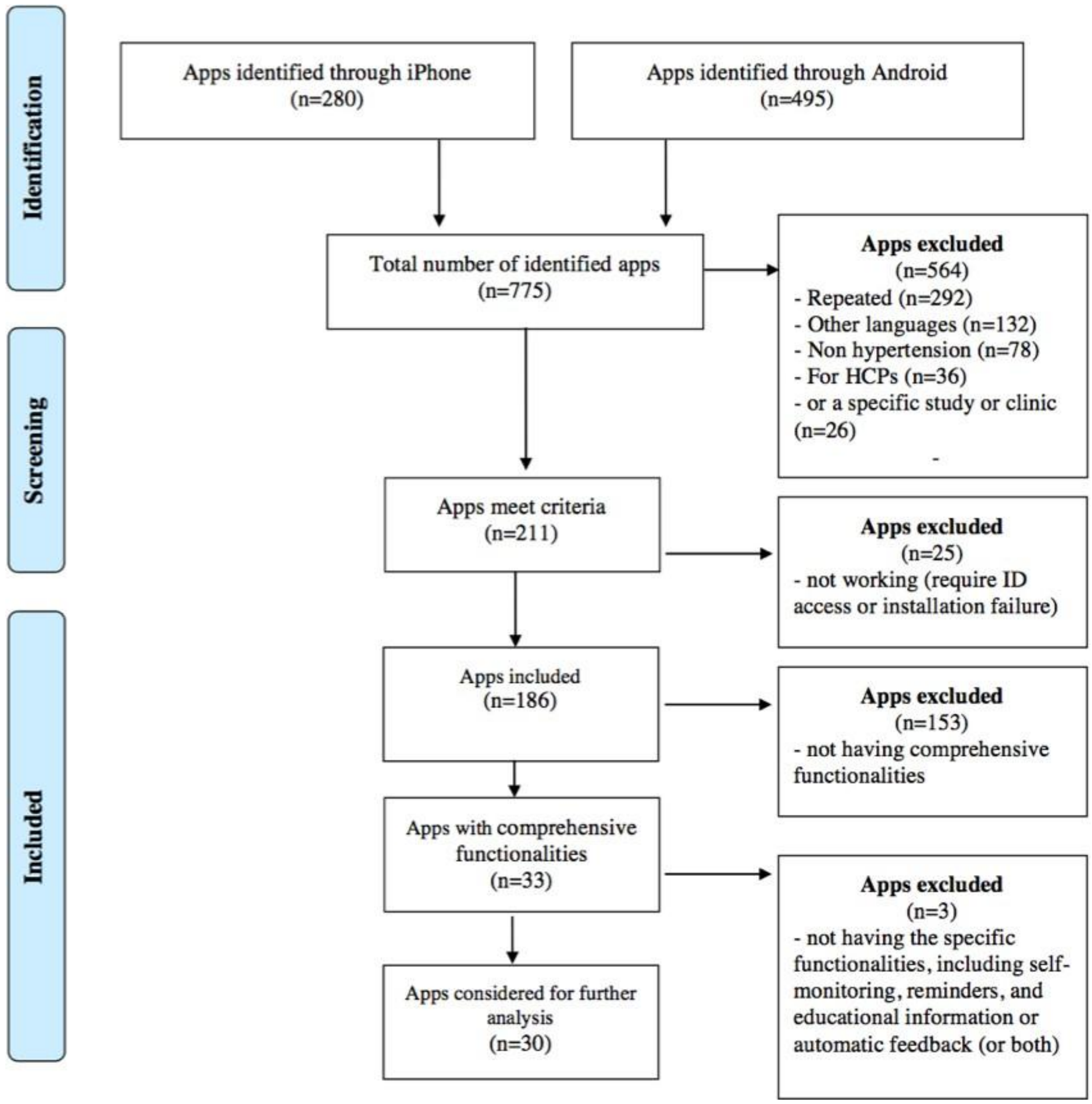


Figure 4.1 Flow diagram of the app-search process.

Table 4.1 Frequency of app functionalities.

Functionality	**iPhone** (Apple; N=80), n (%)	**Android** (Google Play; N=106), n (%)	**Total** (N=186), n (%)
Educational information	34 (43.8)	76 (70.8)	110 (59.1)
Self-monitoring	56 (70)	43 (40.6)	99 (53.2)
Feedback	36 (43.8)	16 (15.1)	52 (28)
Export	29 (36.3)	22 (20.8)	51 (27.4)
Reminder	23 (28.8)	16 (15)	39 (21)
Goal setting	8 (10)	2 (1.9)	10 (5.4)
Stress management	3 (3.8)	2 (1.9)	5 (2.7)
Communication with others	4 (5)	1 (0.9)	5 (2.7)

Table 4.2 Common combinations of app functionalities.

Functionality combinations	Number of Functionalities	iPhone (N=80), n (%)	Android (N=106), n (%)	Total number of apps used in combination, n (%)
Educational informational	1	21 (26.3)	61 (57.5)	82 (44.1)
Self-monitoring	1	10 (12.5)	15 (14.1)	25 (14)
Stress management	1	1 (1.3)	0 (0)	1 (0.5)
Self-monitoring + Feedback	2	18 (22.5)	6 (5.7)	24 (12.9)
Self-monitoring + Educational information	2	3 (3.8)	6 (5.7)	9 (4.8)
Self-monitoring + Reminder	2	5 (6.25)	3 (2.8)	8 (3.8)
Educational information + Communication with others	2	2 (2.5)	0 (0)	2 (1.1)
Educational information + Stress management	2	0 (0)	1 (0.9)	1 (0.5)
Educational information + Reminders	2	0 (0)	1 (0.9)	1 (0.5)
Self-monitoring + Reminder + Feedback	3	5 (6.3)	3 (2.8)	8 (4.3)
Self-monitoring + Reminder + Educational information	3	2 (2.5)	3 (2.8)	5 (2.7)
Self-monitoring + Feedback + Communication with others	3	1 (1.3)	1 (0.9)	2 (1.1)
Self-monitoring + Reminder + Feedback + Goal setting	4	5 (6.3)	2 (1.9)	7 (3.8)
Self-monitoring + Reminder + Feedback + Educational information	4	3 (3.8)	3 (2.8)	6 (3.2)
Self-monitoring + Feedback + Educational information + Goal setting	4	1 (1.3)	0 (0)	1 (0.5)
Self-monitoring + Reminder + Feedback + Goal setting + Communication with others	5	1 (1.3)	0 (0)	1 (0.5)
Self-monitoring + Reminder + Feedback + Educational information + Stress management	5	1 (1.3)	1 (0.9)	2 (1.1)
Self-monitoring + Reminder + Feedback + Educational information + Stress management + Goal setting	6	1 (1.3)	0 (0)	1 (0.5)

The most frequently used combination of functionalities was self-monitoring with automatic feedback (24/186, 12.9%). The second most common combination was self-monitoring and educational information (9/186, 4.8%).

5.3.2 Involvement of Health Care Professionals and Users in App Development and Scientific Evaluation

Six apps (3.2%) claimed to have had contributions from an HCP or medical organizations during their development; the other apps did not. No apps reported end-user involvement (eg, hypertensive patients) in their development. None of the apps appeared to have been scientifically evaluated. The description provided indicates that there is an absence of evidence concerning the effectiveness or usability of apps designed to help manage hypertension.

Data Security and Privacy

Accessibility and Availability of Privacy Policy

Of the 30 apps in the study that had comprehensive functionalities, the availability of a privacy policy in English was found in 20 apps (66.6%; Table 4.3). Of the 10 apps without an English-language privacy policy, only one provided a link to such a policy, but the link was not functional. Further, 4 of these apps provided a privacy policy in non-English languages.

The short-form notice indicating key data practices was not applicable to the 20 apps that provided a privacy policy, since the policies were already concise. Apps rarely offered multilingual policies, with only one app offering a policy in two other languages.

Table 4.3 Data privacy and security assessment of apps (data gathering, sharing, and security) on the basis of the description in the privacy policy.

.

Privacy and security question	iPhone (N=12), n (%)	Android (N=8), n (%)	Total (N=20)[a], n (%)
Is the privacy policy available without the need to download the app?			
No	0 (0)	0 (0)	0 (0)
Yes	12 (100)	8 (100)	20 (100)
Is the privacy policy available within the app?			
No	5 (42)	2 (25)	7 (35)
Yes	7 (58)	6 (75)	13 (65)
Is there a short form notice (in plain English) highlighting key data practices?			
No	0 (0)	0 (0)	0 (0)
Yes	0 (0)	0 (0)	0 (0)
Not applicable	12 (100)	8 (100)	20 (100)
Is the privacy policy available in any other languages?			
No	11 (92)	8 (100)	19 (95)
Yes	1 (8)	0 (0)	1 (5)
Does the app collect personally identifiable information?			
No	1 (8)	0 (0)	1 (5)
Yes	10 (83)	6 (75)	16 (80)
Not specified	1 (8)	2 (25)	3 (15)
Does the app share users' data with a 3rd party?			
No	0 (18)	0 (11)	0 (15)

Yes	8 (67)	6 (75)	14 (70)
Not specified	4 (33)	2 (25)	6 (30)
Does the app say how the users' data security is ensured? For example, encryption, authentication, and firewall			
No	6 (50)	5 (62)	11 (55)
Yes	6 (50)	3 (38)	9 (45)

[a]Only 20 apps had a privacy policy; 10 apps did not have a privacy policy available.

Data Gathering and Sharing

Sixteen of the 20 apps with a privacy policy in English (80%) disclosed the collection of personally identifiable information such as age. In three other apps, the data-gathering practices were not discussed. One app did not report personal data gathering.

The developers of 14 apps revealed that they shared the data they gathered with third parties and discussed sharing practices. In three apps, data-sharing practices were not discussed. In three other apps, the policies stated that data would not be shared, except in exceptional cases that were general and vague. Despite reporting that they did not share data, except in exceptional circumstances, we believe that they share data without specifically discussing their data-sharing practices.

Data Security

Almost half (9/20) of the apps reported how consumer data were secured. In these cases, the privacy policies explained that data safety and security are essential to their practices and that users' data have been encrypted, anonymized, or accessed only by authorized persons.

Behavior Change Techniques and Theoretical Domain Framework

Presence of Behavior Change Techniques

We identified 24 BCTs in the 30 reviewed apps featuring comprehensive functionalities (Table 4.4). The Cohen kappa for agreement between the two reviewers for coding BCTs was 0.85.

The total number of BCTs in each app ranged between 6 and 17 BCTs, with a mean of 18.4 (SD 2.6) and a median of 9. The most frequently used BCTs were "Self-monitoring of behavior," "Prompts/cues," and "Action planning." These were present in all 30 reviewed apps. The next most frequently used BCTs were "Feedback on behavior" and "Monitoring of behavior by others without feedback," which were present in 25 and 24 apps, respectively. Two of these 24 BCTs ("Social comparison" and "Demonstration of the behavior") were present only once. Table 4.4 presents the frequency of BCTs used in these 30 apps.

Table 4.4 Behavior change techniques (N=24) used in the reviewed apps (N=30).

Behavior change technique	Most common function of the app	Number of apps
Self-monitoring of behavior	Allows users to frequently record and self-monitor the performed behavior of their health in a diary, including measuring BP[a], weight, emotion, and record if they took medication or other behaviors	30
Prompts/cues	An alarm is activated when it is time to perform a task with the purpose of cueing and promoting the behavior	30
Action planning	Setting a reminder to perform a task(s) (taking medication, measuring BP, exercise, etc) at a specific time	30
Feedback on behavior	Provides feedback on the entered data by representing data in different color codes or through self-care messages	25
Monitoring of behavior by others without feedback	Allows others to consensually observe the performed behavior to support the management of hypertension	24
Self-monitoring of outcomes of behavior	Allows users to monitor BP readings (eg, average) and view trends over time	22
Feedback on outcomes of behavior	Provides feedback on behavior outcomes over time (eg, average) to allow users to view their health status	17
Pharmacological support	Setting a specific reminder to facilitate medication adherence at a specific time	15
Information about health consequences	Offers educational information about the health benefits and consequences of controlling and managing hypertension	14
Instruction on how to perform a behavior	Provides overall orientation on hypertension management (including how to self-monitor BP) as well as other behaviors	10
Focus on past success	Offers the number of cases where the BP level has been successfully controlled or the successful achievement specific goals	10
Credible source	Contains information from credible sources	9
Goal setting (outcome)	Allows users to set health goals for controlling BP	8
Problem solving	Enables users to analyze BP with other behaviors trends and develop the knowledge required to understand how to achieve optimal BP level by identifying problems that hinder BP control	8
Goal setting (behavior)	Allows users to set goals for the behavior to be attained, including times to measure BP, weight, exercise, and food goals	7
Review outcome goal(s)	Allows users to examine how well the BP level was controlled according to the agreed goal and consider modifying outcome goals accordingly	5
Review behavior goal(s)	Allows users to modify their goals according to their achievements	5
Social support (unspecified)	Offer a space to chat with others (eg, friends or families)	3
Social incentives	Add points or provides badges for users when achieving their target goals and tasks	3
Salience of consequences	Shows pictures of health consequences such as dizziness to shed light the dangers of uncontrolled BP	2
Monitoring of emotional consequences	Allows users to record their feeling after performing tasks including measuring BP or exercises	2
Reduce negative emotions	Provides advice on the ways to minimize negative emotions	2
Demonstration of the behavior	Offers an observable sample of the performance of the behavior with the help of pictures for the person to aspire to or imitate	1
Social comparison	Allows comparison of the user's own performance with others by sharing his/her performance to draw attention to the performance of others	1

[a]BP: blood pressure.

Mechanisms of Action of the Theoretical Domain Framework

BCTs present in the 30 reviewed apps could be linked to 10 TDF mechanisms of action. The number of TDF mechanisms of action underlying each app varied, ranging from 5 to 9, with a mean (SD) of 6 (1) and a median of 6.

The most common TDF mechanisms of action were "Behavior regulation" (30/30, 100%), "Knowledge" (30/30, 100%), "Goals' (30/30, 100%), "Memory attention and decision process" 30/30, 100%), and

"Beliefs about consequences" (30/30, 100%), which were present in all studied apps. The "Behavior regulation" mechanism of action was typically targeted by the "Self-monitoring of behavior" and "Self-monitoring of outcome(s) of behavior" BCTs, while "Knowledge" was mostly targeted by "Feedback on outcome(s) of behavior," "Instruction on how to perform the behavior," "Information about health consequences," and "Feedback on behavior." The "Goals" and "Memory attention and decision process" were mostly targeted using "Action planning" and "Prompts/cues" BCTs, respectively. The next most common mechanisms of action identified were "Beliefs about capabilities" (16/30), which was mostly targeted using BCTs "Problem solving," "Focus on past success," and "Social incentive." Almost one-third of the apps (9/30) had "Skills" as a mechanism of action, which was mostly targeted using "Problem solving" and "Demonstration of the behavior." "Social influences" (4/30 13%) was an infrequently used mechanism of action. The least common mechanisms were "Reinforcement" (3/30, 10%) and "Emotion" (3/30, 10%), which were present in only three apps. The mechanisms of action "Intention," "Optimism," "Professional role and identity," and "Environmental context and resources" were not presented in any app.

Additional Aspects

None of the 30 apps were FDA or CA approved. Eighteen apps (60%) were found to have information available concerning their user rating. Of these 18 apps, 13 (72.2%) scored 4 or more stars (of 5). Only 5 (27.8%) app ratings were below 4 (Appendix 9).

4.4 Discussion

Principal Findings

This study aimed to review all apps developed to support the self-management of hypertension, which are available on the two most popular app stores Google Play (Android) and Apple Store (iPhone).

The review showed that a significant number of apps (n=186) are available to support the self-management of hypertension. These apps had similar functionalities, although they differed in terms of the combination of functionalities provided. The majority of these apps had only one function (n=108, 58.1%), while the remaining offered different combinations of functionalities. This review indicated that there were few apps with comprehensive functionalities. Apps with comprehensive functionalities are potentially more effective (13).

There are also serious issues regarding the privacy and security of the apps and inconsistencies in apps' theoretical underpinning, where in many cases, apps were developed without an explicitly clear theoretical basis. The evaluation of the selected apps' data security and privacy revealed that the privacy policy was not available for 35% of the apps assessed in detail. Most apps gathered identifiable personal information and engaged in sharing user data with third parties and almost half of the selected apps (45%) did so without clearly disclosing how data security was ensured. The evaluation of the theoretical underpinning of apps revealed that a total of 24 BCTs, ranging from 6 to 17 (with median of 9), identified in the 30 reviewed apps mapped to 10 TDF mechanism of actions, ranging from 5 to 9 (with a median of 6), may have supported hypertension self-management behaviors. These findings are similar to reviews of apps related to other chronic diseases that have reported that few apps contain both comprehensive functionalities (10,35) and inconsistent BCTs (17,21). Despite much research that code BCTs underpinning health apps (17,19,21,22), there is little research reviewing how existing apps map BCTs to TDF domains. The linking of BCTs to TDF conducted in the present study may help developers and researchers in selecting appropriate BCTs when developing apps. It may also help researchers understand which BCTs are effective and how they exert their effects [36-38].

None of the reviewed apps made claims based on behavioral theories or strategies relating to various self-management interventions, although self-management programs are likely to be effective if they are supported by theory-based interventions (14-16). This may be because the expertise of health professionals was not factored into the development of the majority of these apps (35,39), despite the stressed importance of involving multidisciplinary perspectives and skills in developing a product within a user-center design framework (19). However, for the 30 reviewed apps with comprehensive functionalities, the examination of the BCT and TDF domains underpinning them shows that a number of BCTs and TDF mechanisms of action were present. There is still no conclusive evidence for which combinations of BCTs or TDFs are the key moderators for effective chronic disease self-management, especially hypertension (21,40,41). This is an area that requires further research. However, all present TDFs in these 30 apps have the potential to stimulate hypertension self-management activities through different mechanisms of action, particularly those of “Behavior regulation,” “Knowledge,” “Memory, attention and decision processes,” and “Goals.” These mechanisms of action are supported by studies identifying the key TDF domains that need to be targeted to influence patient behaviors and support self-management in chronic diseases (42,43). Although other studies have also found that “Skills,” “Emotions,” “Reinforcement,” and “Belief of capabilities” are essential to increase people’s motivation in managing their health, many of the reviewed apps lack these characteristics (44).

The evaluation of the privacy policy showed that the security and privacy of consumers could be substantially improved. Our findings are in accord with those of earlier studies that have evaluated data security and safety of existing apps (19,20). Huckvale et al revealed that one-fifth of apps in the National Health Service Apps Library lacked privacy policies, and the majority of the apps violated user data privacy and security (20). Practices of data gathering and analysis by app developers can be advantageous to users, providing greater levels of personalization and data-informed improvements to the app. However, such practices of data gathering should be disclosed clearly, so that a potential user is aware of the possible risks to their data security (45). To ensure users are able to make fully informed decisions, they must be equipped with the skills and information necessary to scrutinize these privacy and security policies. Because of the large scale of the app market, the regulation and preservation of data protection is difficult. As a result, the management of data privacy and security is entrusted to the developers of apps (46).

This review identified a small number of apps that are able to use smartphones as a medical device (cuff-less device) to measure BP. However, none of these apps were approved as a validated medical device. Indeed, cuff-less devices for measuring BP based on smartphone apps have recently been shown to be highly inaccurate and unfeasible (47) and may negatively affect patients' health and safety. This is of particular concern, since a recent study by Kumar et al (2016) found that even though only a small number of apps have this feature, users have a strong inclination to download and favorably rate these types of apps (12). This highlights the need for extensive clinical validation studies in different patient populations before such technology is used in commercial and clinical capacities. As such, physicians should currently be aware of the use of such apps by their patients and should promote only the use of validated devices for BP measurement.

Apps with more comprehensive functionalities have the potential to be more difficult for patients to use. This study found that there was an absence of evidence concerning the usability of the apps in the apps' descriptions. Although this study did not directly evaluate the apps' usability, user ratings were used as a proxy of the apps' usability. The usefulness of user ratings as a measure of apps' technical usability is questionable. In a review of mobile apps for the self-management of diabetes, Hood et al (48) found that the user rating was poorly correlated with the results of the study's usability evaluation. However, in a general sample of health apps, Mendiola et al found that user ratings could be related to an app's technical usability regarding aspects such as layout, interactive features, and general ease of use (49). The user ratings for the apps considered in this study were high, with 73% obtaining 4 or more stars. This is in line with previous studies (50,51) where participants reported that they were satisfied with apps that include comprehensive functionalities, finding them easy to use.

The majority of apps identified in the recent systematic review of Alessa et al (13) were study specific, that is, developed for the aims of the study alone (13). However, the apps considered in this review were commercially available apps in app stores. The descriptions of these apps lacked evidence about their effectiveness and did not even mention or consider the importance of such evidence. None of them were approved by the FDA or CE as a medical device. This is in line with previous reviews, which reported that the rapid growth of the commercial market for such apps has created an overabundance of apps that lack readily available evidence of their effectiveness (25) and lack FDA or CE approval (52,53). Applying the findings of this recent systematic review within this review of commercial apps indicated that few apps (30/186) seem to have the potential to be effective. Apps that have this potential would need to be scientifically evaluated to ensure that this potential for effectiveness and usability is realized in practice. This indicates a critical gap between the research domain and the work of commercial app developers, emphasizing the importance of cooperation between them.

Limitations and Strengths of the Study

This review has a number of limitations. First, the review only included apps that were developed to be used by English-speaking users, excluding apps in other languages such as Chinese. Second, since these apps are tailored for the self-management of hypertension, they support a wide range of different behaviors such as medication adherence, weight, diet, and physical activity in addition to the self-monitoring of BP, which makes it challenging to code them according to a single specific behavior and exclude other behaviors. This may be attributed to the complexity of the self-management process, which encompasses an array of behaviors and activities to effectively control BP. Third, this study excluded apps that require identification access. Moreover, the content of educational information of included apps was not checked to ensure they were up to date and met medical standards and health literacy guidelines. Finally, data privacy and security were assessed in relation to policy statements rather than practices. There is evidence of inconsistencies in some cases between the real practices of app developers and policy statements (20).

Despite these limitations, the study has several strengths. As this study reviewed all apps supporting the self-management of hypertension, rather than limiting itself to only the most popular apps (12), the results of this review offer a general picture of the present status of smartphone app stores in the field of hypertension. This comprehensive review will guide further research and development of these tools in different ways, for example, by encouraging developers and researchers to assess commercially available apps' effectiveness and usability among potential users and by urging app developers to be more transparent about privacy and security. The study reviewed apps on the two most common smartphone platforms; it thus considered a large user base. Furthermore, this study is the first systematic review to explore the theoretical underpinning of apps by seeking to map BCTs to TDF domains in apps containing comprehensive functionalities. The insights could be useful for content developers designing apps in the area of hypertension or other chronic diseases that aim to engage both users and health care personnel who are likely to encourage patients to utilize these technologies.

Recommendations

Based on the result of this review, some recommendations can be made. Despite the widespread availability of apps, potential users and health care providers should be made aware of the shortcomings in the security of private data as well as in the potential effectiveness of the apps in supporting hypertension self-management. Future efforts (and collaborations) should also be made by both researchers and commercial developers to encourage the development of apps that demonstrate scientific evidence of their effectiveness and usability to the public. The importance of involving end users in app development should be noted, as it helps improve user satisfaction and acceptance. This study's findings encourage further research to evaluate app effectiveness and technical usability. It is important to assess the effectiveness of commercially available apps in order to determine the positive and potential negative effects of using the app.

4.5 Conclusions

The review identified the widespread accessibility and availability of smartphone apps with a range of combinations of functionalities that can support the self-management of hypertension. However, relatively few of these apps contained comprehensive functionalities, which are more likely to be effective in lowering blood pressure; many lacked security measures; and most lacked a clear theoretical basis. Furthermore, there is a concerning absence of evidence with regard to their effectiveness and usability and involvement of health care professionals in the development process. This raises a serious practical issue for health care professionals and patients in determining which app to choose or use, as there are no specific criteria for them to make an informed selection. These findings demonstrate that the technical usability and effectiveness of apps in supporting the self-management of hypertension urgently need to be evaluated and that clear criteria need to be established to guide the selection of the most suitable app.

Acknowledgments

We thank all authors for their significant contribution. TA is a PhD student at Sheffield University and is funded by King Saud University, Saudi Cultural Bureau.

4.6 References

1. Olsen MH, Angell SY, Asma S, Boutouyrie P, Burger D, Chirinos JA, et al. A call to action and a lifecourse

strategy to address the global burden of raised blood pressure on current and future generations: The Lancet Commission on hypertension. Lancet 2016 Dec 26;388(10060):2665-2712. doi: 10.1016/S0140-6736(16)31134-5
2. Chow CK, Teo KK, Rangarajan S, Islam S, Gupta R, Avezum A, PURE (Prospective Urban Rural Epidemiology) Study investigators. Prevalence, awareness, treatment, and control of hypertension in rural and urban communities in high-, middle-, and low-income countries. JAMA 2013 Sep 04;310(9):959-968. doi: 10.1001/jama.2013.184182.
3. Shahaj O, Denneny D, Schwappach A, Pearce G, Epiphaniou E, Parke HL, et al. Supporting self-management for people with hypertension: a meta-review of quantitative and qualitative systematic reviews. J Hypertens 2019 Feb;37(2):264-279. doi: 10.1097/HJH.0000000000001867.
4. Marcolino MS, Oliveira JAQ, D'Agostino M, Ribeiro AL, Alkmim MBM, Novillo-Ortiz D. The Impact of mHealth Interventions: Systematic Review of Systematic Reviews. JMIR Mhealth Uhealth 2018 Jan 17;6(1):e23. doi: 10.2196/mhealth.8873
5. Bonoto BC, de Araújo VE, Godói IP, de Lemos LLP, Godman B, Bennie M, et al. Efficacy of Mobile Apps to Support the Care of Patients with Diabetes Mellitus: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. JMIR Mhealth Uhealth 2017 Mar 01;5(3):e4. doi: 10.2196/mhealth.6309
6. Whitehead L, Seaton P. The Effectiveness of Self-Management Mobile Phone and Tablet Apps in Long-term Condition Management: A Systematic Review. J Med Internet Res 2016 May 16;18(5):e97 . doi: 10.2196/jmir.4883
7. Logan AG. Transforming hypertension management using mobile health technology for telemonitoring and self-care support. Can J Cardiol 2013 May;29(5):579-585. doi: 10.1016/j.cjca.2013.02.024.
8. Barnes SJ, Pressey AD, Scornavacca E. Mobile ubiquity: Understanding the relationship between cognitive absorption, smartphone addiction and social network services. Computers in Human Behavior 2019 Jan; 90:246-258. doi: 10.1016/j.chb.2018.09.013
9. Zhang L, Hua K, Wang H, Qian G, Zhang L. Sentiment Analysis on Reviews of Mobile Users. Procedia Computer Science 2014; 34:458-465. doi: 10.1016/j.procs.2014.07.013
10. Rivera J, McPherson A, Hamilton J, Birken C, Coons M, Iyer S, et al. Mobile Apps for Weight Management: A Scoping Review. JMIR Mhealth Uhealth 2016 Jul 26;4(3):e87. doi: 10.2196/mhealth.5115.
11. Goldberg EM, Levy PD. New Approaches to Evaluating and Monitoring Blood Pressure. Curr Hypertens Rep 2016 Dec;18(6):49. doi: 10.1007/s11906-016-0650-9.
12. Kumar N, Khunger M, Gupta A, Garg N. A content analysis of smartphone-based applications for hypertension management. J Am Soc Hypertens 2015 Feb;9(2):130-136. doi: 10.1016/j.jash.2014.12.001
13. Alessa T, Abdi S, Hawley MS, de Witte L. Mobile Apps to Support the Self-Management of Hypertension: Systematic Review of Effectiveness, Usability, and User Satisfaction. JMIR Mhealth Uhealth 2018 Jul 23;6(7):e10723. doi: 10.2196/10723
14. Al-Washali AA, Kadri H, Ismail S, Rahman H, Elezzy Y. Systematic review on effectiveness of theory-based intervention on self-care behaviors among patients with type 2 diabetes. Clin Trials Degener Dis 2018;3(3):88. doi:10.4103/2542-3975.242955.
15. Band R, Bradbury K, Morton K, May C, Michie S, Mair FS, et al. Intervention planning for a digital intervention for self-management of hypertension: a theory-, evidence- and person-based approach. Implement Sci 2017 Dec 23;12(1):25. doi: 10.1186/s13012-017-0553-4.

16. Band R, Bradbury K, Morton K, May C, Michie S, Mair FS, et al. Intervention planning for a digital intervention for self-management of hypertension: a theory-, evidence- and person-based approach. Implement Sci 2017 Dec 23;12(1):25. doi: 10.1186/s13012-017-0553-4.
17. Lepard MG, Joseph AL, Agne AA, Cherrington AL. Diabetes self-management interventions for adults with type 2 diabetes living in rural areas: a systematic literature review. Curr Diab Rep 2015 Jun;15(6):608. doi: 10.1007/s11892-015-0608-3
18. Edwards EA, Lumsden J, Rivas C, Steed L, Edwards LA, Thiyagarajan A, et al. Gamification for health promotion: systematic review of behaviour change techniques in smartphone apps. BMJ Open 2016 Dec 04;6(10):e012447. doi: 10.1136/bmjopen-2016-012447.
19. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W, et al. The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. Ann Behav Med 2013 Aug;46(1):81-95. doi: 10.1007/s12160-013-9486-6
20. Bondaronek P, Alkhaldi G, Slee A, Hamilton FL, Murray E. Quality of Publicly Available Physical Activity Apps: Review and Content Analysis. JMIR Mhealth Uhealth 2018 Mar 21;6(3):e53. doi: 10.2196/mhealth.9069
21. Huckvale K, Prieto JT, Tilney M, Benghozi P, Car J. Unaddressed privacy risks in accredited health and wellness apps: a cross-sectional systematic assessment. BMC Med 2015 Sep 25;13(1):214. doi: 10.1186/s12916-015-0444-y.
22. Morrissey EC, Corbett TK, Walsh JC, Molloy GJ. Behavior Change Techniques in Apps for Medication Adherence: A Content Analysis. Am J Prev Med 2016 May;50(5):e143-e146. doi: 10.1016/j.amepre.2015.09.034.
23. Heron N, Kee F, Donnelly M, Cardwell C, Tully MA, Cupples ME. Behaviour change techniques in home-based cardiac rehabilitation: a systematic review. Br J Gen Pract 2016 Oct;66(651):e747-e757 doi: 10.3399/bjgp16X686617.
24. Steinmo S, Fuller C, Stone SP, Michie S. Characterising an implementation intervention in terms of behaviour change techniques and theory: the 'Sepsis Six' clinical care bundle. Implement Sci 2015 Aug 08;10:111. doi: 10.1186/s13012-015-0300-7.
25. Mazoteras Pardo V, Losa Iglesias ME, López Chicharro J, Becerro de Bengoa Vallejo R. The QardioArm App in the Assessment of Blood Pressure and Heart Rate: Reliability and Validity Study. JMIR Mhealth Uhealth 2017 Dec 15;5(12): e198. doi: 10.2196/mhealth.8458.
26. Parati G, Torlasco C, Omboni S, Pellegrini D. Smartphone Applications for Hypertension Management: a Potential Game-Changer That Needs More Control. Curr Hypertens Rep 2017 Jun;19(6):48. doi: 10.1007/s11906-017-0743-0.
27. BinDhim NF, Hawkey A, Trevena L. A systematic review of quality assessment methods for smartphone health apps. Telemed J E Health 2015 Feb;21(2):97-104. doi: 10.1089/tmj.2014.0088.
28. Karthick S, Binu S. Android security issues and solutions. 2017 Presented at: Proceedings of the IEEE Int Conf Innov Mech Ind Appl; 2017; Bangalore, India p. 686. doi: 10.1109/ICIMIA.2017.7975551]
29. Or C, Tao D. A 3-Month Randomized Controlled Pilot Trial of a Patient-Centered, Computer-Based Self-Monitoring System for the Care of Type 2 Diabetes Mellitus and Hypertension. J Med Syst 2016 Apr;40(4):81. doi: 10.1007/s10916-016-0437-1.
30. Logan AG, Irvine MJ, McIsaac WJ, Tisler A, Rossos PG, Easty A, et al. Effect of home blood pressure telemonitoring with self-care support on uncontrolled systolic hypertension in diabetics. Hypertension 2012 Jul;60(1):51-57. doi: 10.1161/HYPERTENSIONAHA.111.188409.
31. ICO. Privacy in mobile apps: Guidance for app developers Available from :https://ico.org.uk/media/for-organisations/documents/ 1596/privacy-in-mobile-apps-dp-guidance.pdf
32. TA: Online Trust Alliance. 2014. Mobile App Privacy & Security Available from: https://otalliance.org/best-practices/ mobile-app-privacy-security
33. Cane J, Richardson M, Johnston M, Ladha R, Michie S. From lists of behaviour change techniques (BCTs) to structured hierarchies: comparison of two methods of developing a hierarchy of BCTs. Br J Health Psychol 2015 Feb;20(1):130-150. doi: 10.1111/bjhp.12102.
34. Michie S, Atkins L, West R. The behaviour change wheel book - a guide to designing interventions. London: Silverback; 2014:9781912141081.
35. Michie S, Johnston M, Francis J, Hardeman W, Eccles M. From theory to intervention: mapping

theoretically derived behavioural determinants to behaviour change techniques. Appl Psychol 2008;57(4):660. doi: 10.1111/j.1464-0597.2008.00341.x
36. Lalloo C, Shah U, Birnie KA, Davies-Chalmers C, Rivera J, Stinson J, et al. Commercially Available Smartphone Apps to Support Postoperative Pain Self-Management: Scoping Review. JMIR Mhealth Uhealth 2017 Oct 23;5(10):e162. doi: 10.2196/mhealth.8230.
37. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, et al. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. Implement Sci 2017 Dec 21;12(1):77. doi: 10.1186/s13012-017-0605-9.
38. Carey RN, Connell LE, Johnston M, Rothman AJ, de Bruin M, Kelly MP, et al. Behavior Change Techniques and Their Mechanisms of Action: A Synthesis of Links Described in Published Intervention Literature. Ann Behav Med 2018 Oct 10:A. doi: 10.1093/abm/kay078.
39. Michie S, Carey RN, Johnston M, Rothman AJ, de Bruin M, Kelly MP, et al. From Theory-Inspired to Theory-Based Interventions: A Protocol for Developing and Testing a Methodology for Linking Behaviour Change Techniques to Theoretical Mechanisms of Action. Ann Behav Med 2018 May 18;52(6):501-512. doi: 10.1007/s12160-016-9816-6.
40. Rosser BA, Eccleston C. Smartphone applications for pain management. J Telemed Telecare 2011;17(6):308-312. doi: 10.1258/jtt.2011.101102.
41. Michie S, West R, Sheals K, Godinho CA. Evaluating the effectiveness of behavior change techniques in health-related behavior: a scoping review of methods used. Transl Behav Med 2018 Dec 01;8(2):212-224. doi: 10.1093/tbm/ibx019.
42. Kebede MM, Liedtke TP, Möllers T, Pischke CR. Characterizing Active Ingredients of eHealth Interventions Targeting Persons with Poorly Controlled Type 2 Diabetes Mellitus Using the Behavior Change Techniques Taxonomy: Scoping Review. J Med Internet Res 2017 Dec 12;19(10):e348. doi: 10.2196/jmir.7135.
43. McCullough AR, Ryan C, O'Neill B, Bradley JM, Elborn JS, Hughes CM. Defining the content and delivery of an intervention to Change AdhereNce to treatment in BonchiEctasis (CAN-BE): a qualitative approach incorporating the Theoretical Domains Framework, behavioural change techniques and stakeholder expert panels. BMC Health Serv Res 2015 Aug 22; 15:342. doi: 10.1186/s12913-015-1004-z.
44. Connell LA, McMahon NE, Tyson SF, Watkins CL, Eng JJ. Mechanisms of action of an implementation intervention in stroke rehabilitation: a qualitative interview study. BMC Health Serv Res 2016 Dec 30;16(1):534. doi: 10.1186/s12913-016-1793-8.
45. Thomas S, Mackintosh S. Use of the theoretical domains framework to develop an intervention to improve physical therapist management of the risk of falls after discharge. Phys Ther 2014 Nov;94(11):1660-1675. doi: 10.2522/ptj.20130412.
46. Singh K, Drouin K, Newmark LP, Rozenblum R, Lee J, Landman A, et al. Developing a Framework for Evaluating the Patient Engagement, Quality, and Safety of Mobile Health Applications. Issue Brief (Commonw Fund) 2016 Feb;5: 1-11.
47. Wicks P, Chiauzzi E. 'Trust but verify'--five approaches to ensure safe medical apps. BMC Med 2015 Sep 25;13: 205. doi: 10.1186/s12916-015-0451-z.
48. Plante TB, Urrea B, MacFarlane ZT, Blumenthal RS, Miller ER, Appel LJ, et al. Validation of the Instant Blood Pressure Smartphone App. JAMA intent Med. JAMA Intent2016 Dec 01;176(5):700-702. [doi: 10.1001/jamainternmed.2016.0157
49. Hood M, Wilson R, Corsica J, Bradley L, Chirinos D, Vivo A. What do we know about mobile applications for diabetes self-management? A review of reviews. J Behav Med 2016 Dec;39(6):981-994. doi: 10.1007/s10865-016-9765-3.
50. Mendiola MF, Kalnicki M, Lindenauer S. Valuable features in mobile health apps for patients and consumers: content analysis of apps and user ratings. JMIR Mhealth Uhealth 2015 May 13;3(2):e40. doi: 10.2196/mhealth.4283.
51. Hallberg I, Ranerup A, Kjellgren K. Supporting the self-management of hypertension: Patients' experiences of using a mobile phone-based system. J Hum Hypertens 2016 Feb;30(2):141-146. doi: 10.1038/jhh.2015.37.
52. McGillicuddy JW, Weiland AK, Frenzel RM, Mueller M, Brunner-Jackson BM, Taber DJ, et al. Patient attitudes toward mobile phone-based health monitoring: questionnaire study among kidney transplant recipients. J Med Internet Res 2013 Jan 08;15(1):e6. doi: 10.2196/jmir.2284.

53. Wisniewski H, Liu G, Henson P, Vaidyam A, Hajratalli NK, Onnela J, et al. Understanding the quality, esffectiveness and attributes of top-rated smartphone health apps. Evid Based Ment Health 2019 Feb;22(1):4-9. doi:10.1136/ebmental-2018-300069.
54. Eng DS, Lee JM. The promise and peril of mobile health applications for diabetes and endocrinology. Pediatr Diabetes 2013 Jun;14(4):231-238. doi: 10.1111/pedi.12034.

4.7 Additional data

Table 4.7.1 Linking functionalities to BCT and TDF

Functionalities	BCTs	TDF
Self-monitoring	Self-monitoring of behaviour	Behaviour regulation
	Self-monitoring of outcomes of behaviour	Behaviour regulation
Use of prompt/cues (reminder and alert)	Prompts/cues	Memory attention and decision process
	Action planning	Goals
	Pharmacological support	Memory attention and decision process
Educational information	Information about health consequences	Knowledge
	Instruction on how to perform a behaviour	Knowledge
	Credible source	Beliefs about consequences/knowledge/reinforcement
Automatic Feedback	Feedback on behaviour	Knowledge/ beliefs about consequences
	Feedback on outcomes of behaviour	Knowledge/ beliefs about consequences
	Problem solving	Skills, beliefs about capabilities Behaviour regulation
	Focus on past success	Beliefs about capabilities
	Social incentives	Beliefs about capabilities
Goal setting	Goal setting (outcome)	Goals
	Goal setting (behaviour)	Goals
	Review outcome goal(s)	Goals
	Review behaviour goal(s)	Goals
Communication with others	Social support (unspecified)	Beliefs about capabilities
Stress Management	Monitoring of emotional consequences	Emotion
	Reduce negative emotions	Emotion

Table 4.7.1 is a supplementary table showing how the various functionalities identified in the apps linked to specific BCTs and TDFs. For example, the functionality of 'self-monitoring' was linked with the BCTs of 'Self-monitoring of behaviour' and 'Self-monitoring of outcomes of behaviour', and to the TDF mechanism of action 'behaviour regulation'.

In one section of the published article (Data Gathering and Sharing), it was stated that 'we believe that they [apps] share data without specifically discussing their data-sharing practices'. This was because the definition of the 'exceptional cases' in which these apps might share data was not explained, and it was therefore assumed they might share data without specifically discussng their data-sharing practices.

Chapter 5 Study 3: Selection of the most suitable app for Saudi Arabia; exploration of its acceptance among end users

The previous chapter presented the app store review to identify and assess commercially available hypertension self-management apps. This chapter presents the systematic selection approach used to identify which of these apps is most suitable, based on the criteria of effectiveness, theoretical underpinning, and privacy and security. It also presents the qualitative study among Saudi patients and doctors conducted to select the most suitable app for the Saudi context. This selected app will then be assessed via the final study of this research, presented in the next chapter.

5.1 The Selection process of the most suitable apps

There is not an established systematic approach to select the most suitable apps to support the self-management of hypertension. Three criteria were therefore devised. The first criterion was likely effectiveness; it is imperative and fundamental in the field of healthcare to only implement and use interventions that are effective. The existing evidence of apps' effectiveness was collected in Chapter 3 (the systematic review). This evidence was drawn on here to assess the effectiveness of the apps.

While many apps are not based on theoretical frameworks (1,2), the theoretical background of the app was added as an additional criterion because interventions that are based upon theory/theories tend to be more effective in self-management (3). The existing evidence of the apps' mechanisms of action (from TDF), that was discussed in Chapter 4 (app store review), was used here to check this criterion.

The last criterion is privacy and data security. The research needs to be in accordance with ethical guidelines to ensure the privacy of patients (4). The evidence of the apps' privacy, that was presented in Chapter 4, was used here to check this criterion.

Figure 5.1 summarizes the three criteria in the process with the criteria to be used. In the next paragraphs the criteria are discussed in more detail.

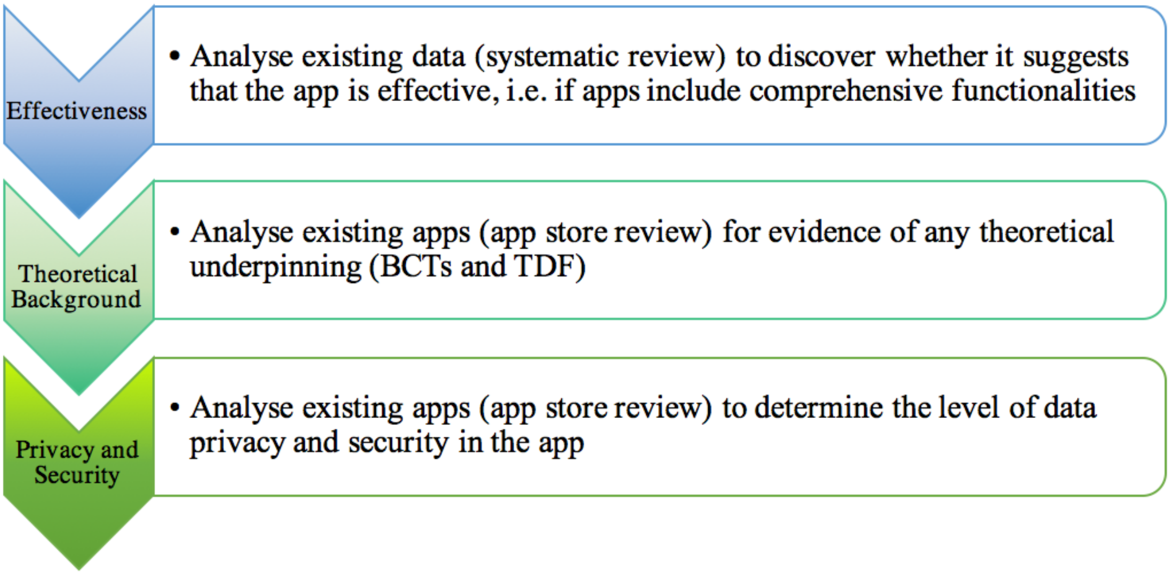


Figure 5.1 Selection process of the apps

5.1.1 The Effectiveness of the App

The systematic review presented the evidence of apps' effectiveness, and considered factors that might influence this. The evidence suggests that apps including comprehensive functionalities tend to be more effective (2). Comprehensive functionalities was defined as having the functionalities of self-monitoring and reminders, as well as educational information and/or automatic feedback.

In order to grade effectiveness, the apps were scored in the following way: if an app has been evaluated and found to be effective it was marked '++'; if an app is *assumed* to be effective, which is the case when is has not been evaluated as such but does possess comprehensive functionalities, it was marked with '+'. An app was marked with a '-' if there was no previous evidence of its effectiveness and it did not include comprehensive functionalities. Lastly, evidence that is neither positive nor negative was marked with a '+/-', such as when an app did not show a significant difference following the intervention, or between the intervention and control groups.

5.1.2 Theoretical background

As mentioned earlier in the section 'Self-management Theories' (Section 2.4), there is no single preferable theory that underpins effective intervention in the self-management of chronic diseases, (e.g. hypertension), that could be drawn upon directly and used to select potentially suitable apps (3,5-7). However, the presence of theoretical underpinning is desirable as a theory-based intervention is more likely to be effective in supporting self-management (3). They can also help to understand how and why an intervention is working

(3,5). Therefore, apps were analysed to discover if they are informed by a theoretical framework 'TDF mechanisms of action'.

To understand whether an app is informed by a theoretical framework or not, the app store review aimed to identify the theoretical basis of available apps. First, BCTTv1, a prominent model in the health field (8), was used to code the content of apps. This was used to identify BCTs used within the apps' content in the intervention (8). Then, as mentioned above (see section 2.4.5), the BCTs of the app contents were linked with 14 TDF mechanism of actions to investigate these domains underpinning the apps[1]. If a link is found to any number of the mechanisms of action the app was considered to have a theoretical basis. This was presented in Chapter 4.

If the app is based on theoretical background(s), it was marked with a '√' to show that it is theory-based, and the number of mechanism of actions was added. If not, it was marked with an 'x' to show that it is not theory-based.

5.1.3 Privacy and Security

The final criterion to be considered was privacy and security. Privacy and security is one of the main indicators of the quality of an app, as protection of the privacy of patients is in accordance with ethical guidelines (4). This criterion was assessed in the app store review (Chapter 4). The assessment of privacy and security was based on the recommendations of the Online Trust Alliance and Information Commissioners Office (9,10). The privacy and security of each app was assessed via 8 questions, to which the answers can only be 'yes' 'no', or 'NS'. If they meet the criteria for data gathering, sharing and security (see Chapter 4 Table 4.3), they were considered safe for participants to use and marked with a '√' (9,10). If they did not meet the criteria they were marked with an 'X' and were excluded from the selection.

5.1.4 Results

Of the 186 apps reviewed, 30 were identified with the potential to be effective (see Table 5.1). These 30 are assumed to be effective because they included comprehensive functionalities (see systematic review on effectiveness of existing apps – Chapter 3). Two apps were directly evaluated for effectiveness (11). These two were versions of the same app running on different systems (iPhone and Android). Theoretical underpinning was present in all apps reviewed. The BCTs in these apps linked to 10 out of 14 TDF mechanisms of action. The number of different TDF mechanisms of action that underpinned each app varied from 5 to 9, as presented in the app store review (Chapter 4).

[1] There is a more recent example of linking BCTs to more comprehensive mechanism of actions from Michie team (Michie et al. 2019). But as the paper was under review during linking process it has not been included in this research.

When assessing the criteria regarding privacy and security, 20 out of the 30 apps made their privacy policy available before download. So, 10 apps were excluded because they do not have a privacy policy to be assessed. However, despite collecting personal data, 12 of the 20 remaining apps did not discuss the sharing practices and/or provide adequate security measures (encryption and anonymised data) to protect users' data. As a result, these 12 were excluded from our selection.

Of the remaining 8 apps, 3 are duplicated, meaning they have both android and iphone versions. Initially, these were treated and scored separately to ensure both versions met the selection criteria. Unlike some apps which failed on one system but not on the other (e.g., ESH care), both the iphone and android versions of Qardio, HyTen Life-course and Braun heart healthy met the selection criteria. The versions are identical between the two platforms, having the same functionalities, style and design, created by the same developers. For this reason, these were considered as three apps rather than six, leaving a total of 5 unique apps.

Of these 5, 4 had privacy policies only available in English. Although the OTI recommend privacy policies are made available in other languages, this is not an essential requirement, and these apps were included. A further 2 of the 5 apps do not provide a privacy policy within the app. These have likewise been included since it is not considered an essential requirement when the privacy policy has already been made available before downloading the app. Therefore, a total of 5 apps were selected that met the assessment criteria. These are ESH care, Qardio, Cora health, HyTen Life-course and Braun Healthy Heart, which are highlighted yellow.

Table 5.1 Selection process of the apps

Number	App name	Version Type	Effectiveness	No. of TDF mechanisms of action		Privacy & Security
1	Blood pressure - Smart BP	iPhone	+	7	√	X
2	Fast BP	iPhone	+	6	√	X
3	BP Wiz	iPhone	+	6	√	X
4	Blood pressure and plus diary	iPhone	+	7	√	X
5	BP Grapher simpler	iPhone	+	7	√	X
6	BP matters	iPhone	+	5	√	X
7	Braun Healthy Heart	iPhone	+	7	√	√
8	Braun Healthy Heart	Android	+	7	√	√
9	Qardio	iPhone	+	5	√	√
10	Qardio	Android	+	5	√	√
11	my heart (Blood Pressure)	Android	+	7	√	X
12	Blood Pressure Diary	Android	+	5	√	X
13	Homedic	iPhone	+	7	√	X
14	Hemie	iPhone	+	4	√	X
15	HyTen Life-course	iPhone	+	5	√	√
16	HyTen Life-course	Android	+	5	√	√
17	Goal Achiever	Android	+	7	√	X
18	Cardio journal Blood Pressure diary	Android	+	6	√	X
19	control tension	iPhone	+	6	√	X
20	control tension	Android	+	6	√	X
21	ESH care	iPhone	++	7	√	√
22	ESH care	Android	++	7	√	X
23	Paracelsus (Pressure control)	Android	+	7	√	X
24	BP Companion	iPhone	+	7	√	X
25	Cora Health	iPhone	+	9	√	√
26	Heart Star BP	iPhone	+	7	√	X
27	Kang	iPhone	+	6	√	X
28	BP diary	Android	+	7	√	X
29	BP diary	iPhone	+	7	√	X
30	Bprsseo pro	Android	+	7	√	X

5.2 Selection and acceptance by Saudi patients and doctors: A qualitative study

In the previous section, we identified five apps that were potentially effective and secure. In this section, we explore patients' and doctors' views towards using hypertension self-management apps in general, and towards these five apps specifically, to select the most suitable for the Saudi context.

5.2.1 Introduction

In order for these five apps to be successfully implemented in practice it would be necessary to include the main stakeholders, including doctors and patients, in investigating their needs, acceptance of, and attitudes towards the use of hypertension apps in general and their preference toward the five identified apps, helping to select the most suitable app. User-centered design (UCD) is a common process for factoring the experience of patients into the design process (12,13). However, there is little evidence that developers of mHealth apps have given attention to the needs and wants of users by involving them (14,15). The questions of what specific areas of self-management users need more support with, and even whether they are willing to use such apps that support self-management, need to be considered.

However, despite the increasing number of hypertension apps on the market and the expectation that such apps are able to support the self-management of hypertension in clinical and personal contexts, at the time this research was conducted there were very few studies that have explored patient and doctor views towards these apps in general (16-18), and none exploring the in the Saudi context in particular, or the other Gulf countries. The second search phase identified more recent studies considering patients' and/or doctors' views towards these apps, but still none assessing the Saudi context and focus on user experience after using the app as an intervention (19,20). Moreover, the studies by Morrissey et al (17,18) exploring patient and doctor attitudes towards hypertension self-management apps, mainly focus on apps' potential to improve medication adherence, and not on selecting the most suitable app. It was therefore currently unknown whether these five commercial apps would be suitable and acceptable for the self-management of hypertension, and what preferences doctors and patients may have with respect to such apps in particular, or their interest in and acceptance of mHealth apps in general. Since acceptance of an app positively influences its successful use in self-management (21,22), this study explored the acceptance and attitudes of patients and doctors towards the five hypertension self-management apps identified in the systematic approach above, with the aim of selecting the most suitable app.

The specific objectives of this study were as follows:

1- To explore patients' and doctors' views and attitudes towards the use of mobile apps to support the management of hypertension by patients and identify the potential benefits and challenges in the use of such apps

2- To identify the most suitable app based on the views of both doctors and patients and the reasons why this is considered the most suitable

3- To explore patients' willingness to use the selected app.

5.2.2 Study Design and Methods

This study used an exploratory qualitative approach to elicit patients' and doctors' views and experiences toward using apps in self-management of hypertension (26). The goal was to to identify which of five presented apps would be most suitable for use in Saudi Arabia the factors patients identified as contributing to an app's suitability.

The study explored new insights and in-depth understanding within a small sample size, which are key aims of a qualitative approach that 'explores' a topic in greater detail (26, 28). This contrasts with quantitative research which focuses on collecting statistical data from a large group of individuals and generalizing its findings across groups (23).

Focus groups were used to explore Saudi patients' attitudes, while semi-structured interviews were used to explore doctors' attitudes and acceptance. The research first captured participants' insights about the use of apps by patients in supporting the management of hypertension, their potential benefits, and challenges to their use. The researcher then presented five apps in video format. Although interaction with the apps themselves could better capture acceptance and attitudes (17,18), video format was chosen so as to present them in a standardized way. This format also skirted the problem of the apps being unavailable in Arabic at the time. Presentation in video format enabled the researcher to showcase the functionalities of the apps and how they work in a much more visual and informative manner than if the apps had merely been described. The rationale behind using focus groups for patients and individual interviews for doctors is discussed further below.

5.2.2.1 Participants

Population and setting

The population of interest were Saudi adults with hypertension as primary disease, and doctors treating hypertension. Data collection took place between December 2018 and February 2019. The research was conducted in the capital city of Saudi Arabia, Riyadh, because it has the highest number of adults with hypertension in Saudi Arabia (Ministry of health (MOH) 2013). This study was undertaken at the two largest primary care centers in Riyadh and two hospitals (in outpatient clinics): King Fahad Medical City (KFMC) and King Khalid University Hospital (KKUH), which are the largest hospitals related to MOH and university hospitals respectively.

Sampling method

A convenience sample was used to recruit doctors and patients (26,60) at the hospitals and centres mentioned above. This sampling method is regularly used as it is cost-efficient, easy and fast (26). Despite its disadvantages, including the possibility of increasing the risk of selection bias and the lack of transferability to the whole population (26), this method was used in this research for practical reasons.

Eligibility criteria

The eligibility criteria for focus-group participants were as follows: being at least 18 years old, having hypertension as a primary disease for a minimum of 6 months, being able to speak and give consent. The exclusion criteria were as follows: having cognitive impairment that limited their ability to give informed consent or being able to actively take part in the focus groups, or having prehypertension or hypertension during pregnancy. Doctors were eligible if they have treated people with hypertension for a minimum of six months.

Participant Recruitment

Once the permissions from care settings to conduct research were obtained, posters and flyers were distributed at the hospitals and primary care centers, advertising the focus groups and interviews separately. These posters and flyers included a brief description of the aims of the focus groups and interviews.

Posters directed at patients advertising the research were displayed at the entrances and waiting area rooms of the two primary care centers and the outpatient clinics of the hospitals. Flyers advertising the research were also placed in waiting area rooms and receptions for patients. In addition, the researcher directly handed out flyers to potentially suitable patients in the waiting areas of the hospitals and primary care centers.

Posters directed at doctors were displayed at the entrances of the two primary care centers and the outpatient clinics of the hospitals. The researcher also approached potential participants in doctors’ weekly morning meetings to inform them about the study. Flyers were handed to them.

Participants who were interested were asked to contact the researcher, whose details were included on the posters and flyers. The researcher verbally explained the aim and objectives of the study and gave them the opportunity to ask any questions about the study. Interested participants were then sent an information sheet in Arabic, relevant to their involvement as either a doctor or patient (Appendix 12 and 13 - English version and Arabic version). The information sheet included further information about the study, and participants were then given sufficient time to consider whether they would like to participate. When participants agreed to take part in the study, suitable times and locations of the focus groups or interviews were agreed that were convenient for participants. A reminder was sent at least 24 hours before the meeting via email or SMS. Each session was conducted after the participant's informed consent was given (Appendix 10 and 11). Participants were recruited until data saturation was reached.

Number of Participants

The aim was to recruit approximately eight doctor participants for interviews, and a range of 20-32 patient participants, with a range of five to eight participants in four focus groups, as it has been argued that 4-12 participants in a focus group is desirable (31). Data was checked to ensure saturation at point of preliminary analysis (59). Saturation was achieved once four focus groups and twelve interviews had been conducted, after which no new topics/findings were being expressed.

This number of interviews and focus groups is in line with qualitative methodology recommendations (28-30). Morgan et al. (28) state that it is the first 5-6 interviews which will provide novel data and concepts. Guest et al. (30) make a related observation, identifying 6-12 interviews as normally sufficient to reach saturation, and Guest et al (31) suggested that 3-6 focus groups will identify 90% of the themes and the optimal number of individuals in focus groups is between five and eight.

5.2.2.2 Methods

Focus groups

The rationale for choosing focus groups as the method for data collection is that it provides a more complete picture of participants' experience in self-managing hypertension and their attitudes toward, and acceptance of, using mobile apps as a self-management aid. Focus groups are inherently interactive, and participation in a group discussing areas of disagreement and exchanging ideas may yield a more dynamic discussion, resulting in a cumulative understanding of the discussed topic (26,32). For these reasons focus groups were considered likely to aid the process of selecting the most suitable app and understanding participants' attitudes towards using these apps in the self-management of hypertension.

Focus group Procedures

Each participant was asked to sign a consent form and then complete a brief questionnaire (Appendix 14) about their personal details. The focus groups were conducted in Arabic. The participants were first encouraged to introduce themselves before being asked to discuss how they self-manage their condition. Then, they were asked what they know about health apps and whether they have used health apps to support the self-management of hypertension before. Next, the researcher asked them to watch 5 videos, which described to participants the apps' functionalities and how each one works. The order in which the videos were displayed was randomized. This was done by having participants draw folded slips of paper numbered 1 to 5 to determine the order. The videos demonstrated how each app works and what its functionalities are. After that, participants were asked about their attitude towards using the apps in the self-management of hypertension. The participants were given the opportunity to discuss the features of each app as well as its benefits and limitations, and were asked to rate each app from 5-(' very suitable') to 1- ('not suitable') for self-managing their condition. When the above had been completed, the researcher thanked participants for their participation and briefly explained to them how the research would be enhanced by their data. Participants were also reminded again that procedures were followed to ensure the confidentiality of their data. For more details about focus group questions, see Appendix 15

Interviews

Interviews were chosen as the method of data collection for doctors because, despite the benefits mentioned above, focus groups are difficult to arrange with doctors as participants. This is because the professional demands placed on doctors mean that finding a time and date that is agreeable to all interested participants will be challenging. Tausch and Menold (33), moreover, state that time constraints on clinicians could negatively affect group communication. Additionally, it is claimed that junior doctors may not feel confident disagreeing with certain opinions expressed by more experienced doctors, such as consultants (33,34). Thus, a face to face semi-structured interview method was used. This helps to make sure that each doctor is given sufficient chance to present his/her own point of view. Semi-structured interviews also help to collect in-depth insights and opinions from doctors (26,34).

Interview Procedures

The procedures followed with the focus groups were applied to the interviews with the doctors with some relevant changes. Each participant was asked to sign a form giving consent to the study. The participant was first asked about his/her demographic background, including their age, professional position, years of experience in healthcare, and smartphone experience. Then, the participants were asked how their patients self-manage their condition, whether they had ever suggested that a patient should use an app to help manage their hypertension, and about their attitude towards patients who use apps in the self-management of their condition. Next, the researcher asked them to watch the app videos. The same procedure was followed as in the focus groups. After that, they were asked about their attitude towards patients using the apps in the self-management of hypertension. The participant was given the opportunity to discuss the features of each app as well as its benefits and limitations. Finally, they were asked to rank each app from 5 to 1 on the basis of how they think the apps will help patients manage their condition. Once the above was completed, the researcher thanked the participants for their participation and briefly explained to them how the research would be enhanced by their data. Participants were reminded again that procedures had been followed to ensure the confidentiality of their data. For more details about interview questions, see Appendix 16.

5.2.2.3 Translation and transcription

The topic guides for the interviews and focus groups were translated from English to Arabic. Then, these topic guides were translated back into English by a lecturer in the college of applied medical science at university. These back translations were compared with the original topic guide to ensure that the meaning had not been altered. No changes in meaning were found.

Interviews and focus groups were performed by the researcher in the native language of both the researcher and participants (Arabic) and then transcribed verbatim in the original language. Transcribed data was then translated into English. The transcripts were anonymized and any identifiable personal information was removed. The transcripts were then translated back into Arabic by a professional translation service which specializes in both languages used (Arabic & English). These back translations were compared with the original transcripts to ensure that the meaning had not been altered. No changes in meaning were found.

5.2.2.4 Quality Criteria (Validity of research)

Concepts such as ‘dependability’, ‘transferability’ and ‘credibility’ are used to analyse the quality of qualitative research (whereas the quality of quantitative research is assessed with reference to ‘validity’ and ‘reliability’) (26,35). Yardley (36) has created an itemised list of factors that should be taken into account when assessing the quality of qualitative research, a number of which relate to and intersect with the concepts of credibility and dependability. This includes ‘sensitivity to context, commitment and rigour’ (related to credibility), ‘transparency and coherence’ (related to dependability), and ‘importance and impact’ (36).

In this study, it was important to pay attention to quality during all steps of the study, to ensure that the research is always of a high quality. This will ensure that the findings are transferable and can be replicated.

The credibility and dependability of this research were enhanced by the following: (1) the researcher exhibited a sensitivity to context, through familiarity with the socio-cultural setting within which the research was being undertaken. The credibility was enhanced by maintaining an extended engagement with the topic in general (by means of literature review) and an awareness of participants' perspectives by immersing herself within the data through data collection, transcription and analysis; (2) using reflexivity, exhibiting an awareness of and reflecting the researcher's own position within the research. The researcher's background and relevant personal history were disclosed, and how such details might impact on the findings of the research; (3) the production of an audit trail, documenting the stages and steps of the research process (including data sources, data-collection techniques and analysis, and decision-making) and ensuring a match between research questions and methods, clearly setting out the justification for which method for answering the research question was deemed most appropriate, as explained in the method section; (4) ensuring that data collection and analysis was comprehensive and exhaustive, and that the sample was sufficient to reach 'saturation' (26,35,36).

It is also important to ensure the clear presentation of findings, themes and sub-themes and pay attention to negative cases. This further entails fair dealing with participants, ensuring that an array of perspectives is included in the discussion to ensure that no perspective is over-represented (25,35, 36). This thick description of data-collection and the study findings, entailing how patients and doctors perceived using apps in self-management, help to determine whether the study results can be transferred into similar contexts, groups or settings (26,36). Finally, peer debriefing, in the form of the researcher's supervisions throughout the course of the study, has informed the analysis and therefore contributes to the overall credibility of the research (35).

5.2.2.5 The role of the researcher

Having utilised a qualitative approach, it is important to acknowledge the researcher experiences, beliefs, and values, so as to understand the effect of these on her interpretation of the data.

The researcher background as a teaching assistant in health technology at King Saud University (KSU) may have influenced the study process, including her interpretation of the data results. It is also possible that some participants may have provided answers to please her as the researcher, which do not reflect their own views but rather what they consider to be the ideal in health standards. For instance, they may have suggested that they are more active in self-management of hypertension when they are not. Some participants may also have been disinclined to admit that they did not have experience of hypertension apps, as they may have worried about leaving a bad impression on the researcher. To mitigate against these potential risks of bias, the researcher made sure to inform all interview and focus group participants that there were no right or wrong answers. In addition, she did her best to ask more probing questions, in order to elicit more accurate data and improve her own understanding. Establishing participant-researcher rapport was used as an additional strategy to decrease risk of bias, as a good participant-researcher relationship is key to encouraging participants to answer questions more freely, to increase the richness of the data (37). To achieve this rapport, the researcher began the interviews and focus groups with general conversation to build trust and create a comfortable atmosphere within which participants felt able to give their honest opinions. The researcher also shared information with participants, such as her professional background and experiences as a PhD researcher and health informaticist to help foster a relationship.

Moreover, the researcher's background as a Saudi citizen, i.e. as someone with a similar cultural background to the participants, is likely to have impacted on the research. Working with a Saudi researcher could make participants feel more comfortable, creating a shared understanding within which participants are more likely to share and elaborate on some parts of their experience which they would be more reluctant to share with a non-Saudi researcher. Additionally, the researcher's awareness of aspects of Saudi culture, such as specific social norms, gave her a clearer understanding of the views and experiences of participants, helping her to interpret their responses, as well as to ask relevant follow-up questions.

Her position as a female researcher was also likely to be significant to the data-collection, within the context of a conservative culture where gender segregation is possible. Although there has been a great change in the country in the recent years through the increase of Saudi people working in mixed environments of both males and females, the researcher was aware that there may be some potential difficulties when collecting data from male participants, who would be less likely to speak freely to a woman, particularly in a one-to-one situation. The researcher mitigated this risk by consciously building a good relationship with male participants by using preferred names and ice-breaking questions, as well as asking more suitable probing questions. The researcher also paid attention to whether female participants within focus groups were willing to speak freely to males, and tried her best to encourage all participants, regardless of their gender, to express their opinions. The researcher found that this was not an issue. Female participants did speak freely and their number of contributions was approximately equal to their male counterparts.

At the outset of the research process, the researcher already had her own opinions and beliefs about the importance of patients using apps for the self-management of hypertension; however, she tried to be neutral in the interviews and focus groups, refraining from expressing her views to ensure truly honest answers from participants. During data analysis, the researcher sought to mitigate any potential impact she may have had on the results by keeping a log of her personal feelings in response to each interview and focus group. Doing this helped her to recognise her own feelings and how these might be influencing her interpretations, or preventing her from consistently recording participants' responses. However, it is possible that the researcher's own background may still have influenced her interpretation. Patton (37) showed that the researcher's own biographical position can influence the results of a qualitative study, because researchers may identify with aspects of participants' experiences and attitudes. This potential bias was mitigated by regular discussions with her PhD supervisors.

5.2.2.6 Piloting the interview and focus groups

After the interview and focus groups schedules and questions had been presented to the research team, ensuring they covered the main aims of the study, they were translated to Arabic. The interviews and focus groups were then piloted by one volunteer doctor (male) and two volunteers' patients (male and female). This pilot was carried out to discover whether the ways in which questions were phrased were clear and appropriate; to check how long the participants needed to respond to questions; to assess whether there are other questions that could be included in the study; to check whether the videos which formed part of the study were intelligible; to ensure that the cover letter was intelligible and conveyed information accurately; and finally, to discover if the planned interviews met the aims and objectives. Participants were informed that this was a pilot study being conducted to assess the appropriateness of the interview and focus group questions, and other aspects of the study design. They were also informed that their confidentiality was assured, and that their data would be deleted as soon as possible, before collecting the main data.

The pilot study led to some amendments in the Arabic words/phrases of some questions to make these clearer for the participants, and to encourage more relevant responses. The interview and focus group were conducted within the expected time. However, in the interview with the doctor, the participant talked longer in some question than was expected. He spoke in detail about the first questions, then answered the last questions quickly to go back to his clinic. Following this, the researcher made efforts to manage time properly and divide it sufficiently among all questions.

5.2.2.7 Data Analysis

All qualitative interviews (both focus groups and individual interviews) were recorded, transcribed, checked for accuracy by checking the transcriptions against the audio files and then translated. Participant personal data was not included in the transcription for ethical reasons. In addition to the interview recording, the researcher also kept field notes outlining key observations, seemingly anomalous findings and so forth, to provide the research with richer context.

Preliminary analysis was conducted to establish participant demographic information, such as age and gender. Framework analysis was used to analyze the transcripts using NVivo 12 software (QSR International Pty Ltd). Framework analysis comprises five steps: (i) Familiarization; (ii) identifying a theoretical framework; (iii) indexing; (iv) charting; and (v) mapping (38). Data familiarization was attained through undertaking the interviews and focus groups, transcribing and checking the transcriptions against the audio files.

The framework method is often used to perform a thematic analysis of semi-structured interviews. A framework method was chosen for this study as a framework is able to include existing ideas, such as a priori themes (38,39), and because it allows for unanticipated aspects of participant experience to be included in the study (39). This means the framework analysis is neutral in respect to either inductive or deductive analysis, which are both utilized in this study. The framework approach is also suitable because it is designed to answer specific research questions, as in the present study (40).

This study framework has two parts, corresponding to the two objectives of this study: first, to explore attitudes towards apps for self-management in general and patient experience of self-management; second, to assess participant attitudes towards the use of five specific apps and their preferences.
The initial themes and sub-themes for the first part of the framework were developed and identified through the topic guide of the interviews and focus groups, alongside familiarization with the data. The initial themes and sub-themes for the second part were identified from the results of previous studies, including our own systematic review and app store review, the topic guide, alongside familiarization with information gathered from the interviews, and also through what was presented in the videos in the interviews and focus groups. These initial themes and sub-themes together were used as the basis for the study framework. Transcripts were then indexed using this framework; other themes and sub-themes that were identified during the analysis itself were included in the framework. If a new theme or sub-theme was added, indexed transcripts were checked to identify any potentially relevant information to the new theme or sub-theme. When indexing was complete, the framework was checked to ensure only relevant information had been coded in its themes and sub-themes. In addition, all transcripts were also checked for errors in the coding of data. The data were then charted in framework matrices, with a matrix for each theme. The data were then mapped and interpreted. Each theme was then described in detail, and any contradictory findings were identified and noted, along with differences between sub-groups (i.e., doctors and patients). With these factors in mind, the data were then mapped and interpreted to identify potential explanatory accounts. In order to select the most suitable app, data from the matrices were summarized in a table explaining participant preferences towards each sub-theme for the identified apps.

5.2.2.8 Ethical considerations

Three ethical approvals were obtained before this study was conducted: from the ethics committees at the School of Health and Related Research (SCHARR) of the University of Sheffield, Ministry of health of Health (MOH) King Fahad Medical City (KFMC) and King Khaled University Hospital (KKUH). See Appendix 17, 18 and 19.

Informed consent

Fully informed consent to participate was obtained from all study participants. Participants were provided with an 'information sheet' in which the purpose of the research was explained to them, as well as what the participants are expected to do, and how their data will be used. They were also informed about the potential benefits and harms of participating in this study. Participation in the project was completely voluntary and participants were told that they can withdraw from the study at any point. Participants were also given opportunity to ask questions throughout the research process.

Data recording procedures

All interviews and focus groups were audio recorded. Permission was obtained from all participants prior to recording. Audio recordings are preferred to note-writing, e.g. because they are more accurate (25). As well as audio recordings, the researcher kept handwritten notes documenting items that would not be captured on audio, for example body language, as well as the time and date that the interview took place.

Personal safety

The focus groups and interviews were conducted in a conference room in the hospital and/or primary care centers, that convenient and accessible by participants. These hospitals had security and safety measures such as security staffs and CCTV surveillance, that ensure individuals' safety.

5.2.3 Results

5.2.3.1 Participants

The focus groups were attended by 22 participants, with a range of five to six participants in four focus groups. The gender distribution of participants was not even, with 9 females, and 13 male participants, with mean age of 50 (ranging from 33 to 74). Most participants had a Bachelor degree or higher qualification (n=14/22). The majority of the participants reported that they own a smartphone (20/22), most of which were the iPhone brand (15/20). More than half of the participants had suffered with hypertension for over three years (12/22).

Table 5.2 Characteristics of the patients sample

Characteristics	**Mean (range) or n(%)**
Age (Years)	50 (33-74)
18-30 years	0(0%)
31-40 years	4(18%)
41-50 years	6(28)
51-60 years	8(36%)
>61 years	4 (18%)
Gender	
Males	13(59%)
Females	9(41%)
Time since diagnosed with hypertension (Years)	
<1 year	18%
1-3 years	32%
>3 years	55%
Education Level	
Less than high school diploma	3(14%)
High school diploma	5(23)
Bachelor's degree	8(36)
Master's degree	4(18%)
Doctorate	2(9%)
Smartphone users	
Yes	20(90%)
No	2(10%)
Smartphone Brand	
iPhone	15(75%)
Android	5(25%)

A total of 12 doctors were interviewed, with a mean age of 40 (ranging from 28 to 57). They averaged 16 years' clinical work experience (ranging from 4 to 39 years). All of the doctors interviewed owned a smartphone, 7 of which were the iPhone brand.

Table 5.3 Characteristics of interviewed doctors

Characteristics	**Mean (range) or n(%)**
Age (Years)	40 (28-57)
Gender	
Males	4(33)
Females	8(67)
Work experience with hypertension (Years)	15.8(4-39)
Profession	
Resident doctor	2(17)
Specialist doctor	6(50)
Consultant doctor	4(33)
Smartphone Owner	
Yes	12(100)
No	0(0)
Smartphone Brand	
iPhone	7(58)
Android	5(42)

5.2.3.2 Result of Frame work analysis

5.2.3.2.1 General views towards, and experiences of using mobile apps

This section presents the results from the first part of the study's framework, concerning participants' general views toward using apps for the self-management of hypertension.

The initial themes and sub-themes for the first part of the framework were as follows: self-management experience (including the sub-themes strategies used by patients and their compliance, barriers to using strategies for self-management, and patient knowledge and awareness about hypertension) and using health-apps for self-management (including the sub-themes doctors' experience in using health apps and factors affecting app use). These are presented in Table 5.4, showing the a priori themes and emergent sub-themes. An outline of the results now follows.

Table 5.4 Identified Themes and sub-themes via framework analysis (*Italics indicate A priori themes*)

Theme	Sub-theme	Topics
Self-management experiences	***Strategies used by patients and their compliance***	Adherence to self-monitoring BP Taking required action Adherence to taking medication Adherence to lifestyle Managing stress
	Barriers and issues of using strategies for self-management	Lack of knowledge Busy life Lack of motivation Forgetting Acceptance of disease Asymptomatic patients affecting self- Lack of patient initiative Beliefs about medication Social pressure Fear caused by high BP Using impractical tool
	Role of doctors	Education about and encouragement of self-management strategies.
	Patient knowledge and awareness about hypertension	Current patient knowledge (level) Required information
Using Health Apps for Self-management	***Doctors and patients experience in using health apps***	Patients experience in using general apps and HTN apps Doctors experiences in using health apps or recommending HTN apps
	Expected useful features of smartphone apps	Self-monitoring and reminder Educational information Feedback
	Factors affecting uptake of the app	Demographic factors including, age, education and IT literacy. App usability App's language Doctor support
	Concerns about using health apps for self-management	Credibility – Accuracy - Company intentions Patient commitment in using app App usability

<u>Self-Management Experiences</u>

Self-management strategies

The majority of doctors interviewed noted that although most patients take their medication frequently, some patients fail to monitor and record their BP, despite being asked to do so. Doctors reported that the patients who are more likely to monitor and record their BP are newly diagnosed patients, and older patients who are helped with the monitoring of BP by supportive younger family members.

"[…] only 50% - 60% that we ask to take their BP regularly actually do so" [D2-male]

"[…] with some older people, we found that their children had recorded their BP reading in a table format. They were very committed to helping their parents" [D1-male]

The majority of patients reported that they tried to monitor their BP and take their medication regularly. Despite this, intervals between readings still varied across patients, as did the regularity of medication. Some patients reported monitoring their BP less frequently, citing reasons such as only measuring their BP when they feel uncomfortable (e.g. when experiencing headaches), or forgetting to monitor their BP and/or take their medication due to their busy lives and/or other personal issues. A small number of patients with more stable BPs also reported monitoring less frequently, as they no longer feel that it will have a negative impact on their lives.

"I try to manage my hypertension as much as I can. I self-measure my blood pressure when I feel symptoms like dizziness." [Focus group2-male]

"I tried to self-monitor my blood pressure regularly and take medications, but I am busy with my daily work that negatively affect my adherence." [Focus group3-male]

"The doctor always asked me about monitoring my blood pressure at every visit, but I totally forget to do that because my blood pressure is a little bit controlled" [Focus group2-male]

Patients who measured their BP regularly then managed their BP either by increasing their lifestyle activities or changing the appropriate dose of their medication. Additionally, in emergency cases they can consult their doctor in between consultation time or call the MOH consultation number.

"When it [BP] is high I tried to do anything to reduce it. For example, I sometimes go walking or even take an extra pill to reduce it" [Focus group1-male]
"For me, when it [BP] was extremely high I call 973 which I can speak to a doctor to help me and give me advices" [Focus group1-female]

The majority of patients tried to stay as healthy as they could through lifestyle activities relating to food, exercise and managing stress, which doctors have told them can help control BP. However, many patients expressed difficulties in sustaining these activities. Patients frequently mentioned that they try to eat a healthy diet e.g., by preparing food in advance and avoiding food high in salt. However, some patients only take these measures when their BP is high, and some report work or social pressures as reasons for unhealthy eating. Some patients also said they now try to do more exercise on a regular basis, such as walking and running. Other patients still live very sedentary lifestyles and do not exercise as a result of either health problems (e.g. knee pain) or a lack of motivation to complete activities. These patients wished to be more active.

“I believe my diet is totally ruined at social events and family gatherings, especially when they offer salty food. [Focus group1-male]

“I try to walk every day and make it part of my routine, but mostly I do not walk much and only remember later that I should have... I need something to help encourage me to do it frequently” [Focus group 4-female]

One patient reported that personal and work stresses were the primary causes of his hypertension, but stated that it was difficult to reduce this, and that maintaining good lifestyle habits cannot be the only solution.

“My BP is usually high due to my personal problems and work pressure, I tried to exercise, but I still need to manage my stress” [Focus Group 4-male]

Patients’ Knowledge and Awareness

There was some disagreement between doctors about the role of patient knowledge and awareness.
The majority of doctors believe that patients need more information about their disease in order to effectively self-manage. Doctors mentioned that their patients lacked information relating to the condition itself, its causes, and its complications, such as heart disease and stroke. A few doctors also believed that some patients were poorly informed about how to monitor BP.

“People lack knowledge about hypertension; patients don’t know the type of food that they eat and if they are good or not, what causes blood pressure, hypertension complications, and so on."[D11-female]

Some doctors found that younger patients and more educated patients were more informed, and took greater responsibility for their self-management. However, other doctors found that some informed patients would not change their behavior or take responsibility for their health, due to a lack of determination or concern, in spite of the information that they have.

“In Saudi Arabia, many people know about hypertension, and the benefits of making positive lifestyle changes like exercising. Some people don't take it seriously, as the effects of the diseases aren’t necessarily present at the time of the diagnosis, but will appear later and cause complications, such as high blood pressure and diabetes. When a patient has a clot or something else, some think this is not related to hypertension, even though we told them about this information before” [D1-male]

One doctor also expressed concern about patients accessing inappropriate or incorrect information:

"It sometimes causes problems when people worry about the wrong information that they have found on the internet. I advise people that not everything that they read on the internet and discussion groups is correct, and to only consult their doctor or a medical website" [D10-female]

Patients generally wished to have more information. A few patients mentioned they had gathered some simple information, mostly from their doctors, and some gathered from the internet or leaflets. However, like many of the doctors, patients often wished that they had received more adequate information about the causes and risks of their disease, about BP readings, and about the side effects of medications.

"We need more information on how to measure blood pressure correctly, hypertension risks, and the medicines, but the information in Arabic is not always reliable." [Focus group 2-female]

"I have a problem when I measure as I do not know if it is high or normal, even though the doctors always told me. Is there any information to help me understand the normal ranges?" [Focus group2-male]

Role of doctors

Patients said that their doctors had advised them to implement self-management strategies when they were first diagnosed with hypertension. They set goals with them relating to different strategies, which included monitoring BP at home, exercising, etc. However, few patients have the ability to discuss which is the suitable medication for their case.

"When I was diagnosed with hypertension, I agreed with my doctors on the goals, such as walking, running, and the amount of appropriate food." [Focus group1-male]

Doctors said that at every visit, they ensure that patients are complying with the recommended strategies, and that this is resulting in controlling their BP. Doctors usually do their best to encourage patients who have controlled BP to continue with these strategies. They also try to increase patients' awareness about the negative consequences of uncontrolled disease, and the benefits of these strategies, as well as sometimes discussing the reasons for not following these strategies, to allow patients to think about the possible solutions for improving these.

"We give them different activities to do such as exercises, usually they are old-aged people, so we advise them to walk for half an hour a day. I then start to increase their awareness about what affects BP and their

general health education so they know how important it is. We encourage them and some do their best." [D10-female]

Barriers to self-management strategies

Doctors believe that some patients are not seriously involved in the management of their disease due to personal factors such as lack of patient initiative, acceptance of the disease, inaccurate negative beliefs about medication or even hypertension itself.

"Laziness: they get bored with repeating it over and over again." [D2- male]

"Patients usually did not take their hypertension seriously" [D6-female]

"They do not know they are chronic diseases and should have taken medication for a long time." [D8-female]

Some doctors also believed that patients' fear of finding a high BP reading when measuring BP could be an important issue affecting the efficient self-management of hypertension:

"They know how to manage the problem, but the most of them panic when they see the blood pressure is high. [D4- female]

Patients themselves reported experiencing several different barriers that affect their commitment to self-management strategies. The most commonly mentioned barriers were: lack of knowledge relating to hypertension management, including BP readings, complications, risk factors and side effects of medications; lack of motivation; forgetting; and busy lifestyle. Social pressures were mentioned as reasons for unhealthy eating, while bad weather and lack of facilities were cited as a barrier to increasing exercise.

"I sometimes self-measure my blood pressure, but sometimes I forget or because of busy daily life." [Focus Group1-female]

"In my opinion, I feel hypertension is a simple disease, it does not need a serious care. If my blood pressure raise what is the problem" [Focus Group1-male]

Some patients reported that instruments for recording BP were impractical.

"Nothing helps me, even putting paper next to my bed to remember before going to sleep, because I will be tired and forget to do anything. "' [Focus Group2-female]

"Using paper is not practical because a paper or pen is not always available, and it is not very reliable either." [Focus Group2-male]

<u>Using Health apps for self-management</u>

Doctors' and patients' experiences of using smartphone apps

Most doctors reported having experience of using health apps themselves. However, none had recommended an app for supporting hypertension to their patients, usually because of a lack of awareness of available apps, and their effectiveness and suitability.

"I had no idea that there were apps that I could recommend to patients - I only use health apps that help me as a doctor to calculate scores, and choose satisfactory ways to prescribe the appropriate dose, as well as decision support apps, but I have not used them at the level of patients." [D3-female]

"I haven't recommended apps specifically for patients - generally, we don't know if the app is useful. This is the main aspect: we don't know if monitoring apps helps patients or not, unless there is a study proving that they are useful." [D2-male]

Similarly, most patients across all groups had extensive experience in using apps in day-to-day life (such as for socialising, entertainment, etc). However, only one patient had used a hypertension app to manage their condition before participating in this study. Other participants like the idea of using an app but were unaware of their availability, or different apps' suitability for managing for hypertension.

"Yes, I used an app for blood pressure, I forget its name." [Focus group2-male]

"Doctors have not recommended anything or even told me but I searched for apps and there are too many but I cannot choose which is best. -I did not know about these apps and I did not try to find them." [Focus group1-female-male]

Expected useful features of smartphone apps

Doctors and patients believed that apps could be a good tool for monitoring the treatment of hypertension.

Participants mentioned a range of features that would be helpful, including recording BP data and medication, and daily tasks, especially if it this data is stored for a long period of time and the app provides reminders - e.g. to take medication.

It was felt that these features would benefit patients by raising awareness of their health and encouraging active participation in their own care. Participants also felt that an increase in patient awareness would benefit both patients and doctors as patients would be more communicative during appointments with healthcare professionals.

"Everything will be documented. It helps them [patients] to adhere in taking medications and so on [….] apps have reminders that help to increase patients' participation in managing their health, to make decisions for themselves, and pushing them to do what they always miss, for example, it will remind them to self-monitor." [D8-female]

"Apps allowed recording, BP data where patients usually at hospital visits discuss their BP data verbally with their doctors … they will be involved in their own health decision-making." [D4-female]

FG1P3: Based on what you say, [if these kinds of apps help us to record our data], this app helps us to understand our blood pressure status and to share it with doctors" [Focus group1-male]

Patients and doctors felt apps can be used as an educational source for patients to improve understanding and gain essential knowledge for managing their diseases, which would supplement advice given by doctors, as well as having the benefit of being accessible at any time.

"If apps have information, it will enhance knowledge. We educate them and they absolutely will forget what I said. So, if the information is written in this app, they can read anytime." [D9- female]

"I think apps will help to increase my knowledge through knowing hypertension symptoms, etc. ---The app information will be available 24/7, it is accessible and more cost effective" [Focus group3, male--- female]

Doctors reported apps that some specific features would be likely to increase the usefulness of an app in supporting self-managing of hypertension, including, whether BP data are stored over-time on a graph to help track data, and whether they provide BP average to enhance tracking at a hospital visit.

"I think it becomes clear or clearer when presented on a graph, but is it measured enough to plot on a graph?" [D1-male]

"If the app gives BP average readings, I think it will help. During patients' hospital visits, it will help doctors to track patients' blood pressure reading, to understand his health- as doctors, we can use it to monitor his blood pressure readings." [D4-female]

Factors affecting uptake of the app

The most common factor discussed in interviews with doctors was the age of users. They felt older patients, aged 60 and over, may face difficulties in accepting and using this app due to unfamiliarity with newer technology and/or poor eyesight. However, some doctors believed that well-educated older people will be more likely to accept using this technology, and others would be able to easily engage with apps through doctor support.

"I think it depends on the age; much more difficult for older generations to use them" [D2-male]

However, the ease of using apps was the most common factor discussed among patient groups. They preferred interfaces to be simple and easy to navigate and to offer customizable font size to suit all users, particularly the elderly.

"If there is good app, I will use it because it encourages us to use especially if it has good interface/menu." [Focus group1- female]
"I read daily news on my phone, I always zoom out the font to be very clear to read, so I suggest apps should have this feature" [Focus group4-female]

The language of apps is another factor affecting uptake, and is discussed by both doctors and patients:

"…apps should be in Arabic because there are not many Arabic apps available" [D12-male]
"When I searched in apps stores there is not app supported hypertension in Arabic language" [Focus group2-male]

Concerns about using health apps for self-management

Patients and doctors raised different concerns about using apps, which were likely to impact on their decision whether to use them or not.

Doctors expressed concerns about the credibility and accuracy of the apps, or doubt about their continued availability They felt that they would be more willing to recommend an app to patients if it was tested through scientific research, it was based on our practice guidelines or even checked by doctors.

"I am concerned that the new apps are not yet tested and may be removed [from the app store]. " [D7-male]

“I tried to download apps, however, information seems to be inaccurate (not 100% correct), with practice guidelines etc. …. The credibility of app content is very important. I can ensure credibility for patients if it is based on scientific research or checked by other doctors" [D10-female]

One doctor also believed that apps may only benefit patients who already monitor their BP regularly at home and he questioned whether patients will regularly be using it.

“We have this problem; does the patient already measure blood pressure? If they record it, this will be ok and will mean we can track their BP over time on a graph…. I think it becomes clear or clearer when presented on a graph, but is it measured enough to plot on a graph? We go back to the same question about whether it is used enough” [D1-male]

Patients also stressed usability as an important factor, e.g. that it should be easy to enter data, especially for older people.

“I fear that the app is not easy to use, because I already used one of the Ministry of Health apps which was so difficult to use, and I never used it again. I’m just thinking how the elderly can enter data - it should be easy.” [Focus group4- male]

5.2.3.2.2 App preference

This section presents the results from the second part of the study framework, concerning participants’ views toward the five apps for self-management of hypertension, which are [Cora Health (Cora), ESH care (ESH), LifeCourseHyTen (Hyten), Qardio, Braun Healthy Heart (Braun)]. Themes for this part are app usability (including the sub-themes training and how easy to use), and Adequacy of app content (including the sub-themes information provided, reminders, user data collected, and feedback and tracking progress), as well as Overall app assessment (including the sub-themes app rank and recommendation and app estimated uptake). The prior and emergent themes of this phase of the analysis are presented in Table 5.5. This is followed by a description of the results. A table showing side-by-side data for each of the five apps is then provided to aid comparison between them (Appendix 20).

Table 5.5 A final framework developed to evaluate five apps after completing the analysis process. *(A priori themes indicated in italics)*

Theme	Subtheme	Topics
Adequacy of app content	***User data collected***	Accuracy and method of data inputting; Type of data collected
	Feedback and tracking progress	Presentation of feedback Accuracy of feedback
	Reminder	

	Information provided	Level of details and type of information (information topics)
	Social Support	Communication with others
	Content credibility	Credibility
App usability	***How easy to use***	App design/layout/navigation
	Training	Type and intensity of training required
Overall app assessment	**Factors affecting uptake and usage**	Demographic factors including, age, education and IT literacy. App feature Language Price Privacy Ads & Promotion
	Rating and recommendation	App ranting Doctors' willingness to recommend apps Doctors' estimated uptakes Patients' willingness to use and recommend apps General recommendations
Potential benefits and drawbacks of app use	**Expected risks of inappropriate content**	Difficulties, including stress, anxiety, and confusion Decreased app use and poor self-management
	Support patients' self-management	Controlled BP Empowered self-management Improved compliance and knowledge Supportive doctors

Adequacy of app content

This section discusses participants' opinions about different features of the apps including 'Feedback and tracking progress', 'Reminder', 'Information provided' and 'User data collected', and two emerging sub-themes ('Social support' and 'Content credibility').

Feedback & tracking progress

Most doctor and patient participants liked the way that all five apps present the data users had entered (BP readings) in different formats, such as graph and tabular formats, that enable the user to easily track their BP and other health data over time. However, they agreed that Cora and ESH apps have graphs of sufficient quality and clarity containing relevant data so their readings can be easily understood, whereas the graphs and diagrams of the other apps were generally considered less clear.

"I liked the second one [Cora app]. It is easy … and represents important data [BP readings] in the chart and has good quality graph" [D8-female]
"It's difficult for them [patients] to understand and browse the diagram/chart in the third app [Braun] It's more elaborate .. there is a lot of detail on the chart. So, I don't think it's as practical as the last one [Cora]. " [Focus group3-male]

Doctors favored apps that automatically calculate scores for patients. They believed the app Cora, which automatically calculates BP average, and Qadio and ESH, which automatically calculate BMI, would allow for more patients' engagement in their health and more accurate decisions about patients' health than if they had to manually calculate the readings.

"When a patient records their reading [in Cora], and sees their average… (e.g., normal), which it is difficult to calculate with manual BP reading, Definitely, they will be enthusiastic to be in this healthy state". [D9-female]

"It [ESH] includes BMI, as it is positively influenced BP control" [D1-male]

Both doctors and patients like the way the apps Hyten, Qardio, Braun and Cora provide color-coded feedback indicating any deviation from the normal range in the measurement level.

"I only like classifying blood pressure readings into stages that may help. [Qardio]" [Focus group1-female]

However, some doctors believed Cora would be more effective because it supplemented this color-coded feedback with explanatory text or other visual aids.

"I see more detailed feedback [Cora app] compared with other apps [that only use color codes] that may encourage patients to involve themselves more in the management of hypertension" [D12-male].

Doctors felt that the feedback features of all five apps should be further encouraging patients to reach their self-management goals by containing BP goal-setting features that take account of patients' circumstances and demographic details, such as age.

"I think in this regard; the app [Hyten] isn't so good. Because it gives you an alarm when the range is high, whatever the patient's age is. Thus, this alarm may cause stress for patient and this scientifically wrong. As the range depends on the age." [D3-female].

Reminders

Doctor and patient participants like the way all five apps offer a reminder feature for patients to do activities for the effective management of BP. Both Doctors and patients preferred Cora app, which provides reminders for different tasks (e.g., self-monitoring of BP, exercises etc.) to the other four apps, which provide reminders only for a single task (either to take medication or to self-monitor BP).

"I think I like this app [ESH], but I feel it just focuses on monitoring and reminders for medication -- there is no reminder for self-monitoring or for walking that we need with our busy lives. [Focus group 2-female].

"This app [Cora] helps patients to set different activities or challenges to remind them. It is really helpful." [D6-female]

Some patients found the reminder feature of Braun and Qardio is very limited because it only allows users to set a generic reminder that does not specify the task to be completed, rather than allowing users to set individual reminders for particular tasks (such as for self-monitoring, taking medication, etc.).

"I like the reminder feature [in Braun], but it does not allow you to enter the title of the reminder so you can know if this is a reminder for medication or for self-monitoring of blood pressure." [Focus group1-male]

A few doctor liked the ESH and Hyten app reminder for medication because it allows users to set different reminders for different medications and doses:

"It is good to remind patients about his medication time [in ESH], because some patients take different two or three medications. The times patients find it difficult that they take all of them at once, each 24 throughout the day, and this app can remind them about the doses they are needed." [D6-female]

Information provided

Participants considered one app to be not useful due to an absence of any features that may help to increase user awareness and knowledge.

"I totally agree I do not think this app [Qardio] is useful as you notice this app does not offer educational information" [Focus group2-female]

"But It [Qardio] does not offer any information for patients as other apps" [D6-female]

As apps differ in terms of their detail and topics of information offered, opinions vary among patients and doctors on whether the information offered by apps is helpful and suitable for patients. Some doctors noted that the apps [Hyten] contain more suitable information for patients on topics such as side effects of medication and life style. Both patients and doctors agreed that Cora app have data about hypertension in general as well as data on hypertension risks, BP readings and how to measure BP, which may help patients.

"I also think this app [Cora] has valuable information; it offers sufficient information about BP complications, how to measure BP -- our people really need that." [D10-female]

"The patient would be more confident and secure [using the Hyten app] because they know information about the medication they will take, and there is a lot of literature there, even about the illness - there is an explanation of the types of hypertension in all those things." [D6-female]

Most doctors commented that Braun and ESH lacked any information about medication and side-effects that might help save their time and improve patient knowledge. However, two doctors and patients believe that the detailed information about the side effects of medication offered by Hyten may lead patients to be stressed or confused and resistant to taking medication.

"Too much detail will make the patients uncomfortable … even if they start to use it [Hyten], they will not regularly use it or adhere to medication" [D5-female]

User data collected

All participants like inputting BP data in all five apps, but they prefer apps that also track other data, including life style factors such as exercise (Cora, Braun), weight (Qardio, ESH), medication (Hyten and Cora) and stress or feelings (Hyten and Cora) over a period of time. They also felt some apps are not supportive due to a lack of tracking important data about lifestyle (Qardio or ESH). A few doctors also believe that some apps could be further improved by considering weight.

"A feature detailing factors that affect hypertension [Qardio] should be included, which concerns the welfare and health care of the patients. This would be a more holistic approach" [D7- male].

Patients dislike the way of entering data (e.g. symptoms and lifestyles) in some apps as it is ambiguous (Braun), simplistic or unnecessary, or not well organized (Hyten).

"For me I think the details [of entering] does not matter, but the method of data input [in Hyten] is not organized, which make difficult to follow." [Focus group1-male]

"When I enter the diet, I have to enter one to five. So, if I eat rice, vegetables, fruit with dessert, will I enter 1 or 5? It is not clear.
I agree with you --- It is a very important point that needs to be considered. [Focus geoup1-female---male]

Doctors expressed that Braun is not detailed enough to capture all relevant information (e.g. it is not possible to enter a type of exercise, and the app does not include typical Saudi food options) and that the 1-5 scale for inputting lifestyle data is ambiguous.

"The app should support somethings like exercise, and add to it matters that fit our patients' needs such as swimming, walking and so on, which is determined in same the previous app [Cora]. It also should add features that meet our patients' needs like Saudi food including rice, Arabic bread and dates and other fatty food or carbohydrate, as most hypertensive patients can benefit of these things." [D8-female]

"Entering data of food is somehow vague, it allows patient to assess and chooses their eating between healthy and unhealthy, but patients mostly do not know. It may misevaluate themselves" [D5-female]

A few doctors disliked ESH care's method of inputting data by typing, instead of choosing from a list, as this may cause typo mistakes.

"This app [ESH] is easy to use; the method of inputting data may lead to some mistakes, for example if he enters a wrong name for a medication reminder and takes it [the medication] what will happen" [D12-male]

Generally, it seems that Cora and Qardio are accurate and that there are no limitations in entering data, compared with other apps. All these apps require some edits to allow for the entering of more data: such as lifestyle, medication, feelings etc. but some require less than others.

Social Support

Patients have mixed opinions about the social support feature. Some found it useful while others found it unhelpful or unnecessary, given increased access to social media platforms. Two doctors liked this feature because the more that family and friends used it, the more it encouraged the individual to use it. However, doctors generally did not express any request for a social support feature in other apps.

"I think it [Qardio] helps you to keep in touch with your friends or family —--I think keeping in contacting with families or friends is not helpful because many social media allow you. We can just take screen shot of the readings and share it through social media. [Focus group1-male---female]

Content Credibility

Doctors felt that the credibility of educational information should be checked. One doctor also stressed the importance of checking the reference of readings. They stated that they cannot read the information from the app to ensure whether it is correct. However, they asked whether the credibility can be checked; whether the information is based on medical guidelines and if the app was reviewed by other doctors or medical companies. Finally, they asked whether the purpose of developing this app is to gain money or help people?

"The information it presents is very organized. Moreover, I can see that this app is based upon the guidelines of medical organizations, which enhances its credibility. Credibility could also be checked by other doctors or medical companies providing a review of this app; or by additional reviews by other users whom I can trust. [D8-female]

App Usability

Participants preferred the interface design and navigability of Cora and ESH, in which the app features are easy to reach because they are visible in the main menu. Participants reported that their navigation of Qardio and Braun Health was hindered by complex and unclear layouts where functions are embedded in other functions.

"I feel this app [ESH] is excellent and icons/menus pane are well organized. At the beginning, we find a menu for monitoring blood pressure and medication separately. This presents app sections clearly." [Focus Group2-male]

"Accessing reminders [of Braun app] is not easy at all, I have to go through many windows so as to set the reminder and it is not clear if it is specific for medication or self-montring." [D12, male, 57]

Some patient found the muted colour scheme of Hyten, Cora and ESH more user-friendly, whereas another patient found the strong, bright colors of Braun off-putting.

"I am not very satisfied because I think the color [of Braun app] is very strong and annoying, so it will be not comfort for my eye" [Focus group1-male]

Training

Most doctors and patients think that some level of training would be required for all five apps. However, they disagreed over the length and intensity of training that would be required. 4 doctors believed that ESH would require no training, while 3 doctors thought the same for Cora. Some doctors said some patients would need training, depending on patient background. Patients mention that apps which are more difficult to use may require further training and/or practice.

-*"I think it is likely that patients who used to use apps don't need training and patients who don't use apps will sneed it, this depends on the experience of the patient." [D1-male]*

The most common opinion about suitable training is that it should be sufficient to teach users how to use the app.

"Training should be explained by physicians/educator/researcher for patients how to use it, then it can be used by patients" [D6-female]

"Any method of training, for example, instructions on a paper or simple sessions helped a lot in how to use the app" [Focus group4-male]

<u>Potential benefits and drawbacks of app use</u>

All of these apps contain monitoring and reminder features which allow patients to control their BP, increase their engagement and awareness, avoid white coat hypertension and adhere to self-management tasks. However, one app (Qardio's) appears to be more useful for doctors during appointments (rather than patients) due to its simplicity and the tasks included. The Cora app has multiple reminders for tracking different tasks, which may increase adherence to them.

"Benefits of using this app [Cora] are really good or great; this is a monitoring application that you can customize the application to help patients monitoring themselves, so for example if the patient forgets to take medication or go to walk, the reminder will help them. For this, it is a very good potential tool in managing hypertension." [D7-male]

"This app [Qardio] will help me as doctor not patient." [D9-female]

However, some doctors were concerned that too few functions (Qardio and ESH) may lead to patients becoming bored; or, conversely, that too much detail (Hyten) or poor layout (Hyten and Braun) will confuse patients. One doctor worried that if information displayed is too detailed in Cora's, it could possibly cause stress for patients.

"The app [Braun] should support somethings like exercise… as I think people may get bored when use this app and reduce their engagement in managing hypertension." [D8-female]

“The detailed medical information [of Cora] is not needed. They[patients] may be get stressed" [D6-female]

“However, if you notice the method of setting the reminder for medication [of Hyten] is not easy to access, despite of providing the list of medicines, this may lead to confuse and reduce their motivation" [Focus Group2-male]

“Too much medical details [of Hyten], there is no need for all of these medical details. On the contrary, it may affect negatively.
Researcher: How?
You know that doctors give the patient the information that he needs to know, but in some cases, you can give them too much information, it may cause an obstacle in taking their drug. What I mean is sometimes we need to reduce the information given to patients in order to avoid confusing them; they just need to know what we want them to know." [D2-male, 36]

The overall app assessment

Rating and recommendation

App Rating

The results of the doctor participants’ overall satisfaction of the apps (calculated by adding individual doctors 1-5 ratings) are as follows: Cora (51), Hyten (43), ESH (41.5), Qardio (37.5) and Braun (30).

The results of the patient participants' overall satisfaction of the apps (calculated by adding individual patients' 1-5 ratings) are as follows: Cora (97.5), ESH (85.5), Hyten (80), Braun (65.5), Qardio (64).

The results show that Cora has the highest rank among both sets of participants. Doctor and patient participant groups disagreed over further rankings: Hyten was second highest ranked in the doctor group, and ESH the second most preferred among patient groups. Qardio and Braun were the lowest ranked in doctor and patient groups.

Doctors' willingness to recommend apps

Most doctors agreed to recommend the apps Cora (n=10) and Hyten (n=9) apps, which they regard as being 'complete' or 'comprehensive'. Doctors regarded apps as being complete if for instance their functions were detailed, such as offering reminders for a wide range of activities, and if the information they offer, such as for medication, was thorough. More than half of doctors (n=7) were willing to recommend ESH due to features such as its inclusion of BMI measurement and its high-quality information. Of the remaining two apps, two doctors were willing to recommend Braun, and one doctor was willing to recommend Qardio, with a small number of doctors being willing to recommend these apps on account of specific features, but not on their overall functionality. More than half of doctors and patients (n=8) believed that Qardio and Braun are less recommendable because they lack broader features like education, or focus mainly on monitoring BP by recording and offering simple reminders only, in contrast to those apps offering a greater depth of features and detail.

"It [Hyten] is comprehensive in terms of that the one who reads about blood pressure, knows when it is low or normal, in terms of that it includes patient's data, reading and reminders. It is comprehensive like the second one [Cora]." [D8-female]

"Yes, it [Qardio] is easier to use if you just want to look the blood pressure recordings [history], but it is lacking in other factors." [D7-male]

Doctors' Estimates of Potential Uptake

Doctors' estimate* of potential app uptake[2] by Saudi users ranged from 30% to 90%. Cora Health has the highest estimated number, with doctors estimating between 80% and 90% uptake. ESH has the next highest estimated uptake, ranging between 60% and 70%. Uptake for ESH was estimated to be higher than for

[2] Not all doctors provide a percentage estimate of app uptake. Percentages presented here are estimates made by comparing the percentages of those doctors who did provide one.

Hyten (around 50%) due to the former's simplicity, which doctors think can attract more patients even if Hyten is more comprehensive. Doctors felt Braun would be used by around 30% to 40% of patients (though one doctor felt that no patient will use it). Doctors expressed that very few patients would use the app Qardio.

"80% to 90% of patients who I know, would be able manage their hypertension via this app [Cora]." [D9-female]

"I think high percentage of people can easily use it [ESH]. Let say around 65-72%." [D10-female]

"I believe very few of my patients can use it [Qardio] as this is not enough [to support self-management]"[D12-male]

<u>Patient willingness to use and recommend</u>

Most patients in all focus groups stated they would use Cora and ESH, and would recommend these apps to friends, because they found them easy to use in terms of entering data and navigation, and they liked the quality of feedback (e.g. graphs), and features such as tracking and monitoring.

"This app [Cora] form/shape is nice and easy to use. The input method of the app impressed me just need a click. When I input the data, I can immediately surf the graph." [Focus group2-male]

"I feel this app [ESH] is excellent and icons/menus pane are well organized. At the beginning, we find a menu for monitoring BP and medication separately. This presents app sections clearly. [Focus group2-male]

The response to the remaining three apps was mixed, with focus groups disagreeing on their overall preference and their willingness to use them.

Patients' responses to Hyten were mixed. Focus group 3 and 4 were positive about the app and their willingness to use, due to its support for inputting feelings and medication names, and the information provided about medications. Focus groups 1 and 2 were more negative in their appraisal, due to factors such as excessive level of data requested, and low-quality charts.

"I do not like using this app and I will not waste my time with it." [Focus group1-female]

"This app is more than fabulous; it is not difficult to use, it is similar to the first app and more advanced that meet people needs. [Focus group3-male]

Focus group responses to Braun were mostly negative about the app and their willingness to use it, due to issues such as its limited reminder feature and the complexity of its layout and data input.

"I believe that I will not use it because the reminder as I said it is really general; not specific for a task" [Focus group1-female]

Focus groups' responses to Qardio were also mostly negative about the app and their willingness to use, due to lack of information provided, poor quality charts, and its limited tracking. However, one patient approved of Qardio's support for communication with family and friends.

"I expect my usage is low due to defects such as lack of educational information, understandable chart" [Focus group2-female]

"I think the application is perfect and very good, and meets all the needs especially the issue of sending e-mail if used with the specialist doctor, it will be very useful, also very important that the application is in it; (Focus Group3-male)

General Recommendations

Doctors and patients also made occasional recommendations for improvement of app features and content. Cora received the fewest suggestion for improvements. Some of the recommendations were common for all five apps including hospital appointments, and tracking of other medical conditions. Common themes for recommendations included suggestions for additional reminders, changes to the interface and feedback features. The full suggestions are presented in the table.

"This app[Hyten] should include other chronic conditions, more reminders, more daily targeted tips and things like that to engage the patient more." [D1-male]

Factors affecting uptake and usage

Doctors and patients expressed different factors affecting the usage of the five apps; some of them are related to the app while others are related to the ability or means of the patients.

Age was a factor mentioned by several doctors. Doctors felt that two apps (Cora and Hyten) would pose difficulties to older users, and stress the importance of practice for these users to aid their understanding of the apps. Two doctors believe that ESH would be more suitable for older patients, provided they are comfortable with the idea of using smartphone apps.

“[T]he difficulty also lies in old-aged people, even if they can read and write.” [D3-female]

Doctors and some patients felt that some patients’ lack of experience using apps or smartphone technology generally is a significant potential barrier to use.

“If someone who does not own a smart phone were to use it, they would find it more difficult.”[D2-male]

“I have concern when we using any of these app may cannot do all tasks efficiently, we need a lot of help and practice before use it.” [Focus group4-female]

Some patients and doctors felt that the limited functionalities of some apps might mean they were used only by certain groups of patients. Some patients felt that ESH would be most useful to patients who struggle to adhere to their medication schedule. One doctor felt Qardio is more suitable for people who already have controlled blood pressure or focus on monitoring BP.

"I think it [Qardio] is suitable for people who have already controlled blood pressure who are few.” [D10-female]

"Its include a reminder for medication, is suitable for patients who are not adhere with taking medication" (Focus group 2, male)

Patients expressed concern over the app price, and payment method that might be required.

“If apps are for free, it will be great --- Yeah, some people also did not use MasterCard to pay, so they will not download this app." [Focus group3-male---male]

There was mixed opinion amongst doctors and patients regarding the importance of privacy for all apps. One doctor felt privacy was important, and another doctor believed privacy is important in the case of high-profile individuals. Most patients did not express concern with the confidentiality of the apps.

“I don’t think they will accept [personal data being uploaded to the server]. If you mention this, [patients] will refuse out of principle” [D2-male]

"No any concerns regarding patients’ confidentiality, because only the patient will use it.
and all the entered information isn’t sensitive and confidential." [D3-female]

Most patients and doctors considered language to be a main factor affecting patient uptake of all five apps among Saudi people, i.e. because the apps are unavailable in Arabic.

“The app language is still a limitation” [Focus Group3-female]

Two doctors stressed the importance of official endorsement as a factor affecting patient uptake. They felt patients would be more likely to use apps that were supported by e.g. the MOH or mentioned in public health campaigns.

"It is important to promote about this app[Cora] in media or advertisements by Ministry of Health to support using this app by patients, because doctors alone are not enough to support." [D9-female, 28]

5.2.4 Discussion

The selection approach found that of 30 apps previously identified as potentially effective (14), all 30 contained theoretical underpinning, but only 5 contained adequate privacy and security measures. This demonstrates the pitfalls of commercial app availability: most apps are unlikely to be effective and secure, leading to potentially serious effects on users’ health. This suggests a lack of collaboration between researchers, experts and developers, which might improve the potential effectiveness and quality of apps, or provide clear evidence of effectiveness and safety (41-43).

The qualitative study was conducted to gain insights into hypertensive patients’ and doctors’ views on using smartphone apps to support self-management of hypertension, and their preferences toward the five apps. In general, although both doctors and patients were interested in using hypertension apps, most had never used these apps, or been recommended them, due to a lack of awareness of their availability and suitability. Despite raising some potential concerns including the app usability, most participants favored apps that provided activity-specific reminders, coluor-coded feedback accompanied with textual explanations, self-monitoring of BP and other data, and educational content regarding hypertension and potential complications. Participants also favored apps with easy to navigate interfaces, and with desirable color-schemes. When the pros and cons of the five apps were assessed, three apps were identified as being more suitable, based on the benefits and functionalities they provided and their ease of use, with Cora health app rated highest in participants’ ratings.

A study by Morrissey et al (18) exploring patient views towards using hypertension improving medication adherence through showed that few hypertension apps were used by patients to support the self-management of their disease due to a lack of knowledge about hypertension apps, despite the widespread use of technology in other aspects of their lives. Similarly, in this study, even those patients and doctors who were generally active users of smartphone apps were not aware of the availability or suitability of any existing hypertension apps. This highlights the importance of identifying the most suitable app and promoting the existence of such apps among both the healthcare professionals and public through official media and education channels to increase the apps' adoption (44). Moreover, most participants in this research have a higher education level e.g., Bachelor degree or higher and therefore they are likely to have high digital competence This is supported in a research by Bol et al. (45) that found that more educated participants were more likely to engage with mHealth interventions than those with lower education level. A number of patient participants for the study had some preexisting medical knowledge. This preexisting knowledge may also have been a factor effecting patient participants' level of engagement.

One key difference between the findings of this study and that of previous research is in participants reported willingness to engage with mHealth interventions. A study conducted by Morrissey et al (18) in Ireland found that several patients expressed no interest in developing the digital competence required to use mHealth interventions. This contrasts with the present study, which found that the majority of participants were keen to engage with self-management apps. One possible explanation for this is the relative age of the study populations. In Saudi Arabia, the average age of hypertension sufferers is lower than in Europe, meaning the study population recruited for the present study also had a younger average age, and so was likely to have higher digital competence, and more willingness to engage with smartphone technology. Moreover, most participants in this research have a higher education level e.g., Bachelor degree or higher and therefore they are likely to have high digital competence. This is supported in a study by Bol et al (45) that found those with a higher level of education were more likely to engage with mHealth interventions than those with lower education level. A number of patient participants for the study had some preexisting medical knowledge. This preexisting knowledge may also have been a factor affecting patient participants' level of engagement.

The self-management strategies that identified in the present study were largely in line with those identified by Barlow et al. (46). Patients tried to adopt a variety of self-management methods to stay healthy such as self-monitoring BP and doing exercise. However, they face some difficulties and barriers that affect or delay the adoption of these strategies. Lack of motivation, busy life, lack of knowledge, forgetting, were the most common barriers to self-managing hypertension, which again is a finding similar to other studies, including one specifically examining the Saudi context (47-49). Although stress and anxiety have been identified as two of the most common barriers to effective self-management (48) these were not identified as significant barriers in this study. This may be because the main focus of approaches to self-management is on behavioral and medical management, with less focus on assisting patients in dealing with the emotional effects of chronic disease (50). It could therefore be the case that participants were not primed to discuss these topics in detail when they discussed their experience with managing hypertension. A meta-review found supporting self-management interventions with different components, including self-monitoring BP and provision of information and so on, could be effective in controlling BP and improving adherence to adopted strategies (51). Khatib et al. (48) indicated that the barriers patients identified show that they have an interest in finding a solution to effectively self-manage their hypertension, and these authors call for a more targeted, multi-faceted intervention to mitigate the identified barriers affecting self-management. The present study found that patients do indeed have an active interest in using mHealth interventions to support their self-management of hypertension, provided certain barriers can be overcome.

Previous research has shown that despite the many advantages of using apps in supporting self-management, certain concerns regarding their use persist, such as issues concerning the accessibility and usability of the app and the effectiveness of these tools (18,22,52). Our data is in line with these previous findings. Some participants felt that apps could be a helpful tool and they felt motivated by functions that allowed them to track the entered data and their progress over a long period of time. Both patients and doctors raised concerns about the apps, such as the language, with patients also raising concerns about the app's usability. App developers should consider the cultural preferences of target users (e.g., language) and their technical preferences (e.g., ease of use) to ensure the acceptance of and engagement with their apps in the future, and alleviate any hindrance affecting the use of health apps (22).

Previous research has found that doctors are in general less positive than patients about the use of mHealth apps (53). In the current study, doctors were generally positive about the prospect of their use. However, they were generally more concerned than patients about the credibility of the app and patients' ability to continue using it. They also questioned whether older users, who they feel are less competent users of the technology, can easily engage with these apps. Indeed, users continued or ongoing use of apps and the credibility of health apps has become a major concern in recent years (22). Vo et al have suggested that app credibility could be increased if certain standards were developed to ensure they only provide accurate and evidence-based information. Age and digital competence will become less of an issue as younger users, who have been immersed in smartphone culture, carry this competence with them into their old age. Meanwhile, the provision of training for new or older users could further mitigate these concerns (54,55).

In this research, Cora was identified as the highest rated among doctors and patients, although somewhat differing priorities were expressed by doctors and patients. For example, both doctors and patients liked apps that allowed for tracking more than just BP (e.g. medication), which contained more comprehensive reminder features, and whose features could be easily reached from the home screen. However, doctors were generally more concerned with the level of detail and medical accuracy, the inclusion of supplementary textual explanations to accompany visual feedback, and the provision of more comprehensive information about medications and their side-effects. Patients were generally more concerned with usability and design elements, expressing a dislike for the method of data entry in some apps, and a preference for apps with a more attractive or clearer visual design. These outcomes are similar to the findings of previous research revealing that doctors and patients often showed somewhat different priorities or preferences for functional requirements, expectations and needs of an mHealth app (49,56), even if they might agree to some extent on which app was best overall (49).

Powell et al. (57), indicated that apps are likely to be used and accepted if they include key components including pleasing visuals and the facility to personalize, and offer other broader functions, such as education. Similarly, this current research found that patients and doctors generally preferred three apps (Cora Health, ESH care and LifeCourse HyTen) that offer broader functions, pleasant visual design and in-depth features, specifically tailored to their situation. For example, users preferred apps that provide specific reminders instead of generic ones. Detailed features allow users to tailor the app to their circumstances and needs, and provide depth of information to support them (22). It was also found that patients and doctors were less positive about apps that lacked educational information or had relatively simplistic features and/or poor visual design, and were judged to be not useful, as mentioned with two apps (Quardio and Braun). This is also consistent with Lenog et al. (58), who found that hypertension apps with an educational component achieved high quality compared with those that did not have. An educational information function is one of the main components of self-management as it equips users with the main skills and information needed to effectively supporting their self-management in using the apps. Additionally, studies have found that apps that are designed to be easy to use lower the effort a user has to expend in using them (22,44), which could explain why users did not prefer the more complex apps.

Strengths

There are several notable strengths to the design and implementation of this study. First, it uses qualitative methods to generate rich data about the topic as participants are freer to express and explain their needs and ideas in their own words rather than being compelled to select their needs and opinions from pre-made options. Third, this is the first study that focuses on the self-management of hypertension and explores users' opinions on specific identified apps in order to select the most suitable one. Finally, this study uses a framework analysis that was recognized as suitable for analysing the study data, due to the flexibility of the inductive and deductive approach of the method and supports answers to specific research questions.

Limitations

The transferability of the findings with this study population (doctors and patients) to the whole population of doctors and patients is limited. First, this is because the study made use of a self-selecting sample (recruited via response to posters and fliers), meaning the patient sample was comprised only of those who attended during the time these were posted. Second, those who are more interested and willing to use technology are more likely to participate and thus the number of participants who had experience with smartphones is high. The participants' familiarity with smartphone apps could have also influenced results relating to the willingness of using apps in supporting the self-management of hypertension. A number of the patient participants had some preexisting medical knowledge or technical expertise, which may make the findings less generalizable to the general population. Finally, the number of older patient participants in the study sample was relatively low. This may be a limitation, especially since the majority of hypertension sufferers are older people. A further limitation is that, because none of the identified apps were available in Arabic, demonstrations of how the apps worked were presented to participants in video format. Although this meant the apps could be presented in a uniform manner, participants could not interact with the apps and were consequently only able to judge them on the basis of how they were presented. This presentation format could have influenced participant opinions of the apps. Asking participants to rate an app based on being shown a video may offer a less reliable indication of its suitability than if participants had been able to interact with the apps themselves. However, this was not the only indicator that was used to assess app suitability, with participants' discussions of the pros and cons of each app also influencing these selections.

5.2.5 Conclusion

This study showed that participants were favourable towards the idea of using health-apps to aid the self-management of hypertension. It was shown through patients' and doctors' discussions of their pros and cons that three of the five apps are clearly more suitable, with Cora being the most suitable overall. In the following study, we assess this app in a Saudi context by evaluating its use and usability in a field trial.

5.3 References

1. Rabin C, Bock B. Desired features of smartphone application promoting physical activity [online]. Journal of Telemedicine and e-Health. 2011 [cited 2019]. 17(10), 801-803. doi: 10.1089/tmj.2011.0055 review and meta-analysis.

2. Alessa T, Abdi S, Hawley MS, de Witte L. Mobile Apps to Support the Self-Management of Hypertension: Systematic Review of Effectiveness, Usability, and User Satisfaction. JMIR Mhealth Uhealth 2018 Jun [Cited 2020 Nov];6(7): e10723. doi: 10.2196/10723

3. Michie S, Johnston M, Francis J, Hardeman W, Eccles. From theory to intervention: mapping theoretically derived behavioural determinants to behaviour change techniques. Appl Psychol. 2008. 57(4): 660–80. doi: 10.1111/j.1464-0597.2008. 00341.x

4. Bondaronek P, Alkhaldi G, Slee A, Hamilton FL, Murray E. Quality of Publicly Available Physical Activity Apps: Review and Content Analysis. JMIR Mhealth Uhealth 2018 [cited 2018 Mar];6(3):e53. doi: 10.2196/mhealth.9069

5. Lippke S, Zielgelmann J P. Theory-based health behavior change: Developing, testing, and applying theories for evidence-based interventions. Applied Psychology: An international review. 2008 [cited 2018 Aug];57(4), 698 - 716. doi: 10.1111/j.1464- 0597.2008.00339.

6. Michie S, Carey RN, Johnston M, Rothman AJ, de Bruin M, Kelly MP, Connell LE. From Theory-Inspired to Theory-Based Interventions: A Protocol for Developing and Testing a Methodology for Linking Behaviour Change Techniques to Theoretical Mechanisms of Action. Ann Behav Med. 2018 May [cited Jul 2019];52(6):501-512. doi: 10.1007/s12160-016-9816-6.

7. Michie S, Atkins L, West R. The Behaviour Change Wheel: a guide to designing interventions. 2014. London: Silverback

8. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W et al. The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. Annals of Behavioral Medicine. 2013 Aug [cited 2018 Mar];1-15. doi: 10.1007/s12160-013-9486-6

9. TA. Online Trust Alliance. 2014. Mobile App Privacy & Security Available from: https://otalliance.org/best-practices/mobile-app-privacy-security [cited 2019 Jun]

10. ICO.Information Commissioner's Office. 2013. Privacy in mobile apps: Guidance for app developers [cited 2019 May]. Available from: https://ico.org.uk/media/for-organisations/documents/1596/privacy-in-mobile-apps-dp-guidance.pdf

11. Albini F, Liu X, Torlasco C, Soranna D, Faini A, Ciminaghi R et al. Use of Apps to Improve Drug Adherence in Hypertensive Patients. Drug Adherence in Hypertension and Cardiovascular Protection 2016 Aug [cited 2018 Aug]; 2016:517-520. doi: 10.1109/EMBC.2016.7590753.

12. LeRouge C, Wickramasinghe N. A review of user-centered design for diabetes-related consumer health informatics technologies. Journal of diabetes science and technology. 2013 [cited 2019 Aug]; 7(4), 1039–1056. doi: https://doi.org/10.1177/193229681300700429

13. Dabbs ADV, Myers BA, Mc Curry KR, Dunbar-Jacoc J, Hawkins RP, Begey A, et al. User-centered design and interactive health technologies for patients. Comput Inform Nurs. 2009 Jun [cited 2019 Jun];27(3):175–83. doi:10.1097/NCN.0b013e31819f7c7c.

14. Alessa T, Hawley MS, Hock ES, de Witte L. Smartphone Apps to Support Self-Management of Hypertension: Review and Content Analysis. JMIR Mhealth Uhealth. 2019 May [cited 2020 Aug];7(5):e13645. doi: 10.2196/13645.

15. Jamaladin H, van de Belt TH, Luijpers LC, de Graaff FR, Bredie SJ, Roeleveld N, van Gelder MM. Mobile Apps for Blood Pressure Monitoring: Systematic Search in App Stores and Content Analysis.

JMIR Mhealth Uhealth. 2018 Nov [cited 2020 Sep];6(11):e187. doi: 10.2196/mhealth.9888.

16. Hallberg I, Ranerup A, Kjellgren K. Supporting the self-management of hypertension: Patients' experiences of using a mobile phone-based system. J Hum Hypertens 2016 Feb [cited 2019 Jul];30(2):141-146

17. Morrissey EC, Glynn LG, Casey M, Walsh JC, Molloy GJ. New self-management technologies for the treatment of hypertension: general practitioners' perspectives. Fam Pract. 2018 Jun; 23;35(3):318-322. doi: 10.1093/fampra/cmx100. PMID: 29088438.

18. Morrissey EC, Casey M, Glynn LG, Walsh JC, Molloy GJ. Smartphone apps for improving medication adherence in hypertension: patients' perspectives. Patient Prefer Adherence. 2018 May 14;12:813-822. doi: 10.2147/PPA.S145647. PMID: 29785096; PMCID: PMC5957057.

19. Zare, Sahar, Rezaee, Rita, Aslani, Azam, Shirdeli, Mohammad, and Kojuri, Javad. "Moving toward Community Based Telehealth Services Using Mhealth for Hypertensive Patients.International Journal of Technology Assessment in Health Care 2019 Sep; 35(5): 379-83

20. McBride CM, Morrissey EC, Molloy GJ. Patients' Experiences of Using Smartphone Apps to Support Self-Management and Improve Medication Adherence in Hypertension: Qualitative Study. JMIR Mhealth Uhealth 2020 [cited 2020 Nov];8(10):e17470. doi: 10.2196/17470

21. van der Weegen S, Verwey R, Tange HJ, Spreeuwenberg MD, de Witte LP. Usability testing of a monitoring and feedback tool to stimulate physical activity. Patient Prefer Adherence. 2014 Mar [cited Aug 2020];8(March):311-322. Doi: 10.2147/PPA.S57961

22. Vo V, Auroy L, Sarradon-Eck A. Patients' Perceptions of mHealth Apps: Meta-Ethnographic Review of Qualitative Studies. JMIR Mhealth Uhealth. 2019 Jul [cited 2020 Sep] 10;7(7):e13817. doi: 10.2196/13817.

23. Creswell JW, Plano Clark VL. Designing and Conducting Mixed Methods Research. SAGE Publications Ltd. SAGE Publications, lnc.; 2018.

24. Creswell JW, Creswell D. Research Design Qualitative, Quantitative & Mixed Methods Approaches. SAGE Publications Ltd. SAGE Publications, lnc.; 2017.

25. Pope C, Mays N. Qualitative research in health care. Florida: John Wiley & Sons; 2008

26. Bryman A. Social research methods. 4th ed. New York: Oxford University Press; 2012.

27. Bajorek B, Lemay K, Magin P, Roberts C, Krass I, Armour C. Patients' Attitudes and Approaches to the Self-Management of Hypertension: Perspectives from an Australian Qualitative Study in Community Pharmacy. High Blood Press Cardiovasc Prev. 2017 Jun [cited 2018 Dec];24(2):149-155. doi: 10.1007/s40292-017-0181-8.

28. Morgan, MB. et al. Risk Communication: A Mental Models Approach. New York: Cambridge University Press;202.

29. Guest G, Namey E, Taylor J, Eley N, McKenna K. Comparing focus groups and individual interviews: Findings from a randomized study. International Journal of Social Research Methodology. 2017 [cited 2018 Jul] 20(6), 693-708.

30. Guest G, Bunce A, Johnson L. How Many Interviews Are Enough? Field Methods. 2006 [cited 2018 Jul]; 18(1), 59-82.

31. Guest G, Namey E McKenna K. How Many Focus Groups Are Enough? Building an Evidence Base for Nonprobability Sample Sizes. Field Methods.2017 [cited 2020 Sep]; 29(1), 3-22.

32. Huston S, Hobson A. Using focus groups to inform pharmacy research. Research in Social and Administrative Pharmacy. 2008 [cited 2018 Jul];4(3), 186–205. Available from: doi: 10.1016/j.sapharm.2007.09.001

33. Tausch AP, Menold N. Methodological Aspects of Focus Groups in Health Research: Results of Qualitative Interviews with Focus Group Moderators. Global Qualitative Nursing Research. 2016 [cited

2018 Jul];3, 233339361663046

34. Hollander JA. The social contexts of focus groups. Journal of Contemporary Ethnography. 2004 [cited 2018 Jul];33, 602–637. Available from: doi: https://doi.org/10.1177/0891241604266988

35. Long T, Johnson M. Rigour, reliability and validity in qualitative research. Clinical Effectiveness in Nursing. 2002 [cited 2018 Jul];4 (1), 30-37. doi: https://doi.org/10.1054/cein.2000.0106.

36. Yardley, L. Dilemmas in qualitative health research. Psychology and Health.2000 [cited 2018 Jul]; 15, 215–228.

37. Patton MQ. Qualitative research and evaluation methods (3rd Ed.). Thousand Oaks, CA: Sage;2002.

38. Ritchie J, Lewis J, Nicholls CM, Ormston R. Qualitative research practice: A guide for social science students and researchers, Sage;2013.

39. Gale NK, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC Med Res Methodol, 2013 [cited 2018 Jul]; 13, 117,. https://doi.org/10.1186/1471-2288-13-117

40. Ward DJ, Furber C, Tierney S, Swallow. Using framework analysis in nursing research: a worked example. Journal of Advanced Nursing. 2013; 69 (11), 2423- 2431

41. Akbar S, Coiera E, Magrabi, F. Safety concerns with consumer-facing mobile health applications and their consequences: a scoping review. JAMIA. 2020 Feb [cited 2020. Aug]; 27(2):330–340.

42. Scott IA, Scuffham P, Gupta D, Harch TM, Borchi J, Richards B. Going digital: a narrative overview of the effects, quality and utility of mobile apps in chronic disease self-management Ponline. Aust Health Rev. 2020 Feb [cited 2020 Aug];44(1):62-82. doi: 10.1071/AH18064.

43. Jake-Schoffman DE, Silfee VJ, Waring ME, Boudreaux ED, Sadasivam RS, Mullen SP, Carey JL, Hayes RB, Ding EY, Bennett GG, Pagoto SL. Methods for Evaluating the Content, Usability, and Efficacy of Commercial Mobile Health Apps. JMIR Mhealth Uhealth 2017 [cited 2020 Aug];5(12):e190. doi 10.2196/mhealth.8758

44. Peng W, Kanthawala S, Yuan S, Hussain SA. A qualitative study of user perceptions of mobile health apps. BMC Public Health. 2016 Nov 14;16(1):1158. doi: 10.1186/s12889-016-3808-0.

45. Bol N, Helberger N, Weert JCM. Differences in mobile health app use: A source of new digital inequalities? The Information Society. 2018[cited 2020 Jul]; 34(3), 183-193.

46. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Educ Couns. 2002 Oct-Nov [cited 2018 Feb];48(2):177-87. doi: 10.1016/s0738-3991(02)00032-0.

47. AlHadlaq RK, Swarelzahab MM, AlSaad SZ, AlHadlaq AK, Almasari SM, Alsuwayt SS, Alomari NA. Factors affecting self-management of hypertensive patients attending family medicine clinics in Riyadh, Saudi Arabia. J Family Med Prim Care. 2019 Dec [cited 2020 Jan];8(12):4003-4009. doi: 0.4103/jfmpc.jfmpc_752_19.

48. Khatib R, Schwalm JD, Yusuf S, Haynes RB, McKee M, Khan M, Nieuwlaat R. Patient and healthcare provider barriers to hypertension awareness, treatment and follow up: a systematic review and meta-analysis of qualitative and quantitative studies. PLoS One. 2014 Jan [cited 2019 Dec];9(1):e84238. doi: 10.1371/journal.pone.0084238

49. Marshall Iain J, Wolfe Charles D A, McKevitt Christopher. Lay perspectives on hypertension and drug adherence: systematic review of qualitative research. BMJ 2012 Jul [cited 2020 Sep]; 345: e3953

50. Elissen A, Nolte E, Knai C, Brunn M, Chevreul K, Conklin A, et al. Is Europe putting theory into practice? A qualitative study of the level of self- management support in chronic care management approaches. BMC Health Serv Res. 2013;13(1):117. doi:10.1186/1472-6963-13-117

51. Shahaj O, Denneny D, Schwappach A, Pearce G, Epiphaniou E, Parke HL et al. Supporting self-

management for people with hypertension: a meta-review of quantitative and qualitative systematic reviews. J Hypertens. 2019 Feb [cited 2019 Jan];37(2):264-279. doi: 10.1097/HJH.0000000000001867.

52. Hallberg I, Ranerup A, Kjellgren K. Supporting the self-management of hypertension: Patients' experiences of using a mobile phone-based system. J Hum Hypertens. 2016 Feb [cited 2020 Mar];30(2):141-6. doi: 10.1038/jhh.2015.37. Epub 2015 Apr 23.

53. Morton K, Dennison L, May Cet al. Using digital interventions for self-management of chronic physical health conditions: a meta-ethnography review of published studies. Patient Educ Couns2017; 100: 616–35.

54. Whitehead L, Seaton P. The Effectiveness of Self-Management Mobile Phone and Tablet Apps in Long-term Condition Management: A Systematic Review. J Med Internet Res. 2016 May [cited 2020 Jan];18(5):e97. doi: 10.2196/jmir.4883.

55. Kirwan M, Vandelanotte C, Fenning A, Duncan MJ. Diabetes self-management smartphone application for adults with type 1 diabetes: randomized controlled trial. J Med Internet Res. 2013 Nov [cited 2020 Jan];15(11):e235. doi: 10.2196/jmir.2588.

56. Flynn SJ, Ameling JM, Hill-Briggs F, Wolff JL, Bone LR, Levine DM, Roter DL, Lewis-Boyer L, Fisher AR, Purnell L, Ephraim PL, Barbers J, Fitzpatrick SL, Albert MC, Cooper LA, Fagan PJ, Martin D, Ramamurthi HC, Boulware LE. Facilitators and barriers to hypertension self-management in urban African Americans: perspectives of patients and family members. Patient Prefer Adherence. 2013 Aug [cited 2020 Jan];7:741-9. doi: 10.2147/PPA.S46517.

57. Powell L, Parker J, Harpin V. ADHD: Is There an App for That? A Suitability Assessment of Apps for the Parents of Children and Young People With ADHD. JMIR Mhealth Uhealth 2017 Oct [cited 2020 Aug];5(10): e149. doi: 10.2196/mhealth.7941

58. Leong AY, Makowsky MJ. Quality of Blood Pressure Tracking Apps for the iPhone: Content Analysis and Evaluation of Adherence with Home Blood Pressure Measurement Best Practices. JMIR Mhealth Uhealth. 2019 Apr [cited 2020 Jan];7(4):e10809. doi: 10.2196/10809. PMID: 30977739; PMCID: PMC6484262.

59. Saunders B, Sim J, Kingstone T, Baker S, Waterfield J, Bartlam B, Burroughs H, Jinks C. Saturation in qualitative research: exploring its conceptualization and operationalization. Qual Quant. 2018;52(4):1893-1907. doi: 10.1007/s11135-017-0574-8.

60. Etikan I, Musa SA, Alkassim RS. Comparison of Convenience Sampling and Purposive Sampling. American Journal of Theoretical and Applied Statistics. 2016 Jan [cited 2018 Jul];5(1):1-4.

Chapter 6: Study 4: Using a commercially available app for self-management of hypertension: Acceptance and usability study in Saudi Arabia

Published as: Alessa T, S Hawley M, Alsulamy N, de Witte L. Using a Commercially Available App for the Self-Management of Hypertension: Acceptance and Usability Study in Saudi Arabia. JMIR Mhealth Uhealth 2021;9(2):e24177. doi: 10.2196/24177.

In the previous chapter, one app was identified as most suitable to assist in patients' self-management of hypertension in Saudi Arabia. This chapter presents the acceptance and usability study that was then conducted among Saudi patients. A mixed methods approach was adopted, comprising a usability test and a usability and acceptance study in real-life. The results from this study form the final stage of the PhD, the overall findings of which are discussed in the next chapter.

Abstract

Background: The use of smartphone apps to assist in the self-management of hypertension is becoming increasingly common, but few commercially available apps have the potential to be effective along with adequate security and privacy measures in place. In a previous study, we identified 5 apps that are potentially effective and safe, and based on the preferences of doctors and patients, one (Cora Health) was selected as the most suitable app for use in a Saudi context. However, there is currently no evidence of its usability and acceptance among potential users. Indeed, there has been little research into the usability and acceptance of hypertension apps in general, and less research considers this in the Gulf Region.

Objective: This study aims to evaluate the acceptance and usability of the selected app in the Saudi context.

Methods: This study used a mixed methods approach with 2 studies: a usability test involving patients in a controlled setting performing predefined tasks and a real-world usability study where patients used the app for 4 weeks. In the usability test, participants were asked to think aloud while performing the tasks, and an observer recorded the number of tasks they completed. At the end of the real-world pilot study, participants were interviewed, and the mHealth App Usability Questionnaire was completed. Descriptive statistics were used to analyze quantitative data, and thematic analysis was used to analyze qualitative data.

Results: In total, 10 patients completed study 1. The study found that app usability was moderate and that participants needed some familiarization time before they could use the app proficiently. Some usability issues were revealed, related to app accessibility and navigation, and a few tasks remained uncompleted by most people. A total of 20 patients completed study 2, with a mean age of 51.6 (SD 11.7) years. Study 2 found that the app was generally acceptable and easy to use, with some similar usability issues identified. Participants stressed the importance of practice and training to use it more easily and proficiently. Participants had a good engagement level with 48% retention at the end of study 2, with most participants' engagement being classed as meaningful. The most recorded data were blood pressure, followed by stress and medication, and the most accessed feature was viewing graphs of data trends.

Conclusions: This study shows that a commercially available app can be usable and acceptable in the self-management of hypertension but also found a considerable number of possibilities for improvement, which needs to be considered in future app development. The results show that there is potential for a commercially available app to be used in large-scale studies of hypertension self-management if

suggestions for improvements are addressed.

Keywords: mHealth; mobile phone; hypertension; usability; acceptance; user satisfaction

6.1 Background

Hypertension is one of the most common chronic diseases in adults and can lead to several serious complications, including stroke, heart disease, and renal failure. The condition affects approximately one billion people globally. In Saudi Arabia, 27.2% of people aged above 30 years have been diagnosed with hypertension (1-5). Lowering blood pressure (BP) lessens the risk of complications, but many patients with hypertension do not control their BP well (3,5,6). Self-management is one of the most effective ways to control hypertension. This involves encouraging patients to take control of their condition, for instance, by changing their lifestyle, by becoming more involved in their treatment, and by managing their symptoms and psychosocial and physical effects (7-9). However, self-management behavior remains to be difficult and is an aspect of treatment with which patients often struggle.

The increase in smartphone use in recent years has led to an increase in health-related apps on these devices. In Saudi Arabia alone, there were an estimated 21.8 million smartphone users in 2018, and as a result, the use of health apps as a means for treating patients has increased (10,11). Many commercial apps are available, offering a potential way to promote and assist the self-management of hypertension (12-15).

This study focuses on one commercially available app (Cora Health) developed by Swiftware. This app was selected based on the findings of previous studies. Alessa et al (16) conducted a systematic review of apps intended to assist in the self-management of hypertension and found that these are potentially effective in lowering BP, particularly when they have comprehensive functionalities, including self-monitoring, reminders, and educational information or automatic feedback. Most apps were developed specifically for an individual study, and there is still a lack of research evidence supporting the effectiveness and usability of commercially available apps. A recent review of apps actually available in app stores found that only few apps (30/186, 16.1%) had the potential to be effective, very few apps (5/186, 2.6%) had the potential to be effective and with adequate security and privacy safeguard, and none of them claim to have involved users in their development (15). A subsequent study explored patients' and doctors' preferences toward the 5 apps found to be effective and with adequate security and privacy measures. When participants were asked to rate the apps, the Cora Health app was considered the most suitable. However, there is still no published evidence regarding its usability or effectiveness (15).

Many commercial apps, including the Cora Health app, did not involve users in app development, although many studies have found that participants' acceptance of apps and their perceptions of usefulness and ease of use are all key factors for mobile health (mHealth) adoption (17-19). Moreover, there is very little research into usability and acceptance in general (15,16) and even less research that specifically examines the Saudi context or the wider Gulf Region. However, Clemmensen et al (20) suggested that usability problems could be influenced by users' cultures, experience, and knowledge. This highlights the importance of assessing a commercially available app's usability, acceptance, and engagement before its effectiveness can be evaluated (21-23). This study aims to assess the usability and acceptance of the Cora Health app to support the self-management of hypertension in Saudi Arabia, which is the first study in this context. The objectives of this study are as follows: 1) to assess how usable the app is; 2) to assess patients' experience using the app: what barriers to use they see and whether they think it could be improved; and 3) to examine how participants engage with the app. Our central hypothesis was that users would find the app acceptable and usable overall but that they might also identify usability issues or specific preferences and needs, which the app did not meet.

6.2 Study Design and Methods

This research used a convergent mixed methods approach to comprehensively assess the app's usability and acceptance (24), conducted via 2 studies: 1) a usability test and 2) a real-world usability and acceptance study.

The qualitative and quantitative data in this research were collected concurrently in both studies and analyzed separately. It was then integrated and synthesized in the interpretation so that the facets of the results could be examined together and compared. Efficient integration of both qualitative and quantitative methods results in a larger knowledge yield than that obtained by treating the 2 strands in isolation (24,25).

Usability is defined as, "the extent to which a product can be used by specific users to achieve specific goals with effectiveness, efficiency and satisfaction in a specific context of use" (26). Acceptance, for the purpose of the study, includes participants' actual app use, their satisfaction, and attitudes toward using the app and intention or willingness to continue using the app (27).

6.2.1 Participants

The population of this study included Saudi adults with hypertension. Participants for both studies were purposively selected from 1 hospital and 2 primary care centers in Riyadh, Saudi Arabia, (see Appendix 25 and 26) based on the predefined inclusion and exclusion criteria (28).

For the usability test, a sample size of 10 eligible participants was used. This is sufficient to discover more than 80% of usability problems (29,30). For the usability and acceptance study, the target sample size was 20 to 30 eligible people, which is a similar number to previous studies assessing the acceptance and usability of health apps (17,31,32).

The inclusion criteria in both studies were as follows: at least 30 years old; diagnosed with hypertension (stages 1-3) as a primary disease for a minimum of 6 months; able to speak Arabic, give consent, and actively participate in the study; and possess or have access to an iOS-compatible smartphone. The exclusion criteria were as follows: having a cognitive impairment that limits the ability to give informed consent or to actively take part in the studies; having prehypertension or hypertension during pregnancy; being unable to read and understand the Arabic language; and (for study 2 only) affected by stage or severe hypertension (180/110 mm Hg).

Participant Recruitment

The study was conducted at the largest hospital related to the Ministry of Health and 2 primary care centers related to the hospital. Participants in study 1 were recruited via posters and flyers advertising the study, with recruitment continuing until data saturation was reached, that is, once new participants were no longer revealing new data, information, or usability issues. (33). For study 2, physicians were approached to recruit participants from among their patients based on the study's eligibility criteria. People who expressed an interest in participating in the studies were provided with a further information sheet and a consent form

6.2.2 Intervention

Figure 6.1 shows the app version used runs on the iPhone. The app was translated into Arabic by the researcher and then back into English to check for translation accuracy. Samples of the Arabic version were then sent to a test group of Arabic speakers with hypertension to check its comprehensibility and clarity. Owing to developer constraints, it was not possible to translate the complete app content; some small sections, for example, labels of figures and names of medication, remained in English.

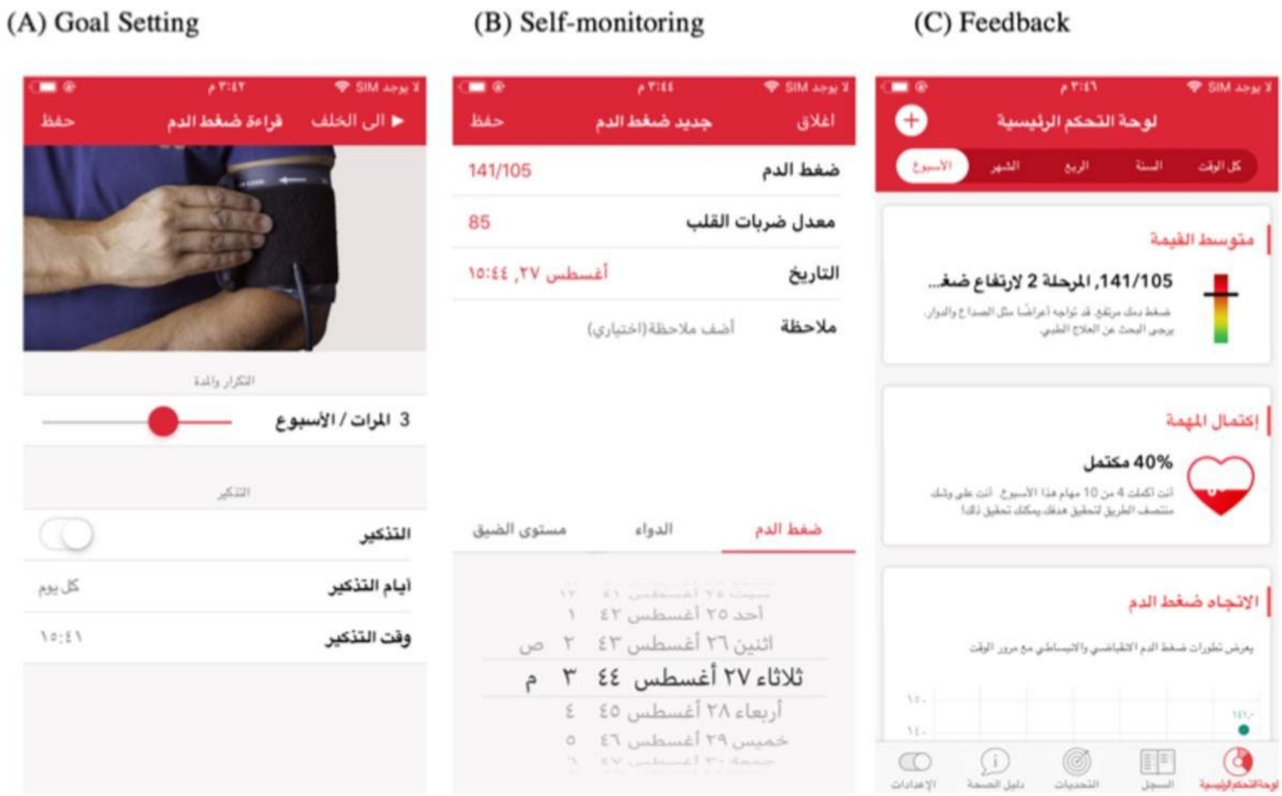


Figure 6.1. The main functionalities of the app.

The app has 3 main features: monitoring (BP, stress, and medication), setting weekly challenges, and medical information. The BP feature allows users to upload their BP measurements to the device either automatically or manually, displays the readings on graphs, and includes feedback. This app also allows users to enter their distress level and its reasons as well as medication names and doses. The second feature allows users to set weekly challenges, such as monitoring BP. The app also has educational materials that allow patients to learn how to self-manage their chronic conditions.

6.2.3 Methods

Study 1: Usability Testing

The usability of the app was studied using a thinking-out-loud technique, where participants verbalize their thoughts and feelings while using the app and performing a set of predefined tasks. An observer collected first impressions and initial reactions (21). A pilot of the usability study was undertaken with 2 eligible participants before the commencement of the full study.

The tasks presented to the participants were based on the main functionalities of the app, ensuring that the app was fully tested and used. The tests were audiorecorded to aid analysis. Participants were given multiple attempts to complete the tasks. If the participant was unable to complete a task after several attempts, assistance was offered. Each session lasted approximately 40-60 min and was conducted by the researcher with a facilitator aiding observations and taking notes.

Each session began by briefly introducing the test aim and its procedures and explaining the think-aloud technique and the purpose of the app. The participants were asked to sign a consent form and complete a short questionnaire, including demographic questions and smartphone experience. The participants then performed the tasks and vocalized their reactions. The observer recorded the number of tasks participants completed, any requests for assistance, and errors made. The observer also asked questions during the tasks to encourage participants to share their opinions. Finally, the participants were given an opportunity to raise any issues relating to topics that were not covered.

Study 2: Real-World Usability and Acceptance Study

A one-group posttest study was carried out to analyze how the app was used in everyday life as a part of the participants' routines. This study assessed the acceptance and usability of the app by means of a questionnaire, user engagement data, and a post interview after 4 weeks of using the app. Owing to the study aims and methods, patients and investigators were not blinded.

Each participant was asked to sign a consent form and complete a brief demographic questionnaire, including smartphone experience. The app was then downloaded onto the patient's iPhone. Face-to-face training was provided by the researcher, and the instruction manual was provided. Participants were provided with a validated home Omron M7 BP monitoring device (34-36). Participants could obtain technical support throughout the study from the researcher by email or phone. For quality and safety reasons, patients continued their usual treatment with their physician. At the 4-week follow-up, participants completed the usability questionnaire and were interviewed using a semistructured interview to assess their personal experience, including acceptance of using the app and their views on its usability. The interviews lasted approximately 40 min and were audiorecorded, and concurrent notes were taken. Finally, the BP devices were collected by the researcher.

User Engagement Data

Information on how often participants used the app was automatically (anonymously) recorded. Participants were supplied with a specific link to download the Arabic version created for the study. The engagement data were provided anonymously, where the app did not collect data on a per-user basis due to data privacy regulations. We recorded the number of log-ins, the types and frequencies of data entered, and the number and frequency of features accessed. These are the 3 most common measurements used to assess user engagement with health apps (37). The study also examined the user's session duration and user engagement over time.

Usability Questionnaire

The mHealth App Usability Questionnaire (MAUQ) was used (38). The questionnaire was translated into Arabic following the guidance offered by the World Health Organization (39). The pilot study found this translated questionnaire to have a Cronbach □ of .9, a scale level content validity index of 0.98.

6.2.4 Data Analysis

SPSS software (package 19) (40) was used to calculate the descriptive statistics for the quantitative analysis. All qualitative data were transcribed, checked for accuracy, and analyzed using thematic analysis (40,41). The qualitative analysis followed 6 steps: 1) data familiarization, 2) creation of initial codes, 3) collection of codes into broader themes, 4) specification of themes, 5) review of themes, and 6) writing the report (41).

The thematic analysis was partly deductive and partly inductive. In total, 2 researchers (TA and NA) independently analyzed 20% of transcripts. The researchers then checked for consensus on these coding. This resulted in standardized codes, in which TA was used for the remaining transcripts. Any new codes were added when necessary.

On the basis of the study aims, the initial themes were devised deductively. Additional themes and subthemes were then devised inductively based on users' initial expectations and their experiences of the app. Final themes and subthemes were confirmed through discussion among the authors. Following data analysis, an integration matrix (24,25) was used to compare data from the different methods. The quantitative and qualitative results of the research were integrated and analyzed together, considering any convergences and divergences between these different data. The matrix is given in Appendix 21.

6.3 Results

6.3.1 Study 1: Usability Testing

Participant Characteristics

The usability study was completed by 10 participants, aged 35 to 69 years, with a mean of 48.8 (SD 11.7) years. In total, 6 participants were female and 4 were male. Overall, 6 participants had a diploma degree (a level of Saudi qualification between high school and bachelor's degree) or higher. Most participants (9/10, 90%) had experience using smartphones for longer than 3 years. Most participants (8/10, 80%) had hypertension for 1 year or more (Table 6.1)

Table 6.1 Characteristics of usability test participants.

Characteristics		Values
Age (years), mean (SD); range		48.8 (11.7); 35-69
Age groups (years), n (%)		
	30-39	2 (20)
	40-49	3 (30)
	50-59	2 (20)
	≥60	3 (30)
Gender, n (%)		
	Male	4 (40)
	Female	6 (60)
Time since diagnosed with hypertension (years), n (%)		
	<1	2 (20)
	1-3	4 (40)
	>3	4 (40)
Education level		
	Less than high school	3 (30)
	High school	1 (10)
	Diploma	2 (20)
	Undergraduate degree	2 (20)
	Postgraduate degree	2 (20)
Smartphone users		
	Yes	10 (100)
	No	0 (10)

Usability Test Results

The analysis of the usability test transcripts resulted in 2 themes: overall usability and user satisfaction and app content to support self-management.

Overall Usability and User Satisfaction

Users gave numerous positive comments relating to the usability of the Cora Health app interface and were generally satisfied. They described it as *helpful*, *fab*, and *easy to use*, and some asked to continue using the app by downloading the original English version from the app store. Patients felt that using the app would help improve their understanding of hypertension and their management of the condition. More than half of the participants completed all but 2 tasks. Participants often needed assistance while performing tasks, as they were unfamiliar with the app. They would require some time to become familiar with the app before being able to use it proficiently. The theme of overall usability and user satisfaction is separated into the 2 subthemes of app accessibility and user interface issues. Further details of these are presented in Appendix 22.

App Content to Support Self-Management

User comments on the app content were generally positive, with participants describing it as "useful in self-managing." Some users liked the information available in the health guide and accompanying the BP feedback. They felt that this would increase their understanding and encourage them to take action to control their BP:

> *I really love the additional explanation. It offers some helpful advice that encourages me to take action because my BP is not normal. It helps me to understand my situation and to do something to control [my BP].* [P2]

Some participants expressed that the tick feature of the app (ticking off completed tasks) would encourage completion of the challenges:

> *it encourages me to do more tasks.* [P4]

Task Completion

Most participants downloaded the app (task 1) without any assistance, except for 3 older participants who required help. However, this difficulty may have been related to the method of downloading the trial version, which is different from a typical app. All participants completed both the *Entering Stress Data* task (task 3.2), inserting a tick to mark self-monitoring as completed (task 8), and *indicate how many challenges* are set (task 9), without making any errors or asking for any assistance. Therefore, these tasks had the highest completion rate.

Very few users completed task 7: setting a reminder for self-monitoring BP. Only 20% (2/10) of participants completed this task without errors, whereas 80% (8/10) of participants completed the task with errors. Similarly, in task 10, only 2 participants completed the task without errors, whereas 5 participants (5/10, 50%) completed the task with errors and 3 participants (3/10, 30%) required help.

The remaining tasks were completed by most participants without errors or assistance (60% for tasks 2, 3.1, 4, and 11; 70% for tasks 5 and 6). The full completion, error, and assistance rates are presented in Table 6.2.

Table 6.2 Usability test tasks.

Task	**Participants who completed the task , n**	**Participants who made errors**, n	**Participants who needed an assistance**, n
1. Downloading the app and log-in	7	0	3
2. Monitoring and registering BP[a] with the app	6	0	4
3. Recording other data (medication and distress)			
3.1 Enter the medication name and its dose	6	4	0
3.2 Enter the distress level you feel and select any applicable problems	10	0	0
4. Indicate whether the BP average value and see if its normal or not	6	2	2
5. Compare the new measurement of BP data with those measured before	7	1	2
6. Indicate whether the current measured BP is normal or not using the Blood Pressure Scatter Char	7	1	2
7. Set a reminder for self-monitor BP 4 times a week	2	8	0
8. Inserting a tick to mark self-monitoring as completed	10	0	0
9. Indicate how many challenges are set	10	0	0
10. Indicate how many tasks have you completed and how many tasks do you still to need finish	2	5	3
11. Read the information about BP monitors	6	0	4

6.3.2 Study 2: Real-World Usability and Acceptance Study

Participant Characteristics

In total, 23 participants agreed to participate in this study. A total of 2 participants decided to withdraw after a few days because of their busy schedule. One other participant had to withdraw because of technical issues related to their device. In total, 20 participants (11 males and 9 females) completed the study. They were aged between 33 and 71 years, with a mean of 51.6 (SD 11.7) years. Overall, 80% (16/20) of participants had a diploma degree or higher. Most participants had experience using smartphones for more than 3 years. Most participants (16/20, 80%) had hypertension for 1 year or more (Table 6.3)

Table 6.3 Participant characteristics.

Characteristics		**Values**
Age (years), mean (SD); range		51.6 (11.7); 33-71
Age groups (years), n (%)		
	30-39	3 (15)
	40-49	6 (30)
	50-59	6 (30)
	≥60	5 (25)
Gender, n (%)		
	Male	11 (55)
	Female	9 (45)
Time since diagnosed with hypertension (years), n (%)		
	<1	4 (20)
	1-3	7 (35)
	>3	9 (45)
Education level, n (%)		
	Less than high school	4 (20)

	High school	0 (0)
	Diploma	5 (20)
	Undergraduate degree	7 (35)
	Postgraduate degree	4 (20)
Smartphone users, n (%)		
	Yes	20 (100)
	No	0 (0)

Usability Questionnaire

This section presents the results pertaining to the usability of the app and participants' satisfaction (as measured by the MAUQ). Participants perceived the app as a useful tool (mean score 6.3, SD 0.40 on a scale of 1-7). They were also satisfied with the app and its interface (mean score 6.2, SD 0.25) and expressed that the app was easy to use (mean score 6, SD 0.2).

Participants scored high when asked whether the app is a useful tool in helping them to manage their condition effectively (mean score 6.6, SD 0.50). A high score was also given when asked whether the app is useful for receiving health care services such as accessing educational information, tracking their own activities, and performing self-assessment (mean score 6.7, SD 0.47). However, participants scored lower (mean score 5.7, SD 1.49) when asked if they could use the app even when the internet connection was poor or unavailable.

App Engagement Data

Table 6.4 shows group-level data on participants' engagement with the app over a month, measured by the length of time of each user's session. The average session duration was 1 min and 35 seconds, with around 72.9% (346/474) of users' sessions being in the *meaningful engagement* ranges of 30 to 60 seconds or longer (42).

Figure 6.2 shows the retention data for study participants, that is, the number of users who continued to use the app. A total of 6 users ceased using the app following the first day's use. From day 1 to day 6, 74% of the participants were active. From day 7 to 18, 70% were active. User retention then gradually decreased to 48% on day 30.

On average, the app was opened 21.4 times per user, totaling 493 times over a month, as shown in Table

6.5. The most accessed functionality was viewing the Logbook, which allows users to self-monitor their previously entered data. The least accessed functionality was setting behavior goals (*Challenge Created*

Table 6.4 Participant session duration.

Sessions durations	**Sessions**, n
0 seconds	0
0-3 seconds	38
3-10 seconds	40
10-30 seconds	50
30-60 seconds	96
1-30 minute	141
3-10 minute	93
10-30 minute	16

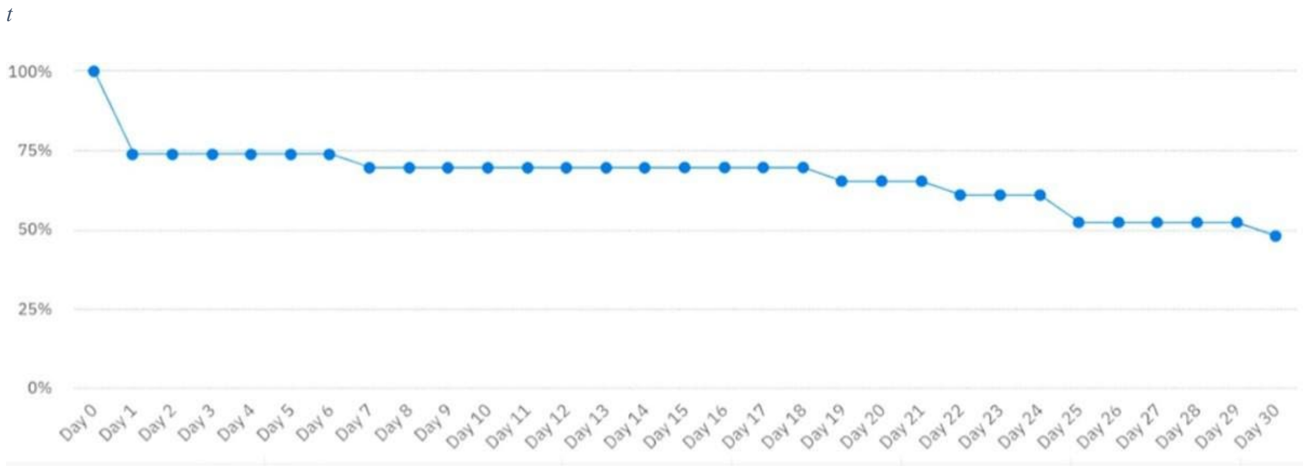


Figure 6.2 Participant engagement over time

Table 6.5 App functionalities use.

App section and app functionalities	**Number of participants who used the functionalities**	**Number of times**	**Average per participant**
General			
App opened	23	493	21.4
App closed	23	768	33.4
Logbook and dashboard			
Feedback on behavior or outcome of behavior (dashboard viewed)	23	1002	43.6
Self-monitoring of previous data (logbook viewed)	23	1384	60.2
Self-monitoring of blood pressure	21	416	19.8
Self-monitoring of medication	20	234	11.7
Self-monitoring of distress	20	246	12.3
Challenges			
Setting behavior goal	19	72	3.78
Review of behavior goal(s)	21	704	33.52
Task completed	19	721	37.94

The most common self-monitoring behavior was entering BP, followed by stress and medication: each user self-monitored their BP and inputted an average of 19.8 times.

The user engagement data over the month for entering BP, medication, and stress levels and for viewing previously entered data are presented in Appendix 23. These graphs clearly show a distinction between a group of users who engage regularly (more than 6 times) and a group with lower engagement figures. The majority of participants engaged regularly with the app. In total, 15 (71.4%) participants recorded data for at least 3 days per week (the level considered sufficient for treatment and adherence with self-monitoring (43). The figures for recording emotion and medication use are lower.

The user engagement data over the month for goal setting (challenges), task completion for each goal, and reviewing behavior goals are presented in Appendix 23. Most participants (n=19) set at least one goal, with a number ranging from 1 to 10. Most participants (n=14) set 3 or more different types of goals.

Interview Results

Analysis of interviews resulted in 3 themes: usage of the app, capacity to support self-management, and usability of the app. Some participants' quotations for this section are provided in Appendix 24.

Usage of the App

General Satisfaction and Use

Patients were satisfied with the app and saw it as an *enjoyable*, *interesting, accessible and convenient, useful, and informative* tool in managing hypertension. They generally found it easy to incorporate the app into their routines. Few participants (n=2) felt that the app felt the app required time and effort.

Patients expressed that they would be likely to continue using this app after the study and that they would recommend it to others. They gave several reasons, including that the app offered a single easily accessible location for their data, that it provides a good overview of their BP level, and because of its ease of use and convenience for managing their diseases.

App Functionality Use

Participants used most of the app functionalities. Interviewees reported that the most commonly used app function was self-monitoring BP data, followed by viewing the graphs and lists showing trends over a week or month. They stated that the visual representations were valuable, as was the quick and direct transmission of BP data from a BP monitoring device to the app.

Most people recorded medications and stress and perceived the facility to enter these as a positive feature. They also reported setting different types of challenges, the most common being entering BP and taking medication. Most also set challenges for other activities intended to increase exercise, and a few set challenges to reduce stress.

Hypertension information was generally considered useful, but a few patients stated that information was lacking, or already known, for example, regarding meals (especially Saudi foods), mental health, smoking, or information about pregnancy. Some participants emphasized that it was the overall range of functionalities that made the app valuable and worth using.

External Factors Influencing Use of the App

Participants reported a range of external factors that affected their use of the app. Family was one of the key factors mentioned, as both a motivating and demotivating factor for using the app. Busy lifestyles and other health issues reportedly prevented some participants from undertaking and/or completing additional challenges.

Capacity to Support Self-Management

A Daily Monitoring Tool

The app provides patients with a routine and structured system, helping them to maintain discipline in self-monitoring different types of data. Transmission of BP data by Bluetooth was easier and quicker than conventional recording methods or relying on memory. Presenting data immediately in a graphical view helped patients see trends over time.

Monitoring emotions and indicating the reasons behind them was a positive feature, but it would be good to allow monitoring of the symptoms that patients feel.

An Informative Tool

Participants found the feedback functionalities to provide a clear picture of BP levels and to show the relationship between their challenges completed and their BP level. However, participants would have liked more detail in the feedback on task completion and more tailoring of BP feedback to their individual cases.

A Commitment Tool

Participants expressed that this app increased their commitment and encouraged them to add and achieve more self-management strategies to their routine. Some participants also found that repeated reminders further encouraged them to complete their activities, but showing more written details would encourage them more rather than relying on notification alone. In total, 2 participants felt that it would increase their commitment if they were able to set their own challenges.

A Communication Tool

Participants felt that the app would be a valuable tool to increase patients' participation in their care, for example, by aiding communication and sharing of data at doctors' visits more easily than carrying manual copies. This aspect of the app was considered particularly beneficial for assisting during medical emergencies, with one suggesting that doctors should have real-time access to the app data.

Usability of the App

Overall Usability

Most participants found the app easy to use and reported high levels of confidence. Those who had little experience required some practice to increase their confidence or ability, some being more reliant on the study training and instructions or assistance.

Most participants found it easy to navigate the app and enter data, except when attempting to enter multiple readings at once, which requires the save button to be pressed multiple times. The ability to enter data retrospectively and to edit previously entered data were valued features. However, patients reported some issues with the *tick* feature for marking completed challenges, either because of physical difficulties in using the functionality or being unable to undo *ticks* made in error. To improve this feature, some participants suggested that ticking could be prompted by the app.

App Accessibility

Some participants, particularly older people, had difficulty reading text within the app. They liked the zoom feature in the health guide but would like to be able to change the font size elsewhere. Some suggested that the contrast in the BP entry screen could be improved to make buttons easier to find.

Not all words in this version were translated into Arabic (eg, medication names), which was an issue for some participants, as was the default calendar (ie, Gregorian rather than Islamic).

Suggested Improvements

The study results found some aspects of the app that should be considered for improvement. There is a need to increase the app accessibility by 1) translating some words into Arabic (eg, medication names); 2) allowing changing between Islamic and Gregorian calendars; 3) increasing the color contrast in the BP entry screen; and 4) allowing changing font size. Suggested improvements regarding user interfaces include 1) using clear and meaningful terminology (such as health information); 2) making the data entry button more visible; 3) allowing inputting of multiple data at once; 4) adding text in some charts to supplement the color coding; and 5) displaying a message when tasks are marked as complete or making this data visible from the Challenge screen."

There were also some more general recommendations regarding app content. The feedback of BP should be more detailed and tailored for individual cases. The app should allow entering the symptoms that patients feel and allow them to set their own challenges. The *tick* function could be improved if it prompted participants to tick off items they have set reminders for and if it allowed participants to edit a tick when it was made in error.

6.4 Discussion

Principal Findings

This study evaluated a commercially available app that was carefully selected on the basis of existing evidence regarding the effectiveness, usability, privacy and security, and preferences of end users and health care professionals. This process resulted in selecting an app that was expected to have the best potential for being usable, acceptable, and effective in general, particularly in the Saudi context. The results presented in this paper do indeed show relatively good usability outcomes but still a considerable number of possibilities for improvement because of users' differing needs, expectations, and preferences that need to be considered (44). The actual usage data show that even this *best practice* app is not used by all participants and that only some of the functionalities are regularly used. This demonstrates the complexity of *getting it right* when developing smartphone apps and once again emphasizes the importance of acceptability, usability, and effectiveness evaluation, among target users, who are rarely consulted or involved in the commercial app development process, typically only being asked to evaluate once the app is released (45).

The results suggest that the provision of training could be a possible way to mitigate most usability issues and enhance user acceptance. The interview and MAUQ showed that the app is easy to use and generally accepted by participants. Some of these participants commented that training and instructions helped them use it more easily. The usability test, however, found that app usability was only moderate, and participants needed some familiarization time before they could use the app proficiently. A small number of tasks remained uncompleted by most people. Similarly, in the interview and questionnaire, participants reported that it was easy to navigate the app and enter data, whereas the usability test showed that participants faced issues with these aspects. This difference might be a consequence of the usability test being conducted in a controlled setting, in which participants had not received any previous training or practice. This finding appears to be in line with previous evidence indicating that a wide range of different users can use apps given the right training and support (46-48).

The results indicate that commercial apps have the potential to be met with sustained engagement from users. Engagement data showed that users' sessions with the app were similar to other studies using similar apps for other chronic diseases (42). However, the actual usage data show a higher level of sustained engagement with the app, with a 48% retention rate on day 30, in comparison with another study of self-monitoring apps, which showed a retention of 3.3% (49). This study also found much higher levels of BP monitoring than some other studies concerning other chronic conditions. Most participants (71.4%) recorded their BP around 3 times or more per week. In contrast, Goyal et al (44) found that only

9% of participants achieved similar levels of engagement (>=3 times). There are several possible explanations for this, with potential implications for future research and app development: doctors asked patients to record BP measurements twice for each reading to ensure accuracy, which could increase the frequency of measuring (43). This study did not provide patients with a secondary phone, which could have led to higher engagement (44); the app's feature for transmitting data either automatically or manually could have increased BP measurement. User motivation has been shown to be key to adherence with self-monitoring (22), so this may be another factor.

The study showed that participants in all strands expressed enthusiasm for using an app to support self-management because of its benefits in increasing their understanding and participation. All strands found that the app content (eg, information, etc) was considered a good potential tool to support self-management and to increase participants' understanding and commitment. However, participants' responses in interviews also revealed several concerns or limitations, suggesting that an app alone would not be a sufficient tool for self-management. Some external factors and barriers, for example, family, affected participants' use of the app such as positively or negatively affecting patients' optimism and self-esteem, or easing the stress of using the app to support the self-management of their disease (50). These factors must also be considered when assessing the benefits of using apps to support the self-management of hypertension.

The usability test and interviews reported similar difficulties with app accessibility, for example, font size and color scheme. Previous research has shown that older people are likely to encounter more difficulties and have lower engagement with these types of technological interventions (51,52). It is therefore important to assess how engagement levels might differ between younger and older participants and who are most likely to benefit from these interventions, particularly because most patients with hypertension are older (52). Owing to data privacy regulations, the engagement data were collected anonymously in this study, so it is not possible to compare older and younger participants. These older members of the study sample highlighted some issues regarding the accessibility of the app, such as the inability to change font sizes, app presentation, data entry, and the need for help from family members. This suggests that the engagement of these older members of the population might be improved if such accessibility issues were addressed. Understanding and considering older adults' opinions and needs is crucial to help introduce apps to this population and maximize their usability (53).

Participants in this study suggested that sharing their data with health care professionals for ongoing care should be effectively supported. Previous studies have suggested that apps that share health data with health care professionals can aid in treatment, especially in emergencies (54). Apps that are limited to one specific condition may be less helpful if not properly integrated with health information systems, particularly for patients who have comorbid conditions that might complicate their treatment needs and require a large treatment team (54,55). However, there are several potential barriers to mHealth integration with existing systems that should be considered (56).

Strength and Limitations

Our study has several strengths. First, it evaluates the selected app, Cora Health, in 2 different situations: in real-life and under controlled settings, integrating different methods (eg, interview, questionnaire, etc) to gain in-depth insight and provide a complete picture of the usability of the app. As the convergent and divergent results from these strands indicate, such a mixed methods approach yields a more detailed picture of the research area. Second, through our analysis, we were able to identify areas where usability was a potential concern. From these findings, we were able to comprehensively establish ways to further refine the app to make it more usable. These conclusions could be extended to other mHealth apps. Third, this is the first study to evaluate the usability and acceptance of a commercially available app for people with hypertension in Saudi Arabia.

However, there are also some limitations to this study. For instance, the study only focused on patients' opinions without considering health care professionals' or experts' opinions, which might have provided different clinical insights. This is because the app did not support any access for health care professionals. The small number of participants and selection bias are likely to have been other limitations: in order to be eligible, participants had to own an iOS-compatible smartphone; and as recruitment for the usability test was conducted via posters and flyers, the sample was therefore self-selecting and may have been biased in favor of highly motivated individuals. For the interviews, participants were recruited via their physicians. The study also used self-selecting and purposive sampling, which may be influenced by errors in judgment or assumptions by the researcher, leading to higher levels of bias and lower reliability. The number of older participants in the study sample was relatively low (8/30, 27%). This may have been a limitation, especially because the majority of patients with hypertension are older people. For these reasons, the generalizability of the study to the general population is somewhat limited. Despite attempts by the researcher and moderator to create a comfortable and welcoming research space, it is possible that the presence of a session moderator in the usability test may have affected user confidence or performance in a way that they may have differed from field use. Similarly, the potential generalizability of these findings beyond the Saudi context may also be limited: it may only be possible to generalize them to similar cultural contexts and to health care settings that are similar to the Saudi Ministry of Health. Finally, this study showed engagement over a 30-day period. As such, it is not possible to draw conclusions as to whether this might be sustained over a longer period. The study was concerned with describing users' engagement rather than examining how this engagement might contribute to achieving certain health outcomes or behavior change, meaning it is also not possible to draw conclusions as to whether this constituted *effective engagement*.

Recommendation for Further Studies

On the basis of the study results, it is important for future studies to investigate whether the levels of engagement recorded in this study could be sustained over the longer term to achieve the desirable outcomes (48,57). There is also a need to evaluate the effectiveness of the app as well as *effective engagement*, that is, engagement that achieves desired behavior changes (58,59) and compare these results with usual care to reach clinical conclusions. This would require studies with larger numbers of users and longer follow-up periods. Future research should also consider how participant age might influence their engagement and should also examine contexts outside Saudi Arabia. Some issues raised by participants in this study will need to be addressed before the Cora Health app can be maximally effective in large-scale studies. Future studies should undertake a more collaborative approach between app developers and potential users to be mutually beneficial and lead to higher quality apps that can more fully support patients' self-management.

6.5 Conclusions

This study showed that a commercially available app can be usable and acceptable for the self-management of hypertension. Participants were generally satisfied and found that the selected app was easy to use and useful in supporting their self-management activities. However, some participants experienced issues with the app's interface that need to be considered in future studies and app development. The results of this study suggest that there is potential for a commercially available app to be used in large-scale studies of the self-management of hypertension if suggestions for improvement are addressed.

Acknowledgments

The authors thank all authors for their significant contributions. TA (the Corresponding Author) and NA are PhD students at the University of Sheffield, funded by King Saud University and the University of Jeddah, respectively, Saudi Cultural Bureau. The authors would also like to thank the Cora Health development team (Josef Moser and Melanie Hetzer) for their significant cooperation.

6.6 References

1. Aldiab A, Shubair MM, Al-Zahrani JM, Aldossari KK, Al-Ghamdi S, Househ M, et al. Prevalence of hypertension and prehypertension and its associated cardioembolic risk factors; a population based cross-sectional study in Alkharj, Saudi Arabia. BMC Public Health 2018 Nov 29;18(1):1327. doi: 10.1186/s12889-018-6216-9.
2. Chow CK, Teo KK, Rangarajan S, Islam S, Gupta R, Avezum A, PURE (Prospective Urban Rural Epidemiology) Study investigators. Prevalence, awareness, treatment, and control of hypertension in rural and urban communities in high-, middle-, and low-income countries. J Am Med Assoc 2013 Sep 04;310(9):959-968. doi: 10.1001/jama.2013.184182.
3. Al-Nozha MM, Abdullah M, Arafah MR, Khalil MZ, Khan NB, Al-Mazrou YY, et al. Hypertension in Saudi Arabia. Saudi Med J 2007 Jan;28(1):77-84.
4. World Hypertension Day. Health Days 2017.: Ministry of Health (MHO); 2017. Available from: https://www.moh.gov.sa/en/HealthAwareness/healthDay/2017/Pages/HealthDay-2017-05-17.aspx
5. El Bcheraoui C, Memish ZA, Tuffaha M, Daoud F, Robinson M, Jaber S, et al. Hypertension and its associated risk factors in the kingdom of saudi arabia, 2013: a national survey. Int J Hypertens 2014;2014:564679. doi: 10.1155/2014/564679.
6. Saeed AA, Al-Hamdan NA, Bahnassy AA, Abdalla AM, Abbas MAF, Abuzaid LZ. Prevalence, awareness, treatment, and control of hypertension among saudi adult population: a national survey. Int J Hypertens 2011;2011:174135. doi: 10.4061/2011/174135.
7. Bodenheimer T, Lorig K, Holman H, Grumbach K. Patient self-management of chronic disease in primary care. J Am Med Assoc 2002 Nov 20;288(19):2469-2475. doi: 10.1001/jama.288.19.2469.
8. Barlow J, Wright C, Sheasby J, Turner A, Hainsworth J. Self-management approaches for people with chronic conditions: a review. Patient Education and Counseling 2002 Oct;48(2):177-187. doi: 10.1016/s0738-3991(02)00032-0.
9. Grady PA, Gough LL. Self-management: a comprehensive approach to management of chronic conditions. Am J Public Health 2014 Aug;104(8):25-31. doi: 10.2105/AJPH.2014.302041.
10. Rafiullah M, David SK. Health apps usage and preferences among Saudi patients with diabetes: a survey. Int J Clin Pract 2019 May;73(5):13345. doi: 10.1111/ijcp.13345.
11. Albabtain AF, Almulhim DA, Yunus F, Househ MS. The role of mobile health in the developing world?: a review of current knowledge and future trends. J Sel Areas Heal Informatics 2014;4(2).
12. Jamaladin H, van de Belt TH, Luijpers LC, de Graaff FR, Bredie SJ, Roeleveld N, et al. Mobile apps for blood pressure monitoring: systematic search in app stores and content analysis. JMIR Mhealth Uhealth 2018 Nov 14;6(11):187. doi: 10.2196/mhealth.9888.
13. Edwards EA, Lumsden J, Rivas C, Steed L, Edwards LA, Thiyagarajan A, et al. Gamification for health promotion: systematic review of behaviour change techniques in smartphone apps. BMJ Open 2016 Oct 04;6(10):012447 . doi: 10.1136/bmjopen-2016-012447.
14. Kumar N, Khunger M, Gupta A, Garg N. A content analysis of smartphone-based applications for hypertension management. J Am Soc Hypertens 2015 Feb;9(2):130-136. doi: 10.1016/j.jash.2014.12.001.
15. Alessa T, Hawley MS, Hock ES, de Witte L. Smartphone apps to support self-management of hypertension: review and content analysis. JMIR Mhealth Uhealth 2019 May 28;7(5):13645. doi: 10.2196/13645.
16. Alessa T, Abdi S, Hawley MS, de Witte L. Mobile apps to support the self-management of hypertension: systematic review of effectiveness, usability, and user satisfaction. JMIR Mhealth Uhealth 2018 Jul 23;6(7):10723. doi: 10.2196/10723.
17. van der Weegen S, Verwey R, Tange HJ, Spreeuwenberg MD, de Witte LP. Usability testing of a monitoring and feedback tool to stimulate physical activity. Patient Prefer Adherence

2014;8:311-322. doi: 10.2147/PPA.S57961.

18. Jaspers MWM. A comparison of usability methods for testing interactive health technologies: methodological aspects and empirical evidence. Int J Med Inform 2009 May;78(5):340-353. doi: 10.1016/j.ijmedinf.2008.10.002
19. Maramba I, Chatterjee A, Newman C. Methods of usability testing in the development of eHealth applications: A scoping review. Int J Med Inform 2019 Jun;126:95-104. doi: 10.1016/j.ijmedinf.2019.03.018.
20. Clemmensen T, Hertzum M, Hornbæk K, Shi Q, Yammiyavar P. Cultural cognition in usability evaluation. Interacting with Computers 2009 Jul;21(3):212-220. doi: 10.1016/j.intcom.2009.05.003
21. Zapata BC, Fernández-Alemán JL, Idri A, Toval A. Empirical studies on usability of mHealth apps: a systematic literature review. J Med Syst 2015 Feb;39(2):1. doi: 10.1007/s10916-014-0182-2.
22. Boessen AB, Vermeulen J, de Witte LP. Acceptance and usability of a home-based monitoring tool of health indicators in children of people with dementia: a Proof of Principle (POP) study. Patient Prefer Adherence 2017;11:1317-1324 . doi: 10.2147/PPA.S135022
23. Sullivan PS, Driggers R, Stekler JD, Siegler A, Goldenberg T, McDougal SJ, et al. Usability and acceptability of a mobile comprehensive hiv prevention app for men who have sex with men: a pilot study. JMIR Mhealth Uhealth 2017 Mar 09;5(3):26. doi: 10.2196/mhealth.7199.
24. Creswell J, Plano CV. Designing and conducting mixed methods research. In: SAGE Publications. USA: SAGE Publications; 2018:9781483344379.
25. O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. Br Med J 2010 Sep 17;341:4587. doi: 10.1136/bmj.c4587.
26. Ergonomic requirements for office work with visual display terminals (VDT), guidance on usability. ISO/IEC. 1998. Available from: https://www.iso.org/standard/16883.html
27. Or CKL, Karsh B. A systematic review of patient acceptance of consumer health information technology. J Am Med Inform Assoc 2009 [cited 2020 Aug];16(4):550-560 doi: 10.1197/jamia.M2888.
28. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. Adm Policy Ment Health 2015 Sep [cited 2020 Aug];42(5):533-544. doi: 10.1007/s10488-013-0528-y
29. Hwang W, Salvendy G. Number of people required for usability evaluation. Commun ACM 2010 May [cited 2020 Aug];53(5):130-133. [doi: 10.1145/1735223.1735255
30. Alroobaea R, Mayhew P. How many participants are really enough for usability studies? In: Proceedings of 2014 Science and Information Conference. 2014 Presented at: 2014 Science and Information Conference; Aug. 27-29, 2014; London, UK. doi: 10.1109/SAI.2014.6918171
31. Bavelloni A, Piazzi M, Raffini M, Faenza I, Blalock WL. Prohibitin 2: At a communications crossroads. IUBMB Life 2015 Apr [cited 2020 Aug];67(4):239-254 . doi: 10.1002/iub.1366.
32. Hochstenbach LMJ, Zwakhalen SMG, Courtens AM, van Kleef M, de Witte LP. Feasibility of a mobile and web-based intervention to support self-management in outpatients with cancer pain. Eur J Oncol Nurs 2016 Aug [cited 2020 Aug]; 23:97-105. doi: 10.1016/j.ejon.2016.03.009.
33. Aiyegbusi OL. Key methodological considerations for usability testing of electronic patient-reported outcome (ePRO) systems. Qual Life Res 2020 Feb [cited 2020 Aug];29(2):325-333. doi: 10.1007/s11136-019-02329-z
34. Greeff AD, Beg Z, Gangji Z, Dorney E, Shennan AH. Accuracy of inflationary versus deflationary oscillometry in pregnancy and preeclampsia: OMRON-MIT versus OMRON-M7. Blood Pressure Monitoring 2009 [cited 2020 Aug];14(1):37-40. doi: 10.1097/mbp.0b013e32831e305d
35. Mazoteras Pardo V, Losa Iglesias ME, López Chicharro J, Becerro de Bengoa Vallejo R. The Qardioarm app in the assessment of blood pressure and heart rate: reliability and validity

study. JMIR Mhealth Uhealth 2017 Dec [cited 2020 Aug];5(12):198 doi: 10.2196/mhealth.8458.
36. Coleman A, Steel S, Freeman P, de Greeff A, Shennan A. Validation of the Omron M7 (HEM-780-E) oscillometric blood pressure monitoring device according to the British Hypertension Society protocol. Blood Press Monit 2008 Feb [cited 2020 Aug];13(1):49-54. doi: 10.1097/MBP.0b013e3282cb57b6.
37. Pham Q, Graham G, Carrion C, Morita PP, Seto E, Stinson JN, et al. A library of analytic indicators to evaluate effective engagement with consumer mhealth apps for chronic conditions: scoping review. JMIR Mhealth Uhealth 2019 Jan [cited 2020 Aug];18;7(1):11941. doi: 10.2196/11941.
38. Zhou L, Bao J, Setiawan IMA, Saptono A, Parmanto B. The mHealth App Usability Questionnaire (MAUQ): development and validation study. JMIR Mhealth Uhealth 2019 Apr [cited 2020 Aug];7(4):11500. doi: 10.2196/11500.
39. Process of translation adaptation of instruments. WHO. Available from: [https://www.who.int/substance_abuse/research_tools/ translation/en/](https://www.who.int/substance_abuse/research_tools/translation/en/)
40. Bryman A. Socail research methods. In: Vol fourth. 4th ed. New York: Oxford University Press; 2012.
41. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology 2006 Jan [cited 2020 Aug];3(2):77-101. doi: 10.1191/1478088706qp063oa
42. Davies EB, Craven MP, Martin JL, Simons L. Proportionate methods for evaluating a simple digital mental health tool. Evid Based Ment Health 2017 Nov [cited 2020 Aug];20(4):112-117. doi: 10.1136/eb-2017-102755.
43. Hodgkinson JA, Stevens R, Grant S, Mant J, Bray EP, Hobbs FDR, et al. Schedules for self-monitoring blood pressure: a systematic review. Am J Hypertens 2019 Mar [cited 2020 Aug];32(4):350-364. doi: 10.1093/ajh/hpy185.
44. Goyal S, Nunn CA, Rotondi M, Couperthwaite AB, Reiser S, Simone A, et al. A mobile app for the self-management of type 1 diabetes among adolescents: a randomized controlled trial. JMIR Mhealth Uhealth 2017 Jun [cited 2020 Aug] ;5(6):82. doi: 10.2196/mhealth.7336.
45. Wykes T, Schueller S. Why reviewing apps is not enough: transparency for trust (T4T) principles of responsible health app marketplaces. J Med Internet Res 2019 May [cited 2020 Aug]; 21(5):12390. doi: 10.2196/12390.
46. Kirwan M, Vandelanotte C, Fenning A, Duncan MJ. Diabetes self-management smartphone application for adults with type 1 diabetes: randomized controlled trial. J Med Internet Res 2013 Nov [cited 2020 Aug];15(11):235. doi: 10.2196/jmir.2588.
47. Hamine S, Gerth-Guyette E, Faulx D, Green BB, Ginsburg AS. Impact of mHealth chronic disease management on treatment adherence and patient outcomes: a systematic review. J Med Internet Res 2015 Feb [cited 2020 Aug];17(2):52. doi: 10.2196/jmir.3951.
48. Whitehead L, Seaton P. The effectiveness of self-management mobile phone and tablet apps in long-term condition management: a systematic review. J Med Internet Res 2016 May [cited 2020 Aug];18(5):97 . doi: 10.2196/jmir.4883.
49. Baumel A, Muench F, Edan S, Kane JM. Objective user engagement with mental health apps: systematic search and panel-based usage analysis. J Med Internet Res 2019 Sep [cited 2020 Aug];21(9):14567 doi: 10.2196/14567.
50. Etminani K, Tao Engström A, Göransson C, Sant'Anna A, Nowaczyk S. How behavior change strategies are used to design digital interventions to improve medication adherence and blood pressure among patients with hypertension: systematic review. J Med Internet Res 2020 Apr [cited 2020 Aug]; 22(4):17201. doi: 10.2196/17201
51. Heart T, Kalderon E. Older adults: are they ready to adopt health-related ICT? Int J Med Inform 2013 Nov;82(11):209-231. doi: 10.1016/j.ijmedinf.2011.03.002.
52. Morrissey EC, Casey M, Glynn LG, Walsh JC, Molloy GJ. Smartphone apps for improving medication adherence in hypertension: patients' perspectives. Patient Prefer Adherence 2018[cited 2020 Aug]; 12:813-822. doi: 10.2147/PPA.S145647
53. Vaportzis E, Clausen MG, Gow AJ. Older adults perceptions of technology and barriers to

interacting with tablet computers: a focus group study. Front Psychol 2017 Oct [cited 2020 Aug]; 8:1687. doi: 10.3389/fpsyg.2017.01687.

54. Woods LS, Duff J, Roehrer E, Walker K, Cummings E. Patients' experiences of using a consumer mhealth app for
self-management of heart failure: mixed-methods study. JMIR Hum Factors 2019 May 02;6(2):13009. doi: 10.2196/13009.

55. Mileski M, Kruse CS, Catalani J, Haderer T. Adopting telemedicine for the self-management of hypertension: systematic review. JMIR Med Inform 2017 Oct [cited 2020 Aug]; 5(4):41. doi: 10.2196/medinform.6603.

56. Matthew-Maich N, Harris L, Ploeg J, Markle-Reid M, Valaitis R, Ibrahim S, et al. Designing, implementing, and evaluating mobile health technologies for managing chronic conditions in older adults: a scoping review. JMIR Mhealth Uhealth 2016 Jun [cited 2020 Aug]; 4(2):29. doi: 10.2196/mhealth.5127.

57. Lin Z, Althoff T, Leskovec J. I'll be back: on the multiple lives of users of a mobile activity tracking application. Proc Int World Wide Web Conf 2018 Apr [cited 2020 Aug]; 2018:1501-1511. doi: 10.1145/3178876.3186062.

58. Yardley L, Spring BJ, Riper H, Morrison LG, Crane DH, Curtis K, et al. Understanding and promoting effective engagement with digital behavior change interventions. Am J Prev Med 2016 Nov [cited 2020 Aug] ;51(5):833-842. doi: 10.1016/j.amepre.2016.06.015

59. Michie S, Yardley L, West R, Patrick K, Greaves F. Developing and evaluating digital interventions to promote behavior change in health and health care: recommendations resulting from an international workshop. J Med Internet Res 2017 Jun [cited 2020 Aug] 29;19(6):232. doi: 10.2196/jmir.7126.

6.7 Additional Explanatory Notes

Selection and translation of Cora Health

Cora was rated the most suitable app overall, and ESH care and LifeCourse Hyten were rated next highest by patients and doctors respectively. As a result, we approached the developers of all three apps to explore the possibility of an Arabic translation. However, Cora was the only developer to respond to our email requests. We therefore entered into a collaboration with their developers to translate the app into an Arabic version which could be tested for its usability and acceptance among Saudi users.

Study Design and Methods

The rationale of utilising mixed-methods in this study was to generate a more comprehensive picture of the topic, which is referred to as '*complementarity'* (1). Efficient integration of both qualitative and quantitative methods results in a larger knowledge yield than what would be gained by treating the two strands in isolation (2,3).

In order to provide a more comprehensive view of participants' acceptance and usability of the selected app, a usability test, post-interview experience, questionnaire, and user-engagement data were used (4,5). The rationale for selecting these methods are further discussed below.

Participants

Participants were selected purposively. The purposive method involves 'judgement sampling', where participants are deliberately chosen on the basis of characteristics/criteria that will be able to better assist the completion of the research (6). In this study, we searched for Saudi participants who had hypertension for six months and possessed iPhone devices. We excluded from the study pre-hypertensive individuals and pregnant women and so on.

The consent form and information sheet were provided for participants (See Appendix 30-33). The confidentiality agreement for use with the Cora Health app developer was also obtained to ensuring protect participant's confidentiality (See Appendix 34).

The number of participants who completed study 2 (usability and acceptance study) was 20. There are no guidelines in the literature for selecting the optimum number of participants for this type of study. For pilot and feasibility studies there is a recommendation of a median of around 30 participants (8). However, a search of similar studies assessing acceptance and usability of health apps revealed sample sizes around our study's number of participants (10-12).

Methods

The justifications for the selected methods of the two studies are detailed below.

Study 1: Usability testing (controlled use testing)

Usability testing was chosen because it is one of the most common and accepted methods in assessing usability. It is a suitable method to understand how end-users experience a system. This test typically uses a thinking-out-loud feature, where participants verbalize their thoughts, reaction and feelings aloud while working on or navigating the software (9). The main feature of this test is that it offers information which is stored in the participant's short-term memory. This results in collecting first impressions, initial thoughts and reactions while engaging with the software. It is suggested that the key usability issues, including resolving language or content gaps and rectifying poor design layout, can be identified while using the app (9).

Study 2: Usability and Acceptance study in real life

This study was conducted because there is a need to consider how software will work over a period of time (i.e. a few weeks) in a real-life environment (21). The importance of this type of study for understanding long-term user experience and usability issues has been increasingly recognized in healthcare research in recent years (23-25).

Usability questionnaire

A questionnaire was used because it poses direct questions to participants, and obtains quantifiable answers from them. Questionnaires also enable participants to provide objective answers concerning sensitive and specific issues (1). However, self-administered questionnaires do not allow participants to disclose information that is not in response to the questions, and so may fail to capture other relevant information. A post-experience interview (see below section) was therefore also conducted to complement this tool by eliciting further insight and understanding of detailed issues.

The mHealth App Usability Questionnaire (MAUQ) was utilised as it was created particularly for mHealth apps, based on existing validated usability questionnaires including the System Usability Scale (SUS) (14). The MAUQ is valid and reliable, with Cronbach's alpha 0.9 (15).

Interview

A semi-structured interview was conducted following the questionnaire. Semi-structured interviews are commonly used to help capture participants' reflections after using an app, offering a more detailed account of their experiences than a questionnaire alone (2,9,16). The Arabic and English versions of the interview topic guide are in appendix 28 and 29.

Translation

All study documents were translated into Arabic by the researcher. Then, they were translated back into English. These back translations were compared with the original versions to ensure that the meaning had not been altered. No changes in meaning were found. Anonymized study transcripts were translated into natural English conveying intended meaning. The anonymized transcripts were then back-translated by a professional translation service and the two versions compared to ensure translation accuracy.

Data analysis

Thematic analysis was used because it is a flexible approach and the most commonly method used in qualitative research (17).

Thematic analysis is a common and flexible method for any qualitative approach, as it allows data to be encoded according to codes and themes (17). Thematic analysis is appropriate for studies seeking to elicit participants' viewpoints, and offers the possibility to gain a clearer insight into a particular research area (18). As Braun and Clarke (17) state, thematic analysis can be used to facilitate inductive or deductive methods, or a combination of these. For this reason, it is particularly suited to a research area that is relatively new or under-researched, and helps to provide a comprehensive description of a whole data set. This approach was adopted in this study to provide a more comprehensive picture of app usability and acceptance because it allowed data to be analysed according to a priori themes, whilst remaining flexible enough to incorporate emergent themes that were identified based on participants' responses.

To ensure the credibility and dependability of the qualitative data, the following measures were undertaken: 1) disclosure of the researcher's sensitivity to context and the socio-cultural setting of the study, and immersion within the data through data collection, transcription and analysis; 2) written disclosure of the researcher's background and relevant personal history and the potential impact of these (see Chapter 5); 3) maintenance of a thorough audit trail documenting stages and steps of the research process; 4) ensuring sample size was sufficient to reach 'saturation' (16,19,20) and that analysis was comprehensive and exhaustive. Attention to negative cases, fair dealing and thick description and peer debriefing (by constant discussion and feedback with supervisors) were all undertaken.

6.7.1 Additional References

1. Creswell JW, Creswell D. Research Design Qualitative, Quantitative & Mixed Methods Approaches. SAGE Publications Ltd. SAGE Publications, lnc.; 2017.
2. Creswell JW, Plano Clark VL. Designing and Conducting Mixed Methods Research. SAGE Publications Ltd. SAGE Publications, lnc.; 2018.
3. O'Cathain A, Murphy E, Nicholl J. Three techniques for integrating data in mixed methods studies. Br Med J 2010 Sep 17;341:4587. doi: 10.1136/bmj.c4587.
4. Jaspers MWM. A comparison of usability methods for testing interactive health technologies: methodological aspects and empirical evidence. Int J Med Inform 2009 May;78(5):340-353. doi: 10.1016/j.ijmedinf.2008.10.002
5. Zapata BC, Fernández-Alemán JL, Idri A, Toval A. Empirical studies on usability of mHealth apps: a systematic literature review. J Med Syst 2015 Feb;39(2):1. doi: 10.1007/s10916-014-0182-2.
6. Patton MQ. Qualitative research and evaluation methods (3rd Ed.). Thousand Oaks, CA: Sage;2002.
7. Palinkas LA, Horwitz SM, Green CA, Wisdom JP, Duan N, Hoagwood K. Purposeful sampling for qualitative data collection and analysis in mixed method implementation research. Adm Policy Ment Health 2015 Sep [cited 2020 Aug];42(5):533-544. doi: 10.1007/s10488-013-0528-y
8. Billingham SA, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. BMC Med Res Methodol. 2013 Aug 20;13:104. doi: 10.1186/1471-2288-13-104
9. Zapata BC, Fernández-Alemán JL, Idri A, Toval A. Empirical studies on usability of mHealth apps: a systematic literature review. J Med Syst 2015 Feb;39(2):1. doi: 10.1007/s10916-014-0182-2.
10. van der Weegen S, Verwey R, Tange HJ, Spreeuwenberg MD, de Witte LP. Usability testing of a monitoring and feedback tool to stimulate physical activity. Patient Prefer Adherence. 2014 Mar [cited 2020 Aug]; 8:311-22. doi: 10.2147/PPA.S57961.
11. Hochstenbach LMJ, Zwakhalen SMG, Courtens AM, van Kleef M, de Witte LP. Feasibility of a mobile and web-based intervention to support self-management in outpatients with cancer pain. Eur J Oncol Nurs 2016 Aug [cited 2020 Aug]; 23:97-105. doi: 10.1016/j.ejon.2016.03.009.
12. Sun N, Rau PP, Li Y, Owen T, Thimbleby H. Design and evaluation of a mobile phone-based health intervention for patients with hypertensive condition. Computers in Human Behavior. 2016 Oct [cited 2020 Aug]; 63:98–105. doi: 10.1016/j.chb.2016.05.001.
13. Lazar, J., Heidi, J. and Hochheiser, H. (2010) Research methods in human-computer interaction. Wiley, Glasgow, Great Britain. 426 p.
14. Zhou L, Bao J, Setiawan IMA, Saptono A, Parmanto B. The mHealth App Usability Questionnaire (MAUQ): development and validation study. JMIR Mhealth Uhealth 2019 Apr [cited 2020 Aug];7(4):11500. doi: 10.2196/11500.
15. Process of translation adaptation of instruments. WHO. Available from: https://www.who.int/substance_abuse/research_tools/ translation/en/
16. Bryman A. Social research methods. In: Vol fourth. 4th ed. New York: Oxford University Press; 2012.
17. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology 2006 Jan

[cited 2020 Aug];3(2):77-101. doi: 10.1191/1478088706qp063oa

18. Maguire M, Delahunt B. Doing a thematic analysis: A practical, step-by-step guide for learning and teaching scholars. 2017 9(3). Available from https://ojs.aishe.org/index.php/aishe-j/zarticle/view/335
19. Yardley, L. Dilemmas in qualitative health research. Psychology and Health.2000 [cited 2018 Jul]; 15, 215–228.
20. Long T, Johnsonb M. Rigour, reliability and validity in qualitative research. Clinical Effectiveness in Nursing. 2000 Mar [cited 2018 Jul]; 4 (1), 2000:30-37. doi: https://doi.org/10.1054/cein.2000.0106
21. Shneiderman, B. (1998). Designing the user interface: Strategies for effective human-computer interaction (3rd ed.). Reading, MA: Addison-Wesl
22. Sullivan PS, Driggers R, Stekler JD, Siegler A, Goldenberg T, McDougal SJ, et al. Usability and acceptability of a mobile comprehensive hiv prevention app for men who have sex with men: a pilot study. JMIR Mhealth Uhealth 2017 Mar 09;5(3):26. doi: 10.2196/mhealth.7199.
23. Maramba I, Chatterjee A, Newman C. Methods of usability testing in the development of eHealth applications: A scoping review. International Journal of Medical Informatics (Shannon, Ireland) 2019[cited 2020 Oct], 126, 95-104.
24. Holden RJ, Karsh B. The Technology Acceptance Model: Its past and its future in health care. Journal of Biomedical Informatics,2010 [cited 2020 Oct] 43(1), 159-172.

Chapter 7 General Discussion

This chapter presents the overall results of the thesis and reflection on the main findings. The strengths and weaknesses of this research are considered, and recommendations are made for future app development and further research. This is followed by the overall conclusion to the thesis.

7.1 Overview

The primary aims of this research were: to assess the potential effectiveness, theoretical underpinning and privacy and security of commercially available smart-phone apps for the self-management of hypertension; to identify the most suitable smartphone app to support self-management of hypertension in Saudi Arabia; and to evaluate the selected app's usability and acceptance in Saudi Arabia. Smartphone apps hold great promise to support the self-management of hypertension. However, despite the increasing availability and use of commercial apps, there was no evidence in the literature regarding which is the most suitable app to support patients in managing their condition. This chapter discusses the main findings, methodological considerations and recommendations for future research, collaboration and app development.

All available approaches and guidelines relating to the development, implementation and evaluation of medical interventions, such as those of the MRC, recommend that researchers explore and build on the existing evidence base (1). A This research therefore started with a systematic review of the existing literature examining apps targeted at people with hypertension, and an app store review to identify and assess commercially available apps that can support the self-management of hypertension. The findings of these reviews revealed that apps can be effective in controlling blood pressure (BP) and are accepted by users, but most of these apps were designed for specific studies, that is designed for the purpose of a study, being available on app stores. The app store review showed that many apps are available in the app stores but only few of these are safe and effective. A qualitative study was then conducted, based on the results of a systematic selection approach that identified five apps that are safe and likely to be effective. One app was identified as particularly suitable for supporting the self-management of hypertension in the context of Saudi Arabia. A final study was then conducted, employing a mixed methods approach to assess the acceptance and usability of the selected app among Saudi patients.

7.2 Main findings

The main findings of each study are as follows:

7.2.1 Assessing the effectiveness and privacy and security of hypertension self-management apps

Study 1: The Systematic Review

The systematic review findings suggested that app usage can be effective in the self-management of hypertension, showing significantly reduced BP levels. Apps generally were accepted by users and were considered to be easy to use (2) (See chapter 3). The study identified the following app functionalities: goal-setting, self-monitoring, reminder, educational information, stress management, feedback, and communication with others. Due to differences in the quality of the studies analysed, it was not possible to conclude which combination of functionalities was most effective. However, the data suggested that apps with more comprehensive functionalities were more likely to be effective. The study determined that those apps that included self-monitoring and reminders, as well as automatic feedback or educational information were more likely to be effective. 'Comprehensive functionalities' was defined as having at least 3 of these functionalities (including self-monitoring and reminders). The study therefore considered apps that contained three or more of the functionalities identified as more effective (including self-monitoring, reminder setting, and educational information or automatic feedback).

It is essential to note that some articles were returned that met the systematic review criteria at the second search. However, these were not included since by this point the study had already been published in JMIR mHealth and uHealth. Of these new studies assessing the effectiveness of apps in controlling BP, a majority found that apps have the potential to positively support self-management and control of BP (3-10). Most of those studies that explore the usability of apps and their acceptance found that they are generally accepted and users reported positive experiences of using them as a tool to support self-management of hypertension (11-15). In addition to these studies, more recent systematic reviews and meta-analyses of research in this area also support the findings of our study, i.e. that smartphone apps have the potential to assist in hypertension sufferers' self-management (16-26).

<u>Study 2: The App Store Review</u>

The app store review and content analysis study showed that many hypertension apps were available in the app stores (n=186). These apps included a variety functionality combinations that can support the self-management of hypertension (27) (see Chapter 4). However, only a small number (n=30) were likely to be effective, with many of these still lacking appropriate security measures or theoretical underpinning (behavioral change theory). None provided evidence concerning their effectiveness and usability.

Apps originally released or available in Arabic were included in the study search. Only one Arabic-language app was identified. This app was removed from the app review based on the agreement with the research team that the focus was on publishing the article for an English-speaking audience. In addition to this language consideration, the app was found to support only the single function of self-monitoring of blood pressure, meaning it did not meet the effectiveness criteria.

7.2.2 Selection of the most suitable app

Study 3.1: The Systematic Selection Approach

The systematic selection approach identified 30 apps with the potential to be effective, and which had theoretical underpinning. A total of 5 apps also met the privacy and security criteria, meaning they could be considered potentially effective and safe.

Study 3.2 The Qualitative Study of the Selection of the Most Suitable App within Saudi Context

In the qualitative study, the patient participants were not currently using apps to self-manage their hypertension and doctors had never recommended these apps for their patients before, even though most participants owned smart phones and were interested in using apps. They were not aware of the availability and suitability of any existing apps for hypertension management. This stresses the need to identify the most suitable app within a Saudi context, to help inform both doctors and patients. Both doctors and patients could see the potential benefits that apps in general, and specific functionalities, could bring to their situation. However, they raised some concerns regarding their usability and privacy.

After considering and discussing the pros and cons of each of the five apps, three were found to be more suitable than the others, based on the functionalities and benefits they offer and their usability, with Cora Health app being the most suitable based on participants' ratings. Most participants believed the other two apps (Qardio heart health and Braun healthy heart) were less recommendable due to their relatively simplistic features and/or poorer visual design.

Study 4: Usability and Acceptance Study of the selected app

Usability and acceptance evaluation is an essential step before an app can be used and assessed in wider clinical or research practice (28-30). We therefore undertook a mixed-methods study, in which thirteen patients evaluated the app in a usability test and in real life. This study found that the Cora health app is acceptable and useable in the self-management of hypertension. This study also revealed that participants generally accepted the app and found it easy to use. The engagement level and retention rate were good, and most participants' sessions with the app were considered 'meaningful'. There are some issues that were identified with the app that could be improved, which demonstrates the importance of acceptability and usability evaluation. Training and practice were identified as two factors likely to affect participants' proficiency with the app. The app was shown to have potential for use in large-scale studies into self-management of hypertension, assuming the issues identified are addressed.

7.3 Reflection on the main findings

7.3.1 Effectiveness, Safety and Availability of Hypertension Apps

On the one hand, there are a few apps with evidence of their effectiveness which are typically developed by researchers, but these generally do not reach the market (2). On the other hand, there are hundreds of apps which are commercially available, but which have no evidence of their effectiveness (27). This constitutes a system failure and leaves potential users with a lack of information on which to base their decisions on which app to buy/use, leading to potentially serious effects on their health.

Jake-Schoffman et al. (31) revealed that, despite the increase in mHealth apps research, academic research operates at too slow a pace to be able to respond to the relatively swift development of new apps, and that it is relatively difficult for researchers to launch their own apps. This is because of the high design expertise, time, cost and ongoing resources that this would require (31,32). On the other hand, developers are able to launch hypertension apps without ensuring their validity via supporting peer-reviewed research or getting regulatory approval (e.g., FDA or CE), such as would be needed for medical devices or pharmaceuticals, leading to an overabundance of apps (33,34). Lewis and Wyatt (35) showed that uncertainty regarding whether medical apps are considered medical devices means developers do not consider seeking formal medical regulation, potentially compromising patient safety. This problem is not unique to hypertension apps but is common to all health apps (33,36-39). This demonstrates a lack of collaboration between researchers and developers, which might otherwise improve app provision by combining research-based development and ongoing resources required to make these widely available to prospective users (31, 40-42).

The design of mHealth apps is far more likely to be effective if it is multidisciplinary, i.e. in which multiple stakeholders, including target users, healthcare professional and scientists, are involved (43). Most development frameworks, like user-centered design, stress the importance of multidisciplinary skills and perspectives in product development, and most hypertension apps developed for research purposes actively involved multidisciplinary teams, particularly target users, in the development process (44-47). Users and health-care providers, however, are rarely involved or consulted in the development of commercial mHealth apps (as shown in Chapter 4), meaning that these apps are less likely to meet users' expectations and needs, or to conform with the latest scientific evidence, and are therefore less likely to be usable, clinically effective and safe (27,33 34,43,48). The current project attempted to further a more collaborative approach by involving doctors and potential users in the selection and evaluation process, ensuring that the app met actual patients' and clinical professionals' needs and preferences (Chapter 5 and 6).

The research also found issues with the security of commercial apps. There is still a gap in adherence of health apps with data protection standards (48,49). The safety of commercially released apps is not adequately monitored (50, 51). There is a need to promote transparency from developers in the way users' data are gathered and used, and to equip them with resources to help improve the security of apps, as well as to increase users' understanding of privacy concerns to help them scrutinize apps' safety and provide them with some tools to determine whether an app is likely to be suitable (27).

The systematic selection approach (according to criteria of effectiveness, theoretical background, privacy and security) identified 5 apps, with the others being considered potentially ineffective and/or unsafe. Our systematic selection approach assessed the apps according to these criteria, based on the results of previous systematic and app store reviews (Chapter 5). This set of criteria is similar to those that have been used in recent studies concerning the quality of commercial mHealth apps, including apps for hypertension. However, there are some key differences in terms of the range of criteria adopted, and the importance attached to each criterion. Although most research in this area is concerned with separating high quality from low quality apps, different studies employ different ways of doing this. For example, a recent study that reviewed BP tracking apps in the Canadian Apple app store, and assessed their quality using a checklist, found apps that contained educational information or an app store rating of ≥4 stars were better quality overall than those without educational information and whose star rating was ≤3 stars (48). Star rating was not included in our selection criteria as these ratings are questionable and not rigorous enough (34, 52). Similarly, whilst their study found that the presence of quality educational content in a given app could be a useful indicator of that app's overall quality, 2 out of the 5 apps selected for our study lacked educational information and were still judged to be potentially effective.

Privacy and security of apps have not always been taken into account. A study by Jamaladin et al. (34) searched two Dutch app stores and assessed the quality of apps using the Mobile App Rating Scale (MARS) to identify the most suitable app targeting hypertension. This study found that Blood Pressure app (=Bloeddruk) had the highest quality rating (34). However, in the current thesis assessment of apps according to effectiveness, and privacy and security criteria (as shown in Chapter 5) this app was excluded because it lacks privacy and security measures. Although the MARS tool is one of the most commonly used systems for rating apps, it omits some rudimentary items, such as app privacy and security (53,54). There is a similar case in a study that assessed pain-management apps, which found that, of 18 apps studied, the 2 that had been subjected to scientific testing received the lowest scores (55). These cases appear to indicate

that the MARS ranking system tends to result in higher scores for commercially available but potentially unsafe apps than it does for those with a strong scientific evidence-base (53).
These different selection criteria may explain the differences in results between this research and previous studies: different selection criteria will lead to different conclusions. The current lack of consensus over what criteria to use also demonstrates that research in this area is still in an early stage. More work is needed to test different criteria and develop a more concrete and agreed-upon approach to assessing the quality of these interventions.

7.3.2 Patients' and Doctors' Preferences and Attitudes towards Hypertension Apps

It is important that any digital intervention is grounded in qualitative work with the users to get their valuable insights (56,57) and ensure their needs and preference are met. The qualitative study in Chapter 5 explored patients' and doctors' views towards apps in general and towards the five potentially effective and secure apps specifically.

Patients raised concerns about the apps' usability, while clinicians were concerned about patients' ongoing use and questioned whether those apps aligned with hypertension management guidelines. These are some of the most common concerns raised in previous mHealth research (11,56). Patients and doctors generally preferred three apps (Cora Health, ESH care and LifeCourse HyTen) that offer broader functions, pleasant visual design and in-depth features, specifically tailored to their situation. For example, users preferred apps that provide specific reminders instead of generic ones. Detailed features allow users to tailor the app to their circumstances and needs, and provide depth of information to support them (56, 57). This is in line with Powell et al. (39) who indicated that apps are likely to be useful and accepted if they include key components including pleasing visuals and the facility to personalise, and offer other broader functions, such as education.

Marshall et al. (58) revealed that doctors and patients usually showed somewhat different priorities or preferences for functional requirements, expectations and needs of an mHealth app, even if they might agree to some extent on which app was best overall. Similarly, in this project, Cora was identified as being the highest rated among doctors and patients, although somewhat differing priorities were expressed by these two groups. Doctors were generally more concerned with the level of detail and medical accuracy, for instance preferring apps that automatically calculated patients' scores like BP average, those that included supplementary textual explanations as well as visual feedback, and which offered more comprehensive information about medications and their side-effects. Another study (48) recommended that doctors consider whether a hypertension app supports BP entry and calculates BP average for specific dates, which the authors consider to be an essential element of ensuring app quality. Patients were generally more concerned with usability and design elements, such as disliking the method of entering data in some apps, and preferring those apps with more attractive or clearer visual design. Doctors and patients both liked apps that allowed for tracking more than just BP, e.g. also medication, exercise and stress levels, and both groups favoured more comprehensive reminder features, and apps in which features could be easily reached from the home screen.

When the acceptance and usability of the Cora health app were evaluated, the results of this evaluation study, shown in chapter 6, were in line with other previous studies that reported the potential of a commercial app to be accepted and easily used (59,60). Despite commercial apps having some limitations, including the lack of user involvement in the development process, many of those apps available on the market have been professionally developed with high standards of functionality and design, and are well marketed (31).

This thesis' findings have implications for both research and industry: the findings with regards to the usefulness of training in ensuring that apps can be used effectively can inform the implementation of such interventions in daily lives and clinical settings; the findings around what functionalities participants reported finding useful and which they actually used may contribute to the future development of apps, thereby increasing the effectiveness of future digital interventions; the findings regarding app acceptance also suggest promising avenues for future research, such as the recommendation for more longitudinal research to assess effectiveness and whether such interventions will continue to be engaged with effectively over time.

In this study, we collaborated with the Cora Health app developers to translate the app, so it could be evaluated in the Arabic population, resulting in an Arabic version of the app. The results of this evaluation study were provided to the developers. The developers were advised that the app accessibility would be increased by 1) translating some words into Arabic (e.g. medication names); 2) allowing changing between Islamic and Gregorian calendars; 3) increasing the colour contrast in the BP-entry screen (which was subsequently actioned); 4) allowing changing font size (Zoom in/out feature). Suggested improvements regarding user interface include: 1) using clear and meaningful terminology (e.g., Health information); 2) improving the visibility of the data-entry button; 3) allowing multiple data to be recorded simultaneously; 4) providing a clearer indication of when tasks are completed, e.g. by making this visible from the 'Challenge' screen.

There were also some more general recommendations regarding app content. The feedback of BP should be more detailed and tailored for individual cases. The app should allow entering the symptoms that patients feel, and allow them to set their own challenges. The 'tick' function could be improved if it prompted participants to tick off items they have set reminders for, and if it allowed participants to edit a tick when it was made in error. Some of the recommendations were addressed by the developer before the Arabic version's release, and the developer reported that further changes would be made as part of a future version of the app.

7.4 Methodological considerations

Some study-specific methodological considerations have already been discussed in detail in each chapter.

This section considers the strengths, challenges and limitations of the PhD research overall.

7.4.1 Strengths, Limitations and Challenges

This research has a number of strengths. One strength is the use of the pragmatic approach that permits use of different methodologies, including mixed-method, systematic selection, and systematic review, to provide the best answer to the research topic (61). Although we did not follow a published framework or guideline, our approach has similarities with established frameworks used for developing and evaluating healthcare interventions, like the MRC model. This multi-method approach provides a variety of different, leading to greater accuracy and detail, and reduced bias. The research also considered the views of both doctor and patient groups groups in the app selection and evaluation phase. These are two of the most important stakeholders in mHealth interventions. By including these stakeholders, it is hoped that the selected app would be acceptable and offer positive health outcomes as these stakeholders offered useful and unique insights into how the app might fit into patients' lives. Moreover, this research is the first to rigorously identify and evaluate the most suitable commercially available app for people with hypertension, via a unique evidence-based approach, resulting in a key contribution in both the practical and research fields.

A thorough systematic selection approach was used to identify the most suitable apps on the basis of effectiveness and privacy and security criteria. At the beginning of the research, there was no established systematic approach for evaluating mHealth apps. Effectiveness and safety were identified as the two most important criteria, because it is essential that healthcare only implements interventions that are demonstrably effective, and because any intervention must not compromise a patient's privacy and/or safety. The use of these criteria is supported by more recent research, which has identified these as two of the essential criteria for ensuring the quality of commercial mHealth interventions (43,53).

Finally, the theoretical underpinnings of the content of the hypertension apps were coded according to the BCTs they employed and linked to the TDF domains (see Chapter 4). Recent research into mHhealth interventions has resulted in a more sophisticated understanding of how these might be designed to affect behaviour change, including a 93-item taxonomy of BCTs (62, 63), as well as the behaviour change wheel, which helps researchers connect these TDF domains and techniques with intervention functions (63). The findings of this research contribute to this growing body of knowledge, and can help future researchers and developers to have a more in-depth understanding of how TDF mechanisms of action promote user engagement, and/or the most effective ways to use BCTs to support self-management of hypertension.

However, there are also some limitations of this research that should be considered. First, most of 30 apps were not directly evaluated for effectiveness, because there was not sufficient evidence in the literature to support this analysis. Instead, the functionalities that each app possesses were used as an indicator of its potential effectiveness, because those apps with more comprehensive functionalities are more likely to be effective; see chapter 5. Apps were coded on the basis of whether or not they possessed certain functionalities. Due to the lack of detail about app functionalities provided by the studies reviewed, it was only possible to discover whether an app had a certain feature, and not whether each functionality was basic or more in-depth. For example, an app was coded as having a reminder without determining the type and frequency, etc., which might influence the selection. These codlings were more interpretative and so may have been more prone to investigators bias. Whilst this is a limitation of the research, this relates to a lack of available data on hypertension app effectiveness, rather than a limitation of the study design. More robust studies (e.g., meta-analysis) will be required to evaluate these functionalities to test and validate how effective they are, and in what combinations. More recent systematic reviews conducted following our research, have also found that apps using various functionalities are more effective than a single one (19,23) and the use of multifaceted functionalities including self-monitoring reminders, education, communication and feedback are likely to be effective (19,23)

Since the five identified apps were not available in the Arabic language, the apps were presented to participants in videos, designed to demonstrate how the apps work and display their functionalities. Although videos allowed the apps to be presented in a standardised format, participants were unable to interact with the app, and could only judge on the basis of what was presented to them, which may have influenced participants' opinions.

There is an increasing emphasis on involving potential users in healthcare research. Patients from primary care centres and hospitals were involved in each study of this thesis, with patients allowed to express their own views, feelings, requirements, and expectations around hypertension app use, as well as to evaluate specific apps in practice. However, the transferability of the findings from these study populations (doctors and patients in the qualitative study, and patients in the evaluation study) to the entire population of doctors and patients is limited. Because the study made use of a self-selecting sample (recruited via response to posters and fliers) it is possible that participants who volunteered were more highly motivated to take part and engage with self-management apps, leading to self-selection bias. In addition, despite efforts to reach the broadest range of potential participants, those who volunteered for the study were likely to have been those patients whose interest in, or willingness to use, technology was already higher than for the general population. Rather than a limitation of the present research, however, this is likely to be a potential barrier affecting uptake of any such intervention, as their use will always depend on patients' willingness to engage with technology. Finally, hypertension is more common among older people, and during study 3 one doctor raised concerns about this population's experience and competence with smartphone apps: *"I think it depends on the age; much more difficult for older generations to use them" [D2-male, 36]*. However, the ownership of smartphones is rapidly increasing globally and particularly in Saudi Arabia (64-66). This issue then will be of less and less concern as future older people will increasingly have grown up with smartphone technology.

The key challenges of this research related to recruitment: it was very difficult to recruit patients to the focus groups (Chapter 5), and to the real-life study (Chapter 6). Some participants showed interest in assisting with future research but were not willing to participate as they did not want to commit, they were not comfortable with the research procedures, or they reported being too busy. The other major challenges related to the limited time/resources of a PhD and the broad scope of the research. It was not possible to directly evaluate the effectiveness of the most suitable app (Cora Health), as this would have required a more longitudinal model than the PhD timeframe allows.

7.5 Recommendation

7.5.1 Recommendation for further research

There are some recommendations that should be considered for further research. First, the adopted selection approach still needs to be refined. Prior to this research, there was no existing guideline or evidence for how to select the most suitable self-management app. The criteria that were utilized were selected because they were deemed to be most essential, and because data for these criteria were available. However, future studies could present a more rounded picture of app suitability if they also took account of additional criteria, such as adherence to hypertension management guidelines, and usability, or if they were able to assess clinical safety, e.g. by considering the opinions of clinicians (40).

This PhD research demonstrates that the selected app is usable and acceptable and has the potential to be effective. To directly assess the app's effectiveness, a larger study with longer follow up periods would be required. This research does not provide in-depth understanding of how TDF mechanisms of action promote user engagement, or the most effective ways to use BCTs to support self-management of hypertension. Neither is there consistent evidence in the existing literature to indicate what combinations of BCTs and/or TDFs are likely to be most effective. Further research would be needed to explore patients' health outcomes and thereby provide in-depth understanding of how the app might support behaviour change through different TDF mechanisms of action, and about the most effective ways to use BCTs to support self-management of hypertension. A meta-analysis of current literature could provide further evidence as to what combinations of these are likely to be most effective.

Finally, this research focused on selecting the most suitable hypertension app and assessing its acceptance and usability in Saudi Arabia, meaning the findings may only be generalisable to locations with healthcare contexts similar to the Saudi Ministry of Health. Further research should explore the apps' use in other contexts.

7.5.2 Recommendation for developers, practices and policy

The potential advantages of smartphone apps will increase if they meet user needs and expectations. Developers should consider the involvement of potential users and experts in app development to ensure that apps meet users' needs and bring the most benefits in self-managing their diseases (43). More collaboration between app developers and researchers is required, and would lead to better apps that can support patients' self-management as fully as possible. This current research demonstrates the possibility of collaboration between researchers and developers to translate this app and then assess its usability and acceptance. Such collaborations have the potential to lead to the development of apps with higher usability and effectiveness. The developer's role should not end when the app is released. The effectiveness of apps could be improved if the developers also provide guidance about how to incorporate the app within the regular healthcare process, including technical support.

Because apps have potentially been developed without knowledge of behaviour change theory, it can be difficult to analyse them according to these theories. It is not always clear whether specific app functionalities are intended to target specific behaviours, or what specific elements of the app are designed to achieve. It is also possible that certain functionalities may influence multiple behaviours. COM-B is generally used to explore what barriers and facilitators correspond to what behaviour, and to identify the function of a certain targeted behaviour. To do this, it is necessary to know the specific behaviour that is being targeted by the app. In order to fully facilitate this sort of analysis, developers would need to determine which elements of their app are meant to achieve certain targeted behaviours, and make this information available to researchers.

The selected app, Cora Health, is currently only available on the Apple store (for iPhone). Distributing it via other platforms, such as Android, which also has a huge user base, would be recommended to increase the app popularity and accessibility. The results of this evaluation study of the selected app have been provided to the developers. If the issues identified in the evaluation are addressed, the app can be improved, although it will still require more evaluation to ensure its effectiveness. Other app developers also could benefit from this research by modifying their apps in accordance with the research findings. This research demonstrates the value of developer collaboration with researchers to enhance their app effectiveness, usability and acceptability, leading to increased popularity and user base.

Although the selection criteria used in this research (effectiveness, theoretical background and security and privacy) can be replicable by other researchers equipped with research skills, frameworks such as this one should also be simplified and clearly explained to make them more accessible to patients, and enable them to make informed decisions before downloading an app (43,53). There is a huge number of apps available commercially in app stores, but there is no standardised way to judge their quality, or to make this information available to potential users. Unlike with medicines or medical devices, there is currently no requirement for apps to be approved before they are made available, which may lead to unsafe apps being released. This should be addressed with more regulation to control and assess apps that are marketed for use by individuals with medical conditions. Curated specialist libraries of apps could also offer an alternative to unregulated app stores (67). The NHS Apps Library, for instance, requires developers to answer questions designed to ensure the safety of their app before they are recommended to users (68).

The actual usage data from study 4 shows that even a 'best practice' app is not used by all participants and that only some of the functionalities are regularly used. This engagement could be increased by addressing users' preferences and needs, via doctor support, and by linking apps within healthcare systems, as well as by providing users with guidance (69).

Implementation of this intervention within the Saudi context would require the following steps to take place: 1) a longitudinal study must be completed to gain evidence regarding the app's effectiveness and clinical safety; 2) the app developers should make any necessary changes to the app, including those the current research has identified; 3) policy makers and technical experts should be consulted to assess how this app could be incorporated within the care pathway in Saudi Arabia; 4) a plan should be put in place to facilitate this implementation, which must include the ability to provide required training and ongoing technical support to users of the app; 5) necessary funding should be secured; 6) the app should be rolled out.

7.6 Conclusion

This thesis has shown that despite the availability of hundreds of commercial apps targeted at managing hypertension, very few are likely to be effective and secure, with the majority being excluded either due to their lack of appropriate functionalities or privacy and security problems. Participants generally preferred apps that were easier to navigate, had more sophisticated features, greater level of detail, etc. Although doctors and patients expressed different opinions in determining which apps they preferred, both groups found one app to be the most suitable. The research explored the potential of a commercial smartphone app to support self-management of patients with hypertension with relatively good usability outcomes. However, the research identified a considerable number of possibilities for improvement due to users' differing needs, expectations, and preferences, which would need to be considered. The research therefore demonstrates the difficulty of 'getting it right' for all users: even a best practice app may not fully accommodate the needs of all patients. The research found that a commercially-available app could be used in large-scale studies of hypertension self-management, if these suggestions for improvement are addressed.

7.7 References

1. Craig, P. et al. Developing and evaluating complex interventions: The new Medical Research Council guidance. British Medical Journal. 2008 May [cited 2020 July]. 337(7676), 979-983. doi: https://doi.org/10.1136/bmj.a1655

2. Alessa T, Hawley MS, Hock ES, de Witte L. Smartphone Apps to Support Self-Management of Hypertension: Review and Content Analysis. JMIR Mhealth Uhealth. 2019 May [Cited 2020 Aug];7(5): e13645. doi: 10.2196/13645.

3. Gong K, Yan YL, Li Y, Du J, Wang J, Han Y, Zou Y, Zou XY, Huang H, She Q; APP Study Group. Mobile health applications for the management of primary hypertension: A multicenter, randomized, controlled trial. Medicine (Baltimore). 2020 Apr; [cited 2020 Nov];99(16):e19715. doi: 10.1097/MD.0000000000019715.

4. Frias J, Virdi N, Raja P, Kim Y, Savage G, Osterberg L. Effectiveness of Digital Medicines to Improve Clinical Outcomes in Patients with Uncontrolled Hypertension and Type 2 Diabetes: Prospective, Open-Label, Cluster-Randomized Pilot Clinical Trial. J Med Internet Res. 2017 Jul [cited 2020 Oct];19(7):e246. doi: 10.2196/jmir.7833.

5. Zha P, Qureshi R, Porter S, Chao YY, Pacquiao D, Chase S, O'Brien-Richardson P. Utilizing a Mobile Health Intervention to Manage Hypertension in an Underserved Community. West J Nurs Res. 2020 Mar [cited 2020 Oct];42(3):201-209. doi: 10.1177/0193945919847937.

6. Lv N, Xiao L, Simmons ML, Rosas LG, Chan A, Entwistle M. Personalized Hypertension Management Using Patient-Generated Health Data Integrated With Electronic Health Records (EMPOWER-H): Six-Month Pre-Post Study. J Med Internet Res. 2017 Sep [cited 2020 Oct];19(9):e311. doi: 10.2196/jmir.7831

7. Chandler J, Sox L, Kellam K, Feder L, Nemeth L, Treiber F. Impact of a Culturally Tailored mHealth Medication Regimen Self-Management Program upon Blood Pressure among Hypertensive Hispanic Adults. Int J Environ Res Public Health. 2019 Apr [cited 2020 Oct];6;16(7):1226. doi: 10.3390/ijerph16071226

8. Kaplan AL, Cohen ER, Zimlichman E. Improving patient engagement in self-measured blood pressure monitoring using a mobile health technology. Health Inf Sci Syst. 2017 Oct [cited 2020 Aug];5(1):4. doi: 10.1007/s13755-017-0026-9

9. Sarfo FS, Treiber F, Gebregziabher M, Adamu S, Nichols M, Singh A, Obese V, Sarfo-Kantanka O, et al. Phone-based intervention for blood pressure control among Ghanaian stroke survivors: A pilot randomized controlled trial. Int J Stroke. 2019 Aug [cited 2020 Oct];14(6):630-638. doi: 10.1177/1747493018816423.

10. Márquez Contreras E, Márquez Rivero S, Rodríguez García E, López-García-Ramos L, Carlos Pastoriza Vilas J, Baldonedo Suárez A, Gracia Diez C, Gil Guillén V, Martell Claros N; Compliance Group of Spanish Society of Hypertension (SEH-LELHA). Specific hypertension smartphone application to improve medication adherence in hypertension: a cluster-randomized trial. Curr Med Res Opin. 2019 Jan [cited 2020 Aug]; 35(1):167-173. doi: 10.1080/03007995.2018.1549026.

11. Morrissey EC, Glynn LG, Casey M, Walsh JC, Molloy GJ. New self-management technologies for the treatment of hypertension: general practitioners' perspectives. Fam Pract. 2018 Jun [cited 2020 Oct]; 23;35(3):318-322. doi: 10.1093/fampra/cmx100.

12. McBride CM, Morrissey EC, Molloy GJ. Patients' Experiences of Using Smartphone Apps to Support Self-Management and Improve Medication Adherence in Hypertension: Qualitative Study. JMIR Mhealth Uhealth 2020 [cited 2020 Nov];8(10): e17470. doi: 10.2196/17470

13. Zare S, Rezaee R, Aslani A, Shirdeli M, Kojuri J. "Moving toward Community Based Telehealth Services Using Mhealth for Hypertensive Patients.International Journal of Technology Assessment in Health Care 2019 Sep [cited 2020 Sep]; 35(5): 379-83

14. Cechetti NP, Bellei EA, Biduski D, Rodriguez JM, Roman, Mateus Klein, and De Marchi, Ana Carolina Bertoletti. "Developing and Implementing a Gamification Method to Improve User Engagement: A Case Study with an M-Health Application for Hypertension Monitoring." Telematics and Informatics 41 (2019): 126-38. Web.

15. Yan M, Or C. A 12-week pilot study of acceptance of a computer-based chronic disease self-monitoring system among patients with type 2 diabetes mellitus and/or hypertension. Health Informatics J. 2019 Sep [cited 2020 Oct]; 25(3):828-843. doi: 10.1177/1460458217724580

16. Santo K, Redfern J. The Potential of mHealth Applications in Improving Resistant Hypertension Self-Assessment, Treatment and Control. Curr Hypertens Rep. 2019 Oct [cited 2020 November]; 21(10):81. doi: 10.1007/s11906-019-0986-z.

17. Liu K, Xie Z, Or CK. Effectiveness of Mobile App-Assisted Self-Care Interventions for Improving Patient Outcomes in Type 2 Diabetes and/or Hypertension: Systematic Review and Meta-Analysis of Randomized Controlled Trials. JMIR Mhealth Uhealth. 2020 Aug [cited 2020 Nov];8(8):e15779. doi: 10.2196/15779.

18. Xiong S, Berkhouse H, Schooler M, et al. Effectiveness of mHealth Interventions in Improving Medication Adherence Among People with Hypertension: a Systematic Review. Curr Hypertens Rep. 2018 Augest [cited 2020 Nov]; 20 (10):1-15. doi: https://doi.org/10.1007/s11906-018-0886-7

19. Li R, Liang N, Bu F, Hesketh T. The Effectiveness of Self-Management of Hypertension in Adults Using Mobile Health: Systematic Review and Meta-Analysis. JMIR Mhealth Uhealth. 2020 Mar [cited 2020 Nov];8(3):e17776. doi: 10.2196/17776.

20. Lu X, Yang H, Xia X, Lu X, Lin J, Liu F, Gu D. Interactive Mobile Health Intervention and Blood Pressure Management in Adults. Hypertension; 2019 Sep [cited 2020 Nov];74(3):697-704. doi: 10.1161/HYPERTENSIONAHA.119.13273.

21. Mao Y, Lin W, Wen J, Chen G. Impact and efficacy of mobile health intervention in the management of diabetes and hypertension: a systematic review and meta-analysis. BMJ Open Diabetes Res Care. 2020 Sep [cited 2020 Nov];8(1): e001225. doi: 10.1136/bmjdrc-2020-001225.

22. Omboni S. Connected Health in Hypertension Management. Front Cardiovasc Med. 2019 Jun [cited 2020 Nov]; 6:76. doi: 10.3389/fcvm.2019.00076.

23. Almasi S, Hosseini A, Emami H, Sabahi A. Mobile Health Technology for Hypertension Management: A Systematic Review. Acta Medica Iranica. 2020 Jun [cited 2020 Nov]; 58(6):249-259. doi: 10.18502/acta.v58i6.4050

24. Fadilah SZ, Susanti IA, Setyorini DY, Pradipta RO. Effectiveness of Mobile-Based Health Interventions for the Management of Hypertensive Patients: A Systematic Review. Jurnal Ners 2020 April [cited 2020 Nov];15(2) 238-245. doi: http://dx.doi.org/10.20473/jn.v15i2.19022

25. Xu H, Long H. The Effect of Smartphone App-Based Interventions for Patients with Hypertension: Systematic Review and Meta-Analysis. JMIR Mhealth Uhealth. 2020 Oct [cited 2020 November];8(10):e21759. doi: 10.2196/21759.

26. Han H, Guo W, Lu Y, Wang M. Effect of mobile applications on blood pressure control and their development in China: a systematic review and meta-analysis. Public Health. 2020 Aug [cited 2020 Nov]; 185:356-363. doi: 10.1016/j.puhe.2020.05.024.

27. Alessa T, Hawley MS, Hock ES, de Witte L. Smartphone Apps to Support Self-Management of Hypertension: Review and Content Analysis. JMIR Mhealth Uhealth. 2019 May [Cited 2020 Aug];7(5):e13645. doi: 10.2196/13645.

28. Boessen AB, Vermeulen J, de Witte LP. Acceptance and usability of a home-based monitoring tool of health indicators in children of people with dementia: a Proof of Principle (POP) study. Patient Prefer Adherence. 2017 Aug [2020 Aug];11:1317-1324. doi: 10.2147/PPA.S135022.

29. van der Weegen S, Verwey R, Tange HJ, Spreeuwenberg MD, de Witte LP. Usability testing of a

monitoring and feedback tool to stimulate physical activity. Patient Prefer Adherence. 2014 Mar [cited 2020 Aug]; 8:311-22. doi: 10.2147/PPA.S57961.

30. Zapata BC, Fernández-Alemán JL, Idri A, Toval A. Empirical studies on usability of mHealth apps: a systematic literature review. J Med Syst. 2015 Feb;39(2):1. doi: 10.1007/s10916-014-0182-2

31. Jake-Schoffman DE, Silfee VJ, Waring ME, Boudreaux ED, Sadasivam RS, Mullen SP, Carey JL, Hayes RB, Ding EY, Bennett GG, Pagoto SL. Methods for Evaluating the Content, Usability, and Efficacy of Commercial Mobile Health Apps. JMIR Mhealth Uhealth 2017 [cited 2020 Aug];5(12):e190. doi 10.2196/mhealth.8758

32. Turner-McGrievy GM, Hales SB, Schoffman DE, Valafar H, Brazendale K, Weaver RG, Beets MW, Wirth MD, Shivappa N, Mandes T, Hébert JR, Wilcox S, Hester A, McGrievy MJ. Choosing between responsive-design websites versus mobile apps for your mobile behavioral intervention: presenting four case studies. Transl Behav Med. 2017 Jun [cited 2020 Aug];7(2):224-232. doi: 10.1007/s13142-016-0448-y

33. Alexander JC, Joshi GP. Smartphone applications for chronic pain management: a critical appraisal [online]. J Pain Res. 2016 Sep [cite Aug 2020]; 26;9:731-734. doi: 10.2147/JPR.S119966.

34. Jamaladin H, van de Belt TH, Luijpers LC, de Graaff FR, Bredie SJ, Roeleveld N, van Gelder MM. Mobile Apps for Blood Pressure Monitoring: Systematic Search in App Stores and Content Analysis [online]. JMIR Mhealth Uhealth. 2018 Nov 14 [cited 2020 Sep];6(11):e187. doi: 10.2196/mhealth.9888.

35. Lewis TL, Wyatt JC. mHealth and mobile medical Apps: a framework to assess risk and promote safer use. J Med Internet Res.2014 Sep [cited 2020 Sep];16(9):e210 15. doi:10.2196/jmir.3133

36. Izahar S, Lean QY, Hameed MA, Murugiah MK, Patel RP, Al-Worafi YM, Wong TW, Ming LC. Content Analysis of Mobile Health Applications on Diabetes Mellitus [online]. Front Endocrinol (Lausanne). 2017 Nov [cited 2020 Sep]; 8:318. doi: 10.3389/fendo.2017.00318.

37. Wisniewski H, Liu G, Henson P, Vaidyam A, Hajratalli NK, Onnela JP, Torous J. Understanding the quality, effectiveness and attributes of top-rated smartphone health apps [online]. Evid Based Ment Health. 2019 Feb [cited 2020 Sep]; 22(1):4-9. doi: 10.1136/ebmental-2018-300069.

38. Hui CY, Creamer E, Pinnock H, McKinstry B. Apps to Support Self-Management for People with Hypertension: Content Analysis. JMIR Mhealth Uhealth. 2019 Jun [cited 2020 Nov];7(6): e13257. doi: 10.2196/13257.

39. Powell L, Parker J, Harpin V. ADHD: Is There an App for That? A Suitability Assessment of Apps for the Parents of Children and Young People With ADHD. JMIR Mhealth Uhealth 2017 Oct [cited 2020 Aug];5(10): e149. doi: 10.2196/mhealth.7941

40. Akbar S, Coiera E, Magrabi, F. Safety concerns with consumer-facing mobile health applications and their consequences: a scoping review. JAMIA. 2020 Feb [cited 2020. Aug]; 27(2):330–340.

41. Scott IA, Scuffham P, Gupta D, Harch TM, Borchi J, Richards B. Going digital: a narrative overview of the effects, quality and utility of mobile apps in chronic disease self-management Ponline]. Aust Health Rev. 2020 Feb [cited 2020 Aug];44(1):62-82. doi: 10.1071/AH18064.

42. Scott IA, Scuffham P, Gupta D, Harch TM, Borchi J, Richards B. Going digital: a narrative overview of the effects, quality and utility of mobile apps in chronic disease self-management. Aust Health Rev. 2020 Feb [cited 2020 Nov];44(1):62-82. doi: 10.1071/AH18064.

43. Wykes T, Schueller S. Why Reviewing Apps Is Not Enough: Transparency for Trust (T4T) Principles of Responsible Health App Marketplaces [online]. J Med Internet Res. 2019 May [cited 2020 Aug];21(5):e12390. doi: 10.2196/12390

44. Duan H, Wang Z, Ji Y, Ma L, Liu F, Chi M, Deng N, An J. Using Goal-Directed Design to Create a Mobile Health App to Improve Patient Compliance with Hypertension Self-Management: Development and Deployment [online]. JMIR Mhealth Uhealth 2020 Feb [cited 2020

Oc]t;8(2):e14466. doi: 10.2196/14466.

45. Kang H, Park HA. A Mobile App for Hypertension Management Based on Clinical Practice Guidelines: Development and Deployment. JMIR Mhealth Uhealth. 2016 Feb [cited 2020 Aug];4(1):e12. doi: 10.2196/mhealth.4966.

46. Sun N, Rau PP, Li Y, Owen T, Thimbleby H. Design and evaluation of a mobile phone-based health intervention for patients with hypertensive condition. Computers in Human Behavior [online]. 2016 Oct [cited 2020 Aug]; 63:98–105. doi: 10.1016/j.chb.2016.05.001.

47. Logan AG. Transforming hypertension management using mobile health technology for telemonitoring and self-care support [online]. Can J Cardiol. 2013 May [cited 2020 Aug];29(5):579–85. doi: 10.1016/j.cjca.2013.02.024

48. Leong AY, Makowsky MJ. Quality of Blood Pressure Tracking Apps for the iPhone: Content Analysis and Evaluation of Adherence with Home Blood Pressure Measurement Best Practices. JMIR Mhealth Uhealth [online]. 2019 Apr [cited Aug 2020];7(4):e10809. doi: 10.2196/10809.

49. Papageorgiou A, Strigkos M, Politou E, Alepis E, Solanas A, and Patsakis C, Security and Privacy Analysis of Mobile Health Applications: The Alarming State of Practice. IEEE Access. 2018 Jan [cited 2020 Aug]; 6:9390-9403. doi: 10.1109/ACCESS.2018.2799522.

50. Hutton L, Price BA, Kelly R, McCormick C, Bandara AK, Hatzakis T, Meadows M, Nuseibeh B. Assessing the Privacy of mHealth Apps for Self-Tracking: Heuristic Evaluation Approach. JMIR Mhealth Uhealth 2018 Oct;6(10):e185. doi: 10.2196/mhealth.921

51. Huckvale K, Morrison C, Ouyang J, Ghaghda A, Car J. The evolution of mobile apps for asthma: an updated systematic assessment of content and tools. BMC Med 2015 Mar; 13: 58. doi: https://doi.org/10.1186/s12916-015-0303-x

52. Plante TB, Urrea B, MacFarlane ZT, et al. Validation of the Instant Blood Pressure Smartphone App [online]. JAMA Intern Med. 2016 Jun [cite 2020 Aug];176(5):700-702. doi:10.1001/jamainternmed.2016.0157

53. Llorens-Vernet P, Miró J. Standards for Mobile Health–Related Apps: Systematic Review and Development of a Guide. JMIR Mhealth Uhealth 2020 Mar [cited 2020 Sep];8(3):e13057. doi: 10.2196/13057

54. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR Mhealth Uhealth. 2015 Mar [cited 2020 Aug];11;3(1): e27

55. Salazar A, de Sola H, Failde I, Moral-Munoz JA Measuring the Quality of Mobile Apps for the Management of Pain: Systematic Search and Evaluation Using the Mobile App Rating Scale. JMIR Mhealth Uhealth 2018 Oct [cited 2020 Oct];6(10):e10718. doi: 10.2196/10718

56. Vo V, Auroy L, Sarradon-Eck A. Patients' Perceptions of mHealth Apps: Meta-Ethnographic Review of Qualitative Studies. JMIR Mhealth Uhealth. 2019 Jul [cited 2020 Sep] 10;7(7):e13817. doi: 10.2196/13817.

57. Yardley L, Spring BJ, Riper H, Morrison LG, Crane DH, Curtis K, Merchant GC, Naughton F, Blandford A. Understanding and Promoting Effective Engagement with Digital Behavior Change Interventions. Am J Prev Med. 2016 Nov [cited 2020 Oct];51(5):833-842. doi: 10.1016/j.amepre.2016.06.015.

58. Marshall Iain J, Wolfe Charles D A, McKevitt Christopher. Lay perspectives on hypertension and drug adherence: systematic review of qualitative research. BMJ 2012 Jul [cited 2020 Sep]; 345: e3953

59. George D, Hassali MA, HSS AS. Usability Testing of a Mobile App to Report Medication Errors Anonymously: Mixed-Methods Approach [online]. JMIR Hum Factors 2018 Dec [cited 2020 Sep];5(4): e12232

60. Chien SC, Islam MM, Yeh CA, Chien PH, Chen CY, Chin YP, Lin MC. Mutual-Aid Mobile App for Emergency Care: Feasibility Study [online]. JMIR Form Res 2020 Mar [cited 2020 Oct];4(3): e15494

61. Creswell JW, Plano Clark VL. Designing and Conducting Mixed Methods Research. SAGE Publications Ltd. SAGE Publications, lnc.; 2018.

62. Michie S, Richardson M, Johnston M, Abraham C, Francis J, Hardeman W et al. The Behavior Change Technique Taxonomy (v1) of 93 Hierarchically Clustered Techniques: Building an International Consensus for the Reporting of Behavior Change Interventions. Annals of Behavioral Medicine. 2013 Aug [cited 2018 Mar];1-15. doi: 10.1007/s12160-013-9486-6

63. Michie S, Atkins L, West R. The Behaviour Change Wheel: a guide to designing interventions. 2014. London: Silverback

64. Saudi Arabia Has the Highest Users of Mobile Phones. Saudi Arabia: Ministry of communication and information technology 2020. Available from: https://www.arabnews.com/node/1075126/corporate-news

65. Albabtain AF, AlMulhim DA, Yunus F, Househ MS. The Role of Mobile Health in the Developing World: A Review of Current Knowledge and Future Trends [online]. Journal of Selected Areas in Health Informatics. 2014 Feb [cited Oct 2020];4(2):10–15.

66. Saudi Arabia ranks 3rd globally for smartphone use. Arab news; 2017 Mar. Available from: https://www.arabnews.com/node/1075126/corporate-news

67. Baxter C, Carroll JA, Keogh B, Vandelanotte C. Assessment of Mobile Health Apps Using Built-In Smartphone Sensors for Diagnosis and Treatment: Systematic Survey of Apps Listed in International Curated Health App Libraries. JMIR Mhealth Uhealth. 2020 Feb [cited 2020 Dec];8(2):e16741. doi: 10.2196/16741

68. Wicks P, Chiauzzi E. Trust but verify'–five approaches to ensure safe medical apps. BMC medicine. 2015 Sep [cited 2020 Oct], 13(1):1-5.

69. Szinay D, Jones A, Chadborn T, Brown J, Naughton F. Influences on the Uptake of and Engagement with Health and Well-Being Smartphone Apps: Systematic Review.J Med Internet Res. 2020 [cited 2020 Dec];22(5): e17572. doi: 10.2196/17572

Appendices

Appendix 1 Study characteristics.

Study and Country	Study Design	Study Setting	Study Duration	Subjects	Interventions	Study device (Operating system)	Study Quality
Anglada-Martínez et al Spain (39)	Single-arm prospective pre-post intervention study	Casanova Primary Care Clinic and Hospital Clinic	6 months	**Patients**: **N=** 42 (F 21.4%, M 78,6%) **Age:** (mean= 56) **SBP**[a]**:** NR[b] **DBP**[c]**:** NR **HCP**: **N=** 5	**I**[d]**=** Medplan platform (website for HCPs + smartphone app) **C**[e]**=** usual care	iPhone (iOS) or NR (Android)	Poor
Mao et al USA (31)	RCT[f] (Retrospective analysis)	Data from a pilot Commercial collaboration	12 months	**Patients:** **N=** 1012 (F 68%, M 32%) **I=** 763, C= 73 **Age** (mean= 44.63; I= 44.87 C= 42.36) **SBP:** I= 131.27 (1.52) **C=**NR **HCP**: **N=**NA	**I=** Vida app + a Bluetooth-connected pedometer and wire§1less scale + a Bluetooth-enabled blood pressure cuff **C=** usual care	iPhone (iOS) or NR (Android)	Fair
Kang et al., South Korea (44)	Technology development study (survey)	Cardiovascular clinics at tertiary hospitals	4 weeks	**Patients**: **N=**38 (F% 34, M 66%) **Age:** 56 years **HCP**: **N=**CD	**I=**Smartphone app + BP monitor **C=**NA[g]	NR (NR)	Poor
Banerjee et al USA (32)	Technology development studies (Survey)	A diabetes and hypertension clinic.	NA	**Patients:** **N=**385 **Age:** NA **SBP:** NR **DBP:** NR **HCP**: **N=**NA	**I=**Smartphone app (My vital signs) **C=**NA	iPhone (iOS) or NR (Android)	Poor
McGillicuddy et al (2013) USA (26)	Survey	Kidney Transplant Clinic at the Medical University of South Carolina (MUSC)	3 months	**Patients:** **N=** 99 (F 35%, M 65% (64/98)) **Age:** (mean= 44.63) **SBP:** NR **DBP:** NR **HCP**: **N=**NA	**I=** SMASH (cellular connected electronic medication device + a wireless (bluetooth-enabled) BP monitor + smartphone (app + messaging) **C=**NA	Motorola Droid X (Android)	Fair
Sun et al China (43)	Longitudinal quasi-experiment design	Tsinghua Elderly University & a nearby community	6 weeks	**Patients:** **N=**19 (F=57.8%, M= 42.1%) **Age:** 49-70 years (mean=59.2) **HCP**: **N=**NA	**I=** Mobile app + BP monitor **C=** NA	NR (NR)	Poor

Appendix 2 MEDLINE search strategy.

1. exp Hypertension/
2. hyperten*.kw,ti.
3. high blood pressure.ab,ti.
4. HTN.ab,ti.
5. 1 or 2 or 3 or 4
6. exp Mobile Applications/
7. mobile health.ab,ti.
8. *Medical Informatics Applications/
9. (ehealth or e-health or e?health).ab,ti.
10. (mhealth or m-health or m?health).ab,ti.
11. (window? adj3 phone?).ab,ti.
12. (window? adj3 mobile?).ab,ti.
13. apps.ab,ti.
14. (iphone? or i-phone?).ab,ti.
15. (ipad? or i-pad?).ab,ti.
16. (ipod?touch or i-pod? or ipod?).ab,ti.
17. nokia.ab,ti.
18. palm OS.ab,ti.
19. blackberry*.ab,ti.
20. symbian.ab,ti.
21. personal digital assistant?.ab,ti.
22. PDA.ab,ti.
23. (smartphone? or smart?phone?).ab,ti.
24. exp cellular phone/
25. cell phone?.ab,ti.
26. mobile phone?.ab,ti.
27. applet?.ab,ti.
28. (software adj3 app*).ab,ti.
29. (mobile adj3 software).ab,ti.
30. (mobile adj3 app*).ab,ti.
31. (smartphone? or smart?phone?).ab,ti.
32. (telemonitor* or tele?monitor*).ab,ti.
33. (telemedicine or tele?medicine).ab,ti.
34. (telehealth or tele?health).ab,ti.
35. exp Computers, Handheld/
36. or/6-35
37. (remote adj2 (monitor* or treat* or care)).ab,ti.
38. exp self care/
39. self care.ab,ti.
40. self monitor*.ab,ti.
41. self manage*.ab,ti.
42. self treat*.ab,ti.
43. self medication.ab,ti.
44. self administration.ab,ti.

Appendix 3 Study outcomes.

Study and Country	Study Design	Study Setting	Study Duration	Subjects	Interventions	Study Device (Operating system)	Study Quality
Anglada-Martínez et al Spain (39)	Single-arm prospective pre-post interventio n study	Casanova Primary Care Clinic and Hospital Clinic	6 months	**Patients**: **N=** 42 (F 21.4%, M 78,6%) **Age:** (mean= 56) **SBP**[a]**:** NR[b] **DBP**[c]**:** NR **HCP**: **N**= 5	**I**[d]**=** Medplan platform (website for HCPs + smartphone app) **C**[e]**=** usual care	iPhone (iOS) or NR (Android)	Poor
Mao et al USA (31)	RCT[f] (Retrospect ive analysis)	Data from a pilot Commerci al collaborati on	12 months	**Patients: N=** 1012 (F 68%, M 32%) **I=** 763, C= 73 **Age** (mean= 44.63; I= 44.87 C= 42.36) **SBP:** I= 131.27 (1.52) **C**=NR **HCP**: **N**=NA	**I=** Vida app + a Bluetooth-connected pedometer and wire§1less scale + a Bluetooth-enabled blood pressure cuff **C=** usual care	iPhone (iOS) or NR (Android)	Fair
Kang et al., South Korea (44)	Technology developme nt study (survey)	Cardiovas cular clinics at tertiary hospitals	4 weeks	**Patients**: **N**=38 (F% 34, M 66%) **Age:** 56 years **HCP**: **N**=CD	**I**=Smartphone app + BP monitor **C**=NA[g]	NR (NR)	Poor
Banerjee et al USA (32)	Technology developme nt studies (Survey)	A diabetes and hypertensi on clinic.	NA	**Patients: N**=385 **Age:** NA **SBP:** NR **DBP:** NR **HCP**: **N**=NA	**I**=Smartphone app (My vital signs) **C**=NA	iPhone (iOS) or NR (Android)	Poor
McGillicudd y et al (2013) USA (26)	Survey	Kidney Transplant Clinic at the Medical University of South Carolina (MUSC)	3 months	**Patients: N=** 99 (F 35%, M 65% (64/98)) **Age:** (mean= 44.63) **SBP:** NR **DBP:** NR **HCP**: **N**=NA	**I=** SMASH (cellular connected electronic medication device + a wireless (bluetooth-enabled) BP monitor + smartphone (app + messaging) **C**=NA	Motorola Droid X (Android)	Fair
Sun et al China (43)	Longitudin al quasi-experiment design	Tsinghua Elderly University & a nearby communit Y	6 weeks	**Patients: N**=19 (F=57.8%, M= 42.1%) **Age:** 49-70 years (mean=59.2) **HCP**: **N**=NA	**I=** Mobile app + BP monitor **C=** NA	NR (NR)	Poor

Appendix 4 Cochrane checklist too for RCTs.

Study	Selection bias		Performance Bias	Detection bias	Attrition bias	Reporting bias	Other bias
	Random sequence generation	**Allocation concealment**	**Blinding of participants and personnel**	**Blinding of outcome assessors to intervention allocation**	**incomplete outcome data**	**Selective reporting of the outcome, subgroups, or analysis**	**Others**
McGillicuddy et al (2013) (27)	?	?	?	√	√	√	X
	Random sequence generation was not noted within the study	Allocation concealment was not noted within the study	The blinding was not described.	The nurses or coordinators blinded to the subject's cohort assignment	Titration rate was good 88.7%.	All reported outcomes in methodology reported in result section.	The study was funded and ethically approved and has similar baseline characteristic. However small sample size may affect detecting the impacts of technology and generalize the findings.
McGillicuddy et al (2015) (25)	?	?	?	√	√	√	X
	Random sequence generation was not noted within the study	Allocation concealment was not noted within the study	The blinding was not described.	The nurses or coordinators blinded to the subject's cohort assignment t	Titration rate was good 88.7%.	All reported outcomes in methodology reported in result section.	The study was funded and ethically approved and has similar baseline characteristic. However small sample size may affect detecting the impacts of technology and generalize the findings.
Davidson et Al (24)	?	X	?	?	√	√	X
	. Random Sequence generation was not noted within the study	Allocation Concealment was not noted within the Study	The blinding was not described.	The blinding was not described.	only one person drop Out for the Intervention Group	All pre-specified outcomes are done	The study was funded and Ethically approved and has some similar Baseline characteristic; it is not similar at DBP, age. However, very small sample size; affects detecting the impacts of

Appendix 5 NIH tools for non-randomized studies.

Criteria/ Study	Albini et al (41)
1-Was the study described as randomized, a randomized trial, a randomized clinical trial, or an RCT?	x[b]
2. Was the method of randomization adequate (i.e., use of randomly generated assignment)?	x
3. Was the treatment allocation concealed (so that assignments could not be predicted)?	x
4. Were study participants and providers blinded to treatment group assignment?	x
5. Were the people assessing the outcomes blinded to the participants' group assignments?	x
6. Were the groups similar at baseline on important characteristics that could affect outcomes (e.g., demographics, risk factors, co-morbid conditions)?	CD[e]
7. Was the overall drop-out rate from the study at endpoint 20% or lower of the number allocated to treatment?	√[a]
8. Was the differential drop-out rate (between treatment groups) at endpoint 15 percentage points or lower?	NR
9. Was there high adherence to the intervention protocols for each treatment group?	NA[d]
10. Were other interventions avoided or similar in the groups (e.g., similar background treatments)?	NA
11. Were outcomes assessed using valid and reliable measures, implemented c all study participants?	√
12. Did the authors report that the sample size was sufficiently large to be able to detect a difference in the main outcome between groups with at least 80% power?	NR[c]
13. Were outcomes reported or subgroups analyzed prespecified (i.e., identified before analyses were conducted)?	√

Appendix 6 NIH tools for non-randomized studies (observational cohort and cross-sectional studied).

Criteria/ Study	Bengtsson et al (37)	Carrera et al (40)	McGillicuddy et al (26)	Mao et al (31)	Kang et al (44)	Sun et al (43)	Banerjee et al (32)
1. Was the research question or objective in this paper clearly stated?	√[a]	X[b]	√	√	√	√	X
2. Was the study population clearly specified and defined?	√	X	√	√	√	NR	X
3. Was the participation rate of eligible persons at least 50%?	√	CD[e]	CD	√	CD	CD	CD
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study pre-specified and applied uniformly to all participants?	√	CD	√	√	CD	CD	CD
5. Was a sample size justification, power description, or variance and effect estimates provided?	√	NR[c]	X	√	√	x	NR
6. For the analysis in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?	NA	NA[d]	NA	NA	√	NA	√
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?	X	CD	CD	√	X	√	CD
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?	NA	NA	NA	NA	NA	NA	NA

Appendix 7 NIH tools for non-randomized studies (Pre-post studies)

Criteria/ Study	Bengtsson et al [37]	Carrera et al [40]	McGillicuddy et al [26]	Mao et al [31]	Kang et al [44]	Sun et al [43]	Banerjee et al [32]
1. Was the research question or objective in this paper clearly stated?	√[a]	X[b]	√	√	√	√	X
2. Was the study population clearly specified and defined?	√	X	√	√	√	NR	X
3. Was the participation rate of eligible persons at least 50%?	√	CD[e]	CD	√	CD	CD	CD
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study pre-specified and applied uniformly to all participants?	√	CD	√	√	CD	CD	CD
5. Was a sample size justification, power description, or variance and effect estimates provided?	√	NR[c]	X	√	√	x	NR
6. For the analysis in this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?	NA	NA[d]	NA	NA	√	NA	√
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if it existed?	x	CD	CD	√	X	√	CD
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?	NA	NA	NA	NA	NA	NA	NA

Appendix 8 CASP tool for qualitative studies.

Criteria/ Study	**Hallberg et al (38)**	**Bengtsson et al (36)**
1-Was there a clear statement of the aims of the research?	√[a]	√
2. Is a qualitative methodology appropriate?	√	√
3-Was the research design appropriate to address the aims of the research?	√	√
4- Was the recruitment strategy appropriate to the aims of the research?	√	√
5. Was the data collected in a way that addressed the research issue?	X[b]	X
6. Has the relationship between researcher and participants been adequately considered?	X	X
7. Have ethical issues been taken into consideration?	√	√
8. Was the data analysis sufficiently rigorous?	√	√
9. Is there a clear statement of findings?	√	√
10. How valuable is the research?	X	√

Appendix 9 Data of the included apps.

App name	App store	The developer	Version date	Cost	Number of downloads	User ratings	Privacy & Security	App Functionalities							
								Self-monitoring	Reminder	Educational information	Feedback	communication with others	Stress management	Goal setting	Expo
1. Accutension Stetho	Apple	Shangahi Hulu Device Co Ltd	19/11/2017	Free	NA[c]	–[d]	–	✔							
2. AGR blood pressure Log	Apple	Angel Garcia rubio	30/11/2016	1.99	NA	–	–	✔			✔				✔
3. Best Way to Lower Your High Blood Pressure Fast and Early Prevention Guide & Tips for Beginners	Apple	Alex Baik	-	2.99	NA	–	–			✔					
4. BGL smart sphygmomanometer	Apple	FIRST RANK tech	5/1/2017	Free	NA	–	–	✔			✔				
5. Blood Pressure – SmartBP	Apple	Evolve medical System, LLC	8/11/2017	Free (5.99)[a]	NA	4.3	Y[e]	✔	✔		✔			✔	✔
6. Blood pressure & plus diary	Apple	Jan-Hendrik Damerau	4/11/2017	0.99	NA	NR[b]	N[f]	✔	✔		✔				✔
7. Blood Pressure Companion	Apple	Maxwell Software	20/12/2017	Free (3.99)[a]	NA	4.7	Y	✔	✔		✔				✔
8. Blood pressure diary	Apple	Openit Inc.	12/2/2018	Free	NA	NR	Y	✔	✔		✔			✔	
9. Blood pressure Diary 2	Apple	cellHigh	8/10/2016	4.49	NA	–	–	✔			✔				✔
10. Blood pressure Grapher	Apple	Ai Imai	11/12 2017	Free (9.99)[a]	NA	–	–	✔							
11. Blood pressure Lite-BP Tracker for Hypertension	Apple	Codulis	3/3/2016	Free (4.99)[a]	NA	–	–	✔			✔				✔
12. Blood Pressure monitor – cloud Ed	Apple	Thomas Kress	24/9/2015	1.99	NA	–	–	✔			✔				✔
13. Blood Pressure Monitor - Health Edition	Apple	Thomas Kress	23/5/2015	2.29	NA	–	–	✔			✔				✔
14. Blood pressure PRO with on	Apple			9.99	NA	–	–	✔			✔				✔
15. Blood pressureDB	Apple	klier.net	26/5/2016	Free	NA	–	–	✔	✔						
16. Bloodnote – blood pressure control	Apple	Matt Ludzen	23/1/2015	1.99	NA	–	–	✔			✔				

17. BP Assistant – Blood pressure	Apple	Josef Moser	2/8/2017	2.99	NA	–	–	✔							✔
18. BP Grapher: Simple	Apple	Ai Lmai	4/1/2018	Free (2.99)[a]	NA	NR	Y	✔	✔		✔			✔	✔
19. BP Log	Apple	ser.soft GmbH	22/11/2017	17.0	NA	–	–	✔							
20. BP Matters	Apple	Nanyang Polytechnic	10/11/2016	Free	NA	NR	N	✔	✔		✔				
21. BP Tracker – Smart Blood Pressure	Apple	Guangodong Biolioght Meditech co., Ltd.	19/9/2017	Free	NA	–	–	✔			✔	✔			
22. bp Trax® – Blood Pressure Treatment Tracker, Lifestyle, Resting, BMI, MAP, Pulse Rate	Apple	IMobLife Inc	25/6/2015	1.99	NA	–	–	✔			✔				
23. BP Wiz Pro – Blood pressure & Drug	Apple	LinkLinks LTD	30/6/2017	1.99	NA	3.9	Y	✔	✔		✔				✔
24. BPMon Pro- Blood Pressure Monitor	Apple	Anatoly Butko	18/4/2017	3.99	NA	–	–	✔			✔				✔
25. BP-Monitor Blood Pressur	Apple	Adappt LLC	15/10/2017	Free	NA	–	–	✔			✔				✔
26. Braun Healthy heart	Apple	Kaz US, Inc	31/10/2015	Free	NA	3.0	Y	✔	✔	✔	✔		✔		
27. Caracal	Apple	Caracal	12/10/2017	Free (12.99)[a]	NA	–	–	✔							
28. Control tension	Apple	Les Laboratories service	15/5/2015	Free	NA	NR	N	✔	✔	✔					✔
29. Cora – Blood Pressure	Apple	Swiftware	21/11/2017	Free (2.79)[a]	NA	4.4	Y	✔	✔	✔	✔		✔	✔	✔
30. Dash diet food	Apple	Mark Patrick Media	12/11/ 2016	2.29	NA	–	–			✔					
31. Dash Diet guide	Apple	Prestige Worldwide Apps LLC	30/9/2015	Free	NA	–	–			✔					
32. Dash Diet Plan - Lower High Blood Pressure Naturally With Dash Diet!	Apple	nipon phuhoi	-	9.99	NA	–	–			✔					
33. Dash diet recipes and more	Apple	Becky Tommervik	-	1.09	NA	–	–			✔					
34. DASH-Sodium Diet App Bundle	Apple	First Line Medical Communications Ltd	-	7.99	NA	–	–	✔		✔					

35. Diet and Hypertension	Apple	SoftPsych LLC	-	4.99	NA	–	–			✔					
36. Easy blood pressure	Apple	Seaside apps	14/1/2016	0.99	NA	–	–	✔							✔
37. Easy Blood Pressure Diary	Apple	SILECI	23/1/2016	Free	NA	–	–	✔							
38. ESH Care	Apple	YouCo	2/12/2015	Free	NA	NR	Y	✔	✔	✔					
39. Fast BP –Blood Pressure Log & Track	Apple	Christion Richert	18/12/2015	0.99	NA	3.7	N	✔	✔		✔			✔	✔
40. HeartStar BP Monitor	Apple	Pattern Health	19/10/2017	Free	NA	3.8	Y	✔	✔		✔			✔	✔
41. Hemie	Apple	Creative Studio	-	Free	NA	NR	N	✔	✔	✔	✔				
42. High Blood Pressure Symptoms	Apple	Chris Bechard		Free (1.99)[a]	NA	–	–			✔					
43. High blood pressure Symptoms	Apple	Chris Bechard	-	Free (2.29)[a]	NA	–	–			✔					
44. High blood pressure Symptoms & BP	Apple	Venture Technology Ltd	28/11/2015	Free	NA	–	–			✔					
45. High blood presure	Apple	Personal Remedies, LLC	17/6/2016	3.49	NA	–	–			✔					
46. HoMedic	Apple	HoMedics	3/11/2016	Free	NA	1.5	Y	✔	✔	✔	✔				
47. How to lower blood pressure	Apple	globalappz	22/9/2016	3.49	NA	–	–			✔					
48. Hypertension BP	Apple	Manal Abuelazem	-	2.99	NA	–	–			✔					
49. HypertensionHealth	Apple	Les Labortires Service	-	Free	NA	–	–			✔		✔			
50. iBP Blood Pressure	Apple	Leading Edge Apps LLC	16/5/2016	0.99	NA	–	–	✔			✔				✔
51. iFORA BP	Apple	ForaCare Inc.	18/11/2017	Free	NA	–	–	✔			✔				✔
52. Iscian health	Apple	HONSUN (Nantong) Co., ltd	17/11/2016	Free	NA	–	–	✔			✔				
53. John Carberry high blood pressure	Apple	John Carberry	18/2/2016	4.49	NA	–	–			✔					
54. Kang BP	Apple	kangkang	9/12/2015	Free	NA	NR	N	✔	✔		✔	✔		✔	
55. LifeCourse HyTen	Apple	PInCH Medical Systems Limited	26/10/2016	Free	NA	NR	Y	✔	✔	✔	✔				

56. Low Sodium Foods	Apple	Nasir Hussain	5/6/2017	Free	NA	–	–			✓					
57. Managing blood pressure	Apple	Semos & Co.	1/7/2016	4.49	NA	–	–			✓					
58. MedM Blood Pressure	Apple	MedM Inc	21/11/2017	Free	NA	–	–	✓			✓				✓
59. Medmobile (en)	Apple	medmobile	27/10/2017	Free	NA	–	–	✓			✓				
60. Microlife Connected Health	Apple	Microlife Corp.	19/8/2017	Free	NA	–	–	✓							✓
61. Monitor My BP	Apple	APG Solutions, LLC	3/11/2017	Free (0.99)[a]	NA	–	–	✓	✓						✓
62. My Blood Pressure Readings	Apple	Puig Labs	31/3/2016	Free	NA	–	–	✓	✓						✓
63. My medication journal	Apple	Ara Wolf	11/4/2015	0.99	NA	–	–	✓	✓						
64. MyBloodWorks	Apple	Gogle LLC.	18/9/2015	3.49	NA	–	–	✓							
65. Naturally Reduce Blood Pressure Guide and Tips	Apple	Xin Tan		3.49	NA	–	–			✓					
66. Normal Blood pressure - How to reduce	Apple	Venture Technology	25/5/2017	Free	NA	–	–			✓					
67. Nutrition Hypertension	Apple	BulitByDoctors	8/1/2017	Free	NA	–	–			✓					
68. Nutrition Wise	Apple	Consultation Massawippi	22/9/2017	2.29	NA	–	–			✓					
69. Potassium Counter & Tracker for Healthy Food Diets	Apple	First Line Medical Communications Ltd	5/7/2017	4.99	NA	–	–	✓		✓					
70. Pukono	Apple	Fundació Althaia	13/7/2017	Free	NA	–	–			✓					
71. Qardio heart health	Apple	Qardio, Inc.	17/6/2016	Free	NA	NR	Y	✓	✓		✓				✓
72. Sodium Counter and Tracker for Healthy Food Diets	Apple	First Line Medical Communications Ltd	5/7/2017	4.99	NA	–	–	✓		✓					
73. Sodium Cravings – Control blood pressure with Sodium Tracker that manages salt food craving and enables healthy food choices	Apple	Blue Eyes Innovation LLC	17/6/2015	2.29	NA	–	–	✓	✓						

74. Sodium In Foods	Apple	Nassir Hussain	15/1/2018	Free	NA	–	–			✔					
75. Stress releaser	Apple	Jim Lu	20/11/2017	0.99	NA	–	–						✔		
76. Systolic - Blood Pressure Made Simple	Apple	Ford Parsons	-	Free	NA	–	–	✔			✔				
77. Tensio	Apple	humetrix.com	31/10/2017	7.99	NA	–	–	✔		✔	✔			✔	✔
78. The Best Blood pressure monitor	Apple	A Cultivated Mindset, Inc	20/7/2015	2.29	NA	–	–	✔			✔				✔
79. Track my BP	Apple	New World Monkeys, LLC	21/8/2015	1.99	NA	–	–	✔							✔
80. ZOI Health - Your Personal Health Coach	Apple	PI Venture LLC, The	9/5/2017	9.99	NA	–	–			✔		✔			
81. ABC of Hypertension, 6th Edit	Google Play	Indextra AB	25/4/2017	16.99	1 - 5	–	–			✔					
82. Afya Pap	Google Play	Afya Pap	8/3/2017	Free	1,000 - 5,000	–	–	✔		✔					
83. Animated Atlas of Hypertension	Google Play	Focus Medica India Pvt. Ltd	23/11/2014	Free (10.99 - 21.23)[a]	5,000 - 10,000	–	–			✔					
84. Best Diet	Google Play	Moe Game	19/6/2017	Free	500 - 1,000	–	–			✔					
85. Best natural Herbs For High blood Pressure	Google Play	Obgynapps	19/11/2017	Free	1,000 - 5,000	–	–			✔					
86. Blood Pressure	Google Play	SiKni8	27/3/2016	0,59	10 - 50	–	–	✔		✔					
87. Blood Pressure (SmartBP)	Google Play	evolvemedsys	8/11/2017	1.28	50,000 - 100,000	–	–	✔							✔
88. Blood Pressure Calculator	Google Play	Center for Research and Knowledge	2/6/2015	Free	500 - 1,000	–	–	✔	✔						
89. Blood Pressure Diary	Google Play	FRUCT	13/2/2018	Free (1.29 - 1.32)[a]	500,000 - 1,000,000	4.1	Y	✔	✔		✔				
90. Blood Pressure easy pro	Google Play	nockilllikout lindefol	-	Free	10,000 - 50,000	–	–	✔							
91. Blood pressure finger print scanner	Google Play	-	9/7/2017	Free	100 - 500	–	–	✔							
92. Blood Pressure Guide	Google Play	Anil	3/12/2014	Free	1,000 - 5,000	–	–			✔					

93. Blood Pressure Guide	Google Play	Nicholas Gabriel	20/11/2016	Free	500 - 1,000	–	–			✔					
94. blood pressure healthy Plus	Google Play	tdtomlou	7/2/2016	1.68	10 - 50	–	–	✔							✔
95. Blood Pressure Logger	Google Play	Time2Relax	18/10/2013	Free	5,000 - 10,000	–	–	✔			✔				✔
96. Blood Pressure Manager	Google Play	Nanjing Yuyue Software Technology Co.,Ltd	19/1/2018	Free	10 - 50	–	–	✔							
97. Blood Pressure manager	Google Play	ne.nemui	30/1/2016	Free	100,000 - 500,000	–	–	✔							✔
98. Blood Pressure Monitor	Google Play	Timevy	20/5/2017	Free	500 - 1,000	–	–	✔		✔					
99. Blood Pressure Monitoring	Google Play	Juan B and Juan H Android Developmen t	20/9/2015	Free	5,000 - 10,000	–	–	✔							✔
100. Blood Pressure Pro	Google Play	abletFactory	9/8/2013	2,38	100 - 500	–	–	✔							✔
101. Blood Pressure Symptoms	Google Play	vmappsoft.c om	-	Free	500 - 1,000	–	–			✔					
102. Blood Pressure Tracker	Google Play	aadhk	12/2/2017	8.99	100 - 500	–	–	✔							✔
103. Blood Pressure Tracker	Google Play	mallikarjunu du chittari	8/11/2017	Free	1,000 - 5,000	–	–	✔							✔
104. Blood Pressure(BP) Diary	Google Play	openit Inc.	6/9/2016	Free (1.49)[a]	1,000,000 - 5,000,000	3.8	Y	✔	✔		✔			✔	✔
105. Blood Pressure(BP) Report Lite	Google Play	TriStarApps	8/2/2012	Free	10,000 - 50,000	–	–	✔			✔				✔
106. BloodPressureDB	Google Play	Horst Klier	4/3/2017	Free	100,000 - 500,000	–	–	✔	✔						✔
107. BP Tracker	Google Play	Guangdong Biolight Meditech Co., Ltd.	19/9/2017	Free	1,000 - 5,000	–	–	✔		✔					
108. BP treatment no net	Google Play	abdo.apps	15/1/2018	Free	5,000 - 10,000	–	–			✔					
109. bpresso PRO	Google Play	Freshware	8/1/2017	4,89	1,000 - 5,000	4.4	N	✔	✔		✔			✔	✔
110. Braun Healthy Heart	Google Play	Kaz USA, Inc.	31/10/2015	Free	10,000 - 50,000	2.1	Y	✔	✔	✔	✔		✔		

111. Caracal	Google Play	Caracal	12/10/2017	Free	100 - 500	–	–	✔							✔
112. Cardio journal - Blood pressure diary	Google Play	mEL Studio	6/2/2017	Free (1.99 - 8.99)[a]	10,000 - 50,000	4.7	Y	✔	✔	✔	✔				✔
113. Complications of Hypertension	Google Play	Focus Medica India Pvt. Ltd	31/10/2017	Free (7.49)[a]	10 - 50	–	–			✔					
114. Control High Blood Pressure	Google Play	StatesApps	6/1/2018	Free	1,000 - 5,000	–	–			✔					
115. Control Tension	Google Play	Les Laboratoires Servier	6/4/2017	Free	-	NR	N	✔	✔	✔					✔
116. DASH Diet	Google Play	Chelin Apps	31/5/2017	Free	10,000 – 50,000	–	–			✔					
117. DASH Diet	Google Play	Nisarg D Parekh	1/1/2018	0.99	100 - 500	–	–			✔					
118. Dash Diet	Google Play	DashDietApps	18/3/2017	Free	100 - 500	–	–			✔					
119. Dash Diet	Google Play	DROPSOFT	4/10/2017	Free	50 - 100	–	–			✔					
120. DASH Diet 5 Days Meal Plan	Google Play	Gtype	12/2/2017	Free	500 - 1,000	–	–			✔					
121. Dash Diet Dynamite	Google Play	Nicole Woodinville	9/6/2016	Free	100 - 500	–	–			✔					
122. Dash Diet For Balanced Weightloss	Google Play	Diet Pundits	14/7/2016	Free	1,000 - 5,000	–	–			✔					
123. Dash Diet Guide	Google Play	Prestige Worldwide Apps, Inc	1/10/2015	Free	5,000 - 10,000	–	–			✔					
124. DASH Diet Meal Plan Recipes : Healthy, Weight Loss	Google Play	Edutainment Ventures-Making Games People Play	18/10/2017	Free (0.89 - 1.39)[a]	10 - 50	–	–			✔					
125. DASH Diet Plan	Google Play	Health Experts	26/3/2016	Free	10,000 - 50,000	–	–			✔					
126. DASH Diet Plan	Google Play	Bubble Shooting	14/7/2016	Free	500 - 1,000	–	–			✔					
127. Diabetes & Blood Pressure Log	Google Play	Cooey Technologies	30/3/2015	Free	100,000 - 500,000	–	–	✔	✔						✔
128. Diet Plan For Hypertension	Google Play	cvsilamedia.id	-	Free	1 - 5	–	–			✔					
129. Diet Plan Recipes	Google Play	hara5b68s	26/3/2015	Free	500 - 1,000	–	–			✔					
130. DynaPulse® PLUS	Google Play	Preventagen, Inc.	24/10/2016	Free	100 - 500	–	–	✔							

131. ESH CARE	Google Play	YouCo	15/11/2017	Free	10,000 - 50,000	2.5	N	✔	✔	✔					✔
132. Exercise Hypertension	Google Play	Built by Doctors World Ltd	19/12/2017	Free	100 - 500	–	–			✔					
133. Finger Blood pressure pro	Google Play	Nicolas Apps	5/1/2016	Free	10,000 - 50,000	–	–	✔							
134. Goal Achiever	Google Play	Techizer Tech Solutions Pvt Ltd	28/8/2017	Free	500 - 1,000	4.5	N	✔	✔	✔	✔				✔
135. Health Report Daily	Google Play	Elapse Technologies	27/6/2017	1.89	10,000 - 50,000	–	–	✔							✔
136. Health, Nutrition & Diet Guide	Google Play	Organic Facts	16/1/2018	Free	100,000 - 500,000	–	–			✔					
137. Healthy Heart	Google Play	Neha Sethi	1/3/2017	Free	50 - 100	–	–			✔					
138. Heart Care - All In 1	Google Play	smart vue	23/9/2017	Free	100 - 500	–	–	✔		✔					
139. High Blood Pressure	Google Play	Free Apps For Everyone	31/5/2017	Free	100-500	–	–			✔					
140. High Blood Pressure	Google Play	bluebirdmedia	5/1/2015	Free	500 - 1,000	–	–			✔					
141. High Blood Pressure	Google Play	Dev Galaxy Store	27/8/2017	Free	1 – 5	–	–			✔					
142. High Blood Pressure	Google Play	Personal Remedies LLC	15/6/2016	2,79	10 - 50	–	–			✔					
143. High Blood Pressure - The 101 Guide	Google Play	harrison.apps	282017/12/	Free	5-10	–	–			✔					
144. High Blood Pressure Diet Tips	Google Play	Data Recovery Software by RecoveryBull.com	20/2/2017	Free (2.19 - 21.99)[a]	10,000 - 50,000	–	–			✔					
145. High Blood Pressure In English	Google Play	COMPRINT	15/6/2016	Free	50 - 100	–	–			✔					
146. High Blood Pressure Pro	Google Play	showartzz	1/6/2016	Free	1 – 5	–	–			✔					
147. High Blood Pressure Symptoms	Google Play	Life Hack Studio	12/2/2018	Free	500 - 1,000	–	–			✔					
148. High Blood Pressure Symptoms	Google Play	Revolxa Inc	5/7/2017	Free	1,000 - 5,000	–	–			✔					
149. High Blood Pressure Symptoms	Google Play	Flames Dev Studio	5/4/2017	Free	10,000 - 50,000	–	–			✔					

150. High Blood Pressure Treatment	Google Play	shubh.techd	-	Free	1,000 - 5,000	–	–			✔					
151. High BP Hypertension Diet High Blood Pressure Help	Google Play	SendGroupSMS.com Bulk SMS Software	21/11/2017	Free 2.99 - 22.49)[a]	100 - 500	–	–			✔					
152. How To Lower Blood Pressure	Google Play	The Almighty Dollar	7/8/2017	Free	100 - 500	–	–			✔					
153. HyperHealth	Google Play	LES LABORATOIRES SERVIER	19/8/2016	Free	100 - 500	–	–			✔					
154. Hypertension	Google Play	MMI	9/9/2015	Free	100 - 500	–	–			✔					
155. Hypertension (An Overview)	Google Play	Focus Medica India Pvt. Ltd	26/10/2017	6.49	100 - 500	–	–			✔					
156. Hypertension Advisor	Google Play	shaon.cpp	16/5/2014	Free	1,000 - 5,000	–	–	✔			✔				
157. Hypertension and treatment	Google Play	mircica	-	0.85	10 - 50	–	–	✔			✔				
158. Hypertension Drugs Dictionary	Google Play	alexeykharchenko	-	Free	50,000 - 100,000	–	–			✔					
159. Hypertension guideline check	Google Play	academy.de	-	Free	1,000 - 5,000	–	–	✔			✔	✔			
160. Hypertension Hi blood pressure	Google Play	twayesh	-	Free	100,000 - 500,000	–	–			✔					
161. Hypertension Management	Google Play	wonderfullife.develloper	-	Free	1,000 - 5,000	–	–	✔							
162. Hypertension management	Google Play	Benson Media	24/2/2017	Free	1,000 - 5,000	–	–			✔					
163. Hypertension Protocols	Google Play	Dr.Isaac's Holistic Wellness	3/12/2017	Free	500 - 1,000	–	–			✔					
164. Hypertension Symptoms	Google Play	ketopoxstudio.inc	18/6/2016	Free	5-10	–	–			✔					
165. Hypertension Treatment JNC 8	Google Play	ahscbc	-	Free	10,000 - 50,000	–	–	✔			✔				
166. iBP Blood Pressure	Google Play	Leading Edge Apps LLC	30/11/2014	0,62	10,000 - 50,000	–	–	✔			✔				✔
167. KKM/BKP Hypertension CPG QR	Google Play	KKM/BKP	30/12/2014	Free	100 - 500	–	–			✔					
168. Know Hypertension	Google Play	Dr. Rabi Ekore	22/2/2017	Free	100 - 500	–	–			✔					

169. LifeCourse HyTen	Google Play	PInCH Medical Systems Limited	26/10/2016	Free	1 – 5	5.0	Y	✔	✔	✔	✔				
170. Lower Blood Pressure Foods	Google Play	FreeAppsForAll	25/3/2016	Free	5,000 - 10,000	–	–			✔					
171. Manage your Hypertension five	Google Play	epat.mobi	3/1/2017	Free	50 - 100	–	–	✔		✔					
172. Manage Your Hypertension Four	Google Play	epat.mobi	-	Free	50 - 100	–	–		✔	✔					
173. Manage your Hypertension six	Google Play	Epat Lda	7/12/2016	Free	50 - 100	–	–			✔					
174. Manuel hypertension artérielle	Google Play	TEMPO MEDICAL INTERNATIONAL	7/12/2015	Free	1-5	–	–			✔					
175. My Food Coach	Google Play	National Kidney Foundation	1/3/2016	Free	10,000 - 50,000	–	–			✔					
176. My heart	Google Play	Klimaszewski Szymon	25/1/2018	Free (1.29 - 3.09)[a]	5,000,000 - 10,000,000	4.2	Y	✔	✔		✔				✔
177. Nutrition Hypertension	Google Play	Built by Doctors World Ltd	9/11/2016	Free	100 - 500	–	–			✔					
178. Overcome hypertension	Google Play	fejriidroid	28/3/2017	Free	100 - 500	–	–			✔					
179. Paracelsus (Pressure control)	Google Play	Medical software of Ukraine	3/10/2016	Free	5,000 - 10,000	3.7	Y	✔	✔	✔					✔
180. Pukono	Google Play	Fundació Althaia	12/7/2017	Free	10,000 - 50,000	–	–			✔					
181. Qardio Heart Health	Google Play	Qardio, Inc.	14/12/2017	Free	100,000 - 500,000	4.4	Y	✔	✔		✔				
182. Reducing Blood Pressure	Google Play	Quilckredapps	27/2/2016	Free	50 - 100	–	–			✔					
183. SA Hypertension	Google Play	Appenberg Digital Publishing	15/1/2016	Free	100 - 500	–	–			✔					
184. Tips for Lowering High Blood	Google Play	sidikdroid	NR	Free	1,000 - 5,000	–	–			✔					
185. Tips to Overcom High Naturally	Google Play	Sutriyanidroid	23/12/2016	Free	500 - 1,000	–	–			✔					
186. Vital Tones Hypertension Pro	Google Play	Vital Tones	13/12/2017	9.99	5 - 10	–	–			✔			✔		

[a] The app was free to download, but require subscription fees; [b]NR, not reported; [c]NA: not applicable; [d]_: the privacy assessment was not carried out/ the app user rating was not extracted; [e]Y: the app had an available privacy policy without the need to download it; [f]N: the app did not have a privacy policy.

Appendix 10 Consent Form (English version)

Doctors participant consent form Version: V2
"Patient and doctor attitudes toward the use of apps to support the self-management of hypertension in Saudi Arabia" Consent Form

Please tick the appropriate boxes	**Yes**	**No**
Taking Part in the Project		
I have read and understood the project information sheet dated DD/Dec/2018 or the project has been fully explained to me. (If you will answer No to this question please do not proceed with this consent form until you are fully aware of what your participation in the project will mean.)	☐	☐
I have been given the opportunity to ask questions about the project.	☐	☐
I agree to take part in the project. I understand that taking part in the project will include being interviewed and being audio recorded and an anonymised transcript will be made by a professional service in Saudi Arabia to ensure accuracy.	☐	☐
I understand that my taking part is voluntary and that I can withdraw from the study before my data has been analysed [usually one week after interview]; I do not have to give any reasons for why I no longer want to take part and there will be no adverse consequences if I choose to withdraw.	☐	☐
How my information will be used during and after the project		
I understand my personal details such as name, phone number, age and email address etc. will not be revealed to people outside the project.	☐	☐
I understand and agree that my words may be quoted in publications, reports, web pages, and other research outputs. I understand that I will not be named in these outputs unless I specifically request this.	☐	☐
I understand that my data will be securely retained by the University of Sheffield through the PhD research period and after all expected publications are performed (for 3 years).	☐	☐
So that the information you provide can be used legally by the researchers		
I agree to assign the copyright I hold in any materials generated as part of this project to The University of Sheffield.	☐	☐

Name of participant [printed]	Signature	Date
Name of Researcher [printed]	Signature	Date

Project contact details for further information:

Name		**Phone**	**Email**
Tourkiah Alessa	Researcher	0114 222 5426	talessa1@sheffield.ac.uk
Mark Hawley	Co-supisover	0114 222972	mark.hawley@sheffield.ac.uk
Luc de Witte	Supervisor	114 222 8277	l.p.dewitte@sheffield.ac.uk
John Brazier	Dean of ScHARR		j.e.brazier@sheffield.ac.uk
Address	ScHARR, 30 Regent Street, Sheffield S1 4DA		

.

Appendix 11 Consent Form (Arabic version)

استمارة موافقة مشارك الأطباء الإصدار نسخه ٢
"مواقف المرضى والطبيب تجاه استخدام التطبيقات لدعم الإدارة الذاتية لارتفاع ضغط الدم في المملكة العربية السعودية"
(نموذج الموافقة)

يرجى وضع علامة في المربعات المناسبة	نعم	لا
المشاركة في الدراسة		
لقد قرأت وفهمت ورقة معلومات المشروع بتاريخ ... / ديسمبر / 2018 وتم شرح المشروع بالكامل لي. (إذا كنت ستجيب ب (لا) على هذا السؤال، يرجى عدم المضي قدمًا في نموذج الموافقة هذا حتى تكون على علم تام بما ستعنيه مشاركتك في الدراسة)	☐	☐
لقد أتيحت لي الفرصة لطرح الأسئلة حول الدراسة.	☐	☐
أوافق على المشاركة في الدراسة. أدرك أن المشاركة في الدراسة ستشمل إجراء المقابلات والتسجيل الصوتي وسيتم تقديم نسخة مجهولة المصدر من المقابلة الى مكتب الترجمة في المملكة العربية السعودية للترجمة للغة الإنجليزية لضمان الدقة.	☐	☐
أفهم أن مشاركتي هو اختياري وأنني أستطيع الانسحاب من الدراسة قبل تحليل بياناتي [عادة بعد أسبوع واحد من المقابلة]؛ لا يتعين علي إعطاء أي أسباب لماذا لم أعد أرغب في المشاركة ولن تكون هناك عواقب سلبية إذا اخترت الانسحاب.	☐	☐
كيف سيتم استخدام المعلومات الخاصة بي أثناء وبعد المشروع		
آتفهم أن تفاصيلي الشخصية مثل الاسم ورقم الهاتف والعمر وعنوان البريد الإلكتروني وما إلى ذلك لن يتم كشفها للأشخاص خارج الدراسة.	☐	☐
أفهم وأوافق على أنه قد يتم اقتباس كلماتي في المطبوعات والتقارير وصفحات الويب ومخرجات الأبحاث الأخرى. أدرك أنه لن يتم تسميتي في هذه المخرجات إلا إذا طلبت ذلك على وجه التحديد.	☐	☐
أتفهم أنه سيتم الاحتفاظ ببياناتي بشكل آمن من قبل جامعة شفيلد من خلال فترة أبحاث الدكتوراه ولمدة ٣ سنوات بمجرد الانتهاء من جميع المنشورات المتوقعة.	☐	☐
بحيث يمكن استخدام المعلومات التي تقدمها بشكل قانوني من قبل الباحثين		
أوافق على تعيين حقوق الطبع والنشر التي أحملها في أي مواد يتم إنشاؤها كجزء من هذا المشروع لجامعة شفيلد.	☐	☐

[مطبوع]اسم المشارك	[مطبوع] التوقيع	[مطبوع] التاريخ
[مطبوع]اسم الباحث	[مطبوع] التوقيع	[مطبوع] التاريخ

الاسم		الهاتف	البريد الالكتروني
تركيه العيسى	الباحث	٠١١٤٢٠٥٤٢٦	talessa1@sheffield.ac.uk
لوك دي ويت	المشرف	٠١١٤٢٠٨٢٧٧	l.p.dewitte@sheffield.ac.uk
مارك هاولي	المشرف	٠١١٤٢٢٢٨٢٧	mark.hawley@sheffield.ac.uk
جون باريزر	عميد الكلية		j.e.brazier@sheffield.ac.uk

A**ppendix 12** Patients Information Sheet Form (Arabic version)

ورقة معلومات المشاركين لمجموعة التركيز الخاصة بالمرضى: الإصدار 2.

.... /ديسمبر / 2018

عنوان الدراسة: وجهات نظر المريض والطبيب تجاه استخدام تطبيقات ارتفاع ضغط الدم وتقبله في المملكة العربية السعودية

أنت مدعو للمشاركة في الدراسة. قبل أن تقرر ما إذا كنت تريد المشاركة ام لا، من المهم اولا أن تفهم سبب إجراء هذه الدراسة وما الذي ستتضمنه. يرجى قراءة المعلومات التالية بعناية ومناقشتها مع الآخرين إذا كنت ترغب في ذلك. اسألني إذا كان هناك أي شيء غير واضح أو إذا كنت ترغب في مزيد من المعلومات. خذ وقتك لتقرر ما إذا كنت ترغب في المشاركة أم لا

يتم إجراء هذه الدراسة من قبل الباحثة الطالبة، كجزء من مشروع الدكتوراه الخاص بها، من كلية الصحة والأبحاث ذات الصلة (ScHARR) في جامعة شفيلد. يُطلب منك المشاركة في هذه الدراسة.
الهدف العام من هذه الدراسة هو الحصول على نظرة ثاقبة من المرضى الذين يعانون من ارتفاع ضغط الدم، حول مواقفهم ووجهات نظرهم حول استخدامهم لتطبيقات الهواتف الذكية لدعم الإدارة الذاتية لارتفاع ضغط الدم

لماذا تم اختياري؟
لقد طُلب منك المشاركة نظرًا لأهمية آرائك في استكشاف مواقف المرضى تجاه استخدامهم لتطبيقات الهواتف الذكية لدعم الإدارة الذاتية لارتفاع ضغط الدم في المملكة العربية السعودية.
هل يجب علي المشاركة؟
الامر متروك لك فيما إذا كنت ستشارك أم لا. إذا قررت المشاركة، فسيقوم الطالب الباحث بإعطائك ورقة المعلومات هذه لقراءتها والاحتفاظ بها، وسيتم شرح الدراسة لك والإجابة على أسئلتك. سيُطلب منك بعد ذلك التوقيع على نموذج موافقة. ستنعقد المجموعة المركزة في وقت ومكان مناسبين لك داخل المستشفيات أو مراكز الرعاية الأولية. إذا قررت المشاركة، فلا يزال بإمكانك الانسحاب في أي وقت ودون إبداء أسباب.
يمكنك التوقف عن المشاركة في أي وقت عن طريق الاتصال بالباحث الطالب (يرجى الاطلاع على الصفحة ٣ للحصول على تفاصيل الاتصال).
إذا قررت التوقف عن المشاركة، أو كنت غير قادر على الاستمرار، فيمكن سحب أي معلومات تم جمعها منك، حيثما أمكن ذلك، من هذه الدراسة إذا أخبرتنا بذلك. لا يتعين عليك إبداء أي أسباب ولن تكون هناك عواقب سلبية إذا اخترت الانسحاب. ومع ذلك، إذا تم بالفعل إخفاء هويتك وتحليلها، فلن يكون من الممكن للباحث تحديدها على أنها بياناتك أو حذفها.

ماذا يجب على ان افعل؟
سيُطلب منك إكمال استبيان موجز حول بياناتك الشخصية (مثل العمر). ستتاح لك الفرصة لإبداء آرائك حول استخدام تطبيقات الهواتف الذكية لدعم الإدارة الذاتية لارتفاع ضغط الدم من خلال مناقشة مجموعات التركيز التي تتكون من مجموعة من ٦ إلى ٨ مشاركين. في هذه المناقشة، سيتم تقديم خمسة تطبيقات بتنسيق فيديو لاستكشاف وجهات نظرك تجاههم. سيكون هذا بهدف تحديد التطبيق الأنسب للمرضى في سياق المملكة العربية السعودية. ستستمر هذه المناقشة حوالي 90 دقيقة، وسيتم تسجيلها. سيتم استخدام التسجيل الصوتي لمناقشتك فقط لتفريغ الصوت كتابتا.

ماذا سيحدث للتسجيلات الصوتية؟
يمكنك سحب موافقتك قبل التسجيل وأثناء التسجيل وبعده، وسيتم حذف البيانات بشرط عدم بدء التحليل. يمكنك إيقاف التسجيل لأي سبب. سيتم الحفاظ على سرية جميع المعلومات التي تم جمعها للمشروع. سيتم تخزين التسجيلات في مجلد مقيد الوصول على محرك الأقراص الآمن عبر الإنترنت بجامعة شفيلد. سيتم عمل نسخ مجهولة المصدر من هذه التسجيلات باللغة العربية وترجمتها إلى الإنجليزية من قبل الطالب الباحث، وبعد ذلك ستتم ترجمة هذه النسخة المجهولة المصدر إلى اللغة الإنجليزية من خلال خدمة ترجمة احترافية في المملكة العربية السعودية لضمان عدم تغيير المعنى.
سيتم استخدام هذه النسخة المترجمة النهائية لضمان دقة أكبر في التحليل والإبلاغ عن النتائج. سيتم حذف التسجيلات عند الانتهاء من مشروع الدكتوراه.

هي الفوائد أو العيوب المحتملة من المشاركة في هذه الدراسة؟
على الرغم من عدم وجود فوائد مباشرة للمشاركة في هذه الدراسة، فمن المحتمل أن يكون هذا البحث مفيدًا في تعزيز فهم الإدارة الذاتية لمرض الضغط. ستساعد مشاركتك في فهم آراء ومواقف المرضى في المجتمع السعودي المستهدف، مما يؤدي إلى اختيار التطبيق الأنسب للمرضى. قد يكون هذا مفيدًا لهم في المستقبل.
هل هناك أي عيوب للمشاركة وماذا سيحدث لمعلوماتي؟
نعتقد أنه لا توجد مخاطر معروفة مرتبطة بالمشاركة في الدراسة. العيب الوحيد هو استغلال وقتك في المشاركة.
هل ستبقى مشاركتي في هذا المشروع سرية؟

1

سيتم الحفاظ على سرية جميع المعلومات التي يتم جمعها منك خلال هذه الدراسة (البيانات الشخصية والتسجيلات والنصوص) ولن تكون متاحة إلا لفريق الدراسة (الباحثة الطالبة والمشرفون عليها) وسيتم الاحتفاظ بها مجهولة. لن تتمكن من تحديد هويتك في أي تقارير أو منشورات. سيتم التعرف عليك بواسطة رمز وليس اسم. سيتم تخزين أي تسجيلات صوتية والملاحظات المصاحبة بشكل آمن. ومع ذلك، في حالات نادرة (مثل الحماية)، سيكون على القائم بإجراء المقابلة التزامات قانونية تتجاوز اتفاقيات السرية.

ما هو الأساس القانوني لمعالجة بياناتي الشخصية؟
وفقًا لتشريعات حماية البيانات، نحن مطالبون بإبلاغك بأن الأساس القانوني الذي نطبقه من أجل معالجة بياناتك الشخصية هو أن "المعالجة ضرورية لأداء مهمة يتم تنفيذها للمصلحة العامة" (المادة 6 (1)) (هـ)). يمكن العثور على مزيد من المعلومات في إشعار الخصوصية بالجامعة https://www.sheffield.ac.uk/govern/data-protection/privacy/general.
نظرًا لأننا سنجمع بعض البيانات المحددة في التشريع على أنها أكثر حساسية (على سبيل المثال، معلومات عن صحتك)، نحتاج أيضًا إلى إعلامك بأننا نطبق الشرط التالي في القانون: أن استخدام بياناتك هو ضرورية لأغراض البحث العلمي أو التاريخي.
ماذا سيحدث للبيانات التي تم جمعها ونتائج هذه الدراسة؟
سيتم تحديد البيانات التي تم جمعها (بما في ذلك النصوص) بواسطة رمز آمن ولا يمكن الوصول إليها إلا من قبل أعضاء فريق الدراسة بالجامعة، الذين سيعالجونها ويحللونها في التقارير. سيتم تخزين جميع البيانات في محرك أقراص جامعي آمن لا يمكن الوصول إليه إلا من قبل أعضاء فريق الدراسة بجامعة شفيلد. سيتم حذف التسجيلات الصوتية بعد الانتهاء من مشروع الدكتوراه.
سيتم حذف النصوص المجهولة بعد ٣ سنوات وبمجرد الانتهاء من جميع المنشورات.
سيتم نشر نتائج هذه الدراسة، بما في ذلك الملخص العام، في تقرير. يمكن أيضًا استخدام النتائج للمخرجات الأكاديمية الأخرى، مثل عروض المؤتمرات والمقالات الصحفية. لن يكون من الممكن التعرف عليك في أي نتائج تم نشرها.
من يقوم بتنظيم وتمويل الدراسة؟
تأسست الدراسة من قبل هيئة الثقافة السعودية. يتم إجراء الدراسة من قبل طالب الدكتوراه في كلية الصحة والبحوث ذات الصلة (ScHARR)، جامعة شفيلد.
من هو مراقب البيانات؟
ستكون جامعة شفيلد بمثابة مراقب البيانات لهذه الدراسة. هذا يعني أن الجامعة مسؤولة عن العناية بمعلوماتك واستخدامها بشكل صحيح.
من قام بمراجعة الدراسة أخلاقيا؟
تمت الموافقة على هذا المشروع أخلاقياً من خلال إجراء مراجعة الأخلاقيات بجامعة شفيلد، كما تديره كلية الصحة والبحوث ذات الصلة، ولجنة الأخلاقيات بوزارة الصحة.
ماذا لو حدث خطأ ما أو أردت المزيد من المعلومات؟
إذا كانت لديك أسئلة أو مخاوف بشأن هذه الدراسة، فلا تتردد في الاتصال ب

الباحث الطالب: تركيه العيسى البريد الالكتروني: Talessa1@sheffield.ac.uk
رقم الجوال: ٠٠٩٦٦٥٥٩٣٤٦٧١١

إذا كانت لديك أي شكاوى ، فيرجى الاتصال بأحد فريق الدراسة من الجامعة في المقام الأول
مشرف البحث: لوك دي ويت البريد الالكتروني: l.p.dewitte @sheffield.ac.uk
رقم الجوال: ٠٠٤٤٧٨٥٠٠٧٦٤٧٨

إذا كنت لا تزال غير راض، فيمكنك الاتصال بعميد الجامعة لكلية الصحة والأبحاث ذات الصلة:
جون برازير البريد الإلكتروني : j.e.brazier@sheffield.ac.uk
الهاتف:٠١١٤٢٢٢٠٧٢٦
إذا كانت هناك شكوى تتعلق بكيفية التعامل مع بياناتك الشخصية، فيمكنك الاتصال بـ انى كولتر ، مسؤولة حماية البيانات بجامعة شفيلد dataprotection@sheffield.ac.uk

إذا كنت تشعر بأنك بحاجة الى التحدث الى شخص ما عن أي القضايا التي تمت مناقشتها في المقابلة أو أي دعم إضافي يرجى الاتصال مقدم الرعاية الصحية الخاص بك كما هو مذكور أدناه

2

مدينة الملك فهد الطبية
البريد الالكتروني: Researchcenter@kfmc.med.sa
الهاتف: 0112889999
مستشفى الملك خالد الجامعي (روبينا ديومبو)
البريد الالكتروني: Rdeocambo@KSU.edu.sa هاتف: 0114670011 بريد إلكتروني
مراكز الرعاية الأولية (هشام محمد)
البريد الالكتروني: Research@moh.gov.sa هاتف: 0112125050 بريد الكتروني

شكرا جزيلا لقراءتك هذه الورقة

3

Appendix 13 Patients Information Sheet Form (English version)

Participant Information Sheet for patients focus group: Version 1.
DD/December/2018

Study title: Patient and doctor attitudes towards, and acceptance of, the use of hypertension apps in Saudi Arabia

You are being invited to take part in the study. Before you decide if you want to take part, it is important that you understand why this study is being done and what it will involve. Please read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

This study is being conducted by the student researcher, as a part of her PhD project, from the School of Health and Related Research (ScHARR) at the University of Sheffield. You are being asked to participate in this study.

The overall aim of this study is to capture insight from the patients with hypertension, on their attitudes toward and views of their use of smartphone apps to support the self-management of hypertension.

Why have I been chosen?

You have been asked to take part due to the importance of your views in exploring patients attitudes toward their use of smartphone apps to support the self-management of hypertension in Saudi Arabia.

Do I have to take part?

It is up to you whether or not to take part. If you do decide to take part, the student researcher will give you this information sheet to read and keep, and the study will be explained to you and your questions will be answered. You will then be asked to sign a consent form. The focus group will take place at a time and place convenient for you within the hospitals or primary care centers. If you decide to take part you are still free to withdraw at any time and without giving a reason.

You can stop taking part at any time by contacting the student researcher (please see page 3 for contact details).

If you do decide to stop taking part, or are unable to continue, any information collected from you, wherever possible, can be withdrawn from this study if you tell us so. You do not have to give any reasons and there will be no adverse consequences if you choose to withdraw. However, if your data has already been anonymised and analysed it will not be possible to identify it as yours or delete it.

What do I have to do?

You will be asked to complete a brief questionnaire about your personal details (e.g., age). You will have an opportunity to give your views about the use of smartphone apps to support the self-management of hypertension through focus groups discussion consisting of a range from 6 to 8 participants. In this discussion, you will be presented five apps in a video format to explore your views toward them. This will be with the aim of identifying the most suitable app for patients within the Saudi Arabian context. This discussion will last about 90 minutes, and will be recorded. The audio recording of your discussion will be used only for transcribing.

What will happen to the audio recordings?

You may withdraw your consent before, during and after the recording, and data will be destroyed providing analysis has not begun. You can stop the recording for any reason. All information collected for the project will be kept confidential. The recordings will be stored in a password protected folder on the University of Sheffield's secure online drive. Anonymised transcripts will be made from these recordings in Arabic and translated into English by the student researcher, and this anonymised transcript will then be translated back into English by a professional translation service in Saudi Arabia to ensure that the meaning has not altered.

This final translated version will be used to ensure greater accuracy in analysis and the reporting of findings. The recordings will be deleted at the completion of the PhD project.

What are the possible benefits or disadvantages of taking part?

While there are no direct benefits of taking part in this study, this research is potentially useful in advancing understanding of the modern management of hypotension. Your involvement will help to understand the views and attitudes of patients in the target Saudi population, resulting in the selection of the most suitable app for patients. This could be of potential benefit to them in the future.

Are there any disadvantages of taking part and what will happen to my information?

We believe there are no known risks associated with participating in the study. The only disadvantage is the use of your time in taking part.

Will my taking part in this project be kept confidential?

All information which is collected from you during this study will be anonymous and will be kept confidential and will only be accessible to the study team (the student researcher and her supervisors). You will not be able to be identified in any reports or publications. You will be identified by a code rather than a name. Any audio recordings and accompanying notes will be stored securely. However, in rare situations (such as safeguarding), the interviewer will have legal obligations that override confidentiality agreements.

What is the legal basis for processing my personal data?

According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)). Further information can be found in the University's Privacy Notice https://www.sheffield.ac.uk/govern/data-protection/privacy/general.

As we will be collecting some data that is defined in the legislation as more sensitive (e.g., information about your health), we also need to let you know that we are applying the following condition in law: that the use of your data is 'necessary for scientific or historical research purposes'.

What will happen to the data collected and the results of this study?

The data collected (including the transcripts) will be identified by a secure code and only accessed by members of the University study team, who will process and analyse it in reports. All data will be stored within a secure University drive that will only be accessed by members of the University of Sheffield study team. Audio recordings will be deleted after the completion of the PhD project. Anonymous transcripts will be deleted after 3 years and once all publications are finished.

The results of this study, including a lay summary, will be published in a report. The results might also be used for other academic outputs, such as conference presentations and journal articles. It will not be possible to identify you in any results that are published.

Who is organising and funding the study?

The study is founded by Saudi Culture Bureau. The study is carried out by the PhD student at the School of Health and Related Research (ScHARR), University of Sheffield.

Who is the Data Controller?

The University of Sheffield will act as the Data Controller for this study. This means that the University is responsible for looking after your information and using it properly.

Who has ethically reviewed the study?

This project has been ethically approved via the University of Sheffield's Ethics Review Procedure, as administered by the School of Health and Related Research, and the MOH ethics committee.

What if something goes wrong or I want more information?

If you have questions or concerns with this study, please feel free to contact the student researcher at:

- Tourkiah Alessa, the student researcher **Email**: talessa1@sheffield.ac.uk
  Phone: +9665599346711

If you have any complaints, please contact one of the study team from the University in the first instance

- Luc de Witte, the research supervisor **Email:** l.p.dewitte@sheffield.ac.uk
  Phone: +44 (0) 7850076478

If you are still not satisfied, contact the University's Dean of the School for Health and Related Research: John Brazier, Dean of ScHARR 0114 222 0726 (email:) j.e.brazier@sheffield.ac.uk
If a complaint relates to how your personal data has been handled, you can contact Anne Cutler, The University of Sheffield Data Protection Officer dataprotection@sheffield.ac.uk

If you feel you need to talk to someone about any issues discussed in the interview or for any additional support please contact your healthcare provider as mentioned below.

King Fahad medical city (KFMC):

- **Tel**: 0112889999 **Email:** Researchcenter@kfmc.med.sa

King Khalid University Hospital (KKUH):

- **Robina Deombo Tel:** 0114670011 **Email:** Rdeocambo@KSU.edu.sa

Primary care centers

- **Hesham Mohammed Tel:** 0112125050 **Email :** Research@moh.gov.sa

Thank you very much for reading this.

Appendix 14 Questionnaire for Focus group

Please answer the following questions:

1- **How old are you?**

   a. 18-30 years
   b. 31-40 years
   c. 41-50 years
   d. 51-60 years
   e. >61 years

2- **Please state your gender**

   a. Female
   b. Male

3- **What is your education level?**

   a. Less than High School Diploma
   b. High School Diploma
   c. Bachelor's Degree
   d. Master's Degree
   e. Doctorate
   f. Other ……………

4- **Do you own/use a smartphone?**

   a. Yes
   b. No

- **If you answered yes to 4, what is the Smartphone operating system?**

   a. iPhone
   b. Android
   c. Others …………

5- **How long have you suffered from hypertension?**

   a. Less than one year
   b. 1-3 years
   c. more than three years

6- **What is your blood pressure classification?**

   a. Stage 1 hypertension
   b. Stage 2 hypertension
   c. Stage 3 hypertension

الرجاء الاجابة على الأسئلة التالية :

١-كم عمرك؟

ا. 18-30 سنة
ب. 31-40 سنة
ج. 41-50 سنة
د. 51-60 سنة
ه. > 61 سنة

٢- اختر نوع جنسك

ا. أنثى
ب. ذكر

٣- ما هو مستواك التعليمي؟

1) ا. أقل من شهادة المدرسة الثانوية
2) ب. شهادة المدرسة الثانوية
3) ج. درجة البكالوريوس
4) د. ماجستير
5) ه. دكتوراه
6) آخرى……………

٤- هل تملك/تستخدم هاتف ذكي؟

ا. نعم
ب. لا

- إذا أجبت بنعم على ٤ فما هو نظام تشغيل الهاتف الذكي؟

ا. آيفون
ب. اندرويد
ج. آخرى……………

٥- منذ متى وأنت تعاني من ارتفاع ضغط الدم؟

ا. أقل من سنة واحدة
ب. 1-3 سنوات
ج. أكثر من ثلاث سنوات

٦- ما هو تصنيف ضغط الدم لديك؟

ا. المرحلة 1 ارتفاع ضغط الدم
ب. المرحلة 2 من ارتفاع ضغط الدم
ج. المرحلة 3 ارتفاع ضغط الدم

Appendix 15 Focus Group Topic guide

Black-questions to be ask participants, Blue- possible probes and my idea that may explored further.

1. In your experience, how do you manage/self-mange your hypertension?

    a. *How often do you check your BP?*
    b. *What actions if any do you take in response to your blood pressure Readings?*
    c. *What other self-management strategies or skills have you adopted to control your blood pressure, and how? (for example, trying to eat a healthy diet, or taking exercise).*
    d. *What problems are you facing in adopting self-management strategies? Please provide details.*

2. How knowledgeable are you about hypertension, e.g. what the risks are?

3. Can you please tell me about your **experience** of using mobile applications (e.g.,"apps")?
    a. Have you ever used an app for any purpose? Provide details.
    b. What were the reasons for using the app that you mentioned? If applicable

4. Have you ever used an app for managing your hypertension? Why/Why not?

5. What do you feel are the potential benefits of using mobile apps to support the self-management of hypertension?

6. What are the potential limitations of, or barriers to, using mobile apps to support the self-management of hypertension?

    a. *Can you tell me about any concerns you had about the use of mobile apps?*

The patients will be given a demonstration of the five apps supporting the self-management of hypertension. The video will then demonstrate how each app works and its functionalities, such as self-monitoring BP, reminders and feedback. The following questions will be asked for each app after stopping the video:

7. Could you describe in as much detail as possible how satisfied you are with the app? Why?
    a. *How useful did you find it? Why/Why not?*
    b. *How easy was it to use the app to self-manage hypertension?*
    c. *How confident do you feel that you could successfully self-manage your hypertension using this app?*

8. What are the potential benefits you might expect from using this app to support the self-management of hypertension?

9. What are the potential limitations of, or barriers to, using this app to support the self-management of hypertension?
    a. Can you tell me about *the use of mobile apps in your home? Please explain*
    b. *How important is it for you to check the credibility of a mobile app's information source (content source, who created it)? If applicable*
10. How likely would you be to use a mobile app? Please explain your answer.
    a. *Are there any other features that you think should be considered to increase your willingness to use a mobile app? What they are? and how would they help you?*

11. Would you recommend this app for your friends or families? Why/Why not?
12. Do you think you may need training to use a mobile app like this? Why/why not?
13. Do you have any questions about the app?
14. Please rate this app from 5 (very suitable) to 1 (not suitable) for self-managing your condition.

Appendix 16 Interview topic guide

Personal details:

1. Age
2. Gender
3. Profession
4. Working experience in years
5. Smartphone owner? (Yes, No).
6. What is your smartphone brand?

Discussion Questions:

Black-question to be ask participants, Blue- possible probes and my idea that may explored further.

1. In your experience, how do your patients manage/self-manage their hypertension?
    a. *How do patients monitor their blood Pressure? (if applicable), provide details about the approach they use*
    b. *Do you encourage them to adopt other self-management strategies or skills to control their blood pressure (e.g., healthy diet, … etc.). Why/Why not? (and, if applicable) How?*

2. In your experience do you know whether your patients have problems with adopting self-management strategies (e.g. Self- monitoring their blood pressure, lack of awareness/understanding of managing hypertension and its risk factors, taking medication, diet, exercise, remembering appointments, communication with their doctors? Provide details.

3. Could you please tell me about your **experience** of using smartphone applications ("apps")?
    a. *Have you ever recommended an app for your patients, for any purpose? For hypertension? Provide details.*
    b. *What were the reasons for recommending the hypertension app that you mentioned? If applicable*

4. What do you feel are the potential benefits for patients of using smartphone apps to support the self-management of their hypertension?

5. What are the potential limitations or barriers to using smartphone apps to support the self-management of hypertension? Please provide details

    a. *Are there any other limitations/barriers that need to be considered?*
    b. *What concerns, if any, do you have about the use of smartphone apps in the self-management of hypertension?*

The doctor will be given a demonstration of the five apps supporting the self-management of hypertension. The video will then demonstrate how each app works and its functionalities, such as self-monitoring blood pressure, reminders and feedback. The following questions will be asked for each app after stopping the video:

6. Could you describe in as much detail as possible how satisfied you would be for your patients to use the apps? Why? (Please provide reasons for your answer).

    a. *Do you think it would be useful for patients? And why/Why not?*
    b. *How easy or difficult would it be for patients to self-manage hypertension by using the app?*
    c. *How confident do you feel that your patients could successfully self-manage their hypertension by using this app?*

7. What are the potential benefits you might expect for your patients using this app to support the self-management of hypertension?

8. What are the potential limitations of, or barriers to, using this app to support the self-management of hypertension?

    a. *Do you have any concern about the use of smartphone apps in your home? Why/Why not?*
    b. *How important is it for you to check the credibility of a smartphone app's information source (content source, who created it)?*

9. How likely do you think your patients would you be to use a smartphone app? Please explain your answer.

    a. *Are there any other features that you think should be considered to increase \patients' willingness to use a smartphone app? What are they? And how would these help patients?*

10. Would you recommend this app for your patients? Why/Why not?
11. Do you think patients may need training to use a mobile app like this? Why/why not?
12. Do you have any other questions about the app?
13. Please rate this app from 5 (very suitable) to 1 (not suitable) for self-managing hypertension

Appendix 17 ScHARR Ethical Approval

The University Of Sheffield.

Downloaded: 04/12/2018
Approved: 04/12/2018

Tourkiah Alessa
Registration number: 160268519
School of Health and Related Research
Programme: PhD/Health & Related Res FT

Dear Tourkiah

PROJECT TITLE: Patient and doctor attitudes towards, and acceptance of, the use of hypertension apps in Saudi Arabia
APPLICATION: Reference Number 023341

On behalf of the University ethics reviewers who reviewed your project, I am pleased to inform you that on 04/12/2018 the above-named project was **approved** on ethics grounds, on the basis that you will adhere to the following documentation that you submitted for ethics review:

- University research ethics application form 023341 (dated 03/12/2018).
- Participant information sheet 1053017 version 2 (02/12/2018).
- Participant information sheet 1053016 version 2 (02/12/2018).
- Participant consent form 1053015 version 2 (03/12/2018).
- Participant consent form 1053014 version 2 (03/12/2018).

If during the course of the project you need to deviate significantly from the above-approved documentation please inform me since written approval will be required.

Yours sincerely

Jennifer Burr
Ethics Administrator
School of Health and Related Research

Appendix 18 MOH Ethical Approval

Kingdom of Saudi Arabia
Ministry of Health
King Fahad Medical City
(162)

وزارة الصحة
مدينة الملك فهد الطبية
King Fahad Medical City

المملكة العربية السعودية
وزارة الصحة
مدينة الملك فهد الطبية
(١٦٢)

IRB Registration Number with KACST, KSA: H-01-R-012
IRB Registration Number with OHRP/NIH, USA: IRB00010471
Approval Number Federal Wide Assurance NIH, USA: FWA00018774

October 30, 2018
IRB Log Number: 18-562E
Department: External - KSU
Category of Approval: EXEMPT

Dear Tourkiah Alessa, Prof. Luc de Witte and Prof. Mark Hawley,

I am pleased to inform you that your submission dated October 25, 2018 for the study titled '**Patient and doctor attitudes towards, and acceptance of, the use of hypertension apps in Saudi Arabia**' was reviewed and was approved according to Good Clinical Practice guidelines. Please note that this approval is from the research ethics perspective only. You will still need to get permission from the head of department or unit in KFMC or an external institution to commence data collection.

We wish you well as you proceed with the study and request you to keep the IRB informed of the progress on a regular basis, using the IRB log number shown above.

Please be advised that regulations require that you submit a progress report on your research every 6 months. You are also required to submit any manuscript resulting from this research for approval by IRB before submission to journals for publication.

As a researcher you are required to have current and valid certification on protection human research subjects that can be obtained by taking a short online course at the US NIH site or the Saudi NCBE site followed by a multiple choice test. Please submit your current and valid certificate for our records. Failure to submit this certificate shall a reason for suspension of your research project.

If you have any further questions feel free to contact me.

Sincerely yours,

[redacted]

Prof. Omar H. Kasule
Chairman, Institutional Review Board (IRB)
King Fahad Medical City, Riyadh, KSA
Tel: + 966 1 288 9999 Ext. 26913
E-mail: okasule@kfmc.med.sa

K F M C
Approved
30 OCT 2018
I R B

Appendix 19 KKUH Ethical Approval

Kingdom of Saudi Arabia
King Saudi University (034)
p.o. Box 7805 Riyadh 11472
Tel: +966 11 467 00 11
Fax: +96611 467 19 92
http://medicalcity.ksu.edu.sa

المملكة العربية السعودية
جامعة الملك سعود (٠٣٤)
ص.ب ٧٨٠٥ الرياض ١١٤٧٢
هاتف: ٩٦٦١١٤٦٧٠٠١١+
فاكس: ٩٦٦١١٤٦٧١٩٩٢+

جامعة الملك سعود
King Saud University
المدينة الطبية الجامعية

09.12.2018 (02.04.1440)
Ref. No. 18/0790/IRB

To: **Ms. Tourkiah Alessa**
Sheffield University, Western Bank, Sheffield S10 2TN, UK
Email: Maalwahbi@ksu.edu.sa

CC: Luc de Witte, Mark Hawely
Co-Investigators

Subject: **Approval of Research Project No. E-18-3463**

Study Title: "Patient and Doctor Attitudes towards, and Acceptance of, the use of Hypertension Apps in Saudi Arabia"
Type of Review: Expedite
Date of Approval: 09 December 2018
Date of Expiry: 09 December 2019

Dear Ms. Tourkiah Alessa,

I am pleased to inform you that your above-mentioned research project submitted to the IRB was reviewed and approved on 09 December 2018 (02 Rabi-II 1439). You are now granted permission to conduct this study given that your study does not disclose participant's identity and poses no risk to the patients.

As principal investigator, you are required to abide by the rules and regulations of the Kingdom of Saudi Arabia and the research policies and procedures of the KSU IRB. If you make any changes to the protocol during the period of this approval, you must submit a revised protocol to the IRB for approval prior to implementing the changes. Please quote the project number shown above in any future correspondence or follow-ups related to this study.

This approval is for a period of one (1) year commencing from the date of this letter. If you wish to have your protocol approved for continuation, please submit a completed request for reapproval of an approved protocol form (KSU-IRB 017E) at least 30 days before the expiry date. Failure to receive approval for continuation before the expiration date will result in automatic suspension of the approval of this protocol on the expiration date. Information collected following suspension is unapproved research and can never be reported or published as research data.

We wish you success in your research and request you to keep the IRB informed about the progress and final outcome of the study in a regular basis. If you have any question, please feel free to contact me.

Thank you!

Sincerely yours, [redacted]

Dr. Abdulrahman Alsultan
Chairman of IRB
Health Sciences Colleges Research on Human Subjects
King Saud University College of Medicine
P. O. B ox 7805 Riyadh 11472 K.S.A.
Email: aalsultan1@ksu.edu.sa

/braezell

Appendix 20 Apps preferences

	Cora	ESH	Hyten	Qardio	Braun
			Theme: Adequacy of app content		
Feedback and **tracking progress**	Participants felt this app contained good quality graphs, color-coded feedback supplemented with text, and offered BP average readings. However, one doctor preferred that the app should offer more direct feedback.	Patients felt that the quality of graphs in this app were good, and doctors liked the BMI feature. However, doctors felt this app lacks feedback in general.	Patients found the graphs unclear in this app. Although feedback was color coded, doctors felt that it should be more directed and linked with age.	Patients found the graphs difficult to understand in this app. Doctors liked the BMI function and the color-coded feedback, but felt it should be linked with age and more directed.	Patients felt the color-coded feedback should be more accurate and directive. Although doctors liked the app presenting lifestyle choice data on charts, they felt that the graphs were not easy to understand and should include more relevant data.
Information provided	Generally, doctors were satisfied with the level of detail of the information provided. Both doctors and patients liked information about correctly monitoring BP, complications, and general information about the disease. Doctors liked the information provided about medication and side-effects.	Generally, doctors felt that the level of information was unsatisfactory. They believed information about complications and medication was lacking. Patients liked the information about the disease in general.	Doctors liked the variety of information provided. However, doctors and patients felt the information was too detailed and complex.	Participants considerer is not useful due to absence of education.	Doctors suggested that they liked the information relating to lifestyle. However, they felt the app lacked medication data.

User data collected	Most doctors felt Cora's health was helped by entering data and tracking BP and medication, which can be entered easily. However, 2 doctors asked to consider weight. Patients and some doctors felt it is unique for allowing patients to enter different tasks, stress levels and sources.	Doctors felt ESH is good for entering BP and weight, but the method of manually typing is a limitation. Some doctors and patients said it lacked relevant lifestyle data.	Doctors and some patients liked the app's support for medication doses, BP and feelings. Doctors disagreed over the symptom tracking feature: one favored it and another found it unhelpful. Some patients also found the app's support for symptoms unhelpful. Some patients found the data inputting to be disorganized. Furthermore, the app does not consider the weight.	Both patients and doctors like the method of entering weight. Doctors said it lacked support for inputting and tracking other lifestyle factors such as diet and, medication other conditions.	Doctors liked the app's inclusion of BP and a lifestyle tracking feature, but they found this inaccurate and too general. They also noted that the app also does not support weight or medication names. Patients also agreed that despite considering lifestyle, the method of entering data is not helpful.
Reminder	Generally, most doctors and patients were satisfied with Cora as it provided reminders. Some doctors said that it provided the best reminders among all the apps.	Patients and doctors were satisfied with the reminders for medication, with a small number of doctors (n=2) liking its inclusion of different reminders for different medication and dosage. A few doctors and patients would have liked it to include reminders for other tasks	Doctors were satisfied with the reminders for medication and few liked the inclusion of reminders for different medication. A few doctors would have liked it to include more reminders. Patients also like the reminder allowing the input of medication name and dose, but some think the reminder setting is not easy.	Doctors felt that Qardio is good to have a reminder for BP, but they also would like reminders for other tasks including medication. Some patients felt the reminder is too generic.	Doctors felt that Braun is good to have reminder, but this is only very simple. They would like reminders for other tasks. Some patients found that the reminder feature of Braun too generic.

Social support				Patients have mixed opinions about the importance of social support feature; some find useful and other not. Two doctors felt this feature encourages patients to use this app.	
Content Credibility	Doctors felt that the credibility of educational information, and the references of the readings, could be checked. They expressed that the credibility of the information could be assessed and that it could be based upon medical guidelines. They also suggested that the app could be reviewed by additional doctors and medical companies. Finally, they asked whether the purpose of the app was to help people or gain profit?				
Theme: App Usability					
How easy to use	Most doctors (n=12) and patients agreed that Cora is easy to use and practical because its interface is easy to navigate and data entry is easy as well as having friendly colours.	Most participants in interviews (n=10) and focus groups agreed that ESH care app is easy to use. Patients felt it was friendly and had simple colors. Very few patients also felt that navigation would be easier if features were organized horizontally.	Many doctors (N=8) and some patients in focus groups found this app easy to use because it simply requires clicking and selecting and having user-friendly colors. However, some agreed that its navigation is somewhat complex.	Opinions were mixed about app usability. Some doctors (n=6) agreed it is generally easy to use due requiring fewer actions/tasks, while most participants in all focus groups felt it is not easy to use due to its unclear layout affecting navigate	Most participants agreed that Braun is not user-friendly (n=8), and most participants in focus groups believed it was difficult to use because of its annoying color, poor layout, and the difficulty of entering data.

Training	3 doctors and some patients said patients would not need any training to use Cora, except older people. Other doctors and patients believed it would need around one training session, or another resource, e.g. a leaflet with instructions, to teach them how to use it.	4 doctors said that patients did not need any training to use it if it will be in Arabic. Other doctors said it would need around one training session. Patients had mixed opinions: some said it need training for anywhere between one session and up to three weeks	Two doctors said it did not need any training. Others said it may need training based on user medical knowledge and app background. Patients agreed that training would be needed, either face-to-face or via video tutorials.	Two doctors said the app would need training. Others said it would need a leaflet, video tutorial or manual guidance. Most patients said it would need training, but there was disagreement about whether this would need to be simple or intensive.	Doctors and patients said that Braun would need training but they disagreed about whether this would need to be intensive or simple, and about how many sessions.
Theme: <u>Overall app assessment</u>					
Doctors' willingness to recommend apps	Most doctors (N=10) are willing to recommend this app and describe it as 'complete' or 'comprehensive' due to its detailed functions e.g,. BP average and multiple reminders.	More than half of doctors (n=7) are willing to recommend it due to features such as its consideration of BMI and its high-quality information.	Most Doctors (n=9) are willing to recommend it and describe it as complete, due to its detailed information. The rest think the level of information is too detailed for patients	One doctor is willing to recommend this app. A small number of doctors were willing to recommend it on account of specific features, but not on its overall functionality. More than half of doctors (n=8) believed that Qardio is less recommendable because it focuses mostly on monitoring BP, and lacks other useful feature, like education.	Two doctors are willing to recommend this app, with a small number of doctors being willing to recommend it on account of specific features, but not on its overall functionality. More than half of doctors (n=8) believed that Braun is less recommendable because its features, e.g. reminders, lack detail, and because of the difficulty of entering data.

Patients' willingness to use and recommend app to other	Most patients in all focus groups stated they would use Cora and would recommend it to friends, as it is easy to use in terms of entering data, and they liked the quality of feedback (e.g. graphs), and features such as suitable information, tracking and reminders.	Most patients in focus groups stated they would use ESH care, and would recommend it to friends, due it being easy to use, and providing good information and tracking.	Two groups were positive about the app, due to its support for inputting medication names and feelings, and the information provided. The other two groups were more negative, due to e.g. excessive level of data requested, and low-quality charts.	Focus groups' responses to Qardio were mostly negative, due to lack of information provided, poor quality charts, and its limited tracking. However, one patient approved of Qardio's support for communication with family and friends.	Focus group responses to Braun were mostly negative, due to issues such as its limited reminder feature and the complexity of its layout and data input.
Doctors' Estimated uptakes	Doctors expected that the majority of patients (around 80% to 90%) would use it to help manage their disease.	Doctors expected that around 60% to 70% of patients would use it to help manage their disease.	Doctor expected that a good percentage of patients (around 50%) would use it.	Doctors expressed that few patients would use it.	Some doctors felt it would be used by around 30% to 40% of patients. However, one doctor felt that no patient will use it.
General recommendations	One doctors asked to add the word 'high and low' on the chart showing BP.	Doctors suggested the addition of more detailed information and reminders and considerations of other lifestyle factors. They also suggested inputting data by selecting rather	Some doctors suggested the addition of more daily tips or reminders about exercise, and for feedback to be more sensitive to age. Patients asked to improve the charts to be clearer and the set reminder to be	Doctors suggested the addition of more reminders, an education feature and for feedback to be more customized. They also suggested the app consider other factors affecting BP, as well as medication. Patients suggested considering other life style factor and adding	Doctors and patients asked to improve the method of entering lifestyle data to make this more accurate. They also suggested the inclusion of more reminders for exercise and healthy diet, and for simplified graphs.

		than manually typing. Patients asked for more reminders and consideration other factors that affect BP.	easier and for the app to provide audio reminder.	messaging with a doctor in emergency cases.	
	A few doctors recommended the addition of other features for all five apps such as adding hospital appointments, doctor access and other medical conditions.				
Factor affecting uptake and usage	Two doctors think the app is more suitable for younger users. Two doctors stressed the need for practice for older patients who do not have IT background before.	Two doctor felt that ESH is more suitable for older people especially who are accustomed to smartphone technology. Some Patients felt that this app is more suitable for people who do not adhere in taking medication.	Some doctors expressed that this app is more suitable for younger or people who have previous experience with IT. Some patients felt	Some doctors expressed that this app is more suitable for people who have controlled BP or are looking only for self-monitoring BP.	Some doctors expressed that technical difficulties may be a main barrier for users.
	For all five apps, some patients expressed that the cost of apps and the payment method required may be a difficulty for some patients. Some patients felt using				
	For all five apps, most patients and doctors considered language to be a main barrier to patient uptake, i.e. the apps being unavailable in Arabic.				
	For all five apps, there was mixed opinion amongst doctors and patients regarding the importance of privacy. One doctor felt privacy was important, and another doctor believed privacy is important in the case of high-profile individuals. One doctor stressed the importance of a passcode to protect app data. Most patients did not express concern with the confidentiality of the apps.				

	Two doctors stressed the importance of official endorsement as a factor affecting patient uptake. They felt patients would be more likely to use apps that were supported by e.g. the MOH or mentioned in public health campaigns.				
Theme: Potential benefits and drawbacks of app use					
Potential benefits and drawbacks of app use	Most doctors and patients felt Cora helped people to: control BP, save time and share information with their doctor during appointments. It also helped to engage patients, increase compliance to different tasks and awareness, due to it having a BP average and a tracker that tells you how many tasks are completed. One doctor felt this detailed information may cause stress for patients.	Most doctors felt that ESH may enhance hospital follow-up and the sharing of data. They also stated that it can increase patient involvement and awareness by monitoring BP and weight, as well as educational information. However, less features may lead the patient to become bored.	Doctors felt that detailed education and medication reminders, in addition to monitoring may increase patient enthusiasm and compliance to take medication. It may also increase their awareness and ability to share data with doctors and control BP. However, patients and doctors felt too much detailed information and the way of setting reminders may confuse some patients and distract them.	Some doctors felt that Qardio may help to increase awareness of why BP is low or high through monitoring, adherence and Feedback. Others also felt this app is more helpful for doctors at follow up visits, rather than patients. However, too few features may lead patients to get bored and decrease their use.	Some doctors felt that Braun may increase health awareness and encourage people to control BP, due to education and monitoring. Some Patients also felt that considering factors may increase enthusiasm. However, some doctors felt that inaccurate inputs and the low-quality of charts may reduce app use, or lead to boredom and confusion in patients.

Appendix 21 Data Integration Matrix

	Usability Test *(QUAN+QUAL)*	**Engagement data** *(QUAN)*	**Questionnaire** *(QUAN)*	**Interview** *(QUAL)*	**Comments to integration**
Theme 1: Usability of the app					
Overall usability	App generally easy to use; more than half of participants (n=7) complete most tasks (8/10) but they stressed they need time until be proficient with the app, Few tasks (setting reminder and found how many tasks completed) were uncompleted by most people.		Most participants agreed app easy to use (18/20) and easy to learn with a mean of (5.8), and all agreed that they recovered any mistake they made easily.	Most participants, who have little experience of technology found app easier than those who have little experience. They also commented provided training & instruction helped them to found it easy.	Somewhat (**Discordant**), interview and questionnaire are similar in founding app easy to use, but interview provide further details (**expansive**) that training, instruction and more practice helped to be easier. However, usability test showed that the app has good usability and they stressed they need time until be proficient with the app
App accessibility	Some aspects like small font size in some section, less contrast between background and button, requiring an internet connections and words have not translated into Arabic (e.g medication names) were faced as struggle to engage users with the app.			Concerns were raised about too small font size, non-preferred calendar, less contrast between background and button and untranslated English words into Arabic and suggested to improve them.	Both UT and interviews had **similar** concerns and difficulties and suggested to change font size, change to a different colour scheme (e.g. with a coloured background) and translating English words into Arabic. **However**, interview also asked to change the calendar to the preferred one while UT asked to access health guide without requiring an internet connection.
Data entry and navigation	Problems raised among users affect their inability to see or find button due to unfamiliar terminology, too small button or buttons were in unclear location. They also suggested to enter BP, medication and stress once.		Participants expressed that the navigation was consistent when moving between screens and allowed them to enter information, respond to reminders, viewing	Perceived app as easy to navigate because of being well-designed and easy to enter data and edit at any time, even retrospectively. A difficulty was faced in entering 'Tick' feature or even undo it. They also encouraged to enter BP, medication and stress once.	**Discordant,** participants in interview and questionnaire found app easier to navigate and enter data than participants in the UT. Interestingly, users in UT were under controlled setting and they had not any previous training or practice.

		challenges created across all users.		other activities intended to increase exercise. A few participants also reported setting challenges to reduce stress.	increase exercise but few of them set to reduce stress.
		The retention data for study participants was good as user retention then gradually decreased, until day 30 when retention was 47.8%. More than ¾ of participants were in the meaningful sessions range of 30-60 seconds or longer. The average session duration was 1 minute and 35 seconds. The app was opened 21.43 times.			Nothing to integrate
External factors influencing use of the app				Range of external factors arisen either positively or negatively affected their use of the app; participants reported that Busy lifestyles and other health issues prevented some participants from undertaking and/or completing additional challenges (e.g. exercise). Family was also mentioned, as both a motivating and demotivating factor for using the app.	Nothing to integrate
Theme3: Capacity to support self-management					
A daily monitoring tool			App perceived as an effective and helpful tool in supporting self-management by performing self-assessment and	App perceived as a powerful tool for facilitating self-management by offering a structured system more disciplined to manage their data, including BP, taking medication and emotions. Entering data was considered	Both 2 strands **confirmed** that the app perceived as a powerful tool for facilitating self-management by tracking different activities and data

			information		
Theme 2: the usage of the app					
General satisfaction and use	People were generally satisfied to use this app and asked to continue using it; they found it easy to use and useful in increasing understanding and managing of their diseases.		People were generally satisfying with the app and preferred to keep using it again.	Participants were very satisfied and found it easily incorporated in their routines; they expressed to keep using it due to offering everything in one place and easily accessible location for their data anywhere at any time, good overview of BP level and it is easy to use	All three strands very **similar** but interview **expand further details** about the reasons why they are satisfied with this app.
App functionality use		The most commonly recorded measurement was BP: each user inputted this an average of 19.8 times. BP was recorded 416 times across all users, compared with medication and stress, which were recorded 234 and 246 times, respectively		Participants frequently recorded BP, followed by medication and stress and consider them as a positive feature	Both 2 strands **confirmed** that the most recorded data is BP, followed by stress and then medication
		The most commonly accessed functionality was viewing the Logbook, with each user accessing this an average of 60.2 times.		Viewing data trends in a list or graph were the most common used and useful feature.	Both 2 strands **confirmed** that the most accessed feature was viewing data trends in a list, except viewing graphs.
		The least accessed functionality was 'Challenge Created', with each user accessing this an average of 3.78 times, and a total of 72		People reported that they used the app to set different types of challenges, the most common being entering BP and taking medication. Most participants reported setting challenges for	They not confirmed or discordant. The most common set challenges were monitoring BP and taking medication compared with others. Most participants set challenges to

			tracking activities.	easier than conventional recording methods, or relying on memory.	
An informative tool	Participants like the breadth of information and the provided information in addition to the feedback help to increase understanding and encourage to take action.		Participants like the provided health information in addition to the feedback that help them to know the progress of them.	Perceived as a powerful tool to receive feedback, and review educational resources about hypertension. The feedback functionalities were considered particularly valuable because they provide a clear picture of participants BP levels and see the relationship between their challenges completed and their BP level. some suggestion was commented like more detail and tailoring of BP feedback to their individual cases and too general, and would have preferred a breakdown of the specific tasks completed that week.	**Expansive**, further detail available from interview that **confirm** data and add more suggestions.
A commitment tool				Participants expressed that this app increased their commitment and encouraged them to add more self-management strategies to their routine. Some participants felt that additional information showing the daily activities they have to be prepared for would increase their completion of challenges, rather than relying on a notification alone. Participants appreciated the alerts advising them that certain activities for unsuited to their level of hypertension.	Nothing to integrate

A communication tool				Participants recognized that app improve patients' communication and sharing of data at doctors' visits.	Nothing to integrate

Appendix 22 Usability test data

A) User Interface Issues

Subtheme	**User Interface Issues**					
Categories	**Unclear or misleading terminology**	**Unintuitive aspects of the design**			**Unclear Visual Presentation**	
Usability issues	Difficulty setting reminders and reading health information	Difficulty checking completed tasks	Difficulty entering BP reading	Issues with inputting multiple data	Unclear colour-coding	Unclear colour contrast
Comments	Several participants found it difficult to find the correct menu to set reminders and read health information, due to unclear or misleading terminology.	Participants remarked that it should be easier to check how many tasks have been completed, e.g. by this being displayed when tasks are marked as complete, or being visible in the 'Challenge'.	Half of the participants could not find the location to enter their BP mostly because they did not correctly interpret the '+' sign.	Participants found the method of inputting data unintuitive, causing them to have to repeat the same procedures multiple times, rather than inputting all data (e.g., BP, medication, and stress) in one go[3].	The app presentation could be made clearer, by adding more text to some charts e.g., to explain the colour-coded classification of BP reading.	The colour of the buttons could be made more contrasting to accentuate some features.
Citation(s)	*"I do not believe the information is here…it cannot be found" (P3).*	*"The location of it [how many tasks have been completed] cannot be shown clearly - the box should appear directly when I tick for completing data." (P9)*	*"I did not think that I can enter BP data via this + button" (P4)*	*"There is a problem in this app, as when I enter BP data... it backed me to the main menu … then I access '+' to enter medication data and press save, then the app backed me again to the main menu [dashboard]… I have to access + again and enter stress then press save… It should allow for all data [BP, medication and stress] to be entered at the same time then save it]". (P6)*	*She can find the data on which color, but she said "I cannot interpret whether it is normal or not; I see the colours, and don't know what each colour means" (P9)*	*"It is better if it is made a bright color to clearly show that the other data needs to be added beside". (P10)*

B) App Accessibility

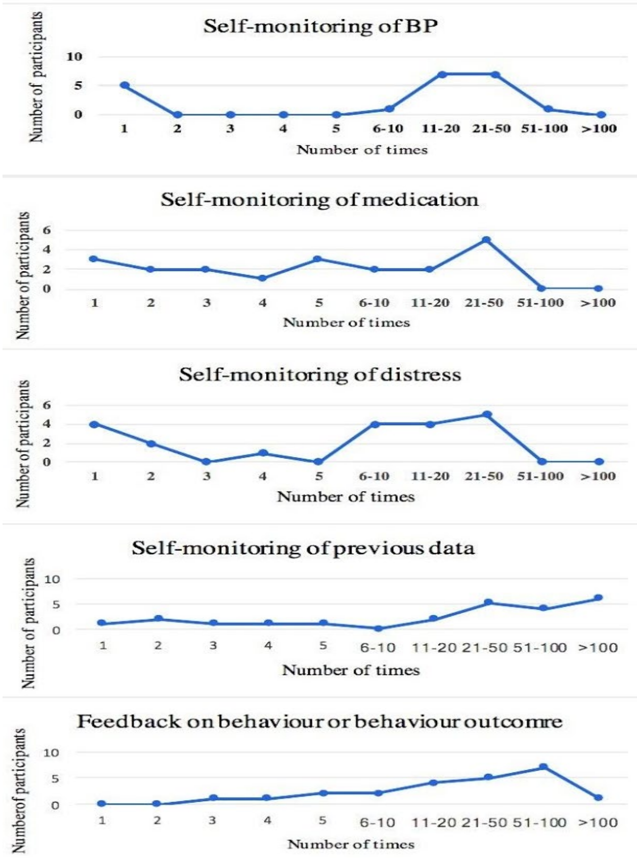
Sub-Theme	**App accessibility**	
Categories	**Readability**	**Additional barriers to use**

[3] This issue only arose in the Arabic-language trial version, and was not present in the commercially available English-language version.

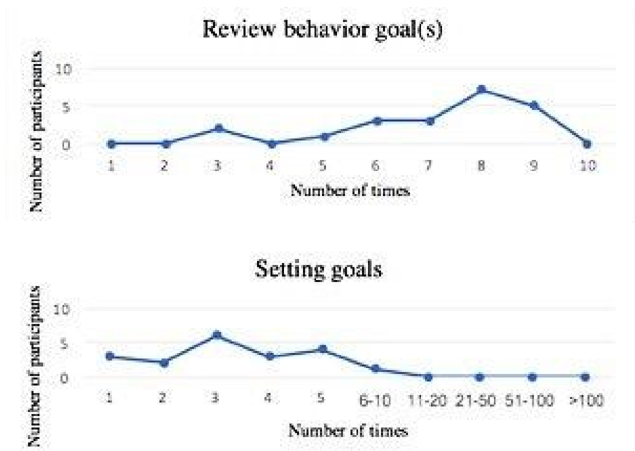
Usability Issues	Zoom feature	Font size	Language issues	Internet
Comments	Participants liked being able to zoom in on the health guide section as it made the text easier to read.	Some users stated that font size should be adaptable.	Participants experienced issues with the language of the app (certain words being untranslated)	Lack of internet access was a factor limiting some participants' use of e.g. the health guide.
	"I understand the text, it is clear - and wow, I can zoom in" (P7)	*"The font in the challenge menu is small and difficult to read." (P10)*	*"I will select any medication name [because they cannot remember their medication name] as it is difficult to read it in English!" (P6).*	*"It needs internet to access. I cannot read it now until I get home." (P6)*

Appendix 23 Engagement data

A) Self-monitoring of behaviour and feedback



B) Goal Setting and Review



Appendix 24 Qualitative data

Theme/Subtheme	**Quotation**
Usage of the app	
General satisfaction and use	*"First I felt using this app is effort and time consuming, but with over time, I see how it was benefits. I see all the data that I did and all the activities I completed and how it works to improve my BP. It is really interesting" (P10)* *"I think this application is enjoyable as it did not consume my time or even require intensive effort." (P12)* *"Yes satisfied with it, as I said earlier, the level of my blood pressure is improved, it is accessible and convenient I can access it any time which is not like other conventional or manual tools. It supports me in tracking my health become more active with accurate picture of my data" (P7)* *"I would like to say that anyone who wants to manage his blood pressure use this application because I found it is very useful" (P5)* *"This app can be really used as an informative tool, storing my data, offering information etc." (P6)* *" I enjoy using it and become part of my daily life" (P6)* *"I feel everything related to my hypertension is in one place" (P8)* *" I was satisfied with it even it takes time, but make me more organized and the app is with me in my pocket at any time everywhere." (P15).* *"I felt using this app is effort and time consuming, but with over time, I see how it was benefit" (P10)* *"I think using this app may require intensive efforts;" (P3)* *"Of course, I will use it again and I will advise my friends about it because it provides a main location to input my data, which I can then access at any time to provide me with clear picture of my BP level." (P10)* *"After seeing its benefits, I definitely will continue using it without any doubt […] but please can I keep this version to use?" (P7)* *"I love it because, instead of holding actual logbook papers at each appointment, which I have forgotten to take with me on many occasions, using this app seemed to be simpler and easier." (P15)*

App Functionality use	*"I used each part of the app. The most common data I entered is BP. I had entered it every day … entering data is simple. I just monitor and the data is transmitted to the screen. I did not have to do anything more- that is why I love it" (P13)* *"Using app is easy to enter my BP and it represents data in different, attractive ways, such as a list or graphs." (P11)* *"I used the app mainly to record my BP data, and I used it to record other data as much as possible such as medication and distress." (P3)* *"I just set goals for medication and BP monitor for every day. I did not add more because I am not interested in exercise or I am so busy when I get back home after work"* *"When I notice my emotion level I was not happy After a while of time I set goal for reducing stress by do messages once a week" (P14)* *"It requires additional information. […] I mostly eat Saudi foods that are not mentioned here" (P12)* *"After days, I felt there is no any new information for me" (p17)* *"It is not one function that is good. It is the combination of functionalities that is effective and valuable." (P1)*
External factors influencing use of the app	*"My daughter helped me read some of the text and enter medication when I started using this app" (P5)* *"My wife said that this app steal you from our life" (P13)* *"I did not set other goals since walking is enough as I have pain in my joint that hurts me more after heavier exercise." (P16)*
Capacity to support self-management	
A daily monitoring tool	*"It changes the way that I manage my hypertension. Before, I just monitor my BP and ate medication, I did not record any task if it was completed. Using this app helps to follow up a system to achieve my goals." (P13)* *"When I use the BP monitor, my BP data directly moved to the app" (P2)* *"I don't keep track of my BP really, but I check it every two days or so and try to remember the reading […] [but with the app] it's good to be able to enter data accurately and quickly and see the trends. It gives you a clearer picture." (P7)* *"I do not know why [my symptoms] are different – sometimes I have headaches, dizziness or*

	I go to toilet many times a day. It would be good to add this feature." (P13)
	"The main thing I do is record my BP data and then check how my condition is and what the relationship is between my mood, taking medication and doing exercise, and my BP. If it is not improved, I try to read information to get more knowledge." (P15)
An informative tool	*"Sometimes I am confused about what the helpful treatment is - should I take more medication, drink fluid or ...; it's very general- not very specific advice for my case." (P8)*
	"I believe the information about how many tasks are completed would better if when I press it, it presents how many tasks from each goal that I set" (P15)
A commitment tool	*"I know I'm going to do a lot more activities than I used to" (P2)*
	"As the reminder pushes me to do it. Even if sometimes I neglect it the additional reminders push me a lot." (P11)
	"The reminder pushes me but it would be better to show more [information] on the menu screen that today I have an activity for a walk." (P8)
	"I cannot add the challenge that I prefer, I just have to choose from what is here." (P17)
	"The negative part that there is no possibility to add/set any activity that I may need to" (P14)
A communication tool	*"I have my iPhone and show the doctors how I did the activities during the previous days and what my BP level is*". (P19)
	"Graphs are quickly and easily understood by both the doctor and me" (P6).
	"*Having this app helps me avoid repeating what I say each time I have new doctor at a clinic or in an emergency." (P3)*
	"If the doctor can follow my recording, I will be more relaxed and also encouraged because he knows what I complete or not" (P15)

Usability of the app

Overall usability	"*As the app is easy to use, my confidence to use it is high because it just needs me to select and click no more things". (P14)* "*I did not have practice using technology when I was young so I find it difficult at first but then with time the app becomes easier." (P6)* *"I found it easy at first because the brochure instructions helped me to understand how the app works. .... If I can't do something at first I either read the instructions or ask my wife who has more experience of using apps in general. (P13)* *"The button or menu can be found smoothly I did not face issue with them, date also entered and edited easily but there are some steps repeated at every time. For example, when I enter data (e.g., BP) it should be in one interface to enter all data. This lead me sometimes to enter only BP and forget to enter the other like medication." (P4)* *"The negative aspect is repeating the same procedures entering the BP, medication and stress data, it should be done once." (P10)* "*If you are unable to use your phone one day or forget to upload data, you can just add data later […] That for me is a big positive." (P11*) "*One time I accidentally ticked for walking although I had not achieved the task! So I feel it is better to allow me to edit or delete [a tick].*" (P9) "*I have big fingers that make it hard to tick properly and sometimes my hands shake which also means I sometimes tick wrongly.*" *(*P13) *"I think rather than having to go and tick after each task, it is easier after any reminder to show me a box asking me whether I have completed the task, then if I 'tick' it, it automatically records it." (P4)*
App accessibility	*"I think this application is excellent and I am satisfied with it and I did not face any difficulty except font size." (P11)* *"Allowing us to customize the colors and size of fonts to meet our needs [would make the app more accessible]" (P5)* *"I expect that the medicines need to be written in Arabic or an open option and the patient is the one who writes the name of the drug in Arabic" (P7)* *"There were some issues that did not hinder my use but affect my use a little bit. For example, in Saudi we mostly use Islamic calendar in hospitals, schools and so on, and few use that English calendar, but in the app, I cannot set it to the Islamic calendar." (P10)*

Appendix 25 ScHARR ethical approval

The University Of Sheffield.

Downloaded: 29/07/2019
Approved: 29/07/2019

Tourkiah Alessa
Registration number: 160268519
School of Health and Related Research
Programme: PhD/Health & Related Res FT

Dear Tourkiah

PROJECT TITLE: Using a smartphone app for self-management of hypertension: Acceptance and usability study
APPLICATION: Reference Number 030091

On behalf of the University ethics reviewers who reviewed your project, I am pleased to inform you that on 29/07/2019 the above-named project was **approved** on ethics grounds, on the basis that you will adhere to the following documentation that you submitted for ethics review:

- University research ethics application form 030091 (dated 25/07/2019).
- Participant information sheet 1068083 version 2 (25/07/2019).
- Participant information sheet 1068084 version 2 (25/07/2019).
- Participant consent form 1068085 version 2 (25/07/2019).
- Participant consent form 1068086 version 2 (25/07/2019).

If during the course of the project you need to deviate significantly from the above-approved documentationplease inform me since written approval will be required.

Yours sincerely

Jennifer Burr
Ethics Administrator
School of Health and Related Research

Appendix 26 MOH Ethical Approval

Kingdom of Saudi Arabia
Ministry of Health
King Fahad Medical City
(162)

وزارة الصحة
مدينة الملك فهد الطبية
King Fahad Medical City

المملكة العربية السعودية
وزارة الصحة
مدينة الملك فهد الطبية
(١٦٢)

IRB Registration Number with KACST, KSA:	H-01-R-012
IRB Registration Number with OHRP/NIH, USA:	IRB00010471
Approval Number Federal Wide Assurance NIH, USA:	FWA00018774

July 23, 2019
IRB Log Number: 19-369E
Department: External - King Saud University
Category of Approval: EXEMPT

Dear Tourkiah Alessa, Prof. Luc de Witte and Prof. Mark Hawley,

I am pleased to inform you that your submission dated July 22, 2019 for the study titled '**Using a smartphone app for self-management of hypertension: Acceptance and usability study in Saudi Arabia**' was reviewed and was approved according to Good Clinical Practice guidelines. Please note that this approval is from the research ethics perspective only. You will still need to get permission from the head of department or unit in KFMC or an external institution to commence data collection.

We wish you well as you proceed with the study and request you to keep the IRB informed of the progress on a regular basis, using the IRB log number shown above.

Please be advised that regulations require that you submit a progress report on your research every 6 months. You are also required to submit any manuscript resulting from this research for approval by IRB before submission to journals for publication.

As a researcher you are required to have current and valid certification on protection human research subjects that can be obtained by taking a short online course at the US NIH site or the Saudi NCBE site followed by a multiple choice test. Please submit your current and valid certificate for our records. Failure to submit this certificate shall a reason for suspension of your research project.

If you have any further questions feel free to contact me.

Sincerely yours,

[redacted]

Institutional Review Board
Approved
Date: 2 3 JUL 2019

Prof. Omar H. Kasule
Chairman, Institutional Review Board (IRB)
King Fahad Medical City, Riyadh, KSA
Tel: + 966 1 288 9999 Ext. 26913
E-mail: okasule@kfmc.med.sa

Appendix 27 PSSUQ (Arabic Version)

استبيان قابلية الاستخدام بعد الدراسة (PSSUQ)

1. عموما، أنا راض عن مدى سهولة استخدام هذا التطبيق.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

2. كان من السهل استخدام هذا التطبيق.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

3. يمكنني إكمال المهام والسيناريوهات باستخدام هذا التطبيق بشكل فعال.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

4. تمكنت من إكمال المهام والسيناريوهات بسرعة باستخدام هذا النظام.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

5. كنت قادرا على استكمال المهام والسيناريوهات بكفاءة باستخدام هذا التطبيق.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده

6. شعرت بالراحة باستخدام هذا التطبيق.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

7. كان من السهل تعلم استخدام هذا التطبيق.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

8. أعتقد أنني اصبحت منجز بشكل أسرع باستخدام هذا التطبيق.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

9. التطبيق قدم رسائل الخطأ التي اخبرتني بوضوح عن كيفية إصلاح المشاكل.

غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

10. يمكنني معالجه الخطأ بسهوله وبسرعة كلما أخطأت.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

11. المعلومات (مثل المساعدة على الإنترنت، والرسائل على الشاشة وغيرها من الوثائق) المقدمة من هذا التطبيق كانت واضحة.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

12. كان من السهل العثور على المعلومات التي أحتاجها.

غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

13. وكان من السهل فهم المعلومات المقدمة من التطبيق.

غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

14. كانت المعلومات فعالة في مساعدتي في إكمال المهام والسيناريوهات.

غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

15. كان تنظيم المعلومات على شاشات التطبيق واضحا
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

16. كان واجهة هذا التطبيق جذابة.
ملاحظة: *تتضمن الواجهة العناصر التي تستخدمها للتفاعل مع النظام. على سبيل المثال، بعض مكونات واجهة هي لوحة المفاتيح، والماوس، والشاشات (بما في ذلك استخدامها للرسومات واللغة).*
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

17. أحببت استخدام واجهة هذا التطبيق.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

18. هذا التطبيق لديه جميع الوظائف والقدرات التي توقعت أن تكون فيه.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

19. عموما، أنا راض عن هذا النظام.
غير موافق بشده 1 2 3 4 5 6 7 اوافق بشده
التعليقات:

Appendix 28 Exit interview (English Version)

Participants will be asked the following questions:

1- How did you find using the app in self-managing of hypertension? Easy/ difficult? Why?
Props: What difficulties/problems you encountered when using this app?
What could help you to overcome these difficulties?

2- How confident are you in using the app?

3- If you had the chance to keep the app, and no-one was monitoring your use of the app do you think you would carry on using it?
Why/ why not? Explore participant's level of confidence in their ability to self-manage their selves.

4- How did you typically use the app?

Probes if any of the following topics are not covered:

How did you find using app to set goals for different activities to support self-managing of hypertension? why? Probe: what goals were set and why.

How did you find the reminder for different activities? Is it helpful?

To what extend do you feel app support you to achieve your goals to support self-management of hypertension?

How useful did you find the self-monitoring features of the app? Probe whether the screen was looked at during measuring BP. Was the information enough/ of interest etc.

How did you find the feedback feature? What information did you find most useful (e.g. average blood pressure, blood pressure trend, task completion)?

5- To what extend did the app improve your knowledge of your hypertension?

6- Did this knowledge improve your self-management? Probe whether the app helped participants to make informed decisions about managing BP, and how.

7- Did you enjoy it? Why? why not?

8- Did the app influence your emotional attitudes to self-management of hypertension? if yes, how?

<u>Overall experiences and suggestions</u>

9- How well did this app help you to manage your hypertension? Probe whether participants feel their blood pressure levels changed/improved, and why they think this may have happened.

10- What is your overall level of satisfaction with it? Why/why not?

11- What are the negative and positive aspects of using the app?

12- Which features would you like to add/change or improve? Probe specific suggestions for changes/improvements

13- How likely are you to use the app again?

14- Would you recommend the app to a friend with hypertension? Why/ why not?

15- Do you have any question or anything you want to add?

Appendix 29 Exit interview (Arabic Version)

المشاركين سوف يسأل المشاركون الأسئلة التالية:

١- كيف وجدت استخدام التطبيق في الإدارة الذاتية لارتفاع ضغط الدم؟ سهل صعب؟ لماذا ا؟
الأسئلة المساعدة: ما الصعوبات / المشكلات التي واجهتها عند استخدام هذا التطبيق؟
ما الذي ساعدك للتغلب ع هذه الصعوبات؟

٢-ما مدى ثقتك في استخدام التطبيق؟

٣-إذا كانت لديك فرصة للاستمرار على التطبيق، ولم يكن أحد يراقب استخدامك للتطبيق، هل تعتقد أنك سوف تستمر في استخدامه؟
.لماذا/ لماذا لا؟ استكشف مستوى ثقة المشاركين في قدرتهم على إدارة أنفسهم
٤-كيف كنت تستخدم التطبيق عادة؟

لأسئلة المساعدة: في حال لم يتم تغطية أي من الموضوعات التالية:
كيف وجدت استخدام التطبيق لتحديد أهداف الأنشطة المختلفة لدعم الإدارة الذاتية لارتفاع ضغط الدم؟ لماذا ا؟ الأسئلة المساعدة: ما هي الأهداف التي تم تحديدها ولماذا؟

كيف وجدت التذكير للأنشطة المختلفة؟ هل هو مفيد؟

إلى أي مدى تشعر أن التطبيق يدعمك لتحقيق أهدافك لدعم الإدارة الذاتية لارتفاع ضغط الدم؟

ما مدى فائدة ميزة المراقبة الذاتية لضغط الدم في التطبيق؟
وهل كانت المعلومات كافية / مثيرة للاهتمام وما إلى ذلك.

كيف وجدت ميزة التعليقات؟ ما المعلومات التي وجدتها أكثر فائدة (مثل متوسط ضغط الدم، اتجاهات ضغط الدم، إكمال المهمة)؟

٥-الى أي مدى ساعد التطبيق بتحسين معرفتك بارتفاع ضغط الدم لديك؟

٦-هل هذه المعرفة حسنت الإدارة الذاتية الخاصة بك؟ هل فيما إذا كان التطبيق ساعد المشاركين في اتخاذ قرارات مستنيرة بشأن إدارة ضغط الدم، وكيف؟
٧-هل استمتعت باستخدام التطبيق؟ لماذا ا؟ لما لا؟
٨-هل أثر التطبيق على مواقفك العاطفية تجاه الإدارة الذاتية لارتفاع ضغط الدم؟ إذا كان الجواب نعم، كيف؟

الخبرة العامة والاقتراحات
٩-إلى أي مدى ساعدك هذا التطبيق في إدارة ارتفاع ضغط الدم لديك؟ دقق فيما إذا كان المشاركون يشعرون أن مستويات ضغط الدم لديهم قد تغيرت / تحسنت، ولماذا يعتقدون أن هذا قد حدث.
١٠-ما هو مستوى رضاك العام عنها؟ لماذا/ لماذا لا؟
١١-ما هي الجوانب السلبية والإيجابية لاستخدام التطبيق؟
١٢-ما هي الميزات التي ترغب في إضافتها / تغييرها أو تحسينها؟ هل من لديك اقتراحات محددة للتغيير/ التحسين

١٣-هل تنصح أصدقائك الذين لديهم ضغط دم باستخدام هذا التطبيق؟ لماذا/ لماذا لا؟

١٤-هل لديك أي سؤال أو أي شيء تريد إضافته؟

Appendix 30 Participant Information Sheet for usability test (English version)

Participant Information Sheet for Patients usability test: Version 2.
--/July/2019

Study title: Using a smartphone app for self-management of hypertension: Acceptance and usability study

You are being invited to take part in the study. Before you decide if you want to take part, it is important that you understand why this study is being done and what it will involve. Please read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

This study is being conducted by the student researcher, as a part of her PhD project, from the School of Health and Related Research at the University of Sheffield. You are being asked to participate in this study.

The overall aim of this study is to capture insights from patients on the usability (how easy you find the app to use) and acceptance (your satisfaction with the app) of the app. The study will involve patients using the app in controlled conditions to achieve this aim.

Why have I been chosen?

You have been asked to take part as you are somebody for whom the app might be useful. In addition, we are interested in finding out what people think of the app, and your views are valuable for exploring attitudes toward the usability and acceptance of this app in supporting the self-management of hypertension in Saudi Arabia so we can improve the user-friendliness of such apps.

Do I have to take part?

It is up to you whether or not to take part. If you do decide to take part, the student researcher will give you this information sheet to read and keep, and the study will be explained to you and your questions will be answered. You will then be asked to sign a consent form. The test will take place at a time and place convenient for you within the hospital or primary care center. If you decide to take part you are still free to withdraw any time before your data has been analysed, which is usually one week after the test, and without giving a reason. However, if you decide to withdraw after your data has already been analysed, your data will be retained by the study.

You can stop taking part at any time by contacting the student researcher (please see page 3 for contact details).

If you do decide to stop taking part, or are unable to continue, any information collected from you, wherever possible, can be withdrawn from this study if you tell us so. You do not have to give any reasons and there will be no adverse consequences if you choose to withdraw. However, if your data has already been anonymised and analysed it will not be possible to identify it as yours or delete it.

What do I have to do?

You will be asked to complete a brief questionnaire about your personal details (e.g., age). You will have an opportunity to give your views about your experience of using the app through a usability test. In this test, you will be asked to complete tasks related to the app's functionalities and think aloud (providing your comments, feelings, and interaction) while performing these tasks. This will be with the aim of identifying any usability issues (or how easy you find it to use this app) and exploring your overall satisfaction towards this app. This test will last about 60 minutes and will be audio- and video-recorded. These recordings of the test will be used only for transcribing.

What will happen to the audio/video recordings?
You may withdraw your consent before, during and after the recording, and data will be destroyed providing analysis has not begun. You can stop the recording for any reason. All information collected for the project will be kept confidential. The recordings will be stored in an access restricted folder on the University of Sheffield's secure online drive. Anonymised transcripts will be made from these recordings in Arabic and translated into English by the student researcher, and this anonymised transcript will then be translated back into English by a professional translation service in Saudi Arabia to ensure that the meaning has not altered.
This final translated version will be used to ensure greater accuracy in analysis and the reporting of findings. The recordings will be deleted at the completion of the PhD project.

What are the possible benefits or disadvantages of taking part?
There are no direct benefits of taking part in this study. However, your involvement will help our understanding of how easy to use the app is and what could help to improve it for future versions.
Are there any disadvantages of taking part and what will happen to my information?
We believe there are no known risks associated with participating in the study. The only disadvantage is the use of your time in taking part.
Will my taking part in this project be kept confidential?
All information which is collected from you during this study (personal data, recordings and transcripts) will be kept confidential and will only be accessible to the study team (the student researcher and her supervisors) and will be kept anonymous. You will not be able to be identified in any reports or publications. You will be identified by a code rather than a name. Any audio recordings and accompanying notes will be stored securely. However, in rare situations (such as safeguarding, meaning measures to protect vulnerable individuals from risk or harm; for example, in medical emergencies), the interviewer will have legal obligations that override confidentiality agreements.
What is the legal basis for processing my personal data?
According to data protection legislation, we are required to inform you that the legal basis we are applying in order to process your personal data is that 'processing is necessary for the performance of a task carried out in the public interest' (Article 6(1)(e)). Further information can be found in the University's Privacy Notice https://www.sheffield.ac.uk/govern/data-protection/privacy/general.
As we will be collecting some data that is defined in the legislation as more sensitive (information about your health), we also need to let you know that we are applying the following condition in law: that the use of your data is 'necessary for scientific or historical research purposes'.
What will happen to the data collected and the results of this study?
The data collected (including the transcripts) will be identified by a secure code and only accessed by members of the University study team, who will process, analyse and report upon it. All data will be stored within a secure University drive that will only be accessed by members of the University of Sheffield study team. Audio recordings will be deleted after the completion of the PhD project. Anonymous transcripts will be deleted after 3 years and once all publications are finished.
The results of this study, including a lay summary, will be published in a report. The results might also be used for other academic outputs, such as conference presentations and journal articles. It will not be possible to identify you in any results that are published.
Who is organizing and funding the study?

The study is founded by Saudi Culture Bureau. The study is carried out by PhD student at the School of Health and Related Research, University of Sheffield.

Who is the Data Controller?

The University of Sheffield will act as the Data Controller for this study. This means that the University is responsible for looking after your information and using it properly.

Who has ethically reviewed the study?

This project has been ethically approved via the University of Sheffield's Ethics Review Procedure, as administered by the School of Health and Related Research, and the MOH ethics committee.

What if something goes wrong or I want more information?

If you have questions or concerns with this study, please feel free to contact the student researcher at:

- Tourkiah Alessa, the student researcher **Email**: talessa1@sheffield.ac.uk
  Phone: +9665599346711

If you have any complaints, please contact one of the study team from the University in the first instance

- Prof Luc de Witte, the research supervisor **Email:** l.p.dewitte@sheffield.ac.uk
  Phone: +44 (0) 7850076478

If you have any complaints, please contact one of the study team from the University in the first instance. If you are still not satisfied, contact the University's Dean of the School for Health and Related Research: John Brazier, Dean of college 0114 2200 0726 (email: j.e.brazier@sheffield.ac.uk)

If a complaint relates to how your personal data has been handled, you can contact Anne Cutler, The University of Sheffield Data Protection Officer dataprotection@sheffield.ac.uk

If you feel you need to talk to someone about any issues discussed in the interview or for any additional support please contact your healthcare provider as mentioned below.

King Fahad medical city (KFMC):

- **Tel**: 0112889999 **Email:** Researchcenter@kfmc.med.sa

Primary care centers

- **Hesham Mohammed Tel:** 0112125050 **Email** Research@moh.gov.sa

Thank you very much for reading this.

Appendix 31 Participants Information Sheet for usability test (Arabic version)

ورقة معلومات المشاركين لاختبار قابلية استخدام المرضى: الإصدار ٢

---- /2019 /---

عنوان الدراسة: استخدام تطبيق هاتف ذكي للإدارة الذاتية لارتفاع ضغط الدم: دراسة القبول وسهولة الاستخدام
أنت مدعو للمشاركة في الدراسة. قبل أن تقرر ما إذا كنت ترغب في المشاركة، من المهم أن تفهم سبب إجراء هذه الدراسة وما ستشملها. يرجى قراءة المعلومات التالية بعناية ومناقشتها مع الآخرين إذا كنت ترغب في ذلك. اسألنا إذا كان هناك أي شيء غير واضح أو إذا كنت ترغب في مزيد من المعلومات. يستغرق بعض الوقت لتقرر ما إذا كنت ترغب في المشاركة أم لا.

تجرى هذه الدراسة من قِبل باحث الطالبة، كجزء من مشروع الدكتوراه الخاص بها، من كلية الصحة والأبحاث ذات الصلة بجامعة شيفيلد. يطلب منك المشاركة في هذه الدراسة.

الهدف العام من هذه الدراسة هو التقاط نظرة ثاقبة من المرضى حول قابليتها للاستخدام (مدى سهولة العثور على التطبيق للاستخدام) وقبول التطبيق (رضاك عن التطبيق). ستشمل الدراسة المرضى الذين يستخدمون التطبيق في ظروف محكومة لتحقيق هذا الهدف.

لماذا تم اختياري؟

لقد طُلب منك المشاركة لأنك شخص قد يكون التطبيق مفيدًا له. بالإضافة إلى ذلك، نحن مهتمون بمعرفة ما يفكر به الناس في التطبيق، وآرائكم قيمة لاستكشاف المواقف تجاه قابلية الاستخدام وقبول هذا التطبيق في دعم الإدارة الذاتية لارتفاع ضغط الدم في المملكة العربية السعودية حتى نتمكن من تحسين المستخدم الود من هذه التطبيقات.

هل يجب علي المشاركة؟

الأمر متروك لك للمشاركة أو عدم المشاركة. إذا قررت المشاركة، فسوف يعطيك باحث الطالب ورقة المعلومات هذه للقراءة والمتابعة، وسيتم شرح الدراسة لك وسيتم الرد على أسئلتك. سيُطلب منك بعد ذلك التوقيع على نموذج موافقة. سيحدث الاختبار في وقت ومكان مناسب لك داخل المستشفى أو مركز الرعاية الأولية. إذا قررت المشاركة، فلا يزال بإمكانك الانسحاب في أي وقت قبل تحليل بياناتك، والتي عادة ما تكون بعد أسبوع من الاختبار، ودون إبداء سبب. ومع ذلك، إذا قررت الانسحاب بعد أن تم بالفعل تحليل بياناتك، فستحتفظ الدراسة ببياناتك.

يمكنك التوقف عن المشاركة في أي وقت عن طريق الاتصال بالباحث الطلابي (يرجى مراجعة الصفحة 3 للحصول على تفاصيل الاتصال).

إذا قررت التوقف عن المشاركة، أو كنت غير قادر على المتابعة، فيمكنك سحب أي معلومات تم جمعها منك، حيثما أمكن، من هذه الدراسة إذا أخبرتنا بذلك. ليس عليك تقديم أي أسباب ولن تكون هناك عواقب سلبية إذا اخترت الانسحاب. ومع ذلك، إذا تم بالفعل إخفاء بياناتك وتحليلها، فلن يكون من الممكن تحديدها على أنها بياناتك أو حذفها.

ماذا على ان افعل؟

سيُطلب منك إكمال استبيان موجز حول تفاصيلك الشخصية (مثل العمر). ستكون لديك فرصة لإعطاء وجهات نظرك حول تجربتك في استخدام التطبيق من خلال اختبار قابلية الاستخدام. في هذا الاختبار، سيُطلب منك إكمال المهام المتعلقة بوظائف التطبيق والتفكير بصوت عالٍ (تقديم تعليقاتك ومشاعرك وتفاعلك) أثناء تنفيذ هذه المهام. سيكون هذا بهدف تحديد أي مشكلات في قابلية الاستخدام (أو مدى سهولة استخدام هذا التطبيق) واستكشاف مدى رضاك العام تجاه هذا التطبيق.
سيستغرق هذا الاختبار حوالي 60 دقيقة وسيتم تسجيله في تسجيل صوتي وفيديو. سيتم استخدام تسجيلات الاختبار فقط للنسخ.

ماذا سيحدث للتسجيلات الصوتية / الفيديو؟

يمكنك سحب موافقتك قبل التسجيل وأثناءه وبعده، وسيتم إتلاف البيانات شريطة عدم بدء التحليل. يمكنك إيقاف التسجيل لأي سبب. سيتم الاحتفاظ بسرية جميع المعلومات التي تم جمعها للمشروع. سيتم تخزين التسجيلات في مجلد مقيد الوصول على محرك الأقراص الآمن عبر الإنترنت لجامعة شيفيلد. سيتم إعداد النصوص مجهولة الهوية من هذه التسجيلات باللغة العربية وترجمتها إلى الباحث من قبل الطالب، وبعد ذلك تتم ترجمة هذا النص المجهول مرة أخرى إلى الإنجليزية من خلال خدمة ترجمة محترفة في المملكة العربية السعودية لضمان عدم تغيير المعنى.

سيتم استخدام هذه النسخة المترجمة النهائية لضمان دقة أكبر في التحليل والإبلاغ عن النتائج. سيتم حذف التسجيلات عند الانتهاء من مشروع الدكتوراه.

ما هي الفوائد أو العيوب المحتملة للمشاركة؟
لا توجد فوائد مباشرة للمشاركة في هذه الدراسة. ومع ذلك، فإن مشاركتك ستساعدنا
.فهم مدى سهولة استخدام التطبيق وما يمكن أن يساعد في تحسينه للإصدارات المستقبلية
هل هناك مساوئ للمشاركة وماذا سيحدث لمعلوماتي؟
.نعتقد أنه لا توجد مخاطر معروفة مرتبطة بالمشاركة في الدراسة. العيب الوحيد هو استخدام وقتك في المشاركة
هل ستبقى مشاركتي في هذا المشروع سرية؟
سيتم الحفاظ على سرية جميع المعلومات التي يتم جمعها منك خلال هذه الدراسة (البيانات الشخصية والتسجيلات والنصوص) ولن تكون متاحة إلا لفريق الدراسة (الباحثة الطالبة والمشرفون عليها) وستظل مجهولة الهوية. لن تتمكن من تحديد هويتك في أي تقارير أو منشورات. سيتم تعريفك برمز وليس اسم. سيتم تخزين أي تسجيلات صوتية والملاحظات المصاحبة بشكل آمن. ومع ذلك، في حالات نادرة (مثل الحماية، أي تدابير لحماية الأفراد المعرضين للخطر من المخاطر أو الأذى؛ على سبيل المثال، في حالات الطوارئ الطبية)، سيكون لدى القائم بإجراء المقابلة التزامات قانونية تتجاوز اتفاقيات السرية
ما هو الأساس القانوني لمعالجة بياناتي الشخصية؟
وفقًا لتشريعات حماية البيانات، نحن مطالبون بإبلاغك بأن الأساس القانوني الذي نطبقه من أجل معالجة بياناتك الشخصية هو أن "المعالجة ضرورية لأداء مهمة يتم تنفيذها في المصلحة العامة" (المادة 6 (1)) (هـ)). يمكن العثور على مزيد من المعلومات في إشعار الخصوصية بالجامعة
https://www.sheffield.ac.uk/govern/data-protection/privacy/general.

نظرًا لأننا سنجمع بعض البيانات التي تم تعريفها في التشريع على أنها أكثر حساسية (معلومات حول صحتك)، نحتاج أيضًا إلى إعلامك بأننا نطبق الشرط التالي في القانون: أن استخدام بياناتك `` ضروري لـ أغراض البحث العلمي أو التاريخي
ماذا سيحدث للبيانات التي تم جمعها ونتائج هذه الدراسة؟
سيتم تحديد البيانات التي تم جمعها (بما في ذلك النصوص) بواسطة رمز آمن ويمكن الوصول إليها فقط من قبل أعضاء فريق الدراسة بالجامعة، الذين سيعالجونها ويحللونها ويبلغون عنها. سيتم تخزين جميع البيانات في محرك أقراص جامعي آمن لا يمكن الوصول إليه إلا من قبل أعضاء فريق الدراسة بجامعة شيفيلد. سيتم حذف التسجيلات الصوتية مجهولة الهوية بعد . بعد 3 سنوات وبمجرد الانتهاء من جميع المنشورات|الانتهاء من مشروع الدكتوراه. سيتم حذف النصوص
سيتم نشر نتائج هذه الدراسة، بما في ذلك الملخص العام، في تقرير. يمكن أيضًا استخدام النتائج للمخرجات الأكاديمية الأخرى، مثل عروض المؤتمرات ومقالات المجلات. لن يكون من الممكن التعرف عليك في أي نتائج تم نشرها
من يقوم بتنظيم وتمويل الدراسة؟
الدراسة مموله ماليا من قبل الملحقية الثقافة السعودية. يتم إجراء الدراسة من قبل طالب دكتوراه في كلية الصحة والبحوث .ذات الصلة، جامعة شيفيلد
من هو مراقب البيانات؟
ستكون جامعة شيفيلد بمثابة مراقب البيانات لهذه الدراسة. هذا يعني أن الجامعة مسؤولة عن العناية بمعلوماتك واستخدامها بشكل صحيح
من قام بمراجعة الدراسة أخلاقيا؟
تمت الموافقة على هذا المشروع أخلاقياً من خلال إجراء مراجعة الأخلاقيات بجامعة شيفيلد ، كما تدار من قبل كلية الصحة .والبحوث ذات الصلة ، ولجنة الأخلاقيات بوزارة الصحة
ماذا لو حدث خطأ ما أو أردت المزيد من المعلومات؟
إذا كانت لديك أسئلة أو مخاوف بشأن هذه الدراسة، فلا تتردد في الاتصال بالطالب.

الباحث الطالب: تركيه العيسى **البريد الالكتروني:** Talessa1@sheffield.ac.uk
رقم الجوال: ٠٠٩٦٦٥٥٩٣٤٦٧١١

إذا كانت لديك أي شكاوى، فيرجى الاتصال بأحد فريق الدراسة من الجامعة في المقام الأول
مشرف البحث: لوك دي ويت **البريد الالكتروني:** l.p.dewitte@sheffield.ac.uk
رقم الجوال: ٠٠٤٤٧٨٥٠٠٧٦٤٧٨

إذا كنت لا تزال غير راضٍ، فيمكنك الاتصال بعميد الجامعة لكلية الصحة والأبحاث ذات الصلة:
جون برازير **البريد الإلكتروني:** j.e.brazier@sheffield.ac.uk
الهاتف:٠١١٤٢٢٢٠٧٢٦
إذا كانت هناك شكوى تتعلق بكيفية التعامل مع بياناتك الشخصية، فيمكنك الاتصال بـ اني كولتر، مسؤولة حماية البيانات بجامعة شفيلد dataprotection@sheffield.ac.uk

إذا كنت تشعر بأنك بحاجة الى التحدث الى شخص ما عن أي القضايا التي تمت مناقشتها في المقابلة أو أي دعم إضافي يرجى الاتصال مقدم الرعاية الصحية الخاص بك كما هو مذكور أدناه

مدينة الملك فهد الطبية
البريد الالكتروني: Researchcenter@kfmc.med.sa
الهاتف: 0112889999

مراكز الرعاية الأولية (هشام محمد)
البريد الالكتروني: Research@moh.gov.sa **هاتف:** 0112125050

شكرا جزيلا لقراءتك هذه الورقة

.

Appendix 32 Consent Form (English version)

Patients participant consent form Version: V2

"Using app for self-management of hypertension: Acceptance and usability study" Consent Form

Please tick the appropriate boxes **Taking Part in the Project**	**Yes**	**No**
I have read and understood the project information sheet dated DD/July/2019 or the project has been fully explained to me. (If you will answer No to this question please do not proceed with this consent form until you are fully aware of what your participation in the project will mean.)	☐	☐
I have been given the opportunity to ask questions about the project.	☐	☐
I agree to take part in the project. I understand that taking part in the project will include downloading and using an app for four weeks (in which anonymous engagement data will be collected), completing a questionnaire and participating in an interview which will be audio recorded and transcribed anonymously and translated by a professional service in Saudi Arabia to ensure accuracy.	☐	☐
I understand that my taking part is voluntary and that I can withdraw from the study before my data has been analysed [usually one week after interview]; I do not have to give any reasons for why I no longer want to take part and there will be no adverse consequences if I choose to withdraw.	☐	☐
How my information will be used during and after the project		
I understand my personal details such as name, phone number, age, and email address etc. will not be revealed to people outside the project.	☐	☐
I understand and agree that my words may be quoted in publications, reports, web pages, and other research outputs. I understand that I will not be named in these outputs unless I specifically request this.	☐	☐
I understand that my data will be securely retained by the University of Sheffield through the PhD research period and for 3 years once all expected publications are finished.	☐	☐
So that the information you provide can be used legally by the researchers		
I agree to assign the copyright I hold in any materials generated as part of this project to The University of Sheffield.	☐	☐

Name of participant [printed] Signature Date

Name of Researcher [printed] Signature Date

Project contact details for further information:

Name		**Phone**	**Email**
Tourkiah Alessa	Student Researcher	0114 222 5426	talessa1@sheffield.ac.uk
Mark Hawley	Co-supisover	0114 222972	mark.hawley@sheffield.ac.uk
Luc de Witte	Supervisor	114 222 8277	l.p.dewitte@sheffield.ac.uk
John Brazier	Dean of ScHARR		j.e.brazier@sheffield.ac.uk
Address	ScHARR, 30 Regent Street, Sheffield S1 4DA		

Appendix 33 Consent Form (Arabic version)

نموذج موافقة المشارك للمريض الإصدار ٢

"نموذج الموافقة" قبول واستخدام دراسة: ضغط الدم ارتفاع لمرضى اللياقة لإدارة تطبيق لاستخدام

يرجى وضع علامة في الخانات المناسبة		
المشاركة في المشروع		
قرأت وفهمت ورقة معلومات المشروع المؤرخة July / 2019 / أو تم شرح المشروع لي شفهياً. (إذا كانت إجابتك "لا" على هذا السؤال فيرجى عدم التوقيع على نموذج الموافقة هذا حتى تكون مدركاً تماماً لما ستعنيه مشاركتك في المشروع).	☐	☐
قد أتيحت لي الفرصة لطرح أسئلة حول المشروع		
أوافق على المشاركة في المشروع. أدرك أن المشاركة في المشروع ستتضمن تنزيل التطبيق واستخدامه لمدة أربعة أسابيع (يتم تسجيل جميع بيانات التمارين مع التطبيق مع ملء الهوية). ومن ثم المشاركة في مقابلة شخصية حول تجربة المشاركة في الدراسة	☐	☐
أدرك أن مشاركتي طوعية وأنه يحق لي الانسحاب من الدراسة في أي وقت [ ] ولا يتعين علي تقديم أي أسباب لعدم رغبتي في المشاركة ولن تكون هناك عواقب سلبية إذا اخترت الانسحاب	☐	☐
كيف سيتم استخدام معلوماتي أثناء وبعد المشروع		
أدرك أن بياناتي الشخصية مثل الاسم ورقم الهاتف والعمر وعنوان البريد الإلكتروني وما إلى ذلك لن يتم الكشف عنها للأشخاص خارج المشروع	☐	☐
أفهم وأوافق على أن يتم نقل كلماتي في المنشورات والتقارير وصفحات الويب وغيرها من مخرجات البحث. أدرك أنه لن يتم ذكر اسمي في هذه المخرجات ما لم أطلب ذلك على وجه التحديد.	☐	☐
أدرك أن جامعة شيفيلد ستحتفظ بالبيانات في مكان آمن خلال فترة بحث الدكتوراه لمدة 3 سنوات بعد الانتهاء من جميع المنشورات ذات الصلة.	☐	☐
كيف يمكن استخدام المعلومات التي أقدمها بشكل قانوني من قبل الباحثين	☐	☐
أوافق على تعيين حقوق الطبع والنشر التي أملكها في أي مواد تم إنشاؤها كجزء من هذا المشروع إلى جامعة شيفيلد.	☐	☐

اسم المشارك **التاريخ** **التوقيع**

اسم الباحث **التاريخ** **التوقيع**

تفاصيل الاتصال بالمشروع لمزيد من المعلومات

الاسم تركي العيسى	باحث طالب	الهاتف: 0114222426	البريد: Talessa1@sheffield.ac.uk
مارك هاولي	المشرف الثاني	الهاتف 0114222972	البريد mark.hawley@sheffield.ac.uk
لوك دي ويت	المشرف الأول	الهاتف 0114228277	البريد l.p.dewitte@sheffield.ac.uk
جون برازير	عميد كلية الصحة والبحوث		البريد j.e.brazier@sheffield.ac.uk

Appendix 34 Confidentiality Agreement with the developer

The University Of Sheffield.

Confidentiality Agreement for use with the Cora Health app developer

Research Study Title: Patient and doctor attitudes towards, and acceptance of, the use of hypertension apps in Saudi Arabia

1. I, Josef Moser developers, agree to maintain full confidentiality of all research data received from the participants/ research team related to this research study.
2. I will hold in strictest confidence the identity of any individual that may be revealed (in case) during the using the app by participants or in any associated documents.

3. I will not make copies of any collected data (e.g., engagement data), or other research data, unless specifically requested to do so by the researcher.
I will not provide the research data to any third parties without the client's/user consent except for partnering service provider that is involved in the data collection process (e.g., data engagement).
5. I will store all study-related data, including engagement data securely with implementing organizational and technological measures appropriate to the nature of the data to prevent the unauthorized or accidental access, use or disclosure of the Data as long as they are in our possession.
6. I will notify the researcher team as soon as reasonably practicable after becoming aware of any unauthorised or accidental access, use or disclosure of the Data, and to co-operate with any investigation made by the research team in connection with the unauthorised or accidental access, use or disclosure of the Data;

7. I will process the Data in accordance with all applicable laws and regulations and according to the GDPR;

6. All data provided or created for purposes of this agreement, including any back-up records, will be returned to the research team and permanently and securely deleted and securely destroyed, pursuant to the instructions of the research team.
7. I understand that University of Sheffield has the right to take legal action against any breach of confidentiality that occurs in my handling of the research data.

Developer name (printed) Josef Moser, CEO at Swiftware OÜ (parent company of Cora Health)
Developer signature [redacted]
Date 09 August 2019

Appendix 35 Contribution Statements

Title	**Paper 1**	Mobile Apps to Support the Self-Management of Hypertension: Systematic Review of Effectiveness, Usability, and User Satisfaction.
	Paper 2	Smartphone Apps to Support Self-Management of Hypertension: Review and Content Analysis
	Paper 3	Using a Commercially Available App for the Self-Management of Hypertension: Acceptance and Usability Study in Saudi Arabia
Publication Status		All published
Students Contribution to the paper		The PhD student developed the studies protocols/methods, collected and analyzed the data and drafted the final manuscripts. Supervisors (Prof. Luc and Prof. Mark) reviewed and contributed to the protocols and the manuscripts.
(Student Author's name)		**Tourkiah Alessa** **Signature:** [redacted]
Co-Authors Name		Luc de Witte, Mark Hawely, Emma Hock, Sarah Abdi and Nouf Alsulmay.

Co-Author Statement

I hereby declare that I am aware the mentioned above works of which I am a co-author will form part of the PhD dissertation by PhD student **Tourkiah Alessa** who made the major contribution to the work mentioned above.

Supervisor Confirmation
I have sighted email or other correspondence from all Co-authors confirming their certifying authorship.

Name: **Prof. Luc de Witte**	Signature	Date
	[redacted]	March 23, 2021