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Effectiveness of mHealth apps and their prescribability in general practice

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Effectiveness of mHealth apps and their prescribability in general practice

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Abstract

Background

The last decade witnessed the unprecedented popularity of smartphones in all aspects of our lives. Two categories of smartphone applications – Medical, and Health and Fitness - which are collectively called 'mobile health apps' or mHealth apps also became universal. Their availability and accessibility to patients make them a potentially prescribable non-drug intervention to enhance self-management of many conditions. However, their effectiveness and usability are not well scrutinized. It is challenging for doctors to navigate 350 000 mHealth apps to find the right ones to recommend. Moreover, mHealth app use by Australian general practitioners (GPs) and the barriers and facilitators they encounter when integrating mHealth apps in their clinical practice have not been studied comprehensively. Potential solutions to overcome the barriers to prescribing effective mHealth apps in practice needs to be explored.

Aims

The overall aim of this thesis is to explore the possibility of better mHealth app prescription in Australian general practice. To achieve this aim, the three main research areas examined were: (1) the evidence of effectiveness of mHealth apps; (2) the barriers and facilitators to prescribing mHealth apps in Australian general practice; and (3) the feasibility of an intervention to increase app prescription by GPs.

Methods and Results

The aims were addressed by four interrelated studies. First, an overview of systematic reviews of randomized controlled trials (RCTs) of stand-alone mHealth apps evaluated the evidence-base behind "prescribable" apps. Prescribable apps were defined as: currently available, proven effective and preferably stand-alone. The overview identified 6 systematic reviews including 23 RCTs evaluating 22 available apps that mostly addressed diabetes, mental health, and obesity. Most trials were pilots with small sample size and of short duration. Risk of bias of the included reviews and trials was high. Eleven of the 23 trials showed a meaningful effect on

health or surrogate outcomes attributable to apps, thus qualifying the tested apps to be prescribable.

Second, semi-structured interviews with GPs and patients were conducted to explore their perspectives on barriers and facilitators to mHealth app prescription in general practice. A total of 20 GPs and 15 adult patients (18-75 years old) were interviewed. From the GPs' perspectives, the main barriers to prescribing apps were: a generational difference in the digital propensity for both the GPs and patients; lack of knowledge of prescribable apps and lack of reliable source to access them; time commitments required of the GPs and patients; and privacy, safety and trustworthiness of health apps. From the patients' perspectives, the biggest barriers were the patients' age and the usability of apps. Surprisingly, patients were not concerned about privacy and data safety issues. The facilitators of app prescription were similar for patients and GPs: (1) ubiquity of smartphones and apps and younger generation; and (2) trustworthy source of prescribable apps – for patients it was their doctors, but the doctors needed a reliable professionally vetted source to access effective apps. Evidence of effectiveness was identified as an independent theme by both GPs' and patients.

Third, a survey of Australian GPs aimed to assess how the barriers identified in the previous study were perceived in a national sample of GPs. Based on the findings of the second study, we developed specific questions to the mHealth section of the 2017 Royal Australian College of General Practitioners (RACGP) Annual Technology survey. The survey gathered a total of 1014 responses, of which 621 completed the mHealth section. The participants' median years practised was 20.7 years. Two-thirds of the GPs use apps professionally as medical calculators and point-of-care references. A little over half of the GPs recommended apps for patients daily, weekly or monthly (13%, 26%, and 13% respectively). Mindfulness and mental health apps were recommended most often (n=337; 33%), followed by diet and nutrition (n=144; 14%), exercise and fitness (n=132; 13%), and women's health (n=104; 10%) related apps. Knowledge and usage of evidence-based apps from the Handbook of Non-Drug Interventions (HANDI) were low. The prevailing barriers to app prescription were lack of knowledge of effective apps (n=372; 60%) and lack of trustworthy source to

access them (n=96; 15%). GPs expressed their need for a list of safe and effective apps from a trustworthy source such as the RACGP. They prefer online video training material or webinar to learn more about mHealth apps.

Lastly, a single group before-and-after study was conducted to evaluate the feasibility of app prescription in Australian general practice and to measure the effectiveness of an intervention to increase app prescription uptake. A two-part intervention was developed: a 6 app prescription pad and short introductory videos for each app. Of the 40 GPs recruited from all around Australia, 36 completed the study. Over 4 months in total, 1324 app prescriptions were dispensed. The median number of apps prescribed per GP was 30 [range 6-111]. The median number of apps prescribed per GP per fortnight increased from the pre-study level of 1.7 to 4.1. Confidence about prescribing apps doubled from a mean of 2 (not so confident) to 4 (very confident). App videos did not affect subsequent prescription rates substantially. Post-study interviews revealed that the intervention was highly acceptable.

Conclusions and implications

The findings of these studies highlight the less than robust evidence-base for mHealth apps including major gaps in the quantity and the quality of the testing. We also identified that mHealth app prescription to be feasible in general practice both from the GPs' and patients' perspectives. Most GPs are using apps professionally and already recommend apps to patients, albeit sparingly. But their main challenges are lack of knowledge of effective apps and lack of trustworthy source to access them. A curated compilation of effective mHealth apps provided by a trustworthy professional organization would address both barriers. Our final study proved the feasibility of such solution in increasing app prescription. Besides creation and maintenance, the future of greater uptake of mHealth app prescription depends on the scalability and sustainability of a reliable app repository.

Keywords

Smartphone; mHealth; mobile health; mHealth applications; smartphone health apps; mHealth app prescription; general practice

Declaration by author

This thesis is submitted to Bond University in fulfilment of the requirements of the degree of Doctor of Philosophy by Research.

I declare that the research presented within this thesis is a product of my own original ideas and work and contains no material which has previously been submitted for a degree at this university or any other institution, except where due acknowledgement has been made.

Name: Oyungerel Byambasuren

Signature:

Date: 17 Jan 2020

Declaration by co-authors

Oyungerel Byambasuren is the sole author of Chapter 1 (General Introduction), Chapter 2 (Literature Review), and Chapter 7 (General Discussion). The remaining chapters (listed below) are multi-authored publications, on which Oyungerel Byambasuren was the lead, with other contributors acknowledged below. The design, conception, and management of all studies; data collection and analysis; initial drafting and subsequent revisions of publications; as well as response to peer-reviewers was primarily driven by the PhD candidate. Co-authors generally provided assistance with study planning and design, interpretation of the data, and critical revision of the manuscript.

Publication co-authored	Statement of contribution
Byambasuren O, Sanders S, Beller E, & Glasziou P. Prescribable mHealth apps identified from an overview of systematic reviews. *npj Digital Medicine,* 1(1), 12, 2018.	OB 70%, SS 5%, EB 10%, PG 15%
Byambasuren O, Beller E, Glasziou P. Current knowledge and adoption of mHealth apps among Australian general practitioners: a survey study. *Journal of Medical Internet Research mHealth and uHealth,* 2019;7(6), e13199.	OB 70%, EB 15%, PG 15%
Byambasuren O, Beller E, Hoffmann T, Glasziou P. mHealth app prescription in Australian general practice: a pre-post study. *Journal of Medical Internet Research mHealth and uHealth,* 2020;8(6):e16497.	OB 70%, EB 5%, TH 10%, PG 15%
Byambasuren O, Beller E, Hoffmann T, Glasziou P. Barriers to and facilitators of the prescription of mHealth apps in Australian general practice: a qualitative study. *Journal of Medical Internet Research mHealth and uHealth,* 2020;8(7):e17447.	OB 70%, EB 5%, TH 10%, PG 15%

Research Outputs

Peer-reviewed publications

1. Byambasuren, O., Sanders, S., Beller, E., & Glasziou, P. Prescribable mHealth apps identified from an overview of systematic reviews. npj Digital Medicine, 2018;1(1), 12. https://doi.org/10.1038/s41746-018-0021-9
2. Byambasuren, O., Beller, E., & Glasziou, P. Current Knowledge and Adoption of Mobile Health Apps Among Australian General Practitioners: Survey Study. JMIR mHealth uHealth, 2019;7(6), e13199. https://doi.org/10.2196/13199
3. Byambasuren O, Beller E, Hoffmann T, Glasziou P. mHealth App Prescription in Australian General Practice: Pre-Post Study. JMIR Mhealth Uhealth. 2020;8(6):e16497. https://doi.org/10.2196/16497
4. Byambasuren O, Beller E, Hoffmann T, Glasziou P. Barriers to and Facilitators of the Prescription of mHealth Apps in Australian General Practice: Qualitative Study. JMIR Mhealth Uhealth. 2020;8(7):e17447. https://doi.org/10.2196/17447

Conference abstracts and oral presentations

1. Byambasuren, O., Sanders, S., Beller, E., & Glasziou, P. Is there an app for that? Overview of systematic reviews. Poster presentation at the Bond University Higher Degree Research student conference, Oct 2016, Gold Coast, Australia.
2. Byambasuren, O., Sanders, S., Beller, E., & Glasziou, P. Is there an app for that? Overview of systematic reviews. Oral presentation at the Gold Coast Health and Medical Research Conference, Nov 2016, Gold Coast, Australia.
3. Byambasuren, O., Sanders, S., Beller, E., & Glasziou, P. Is there an app for that? Lightning talk, Australian Society for Medical Research Annual Scientific Meeting, Nov 2016, Gold coast, Australia.
4. Byambasuren, O., Sanders, S., Beller, E., & Glasziou, P. Can an app a day, keep the doctor at bay? Oral presentation at the Bond University Higher Degree Research student conference, Oct 2018, Gold Coast, Australia.

5. Byambasuren, O., Sanders, S., Beller, E., & Glasziou, P. Current Knowledge and Adoption of Mobile Health Apps Among Australian General Practitioners: Survey Study. Oral presentation at the GP18 conference, Oct 2018, Gold Coast, Australia.
6. Byambasuren, O., Beller, E., Hoffmann T., & Glasziou, P. Can an app a day keep the doctor at bay? Feasibility of mHealth app prescription in general practice. Oral presentation at the National Health and Medical Research Council Annual Symposium on Research Translation, Nov 2019. Melbourne, Australia.

Other presentations by the candidate

1. Three-Minute Thesis competition, Bond University, Australia: People's Choice winner 2016, People's choice and Runner-up 2018.
2. Falling Walls Lab Queensland, Australia 2019: State finalist
3. Queensland FameLab, British Council, Australia, 2018 and 2019: Semi-finalist.
4. The eHealth Expo, Brisbane, Australia, 2019: Invited speaker.
5. Soapbox Science Gold Coast, Australia 2019: Invited speaker
6. Compass Teaching and Learning Conference, Darwin, Australia 2019: Invited speaker.

Ethics declaration

The research associated with this thesis received ethics approval from the Bond University Human Research Ethics Committee (ethics application number 16016 and OB00017) and from the RACGP National Research and Evaluation Ethics Committee (GR00419).

Copyright declaration

Financial declaration

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Last, but not least, my extended family and friends, near and far, past and present, thank you for always being there for me. I wish you all many happy blessings!

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List of Abbreviations

Abbreviations included only in tables within the thesis are excluded from this list, as they are described in footnotes below each table.

AMA	American Medical Association
APA	American Psychiatric Association
BAC	Blood Alcohol Concentration
BMI	Body Mass Index
CBT	Cognitive Behavioural Therapy
CD	Compact Disc
CHERRIES	Checklist for Reporting Results of Internet E-Surveys
COM-B model	Capability, Opportunity, Motivation and Behaviour model
CONSORT	Consolidated Standards of Reporting Trials
COREQ	COnsolidated criteria for REporting Qualitative research
DVD	Digital Versatile Disc
eHealth	Electronic Health
EQUATOR	Enhancing the QUAlity and Transparency Of health Research
FDA	Federal Drug Administration
FTC	Federal Trade Commission
GPs	General Practitioners
GRADE	The Grades of Recommendation, Assessment, Development and Evaluation
HANDI	Handbook of Non-Drug Interventions
HCP(s)	Healthcare professional(s)
ITT	Intention to treat
MARS	Mobile App Rating Scale
mHealth	Mobile Health
NHS	National Health Services
NICE	National Institute for Health and Care Excellence
ORCHA	Organization for the Review of Care and Health Applications
PDA	Personal Digital Assistant
PICO	Population, Intervention, Comparison, Outcome

PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PTSD	Post Traumatic Stress Disorder
RACGP	Royal Australian College of General Practitioners
RCT	Randomised Controlled Trial
ROBIS	Risk Of Bias in Systematic Reviews
SDM	Standard Mean Difference
SDM	Shared Decision Making
TAU	Treatment As Usual
TIDieR	Template for Intervention Description and Replication
uHealth	Ubiquitous Health
UK	United Kingdom
USA	United States of America

Before you become too entranced with gorgeous gadgets and mesmerizing video displays, let me remind you that information is not knowledge, knowledge is not wisdom, and wisdom is not foresight. Each grows out of the other, and we need them all.

— Arthur C. Clarke

1

Chapter 1: General Introduction

1.1 Background

When Alexander Graham Bell invented the first telephone, little did he know that a century and a half later its infinitely smarter descendent would have inspired a new field in medicine called mobile health (mHealth). Nothing else parallels the explosive evolution that the telephone has gone through to become the most widely used piece of technology today - the smartphone. Integrated with another revolutionary invention, the internet, smartphones have made the accessibility of information, including health information extremely easy and more democratic than ever.

A smartphone is a mobile phone that performs many of the functions of a computer with a touchscreen interface, internet access, and an operating system capable of running downloaded applications (apps). The penetration of smartphones globally has been phenomenal. The number of smartphones worldwide is predicted to reach 5.8 billion by 2020, an increase which will be primarily driven by developing countries [1]. The unprecedented mobile computing power and the use of easily modifiable multimedia apps are what gives smartphones a unique advantage over other types of information and communication technologies, making them a vital part of mHealth.

An "app" is the default abbreviation for smartphone software applications; app became a word in its own right in 2010 [2]. Apps are sold or offered for free in centralized digital market places such as App Store for Apple iOS devices and Google Play for Android devices. Between them, they own 96% of the smartphone market and 80% of the corresponding app markets [3]. Since their inception in 2008, the stores now offer more than 3 million apps each with download counts and revenues in the billions [4]. However, the download numbers are skewed; dominated by fewer than 5,000 apps, which account for 90% of the total downloads. The word "app" is also gaining traction as the preferred terminology over "software application" for literature search for studies that used smartphone apps [5].

App stores have two app categories that concern medicine: Medical (related to specific conditions such as diabetes and depression), and Health and Fitness (wellness, diet, and exercise-oriented). Together they account for about 5% of all app downloads, which is a small proportion compared to the 25% of the most popular category of Games [6]. The phrase "mHealth apps" covers both these categories of apps, thus will be used throughout this thesis. The latest market analysis reports that out of more than two million apps in the app stores, 350 000 are mHealth apps [3]. However, the categorization at the app store is not perfect. A report by the IMS Institute for Healthcare Informatics found that only half of the mHealth apps in App store were genuinely health-related [7]. Regardless, over 100,000 mHealth apps are still more than enough to cover all aspects of health and medical conditions.

New terminologies and concepts arise with the creation and adoption of new paradigms. Laxminarayan and Istepanian were first to define mobile health in 2000 as 'unwired e-med', signifying the mobility and wireless-ness of it over e-medicine or eHealth [8]. Mobile health is the practice of medicine and healthcare supported by mobile technology and devices. Because modern mobile devices use the internet to be fully functional, mHealth also fits under the area of electronic health (eHealth), which in turn encompasses virtually everything related to computers, the internet and medicine. Additionally, terms such as 'digital health' and 'ubiquitous health' (uHealth) are used commonly to cover eHealth, mHealth, and other interrelated concepts. It is challenging to clearly define solid borders around and between these new areas as there are many overlaps that keep changing with the technology. An illustration of the interrelationship between these new concepts is shown in Figure 1.

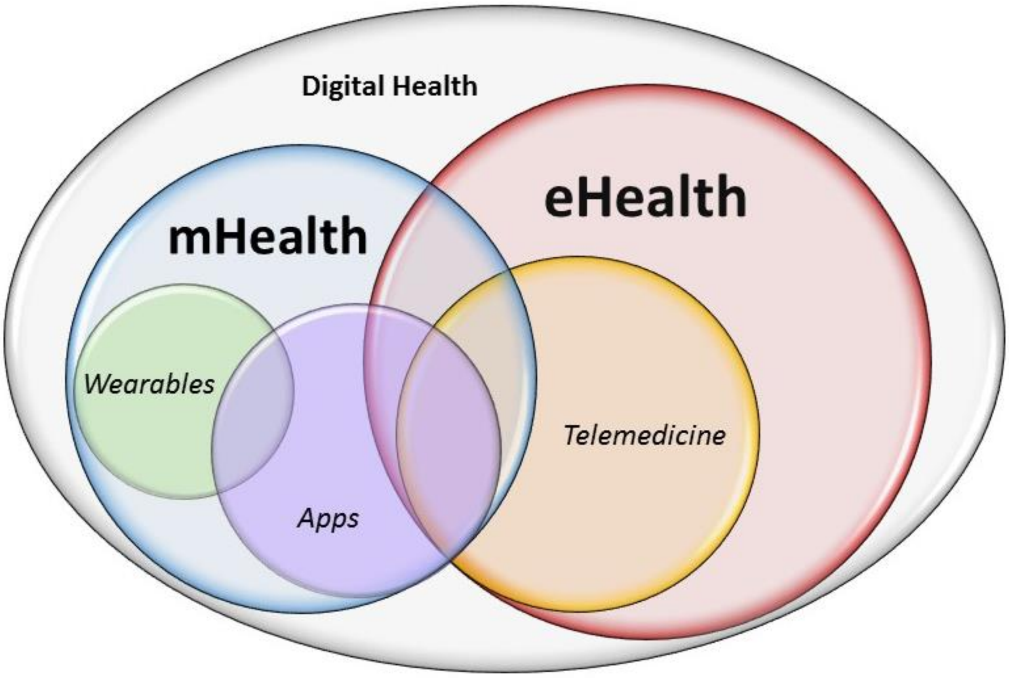

Figure 1. The interrelationship between eHealth, mHealth and some of their components.

mHealth offers many novel and 'mobile' ways to carry out eHealth and telemedicine through mobile internet, new and improved short message service (SMS), and other multimedia apps. Other digital innovations, such as wearable sensor technologies dubbed 'wearables' or 'app-cessories' that work with the associated apps are also an expanding area of mHealth.

Application and benefit of mHealth apps in healthcare, and particularly in the general practice setting, is an intriguing area of research. mHealth apps have the potential to equip an unprecedented number of patients with tools to manage their health and well-being. However, better use of mHealth apps into clinical practice is challenged by the largely unregulated app industry, lack of well-established quality and safety standards, unclear evidence of effectiveness of mHealth apps, poor interoperability with existing medical systems, and a lack of comprehensive and concerted efforts to lead such integration.

1.2 Aim

The overall aim of this thesis was to evaluate the evidence of effectiveness of patient-facing stand-alone mHealth apps and to explore the interest and feasibility of mHealth app prescription in Australian general practice. To achieve this, the studies comprising this thesis aimed to assess the evidence of effectiveness of mHealth apps, determine barriers and facilitators to prescribing mHealth apps in Australian general practice, and evaluate the feasibility of an implementation intervention to overcome the identified barriers to increase app prescription by GPs.

1.3 Research questions

To achieve the aim, 8 research questions were addressed with four independent but interrelated studies (Figure 2).

Study 1: Prescribable mHealth apps identified from an overview of systematic reviews

1. Of the currently available smartphone health apps, how many have been rigorously tested and shown to be effective?
2. How well have they been tested? What are the gaps in the research?

Study 2: Barriers and facilitators to using mHealth apps in Australian general practice: a qualitative study

1. What are the potential barriers to prescribing apps in general practice settings perceived by GPs and patients?
2. What are the potential facilitators to prescribing apps in general practice settings perceived by GPs and patients?

Study 3: Current knowledge and adoption of mHealth apps among Australian general practitioners: a survey study

1. What are the knowledge, and use of health apps by Australian GPs?
2. How do the barriers and facilitators to health app prescription that were identified during the interviews (study 2) reflect in a wider sample of GPs?

Study 4: mHealth app prescription in Australian general practice: a feasibility study

1. Can the barriers to app uptake identified during Project 2 and 3 be overcome by an intervention?

2. How effective is the intervention at increasing the uptake of app prescription by the selected cohort of GPs?

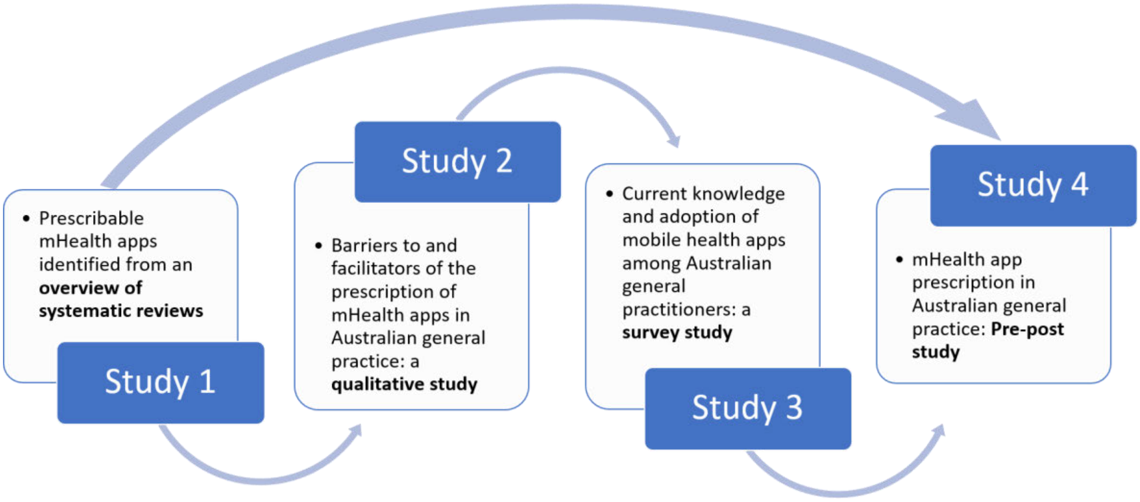

Figure 2. Interrelationship between the studies planned to be conducted in this thesis

1.4 Outline of the thesis

The first chapter introduces the concepts and terminologies that will be used in this thesis along with the overall outline. **Chapter 2** offers a review of the literature on mHealth apps, the effectiveness testing, main areas of application, and their usability in general practice setting. **Chapter 3** reports Study 1, which addressed the first two research questions in an overview of systematic reviews of randomized controlled trials (RCTs) of mHealth apps. **Chapter 4** describes Study 2, which explored the perspectives of GPs and patients towards mHealth app use in general practice. The barriers and facilitators observed in this study were used to inform subsequent studies in this thesis.

Chapter 5 reports Study 3, which was a national survey of GPs that measured the current knowledge and adoption of mHealth apps among GPs and to validate the findings of the preceding qualitative study. **Chapter 6** describes Study 4, which describes the pilot testing of the feasibility of an implementation intervention focused on increasing mHealth app prescription in Australian general practice.

Chapter 7 is a Discussion chapter, which brings together the findings and conclusions from the individual studies and presents an overall discussion about mHealth apps in a broader context. Recommendations for future research and other outstanding issues around mHealth app usability are provided.

Note: The manuscript of study 1 and 3 are published and have been reproduced in compliance with the Creative Commons Attribution licence 4.0 and reformatted to be consistent with the rest of the thesis for improved readability. Manuscripts of study 2 and 4 are currently under review and revision respectively.

1.5 References

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The key is to have humility about our innovations, and put them to rigorous testing. We can then progress by finding the occasional incremental advance, and the even rarer breakthrough.

— Paul Glasziou, BMJ blog

2

Chapter 2: Literature Review

2.1 Current evidence of mHealth app effectiveness

Despite the explosion in the number of mHealth apps, or perhaps because of it, the scientific literature is lagging behind. The exponential increase in the number of apps seems to command unquestioning acceptance of them into all aspects of life. However, for mHealth apps to be used as health interventions, a solid evidence base should be established first. Although many reviews analysed the content of mHealth apps from different fields, few reviews evaluate the effectiveness of apps by intervention studies.

There is an overall trend that more apps are being developed to address chronic conditions such as diabetes and obesity (Figure 3). The global burden of these diseases is posing an imminent threat to population health and they are highly lifestyle-related, hence largely preventable [1]. The latest estimates of diabetes prevalence from the International Diabetes Federation show that the 382 million people with diabetes in 2013 will rise to 592 million by 2035 [2]. Nearly two billion adults worldwide were overweight and obese (BMI>25 and 30kg/m2 respectively) in 2014 [3]. Obesity and diabetes are two areas where smartphone health apps might offer a convenient and cost-effective way to promote and reinforce behaviour change.

What smartphones and apps are offering is not an unforeseen phenomenon, but the result of natural evolution and progress of technological modalities that deliver tried and tested medical information and interventions to assist self-management. For the longest time, the most common approach for information dissemination for patients was printed educational materials [4]. The late 90s and early 2000s saw a few new approaches such as interactive CDs and DVDs and personal digital assistants (PDAs) [5, 6], only to be replaced by the arrival of smartphones. In contrast, web-based and SMS-based communications continue to survive, adapt to and evolve with the smartphones and apps [7-9]. The advanced and unique capacities of smartphones and mHealth apps such as the personalizability, interactivity, and mobility further enhance the convenience and the impact on health information and intervention delivery.

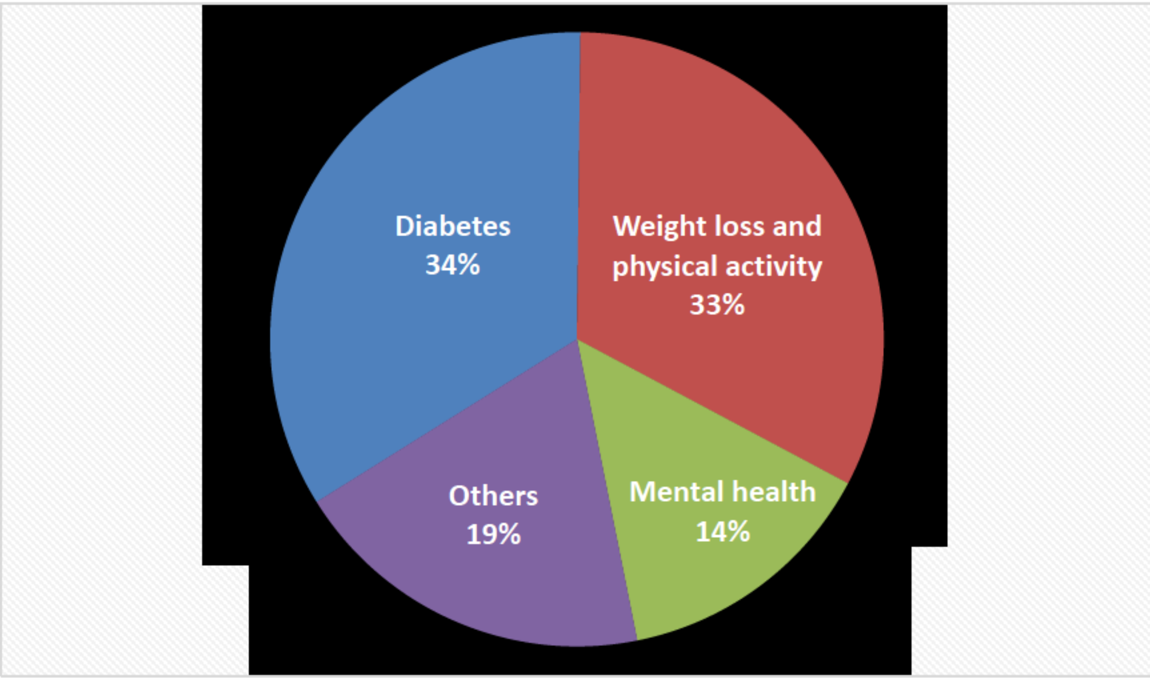

Figure 3. Distribution of articles identified during the full-text screening of systematic reviews by topic area. Diabetes, obesity, and mental health are currently the top three fields of app development and research.

Diabetes

In terms of the number of available apps, literature, and usage for self-management, diabetes is a prolific field. Many reviews offer evaluation of apps from the app stores [10-13], a comprehensive overview of the literature as well as systematic reviews of RCTs [14-16].

Reviews of diabetes apps reveal several issues. Arnhold *et al* analysed 656 diabetes apps from both major app stores and found that about half offered just one function – documentation, effectively proving that apps mostly replaced the traditional paper diary [10]. A review of 46 insulin dose calculator apps found only one app without any serious data input, output and other software issues [13]. Self-management, monitoring, patient education and support, and telemedicine are shown to improve patient outcomes in reviews of studies that used SMS and web-based interventions [14, 17]. All of these aspects can be incorporated into smartphone apps and many are being studied.

Reviews of effectiveness found that mHealth interventions, including diabetes apps, reduce glycated haemoglobin (HbA1c) level on average by 0.5% more than the comparison group [18-20]. A 0.5% reduction in HbA1c is borderline clinically significant and comparable to first-line pharmaceutical treatment [21]. However, to fully evaluate clinical significance and meaningfulness, other measures such as patients' self-management skills, knowledge, and quality of life should also be considered. Heterogeneity is an issue in these meta-analyses due to differences in components of interventions, lengths, and baseline measurements. Overall, the higher the baseline level of HbA1c and the longer the intervention, the better the patient outcomes [17].

Two primary studies report substantial decreases in HbA1c level but have problems with acceptability [22, 23]. The first trial tested a freely available stand-alone app called *Glucose Buddy* in type 1 diabetes patients. The intervention group had HbA1c decrease of 1.28% from baseline at 9-month follow up [22]. *Glucose Buddy* is no longer free of charge, as it has been acquired by an American company and the full functionality is available only by subscription. The second study tested the prototype of *Blue Star* app in type 2 diabetes patients. The intervention group's HbA1c level decreased by 2.03% compared to 0.68% for the control group patients [23]. *Blue Star* became the first app to receive Food and Drug Administration (FDA) clearance in the US. However, it is not a stand-alone app and failed to demonstrate the same level of effectiveness when tested in Canadian primary care [24].

WEIGHT LOSS

The second most common area for mHealth apps is weight-loss and physical activity. Content analysis studies provide some idea of already available apps in the app stores and their quality. Because medical professionals and content experts are rarely involved in creating apps, they are currently designed with an emphasis on appearance over substance. A review of 379 physical activity apps found none of the apps adhered to evidence-based guidelines for aerobic physical activity [25]. Another review evaluated the most popular commercial apps for weight management [26] according to the Mobile App Rating Scale (MARS) devised by Stoyanov *et al* [27]. The 23 apps they investigated scored high in "functionality" with an average MARS score of 4 out of 5, but scored low in "information quality" domain with an average MARS score of 2 out of 5.

As for effectiveness, pooling studies together is challenged by heterogeneity in the interventions and the outcomes. A systematic review by Flores-Mateo *et al* provided three 'forest' plots to examine the effectiveness of app interventions on three outcomes: weight loss, body mass index (BMI) and physical activity [28]. According to this review, the app intervention groups lost 1kg more (BMI -0.43) than the control groups, which were comparable to SMS based weight loss studies [29]. However, the clinical significance of 1kg extra weight loss is minimal. Changes in weight and BMI can be compared or pooled together easily, but different measures of physical activity interventions need an extensive conversion of units to be compared. However, Flores-Mateo *et al* failed to provide any explanation on how they were able to compare step counts with vigorous physical activity, hence their analysis of app effect on physical activity was deemed inconclusive.

For weight loss solely, two individual RCTs demonstrate both statistically and clinically significant results. The first one is *MyMealMate* app that helps make a daily recording of food and calories intake easier and more accurate [30]. It contains information on 23,000 food items that are sold in the United Kingdom (UK). The app intervention group lost 4.6kg over six months compared to paper diary (-2.9kg) and website (-0.5kg) groups. The second trial compared a diet and exercise tracking app called *Lose-It!* with the app paired with intensive counselling (weekly), less-intensive (monthly) counselling, and purely intensive counselling group with no app [31]. All groups lost weight, but the app paired with intensive counselling group lost 3 times more weight (-5.4kg) than the app alone group (-1.8kg). Weight loss equivalent to 2-5% of the initial weight is considered clinically meaningful [32].

In contrast, the most popular health and fitness app from the app stores called *MyFitnessPal* did not demonstrate any benefit when tested against a control group that was free to use any weight loss activity they choose [33]. *MyFitnessPal* is similar to *Lose-It!* and tracks diet and exercise. It has over 3 million food items in the database plus a barcode scanning function. The participants received no other intervention and were weighed at baseline, 3 and 6 months. However, at the end of the trial, there was no difference in weight loss between the groups. The study also examined the app usage data of the participants, which decreased to zero towards the end of the trial.

Step count can be a simple and more direct way to measure physical activity levels, for both patients and researchers [34]. An explosion in wearable technology in recent years has made 10,000 steps a day a ubiquitous target. The term was born when a pedometer manufacturer nicknamed the pedometer “manpo-kei”, a Japanese phrase for “10,000 steps meter” in the early 1960s. However, it is not entirely arbitrary. Japanese researcher Yoshiro Hatano studied walking habits in the following years and established the first classifications of step-related activity levels and energy expenditure, which have been validated globally since [35]. Fewer than 5,000 steps a day is considered ‘sedentary’, and 10,000-13,000 means ‘active’. Perhaps a better interpretation would be to know that 10,000 steps roughly equals walking 8 kilometres, which takes about an hour and forty minutes, burning approximately 300 kcal for an average person. Since baseline activity levels and measuring device accuracy vary, it is important to establish individual starting points and increase it in achievable increments.

A study in Ireland showed a smartphone pedometer app increased daily step counts by 2,017 more than the control group over 8 weeks in a primary care setting, which is equal to walking 1 mile [36]. However, long-term adherence and clinically meaningful outcomes are unknown because of the short duration of the trial. The participants reported that carrying their phones at all times was a practical challenge. Perhaps, commercial popularization of wearable trackers will help overcome this and improve long-term adherence. A recently published RCT reported that the baseline average step count of all participants was 9,670 steps a day and half of the participants already walked more than 10,000 steps a day [37]. However, considering the study goal was to increase daily activity to 10,000 steps a day, it is hard to see the benefit of 300 extra steps on the participants. Studies like this that have not been robustly designed or conducted can taint the reputation of mHealth and hinder its advances.

Khaylis *et al* defined five key components of technology-based weight loss programs more than a decade ago: (1) self-monitoring, (2) counsellor feedback and communication, (3) social support, (4) structured program, and (5) individually tailored program [38]. Weight-loss app studies commonly incorporate number 1, 3, and 4 but frequently exclude what evidence suggests to be the most important: professional feedback and individually tailored program.

MENTAL HEALTH

The number of mental health apps and app studies are rapidly increasing. Several systematic reviews and literature reviews have evaluated mHealth apps for conditions like depression, bipolar disorder, schizophrenia or mental health in general [39-42]. However, the quality of the app contents is shown to be poor or unsafe and the evidence of effectiveness to be small. An analysis of 117 depression apps chosen from the app store found that only 10% of those apps had a minimal level of content based on cognitive behavioural therapy (CBT) or behavioural activation (BA) and none had any efficacy/effectiveness studies behind them [43]. Another analysis showed the majority of 243 depression apps failed to mention their organizational affiliation and content source despite claiming their main purpose to provide therapeutic treatment and psychoeducation [44].

One way to transition mental health into mHealth is to convert already proven web-based psychotherapy interventions into smartphone apps [45-47]. *Managing Depression* app is one such example. Developed as one of 4 mental health apps under *This way up* project, it contains previously tested 12-week online CBT program for depression [45]. The app version has demonstrated to be equally effective as the web version, which was initially shown to decrease depressive symptoms compared to a waitlist control group (moderate to large effect size (Cohen's d 0.63-0.89)). It is important to note that although the program can be used independently, both studies had psychologist support in forms of weekly emails or phone calls in addition to the interventions. The impact of such additional support and whether the same level of follow up and support is feasible in general practice setting remains to be seen.

Studies of bipolar disorder and schizophrenia apps have been less successful. A review of 82 apps for bipolar disorder found 35 of these were symptom monitoring tools while another 32 provided information, but only covered 4 out of 11 core psychoeducation principles and 2 out of 13 best-practice guidelines [48]. A systematic review by Faurholt-Jepsen *et al* identified two research groups who are testing smartphone-based self-monitoring apps for bipolar disorder [41]. However, these studies are yet to yield encouraging results. A 2015 review of smartphone apps for schizophrenia found only five small feasibility studies from research groups working on apps [40]. Only one of these was developed further and tested in an RCT [49]. Symptom monitoring is an important management strategy for chronic conditions and smartphones are well placed to be the medium that enables shared decision making, real-time feedback, ecological momentary assessment and ecological momentary intervention.

Challenges of effectiveness testing

Some researchers have suggested that RCTs are not necessary or suitable to evaluate all mHealth interventions because the average time it takes for an RCT (2 years) is far too long to evaluate fast-evolving technology-based interventions [50]. The challenge of ever-changing operating systems and long-term funding to upkeep the apps support the above argument. However, the effect of app interventions could be marginal, and small benefits can only be reliably detected by rigorous testing. Thus, RCTs should remain as the gold standard [51].

Evidence for the effectiveness of smartphone mHealth apps seems to be small and scarce at the moment. Many pilot studies are just designed inadequately: the population size is too small, the intervention too complex, and duration too short and even fewer studies progress on to full-scale RCTs. To quote my supervisor Paul Glasziou “the key is to have humility about our innovations and put them to rigorous testing. We can then progress by finding the occasional incremental advance, and the even rarer breakthrough” [52].

2.2 Usability of mHealth apps in General Practice

General practice is a major part of the frontline of healthcare – primary care. GPs see hundreds of different conditions and patients of all ages and life stages. mHealth apps have the potential to benefit both doctors and patients in areas such as continuity of care, shared decision making, and the prevention and management of chronic conditions [53]. This section examines a number of app studies that have been conducted in general practice or primary care, which includes allied health and community pharmacy in addition to general practice and explore the usability of mHealth apps in such settings. Although 'general practice' and 'primary care' are often used interchangeably, general practice is the setting of focus throughout the studies conducted for this thesis.

As mentioned previously, diabetes, mental health and weight-loss apps make up the majority of the mHealth apps currently. Patients with diabetes and depression are two of the top ten most common conditions GPs consult with [54]. It is notable that weight loss inquiries are not in the top ten, or in fact in the top thirty most common GP consultations. The availability and variety of weight-loss interventions as a separate industry outside the medical establishment means that individuals can seek such interventions independently from their doctors' advice, or doctors may not readily initiate the weight discussions due to consultation time constraints.

Studies conducted in general practice/primary care

There are several studies of mHealth apps that have been conducted in primary care settings. A systematic review of 16 RCTs that tested technology-assisted weight-loss interventions in primary care concluded that the addition of technology helped to achieve significant weight loss (5-45% of patients lost 5 or more per cent of their initial weight) by incorporating already proven behaviour change elements such as self-monitoring, in-person feedback and targeted, structured lifestyle coaching [55]. More than half of the included studies lasted at least one year and about half of the studies had face-to-face follow-ups and physician consultations as part of the intervention. Both of these correlated with increased weight loss compared to fully automated interventions. Although the interventions included in this review were mostly web-based, it is an encouraging result of successful technology-based intervention in primary care in contrast to some short-term fully automated studies that did not produce tangible results that we discussed earlier [33, 36].

However, there are other large RCTs that were conducted in real-world primary care/general practice settings that failed to demonstrate any benefit of using mHealth apps over the control group. One study used an app as an adherence support tool for increasing physical activity and the Mediterranean diet over 12 months [56]. The control group received the same initial consultation and a leaflet instead of the intervention app. There were no between-group differences in the outcomes at 3 and 12 months. The famed diabetes app BlueStar, which is the first-ever FDA-approved app therapeutic in the US was shown to reduce glycated haemoglobin HbA1c levels by 1-2% in the initial studies [23, 57, 58] but failed to show the same level of effectiveness when tested in Canadian primary care setting in a pragmatic RCT [24]. This highlights the importance of testing mHealth apps in real-world settings before branding them as effective.

General practice consultation is also an important opportunity to address common modifiable risk factors such as smoking and hazardous drinking. In general, text message-based smoking cessation interventions have been shown to improve adherence to quitting and long-term abstinence by 67% [59, 60]. However, implementation of SMS programs in general practice would require additional human and technical resources, unlike stand-alone smoking cessation apps that patients can download directly onto their smartphones.

A Cochrane review of smoking cessation apps showed that there was low-level evidence that cessation apps were as effective as traditional low-intensity support [61]. However, a review of 112 cessation apps available in Australia found only two of them were evaluated for their efficacy [62]. Individual studies of cessation apps show apps with advanced content such as the incorporation of acceptance and commitment therapy (ACT) or cognitive behavioural therapy (CBT) were more effective than simpler information-based apps [63, 64]. An Australian cessation app that provided decision aid with additional structured support such as motivational messages, quitting diary and benefits tracker, was twice as effective as an information-only app at 3 months (RR 2.08, 95% CI 1.38-3.18) [65]. Unfortunately, this app is no longer available due to a lack of ongoing funding to update and maintain it.

There is a scarcity of mHealth apps that address harmful alcohol use except for blood alcohol concentration (BAC) calculating apps [66]. A Swedish study tested a government-backed mobile BAC app among university students [67]. Not only the attrition rate was high (40%), the results showed increased drinking among participants over the seven weeks. The researchers provided explanations such as the heaviest drinking holidays happened during the study and the students were able to drink more because the app did not display BAC over 0.08%, which is the legal limit for driving, therefore, giving a false sense of reassurance. Such backfiring could have dangerous implications; hence more careful intervention design is needed. Another app designed to support abstinence for people who are leaving residential alcohol treatment was evaluated in an RCT and found that the intervention helped people to achieve an extra one and a half alcohol-free day per month compared to people with no such support [68]. The clinical significance of this result is minimal and alcohol use curbing remains an underutilized area of app development.

Patients' perspectives

Patients are the end-users of mHealth apps, therefore their values, needs and preferences should be taken into account during app development and testing. Smartphone ownership is increasing every year and Australia is among the leaders in the world around 90% [69]. mHealth apps download counts are in the billions, however, most apps were used only a few times [70]. A large survey found that younger educated female cohort was more likely to use mHealth apps and consume more fruit and vegetables, and exercise more than people without smartphones or mHealth apps [71].

In contrast, patients with multiple chronic conditions reported that they would like to use mHealth apps and technology to track their life and health more but tracking feels like a job and can evoke negative emotions like being reminded that they are "a sick person" or "a bad patient" [72]. They also felt that their tracking data were not trusted or valued by their doctors who preferred lab reports. This highlights the importance of education and communication about the use of new technology and patient-generated data in healthcare.

Still, there are examples of mHealth apps potential to trigger and support positive behaviour change among patients. Patients reported that participation in a pedometer app study not only helped change their relationship with exercise but also had "sequential and synergistic positive cascade effect" (pp e503) [73]. The researchers termed it the "Know-Check-Move" effect and illustrated the relationship between the identified themes (Figure 4). Knowing the current state of their health helped patients visualize what is it that they need to work with or improve on, and enabled them to check their status and progress, which encourages positive actions in managing health and medical conditions.

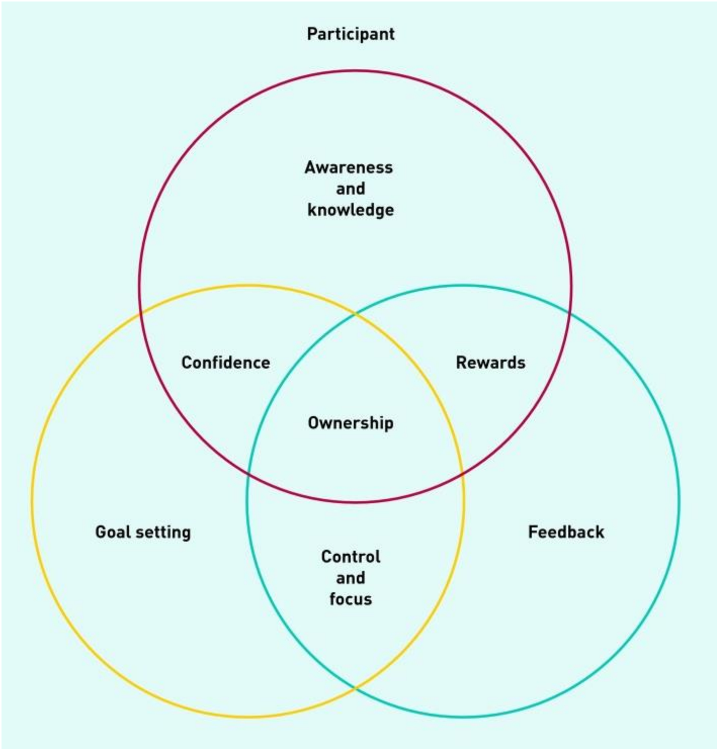

Figure 4. The 'Know-Check-Move' effect. Patients from smartphone pedometer app study reported that their experience of these seven steps shown in the graph during the trial affected their attitudes and behaviours around exercise positively. (Casey M, Hayes PS, Glynn F, G OL, Heaney D, Murphy AW, et al. Patients' experiences of using a smartphone application to increase physical activity: the SMART MOVE qualitative study in primary care. The British journal of general practice : the journal of the Royal College of General Practitioners. 2014;64(625):e500-8 [73]).

Studies increasingly show that the majority of patients are interested in using mHealth apps but mHealth apps can only help patients if the patients can find and access safe and effective apps to use [74, 75]. The overwhelming number of apps in the app stores makes it challenging and patients need trustworthy and reliable guidance or source to find the right apps [76]. A survey conducted by the Consumer Health Forum of Australia showed that GPs were the most trusted source of mHealth app recommendation ahead of government (5th place out of 9) with Google and App store coming in last [77]. This is a clear demonstration of the importance of equipping GPs and other primary care providers with proper information and trustworthy guidance on mHealth apps so that they can provide the same to their patients.

DOCTORS' PERSPECTIVES

American Medical Association (AMA) survey found more than a third of the doctors have recommended mHealth apps to patients [78]. The AMA stated its support for the use of mHealth apps in clinical practice provided that the apps have high-quality evidence for safety and effectiveness and that the doctors adhere to evidence-based practice guidelines.

In Australia, the Royal Australian College of General Practitioners (RACGP) has been surveying GPs' knowledge and use of technology and mHealth apps annually since 2015[79, 80]. Australian GPs' use of apps has increased from 40% in 2016 to 60% in 2018, which is thrice as much as French GPs' [81]. GPs with up to 20 years of experience are more comfortable with new technology compared to older GPs. The most common areas of apps they recommend have been mental health, fitness and nutrition, and women's health. Barriers to using technology more in their daily practice included lack of perceived needs and benefits, lack of knowledge and training on proper use of the new technology, and lack of practice incentives.

Doctors have also expressed their concerns around data safety, interoperability and increased workload when adopting new technology into their practice. A recent review identified almost 180 factors that influence mHealth adoption such as cost, risk-benefit analysis, and ease-of-use in addition to the above concerns [82]. However, successful uptake of Health intervention will require identification of more specific barriers to the location and healthcare setting.

Despite the barriers and concerns, there has been growing efforts to facilitate official "app recommendation" or "app prescription" around the world. In America, private initiatives that offer a repository of mHealth apps such as AppScript, RxUniverse, and iMedicalApps have been popping up [83]. However, such initiatives have been mostly set up by health tech companies and curated by early-adopters in healthcare who are excited about the possibilities of mHealth apps, thus can be fallible to potential bias, conflict of interest, and to the issue of expert curation replacing evidence-base [84].

The UK set up a more official system, where the National Health Service (NHS) Digital Health Choices initiative took the leadership to compile safe and recommendable apps for doctors and patients [85]. In 2019, the National Institute for Health and Care Excellence (NICE) released "Evidence Standards Framework for Digital Health Technologies" to help streamline the app quality assurance in the UK [86]. It outlines three tiers of evidence required according to the functions of the apps and tier three is required for mHealth apps that diagnose, monitor, calculate, treat health and medical conditions. The NHS App library outsources the evaluation of mHealth apps to two private companies [87, 88].

Another approach to support app prescription is to equip doctors with a framework to evaluate apps themselves. The American Psychiatric Association (APA) pioneered the work in this area and released its first framework for doctors in 2017[89]. Since then they have expanded it to include important subcategories in each step of evaluation (Figure 5) [90]. This is a hierarchical pyramid model, which means the privacy and security are evaluated before the evidence base and therefore more important in deciding whether the app is good enough for clinical use. Some would argue that the evidence should be more important, i.e. moved 'down' on the hierarchy or precede the security concerns, because if there is no evidence of benefit of the apps, then no matter how secure their data storage is, the app will be of no use to patients. Perhaps a model where these five levels of evaluation are organized as equally important is better.

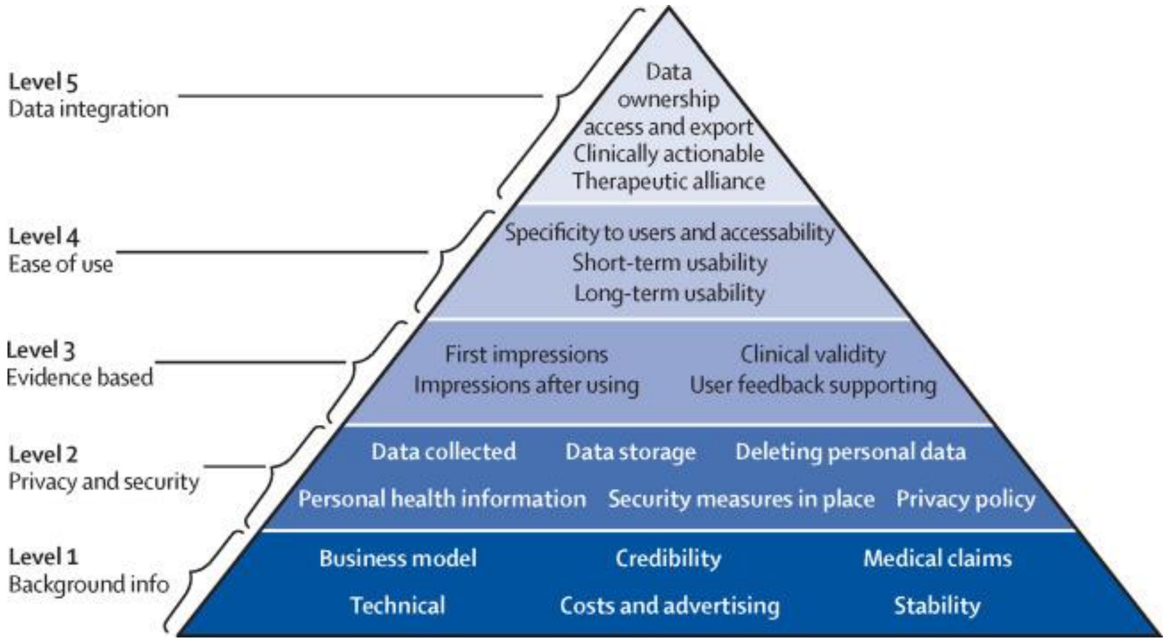

Figure 5. The American Psychiatric Association guideline for app evaluation. (Henson P, David G, Albright K, Torous J. Deriving a practical framework for the evaluation of health apps. The Lancet Digital Health. 2019;1(2):e52-e4. [90]).

It may not be feasible or sustainable to ask time-poor GPs to take on the responsibility to find safe, effective and usable mHealth apps themselves. The key to successful mHealth app prescribing in primary care is not to burden the patients and the doctors with additional infrastructure, human resources, and extensive learning, but to harness existing opportunities such as the patient's own device and motivation, and the doctor's knowledge of reliable mHealth apps. This bottom-up approach will minimise the initial hurdle of integration of mHealth into primary care, compared to top-down systemic changes in healthcare. The following chapters will detail the series of four studies we conducted to explore the feasibility of mHealth app prescription in Australian general practice.

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3

Chapter 3: Evidence of effectiveness of mHealth apps

Prescribable mHealth apps identified from an overview of systematic reviews

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PREAMBLE

In the previous chapters (chapter 1-2) we established the concepts and terminologies that will be used in this thesis, outlined the research questions and chapters, and presented a preliminary literature review that started to explore the research areas we focus on.

In this chapter, we will answer the first two research questions to systematically evaluate the evidence base for prescribable mHealth apps and identify the research gaps in testing and reporting of mHealth apps. This chapter has been published under the title "Prescribable mHealth apps identified from an overview of systematic reviews" in *npj* Digital Medicine journal in May 2018.

Work arising from this chapter has also been presented at the annual Higher Degree Research student conference at Bond University; Gold coast Health and Medical Research conference; and Australian Society for Medical Research annual scientific meeting in 2016.

3.1 ABSTRACT

Background: Mobile health apps aimed at patients are an emerging field of mHealth. Their potential for improving self-management of chronic conditions is significant. Here, we propose a concept of "prescribable" mHealth apps, defined as apps that are currently available, proven effective, and preferably stand-alone, i.e., that do not require dedicated central servers and continuous monitoring by medical professionals.

Objectives: To conduct an overview of systematic reviews to identify such apps, assess the evidence of their effectiveness, and to determine the gaps and limitations in mHealth app research.

Methods: We searched four databases from 2008 onwards and the Journal of Medical Internet Research for systematic reviews of randomized controlled trials (RCTs) of stand-alone health apps.

Results: We identified 6 systematic reviews including 23 RCTs evaluating 22 available apps that mostly addressed diabetes, mental health and obesity. Most trials were pilots with small sample size and of short duration. Risk of bias of the included reviews and trials was high. Eleven of the 23 trials showed a meaningful effect on health or surrogate outcomes attributable to apps.

Conclusion: We identified only a small number of currently available stand-alone apps that have been evaluated in RCTs. The overall low quality of the evidence of effectiveness greatly limits the prescribability of health apps. mHealth apps need to be evaluated by more robust RCTs that report between-group differences before becoming prescribable. Systematic reviews should incorporate sensitivity analysis of trials with high risk of bias to better summarize the evidence, and should adhere to the relevant reporting guideline.

3.2 Introduction

The number of smartphones worldwide is predicted to reach 5.8 billion by 2020 [1] and there are 6 million multimedia applications (apps) available for download in the app stores [2]. According to the latest report from IQVIA Institute for Human Data Sciences (formerly IMS Institute for Healthcare Informatics) 318,000 of these are mHealth apps [3]. As one of the prominent digital behaviour change interventions of our time, mHealth apps promise to improve health outcomes in a myriad of ways: by helping patients actively measure, monitor, and manage their health conditions [4].

Here, we propose a concept of "prescribable" mHealth apps, defined as health apps that are currently available, proven effective, and preferably stand-alone. When proven effective and available, stand-alone mHealth apps that do not require dedicated central servers and additional human resources, can join other simple low-cost non-pharmaceutical interventions that can be "prescribed" by general practitioners (GPs).

However, although there are a number of systematic and other reviews of mHealth apps aimed at particular health conditions that examined different aspects of the apps such as the contents, quality and usability [5-8], no overview of systematic reviews has been done yet to summarize the effectiveness of stand-alone mHealth apps specifically and across different health conditions that present in general practice. Overviews of reviews are an efficient way to gather the best available evidence in a single source to examine the evidence of effectiveness of interventions [9]. Hence, our objectives were to: (1) conduct an overview of systematic reviews of randomized controlled trials (RCTs) to identify and evaluate the effectiveness of prescribable mHealth apps; and (2) determine the gaps and limitations in mHealth app research.

3.3 Methods

The Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) reporting guideline and the Overview of Reviews chapter (Chapter 22) of the Cochrane Handbook of Systematic Reviews of Interventions Version 5.1.0 were used as general guides to conduct this overview [10, 11].

Inclusion Criteria

We included systematic reviews that evaluated at least one randomized controlled trial (RCT) of a stand-alone health app. When the systematic review included other types of primary studies as well as RCTs, we reported only on the results of the RCTs. Our inclusion criteria are summarised in Table 1.

Table 1. Summary of inclusion criteria

Population	Patients of all ages, gender and races, with any type of health conditions
Intervention	Stand-alone smartphone or tablet apps that are readily available from leading app stores
Comparison	No intervention, treatment as usual, traditional or paper-based interventions, waitlist, or another recognized treatment
Outcome	Objective measurable health outcomes (e.g. reduction in HbA1c, waist circumference, BMI or weight loss), quality of life outcomes and mood and behaviour changes reported according to relevant and validated questionnaires (e.g. Depression and Anxiety Stress Scale (DASS)).
Study design	Systematic reviews of RCTs (if the systematic reviews included other study designs, we will only report on the results of the relevant RCTs)
Time limit	Systematic reviews published from 2008 and onwards

Exclusion criteria

We excluded systematic reviews if they did not include any RCTs (i.e. included only case-control or cohort or other observational studies), included RCTs of apps that are not stand-alone or currently available; focused only on content evaluation of apps; reported no measurable health outcome; or were feasibility trials of app development; and used the following interventions: text or voice messages; apps aimed at healthcare professionals (HCPs); appointment and medication reminder apps; PDAs, video games, consoles, or other devices; or only native smartphone features such as built-in GPS and accelerometer. We also excluded study protocols and conference abstracts, of which the full text articles were not found.

Search Methods

Electronic searches

We searched four electronic databases for systematic reviews without language restrictions: Medline Ovid, Cochrane Database of Systematic reviews, EMBASE, and Web of Science from 1 January 2008 through 1 February 2017. The cut-off date of 2008 was chosen as it coincides with the release of smartphones capable of running third-party Apps and when the two major App stores opened. We developed the initial search terms for Medline Ovid, and then modified for other databases. Our search terms included combinations, truncations, and synonyms of “cell phone”, “smartphone”, “application”, “intervention”, “patient”, “public”, “outcome”, “effectiveness”, “improvement”, “reduction”, “review” and “meta-analysis”. The full search strategy for all databases is provided as supplementary information 4.

Searching Other Resources

In addition to the search of electronic databases, we did forward and backward citation searches of included systematic reviews, and hand-searched the Journal of Medical Internet Research (JMIR) from inception. We also contacted the authors of potentially includable trials to ascertain the availabilities and the progress of the app interventions as it was often unclear whether the apps were released, discontinued, or still in testing with plans for release. Additionally, we contacted many authors of trials that used text messages, PDA apps and web-based interventions to find out if those interventions were developed into smartphone apps.

Data Collection and Analysis

Selection of Reviews:

Two authors (OB, PG) screened titles and abstracts of the search results independently. We then retrieved in full text articles and one author (OB) assessed them according to the inclusion criteria outlined above with the second author (PG) assessing a random sample. Where the eligibility of the studies could not be determined due to insufficient information supplied in the abstract or absence of an abstract, the full text articles were obtained. Any disagreements between reviewers were resolved by discussion and consensus or by consulting with a third author (EB). When more than one publication of a study was found, the most recent and or the most complete one was used for data analysis. Systematic reviews excluded after full text review are provided as supplementary materials 2 with reasons for exclusion.

Data Extraction and Assessment of Risk of Bias

Two authors (OB, SS) independently extracted the following data from the included systematic reviews using a form developed by the authors for this review: study ID (first author's last name and publication year), study characteristics (population, intervention, comparator, outcome, study design) and limitations of the review. We also extracted data from the RCTs of currently available stand-alone health apps. Along with general study characteristics information, we presented information gathered via contacting the authors for the availability of the intervention apps and other practical issues regarding their prescribability. Two authors (OB, SS) assessed the risk of bias of the included systematic reviews according to Cochrane's Risk of Bias in Systematic reviews (ROBIS) tool [12]. Any disparities were resolved by consulting with a third author (EB).

3.4 Results

Search results

The PRISMA flowchart of the study selection process is presented as Figure 6. Our electronic searches and the other sources search identified 981 publications. After deduplication, we screened 799 titles and abstracts, and assessed 145 full text articles for eligibility. One hundred and sixteen full text articles were excluded: 22 did not qualify as systematic reviews, 40 studies used non-app intervention, 4 studies were duplicates, 6 were abstracts only, 4 articles evaluated only the contents of the apps, and 40 studies did not meet one or more of the inclusion criteria (supplementary table 1). Of the twenty-nine articles eligible for inclusion, 20 reviews were excluded because they covered the same app trials as 6 more recent systematic reviews that were included in our overview (supplementary table 2) and 3 reviews were excluded due to apps still being unavailable (supplementary table 3).

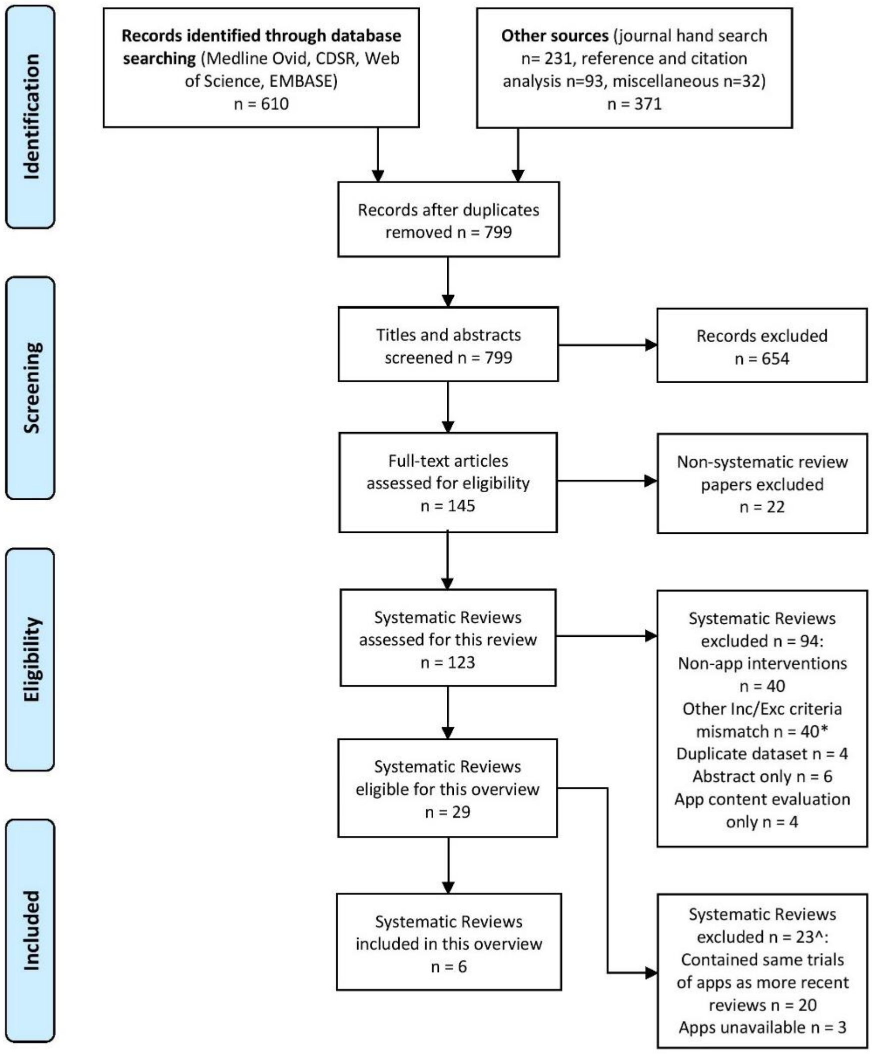

Figure 6. PRISMA flow diagram of selection of systematic reviews.

*Table of excluded articles due to Inclusion and Exclusion criteria mismatch is provided as supplementary table 1.

^Table of excluded articles due to repeated coverage is provided as supplementary table 2.

To achieve our study objectives, we used available systematic reviews of RCTs as a source of stand-alone mHealth apps that have been evaluated. We then determined the availability of those apps to ascertain the prescribability by searching the app stores and by contacting the authors of the RCTs. Figure 7 illustrates the scope of our study. Due to lack of established data on each category, the circle sizes and overlaps are illustrative.

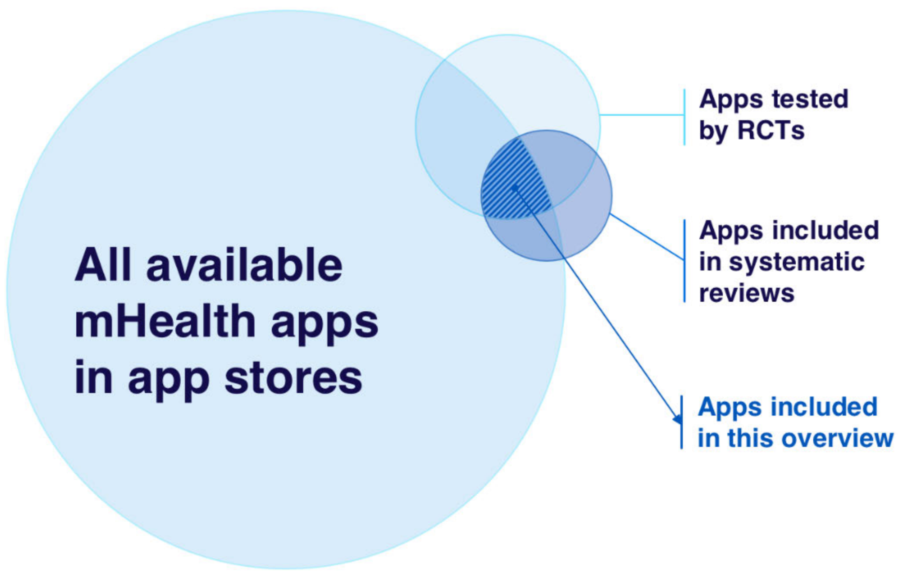

Figure 7. Scope of the overview

We contacted 144 authors to determine the type and availability of their study apps. A little over half of the authors replied and we were able to include 3 app RCTs in our analysis as a result. We also found out that 25 app projects were discontinued.

Description of Included studies

Six published systematic reviews met the inclusion criteria for this overview [13-18]. Characteristics and the limitations of the included systematic reviews are presented in Table 2. The systematic reviews were published in 2015-2017 and included a total of 93 RCTs and 18 studies of other designs. However, only 23 of the RCTs evaluated currently available stand-alone health apps. Characteristics of these RCTs are shown in Table 3 along with information about their availability and prescribability.

One of the systematic reviews addressed diabetes [13], two addressed mental health [14, 18], another two addressed physical activity and weight loss related issues [15, 17], and one addressed all of these areas by addressing the behaviour change aspect of apps [16]. Four of the reviews also included meta-analyses [13-15, 18]. We described the systematic reviews and the RCTs in further detail under thematic subheadings.

Table 2. Characteristics of the included systematic reviews

Review ID	Studies included	Participants/ Population	Interventions	Comparison interventions	Reported outcome measures	Review limitations
Bonoto[13] 2017, Brazil	13 RCTs* (5 RCTs eligible for this overview)	Adults and children with DM	Mobile health apps	Any intervention	Blood glucose, HbA1c, total cholesterol, weight, HDL, LDL, triglycerides, BP, quality of life	Did not address the limitations of their review and how it compares with multitude of other similar diabetes app reviews. Minimal effort in evaluating and addressing the risk of bias in the primary studies. No sensitivity analysis was done to integrate risk of bias assessment to results.
Firth[14] 2017, UK, USA, Australia	9 RCTs* (2 RCTs eligible)	Patients with anxiety	Smartphone-supported psychological interventions to reduce anxiety	Waitlist, anti-anxiety medications, other non-smartphone interventions	Changes in aspects of anxiety	Minimal effort in evaluating and addressing the risk of bias in the primary studies. No sensitivity analysis was done to integrate risk of bias assessment into results.
Flores-Mateo[15] 2015, Spain	9 RCTs*, 2 case-control studies (5 RCTs eligible)	Obese and overweight adults and children	Mobile apps that promote weight loss and increase in physical activity	Traditional intervention, paper hand-out, paper diary etc.	Body weight, BMI, and physical activity meta-analysis	The physical activity meta-analysis showed high heterogeneity (I^2=93%), which was not explained by any sensitivity analysis. Minimal effort in evaluating and addressing the risk of bias in the primary studies. No sensitivity analysis was done to integrate risk of bias assessment to results.
Payne[16] 2015, USA	14 RCTs*, 9 field, pilot or feasibility studies (7 RCTs eligible)	Adults	Mobile apps that disseminate health behaviour interventions	Unclear	Physical activity, diet, weight, alcohol consumption (binge drinking, frequency, blood alcohol concentration etc.), HbA1c, sleep, stress, smoking, BMI	Lacked clearly defined comparator interventions and outcome measures. No risk of bias assessment was done for the included studies. Limitations of the review are addressed minimally.
Schoeppe[17] 2016, Australia	20 RCTS*, 3 CTs, 4 pre-post studies (8 RCTs eligible)	Adults and children	Apps for influencing dietary intake, physical activity, sedentary behaviour	Unclear	Physical activity (MET min/week, steps, types etc.), weight, BMI, BP, cardiorespiratory fitness, diet (fruit & vegetable servings), sedentary behaviour etc.	Lacked clearly defined comparator interventions and outcome measures. Inappropriate use of CONSORT checklist to assess the quality of the primary studies. No risk of bias assessment was done for the included studies.
Simblett[18] 2017, UK	39 RCTs* (1 RCT eligible)	Adults with post-traumatic stress disorder (PTSD)	e-therapies	Waitlist or other active controls other than the intervention	PTSD (validated self-report or clinician-rated measures)	The primary meta-analysis showed high heterogeneity (I^2=81%), which was not explained by the subgroup and sensitivity analysis. Only one of the included studies was a smartphone app therapy.

*Not all trials included in the systematic review were relevant for our overview purposes. Details of the eligible trials are provided in Table 3.

Effects of Interventions

Diabetes

The Bonoto 2017 systematic review assessed app interventions for both types of diabetes mellitus [13]. It included 13 RCTs, of which 5 were relevant to this overview [19-23]. All of the RCTs aimed to improve glycemic control and quality of life as measured by multiple biochemical markers. The meta-analysis showed a mean difference of -0.4% (95% CI -0.6, -0.3) in glycated hemoglobin levels favoring the intervention. Four of the app trials were tested on type 1 diabetes patients, of which two demonstrated a significant between group reduction in HbA1c levels [20, 23]. One that was tested for type 2 diabetes patients did not show any between group differences in HbA1c levels at one year [22]. All the diabetes apps include functions to log blood glucose levels, insulin dose, diet and physical activity, and to set push notifications and reminders. Two of the apps also offer versions for doctors to enroll and monitor multiple patients [19, 21]. At this stage, only two of these diabetes apps are available free of charge worldwide [21, 23].

Mental health

The Firth 2017 systematic review assessed interventions aimed at reducing anxiety [14]. It included 9 RCTs, of which 2 were relevant to this overview. Their meta-analysis of the effects of smartphone interventions on symptoms of anxiety found small-to-moderate positive effect favoring the intervention (Hedges' g=0.3, 95% CI 0.2, 0.5).

Two of the RCTs from this review used stand-alone apps that were available. A breathing retraining game app called *Flowy* did not show any significant reduction in anxiety, panic, and hyperventilation [24]. The basic version of *SuperBetter* app was tested against its "fortified" version, which contains more cognitive behavioral therapy (CBT) and positive psychotherapy (PPT) content, and a waitlist control group [25]. Depression scores were equally reduced in both app groups compared to the control group, but the attrition rate was high (80%) in both app groups over four weeks.

The Payne 2015 systematic review assessed app interventions for their behaviour change potential [16]. It included 14 RCTs and 9 feasibility and pilot studies, of which 7 RCTs were eligible for our overview. Only one of the RCTs tested an app for depression against a previously validated web-based cognitive behaviour therapy (CBT) program [26]. Both groups had equally significant improvements. This app is now called *Managing Depression* as a part of 4 app series called *This Way Up* and available for AUD 59.99.

Two other trials included in Payne 2015 systematic review explored use of mobile apps to curb alcohol use among university students [27] and patients leaving residential treatment for alcohol use disorder [28]. The results showed that alcohol use increased among university students who used the intervention app *Promillekoll*, which calculated blood alcohol concentration (BAC) up to the legal limit [27]. Whereas, the *A-CHESS* app that was designed to provide on-going support for people leaving alcohol rehabilitation was shown to lessen the risky drinking days in the previous 30 days with higher odds (OR 1.94, 95%CI 1.14-3.31, p=0.02) [28]. These apps are available in Sweden and the USA respectively.

The Simblett 2017 systematic review assessed e-therapies aimed at treating posttraumatic stress disorder (PTSD) [18]. It included 39 RCTs. The meta-analysis showed standardized mean difference (SMD) of -0.4 (95% CI -0.5, -0.3) favoring the intervention, however the heterogeneity was high (I^2=81), which was not explained by the subgroup and sensitivity analysis. Only one of the RCTs tested an app called *PTSD Coach* against waitlist control for 1 month; however, there were no significant between group differences in the PTSD Checklist-Civilian questionnaire result [29].

Weight loss and physical activity

Two systematic reviews evaluated apps for weight loss and physical activity. The Flores-Mateo 2015 systematic review assessed studies aimed at increasing weight loss and physical activity for overweight and obese people of all ages [15]. It included 9 RCTs and 2 case control studies of which 5 RCTs were relevant to this overview. A meta-analysis of nine studies showed app interventions reduced weight by -1.0kg (95% CI -1.8, -0.3) more than the control group. Net change in body mass index (BMI) showed mean difference of -0.4 kg/m^2 (95% CI -0.7, -0.1) favoring the intervention. Net change in physical activity resulted in standard mean difference of 0.4 95% CI -0.1, 0.9), however, the heterogeneity was high (I^2=93%) and the authors did not explain why several RCTs that reported physical activity outcomes were excluded from this meta-analysis.

Four of the RCTs from this review used calorie counting apps as interventions [30-33]. However, only one of them (*MyMealMate* app) showed a statistically significant between-group difference in weight loss [31]. The *MyMealMate* app includes calorie information of 23,000 UK-specific brands of food items in the database, and goal-setting, physical activity monitoring and automated text-messages functions. When compared against a self-monitoring slimming website, the app group lost notable amount of weight and BMI, but not compared to the control group that used a calorie counting paper diary. *MyFitnessPal* app is one of the consistently highest rated free apps for calorie monitoring and it contains database of 3 million food items. However, when tested on its own for 6 months, the intervention made almost no difference to the weight of the participants [32]. This study also provided an insight on the usage of the apps during the trial, which showed that the logins to the app dropped sharply to nearly zero after 1 month from acquiring it. These three studies also suffered from a high overall attrition rate of more than 30% and the intervention groups lost more participants than the control groups. Another calorie-counting app *FatSecret* was tested as an addition to a weight-loss podcast made and previously proven effective by the same study team. The results showed no difference in weight loss between the groups [33].

The Schoeppe 2016 systematic review assessed studies aimed at improving diet, physical activity and sedentary behavior [17]. It included 20 RCTs, 3 controlled trials and 4 pre-post studies, but only 8 RCTs were relevant to this overview. It synthesized the trials in tabular and narrative formats, and assessed the quality of the trials using the CONSORT checklist [34]. Two of the RCTs tested so-called "exergame" (gamified exercise) apps called *Zombies! Run*, *The Walk*, *Get Running* and an activity monitoring app *MOVES* [35, 36]. Both studies had very low attrition rates, but failed to demonstrate any significant between group differences in improvements in physical activity and its indicators and predictors such as cardiorespiratory fitness, enjoyment of exercise and motivation.

One trial assessed an app aimed at increasing vegetable consumption called *Vegethon* on a small sample of participants of a 12-month weight loss program [37]. People who used the app consumed adjusted mean difference of 7.4 more servings of vegetable per day than the control group at 12 weeks (95% CI 1.4-13.5; p=0.02). Another physical activity trial tested a tablet-based app *ActiveLifestyle* among independently living seniors [38, 39]. Between-groups comparisons revealed moderate effect for gait velocity (Mann-Whitney U=138.5; p=.03, effect size r=.33) and cadence (Mann-Whitney U=138.5, p=.03, effect size r=.34) during dual task walking at preferred speed in favor of the tablet groups.

There were two apps that were tested in two different studies that were included in both the Flores-Mateo and Schoeppe systematic reviews. The *Lose-It!* app was tested for 6 months [30] and for 8 weeks [40]. Not only they did not find any between group differences in results, in the second study the app group lost less weight than the two control groups that used a paper diary and the memo function of the phone. In contrast, the *AccupedoPro* pedometer app demonstrated a similar amount of increase in daily steps both in general primary care patients [41] and in young adults [42].

Table 3. Characteristics of RCTs of prescribable apps

Study ID (Pilot?)	Population	Intervention	Comparator	Outcome	Availability and Prescribability
Bonoto 2017 Systematic review. Five relevant RCTs out of 13.					
Berndt[19] 2014, Pilot	Youth (8-18yo, n=68) with T1DM, 4 weeks	Treatment with support of telemedicine system **Mobil Diab (mDiab)**	Conventional therapy only	Between-group differences in results were not reported, though both groups saw reduction in HbA1c. Intervention group had higher "diabetes self-efficacy" score. Overall usability and acceptance were rated as "good" (41%).	• Available in Germany in 3 versions: free stand-alone version mDiab Lite, full version mDiab €4.99, mDiab Pro version offers multi user license and connection to central web platform. • Lack of effectiveness is the barrier to prescribe this app.
Charpentier[20] 2011	Adults with T1DM (n=180, HbA1c>8%, 6 months)	Group 1: quarterly visits + paper logbook Group 2: quarterly visits + **DiaBeo** app Group 3: biweekly teleconsultation + **DiaBeo** app (bolus calculator with validated algorithms)		At 6 months G3 patients had 0.91%, and G2 had 0.67% reduction in HbA1c compared to G1 (control) (p<0.001). Also, patients in G1 and G2 spent 5 hrs more than G3 for office consultations.	• Available in France and reimbursed by the government. • Should it become available outside France and ongoing 700 patient trial results pending, it could be a prescribable app.
Drion[21] 2015	Adults with T1DM (n=63, 3months)	**DBEES** app	Standard paper diary	No between-group differences were found in quality of life, HbA1c, daily frequency of self-measurement of blood glucose.	• Available worldwide free of charge. • Lack of effectiveness is the barrier to prescribe this app.
Holmen[22] 2014	Adults with T2DM (n=151, mean age 55.9-58.6, HbA1c>7.1%, 1 year)	Group 1: **Few Touch app** Group 2: **Few Touch app** + nurse counselling for the first 4 months Group 3: TAU with GP (other 2 groups also continued TAU with GP)		HbA1c level decreased in all groups, but did not differ between groups after 1 year. Those aged ≥63 years used the app more than their younger counterparts did (OR 2.7; 95% CI 1.02-7.12; p=.045).	• Available in Norway, Czech and USA under the name Diabetes Dagboka (Diary). • Lack of effectiveness is the barrier to prescribe this app.
Kirwan[23] 2013*	Adults with T1DM (n=72, HbA1c >7.5%, 6 months, +9 months follow up)	TAU + **Glucose Buddy** + weekly SMS support	Usual care (3 monthly visit to healthcare provider)	There was a significant between group difference in HbA1c reduction (p<0.001). At 9 months, the mean HbA1c reduction for intervention group was 1.10% (SD 0.74). The control group HbA1c increased slightly (mean 0.07, SD 0.99).	• Available worldwide free of charge. • It is prescribable for improving glycaemic control.
Firth 2017 Systematic review. Two relevant RCTs out of 9.					
Pham[24] 2016, Pilot	Adults with moderate anxiety (n=63, 4 weeks)	**Flowy** app	Waitlist with weekly psychoeducation emails	There were no between-group differences in reductions in anxiety, panic, and hyperventilation.	• Available worldwide free of charge. • Lack of effectiveness is the barrier to prescribe this app.
Roepke[25] 2015	Adults with depression (n=283, 4 weeks)	Group 1: **SuperBetter** app using CBT and positive psychotherapy (CBT-PPT SB) Group 2: General SuperBetter app Group 3: Waitlist control group		Group 1 and 2 achieved greater reductions in CES-D questionnaire scores than control by post-test (Cohen's d=0.67) and by follow-up (d=1.05).	• Available worldwide free of charge. • It could be prescribable. This trial suffered from high attrition (80%). Larger trials with longer follow ups are needed.

Study ID (Pilot?)	Population	Intervention	Comparator	Outcome	Availability and Prescribability
Flores-Mateo 2015 Systematic review. Five relevant RCTs out of 9.					
Allen[30] 2013*, Pilot	Obese adults (BMI >28kg/m^2, n=68, 6 months)	Group 1: Intensive counselling Group 2: Intensive counselling + **Lose It!** app Group 3: less intensive counselling + app Group 4: app alone		At 6 months, there was no statistically significant weight loss between the groups (mean weight loss in G1 was -2.5kg, in G2 -5.4kg, in G3 -3.3kg, and in G4 -1.8kg respectively.)	• Available worldwide. Basic version is free. • Lack of effectiveness is the barrier to prescribe this app on its own. Could be helpful as a support to weight loss counselling.
Carter[31] 2013*, Pilot	Overweight adults (BMI>27 kg/m^2, n=128, 6 months)	**MyMealMate** app	Self-monitoring slimming website OR calorie counting book by Weight Loss Resources company.	At 6 months, there was statistically significant difference in mean weight loss between app group (-4.6kg) and website group (-1.3kg) (p=0.004), but not between app and diary group (-2.9kg) (p=0.12).	• Available worldwide free of charge. • It is prescribable for weight loss.
Glynn[41] 2014^	Rural primary care patients (mean BMI 28.2 kg/m^2, n=90, 8 weeks)	**Accupedo-Pro** app and physical activity goal of 10,000 steps/day	Information on benefits of exercise and physical activity goal of walking for 30 minutes per day	There was a difference in mean improvement of 2017 (95% CI = 265 to 3768, p=0.009) steps per day between the groups, favouring the intervention. No significant changes were observed for secondary outcomes of blood pressure, weight, & BMI.	• Available worldwide free of charge. • It is prescribable. An increase of over 1000 steps per day is clinically meaningful and, if continued, expected to result in long-term health benefits. Longer trials are needed to measure such effects.
Laing[32] 2014	Adult primary care patients (BMI >25 kg/m^2, n=212, 6 months)	**MyFitnessPal** app	Usual care + "any activities you would like to lose weight"	At 6 months, there was no significant between group difference in weight change (-0.67lb, 95% CI-3.3 to 2.11lb, p=0.63) and in self-reported behaviours around physical activity, diet and self-efficacy in weight loss.	• Available worldwide free of charge. • Lack of effectiveness is the barrier to prescribe this app on its own.
Turner-McGrievy[33] 2011*	Overweight adults (BMI 32.6kg/m^2, n=96, 6 months)	Weight loss podcast + **Fat Secret** calorie counter app and Twitter support group	Podcast only (same as intervention, twice a week for 3 months, and 2 minipodcasts a week for months 3-6)	Overall the two groups lost exactly the same amount of weight (-2.7kg) and there was no significant difference in percentage weight loss between the groups (3.5% in intervention vs. 3.8% in control).	• Available worldwide free of charge. • Podcast was designed by study team & proven effective in their 2009 RCT. However, the app addition did not make any difference in the results. Lack of evidence to prescribe this app.
Payne 2015 Systematic review. Seven relevant RCTs out of 14.					
Gajecki[27] 2014	University students with risky alcohol consumption (mean age 24.7, n=1929, 7 weeks)	Group 1: smartphone app **Promillekoll** Group 2: web-based app **PartyPlanner** that calculate blood alcohol concentration (BAC)	No intervention	Per-protocol analyses revealed only one significant time-by-group interaction, where Group 1 participants increased the frequency of their drinking occasions compared to controls (mean at baseline 2.24/wk, mean at FU 2.36/wk, p = 0.001).	• Available in Sweden. • However, this study showed youth drinking behaviour needs to be explored further and apps need to provide more in-depth information than just the BAC. Such apps are not prescribable as they are.

Study ID (Pilot?)	Population	Intervention	Comparator	Outcome	Availability and Prescribability
Gustafson[28] 2014	Alcohol dependent adults leaving residential programs (mean age 38.3, n=349, Intervention 8 months + follow up 4 months)	TAU + Addiction-Comprehensive Health Enhancement Support System (**A-CHESS**) app	TAU (ie., no continuing care)	A-CHESS group reported fewer risky drinking days than the control group, with a mean of 1.39 vs 2.75 ds/previous 30 ds (mean difference, 1.37; 95%CI 0.46-2.27; P = 0.003).	• Available in the USA through the agency involved with the study. • Should this app be made widely available, it can be prescribed to help with continuing care for people leaving residential programs and generally for people with alcohol dependency.
Watts[26] 2013, Pilot	Adults with mild and moderate depression (n=35, 8 weeks, + 3 month follow up)	**The Sadness Program** CBT lessons adapted for **Get Happy** app	Same content on a website (previously proven effective)	The results indicate that reductions in PHQ-9, the BDI-II and K-10 pre- to post-intervention and pre-to follow up, were significant, regardless of experimental group.	• Available in Australia as **Managing depression** for AUD 59.99. • It is prescribable. The price could be a barrier for widespread use. It needs to be tested in a larger trial.
Schoeppe 2016 Systematic review. Eight relevant RCTs out of 20.					
Cowdery[35] 2015	Adults (n=40, 12 weeks)	Choice of either **Zombies! Run or The Walk,** + MOVES app	MOVES (activity monitoring app)	There were no significant between-group differences in physical activity, enjoyment of exercise and motivation to exercise.	• All apps are available worldwide free of charge. • Lack of effectiveness is the barrier to prescribe this app.
Dirieto[36] 2015	Insufficiently active healthy young people (14-17 years old, n=51, 8 weeks)	Group 1: Immersive exergame **Zombies! Run** Group 2: non-immersive app **Get Running**	No intervention	There were no significant between-group differences in cardiorespiratory fitness (1-mile walk/run test) and self-reported physical activity levels and its predictors.	• Both apps are freely available. • Lack of effectiveness is the barrier to prescribe this app.
Mummah[37] 2016, Pilot	Overweight adults (BMI 32 kg/m^2, n=17, 12 weeks)	**Vegethon** app (to monitor vegetable consumption, set goals, get feedback and comparison)	Waitlist	Intention to treat analysis at the end of 12 weeks showed the between group vegetable consumption difference was 7.4 servings a day (95% CI 1.4-13.5; p=0.02).	• Available worldwide free of charge. • This study was done on select participants of a 12-month weight loss program. It is prescribable; however, larger trial is needed.
Silviera[38] 2013, VanHet Reve[39] 2014	Autonomous-living seniors (mean age 75, n=44, 12 weeks)	Group 1: **ActiveLifestyle** tablet app for strength-balance exercises, social motivation version Group 2: **ActiveLifestyle** tablet app, individual motivation version Group 3: brochure-based intervention		Between group comparison showed moderate improvement for gait velocity and cadence in tablet groups. Social individual motivation strategies proved equally effective.	• Available in Italy free of charge. • The study measured surrogate outcomes for falls prevention. Should it become available worldwide, it is prescribable to seniors and other people who need to improve their balance and gait.

Study ID (Pilot?)	Population	Intervention	Comparator	Outcome	Availability and Prescribability
Walsh[42] 2016, Pilot	Young adults (17-26 years old, n=55, 5 weeks)	Aim for 10 000 steps/d using **Accupedo-Pro** pedometer app with feedback and goal setting functions	Information on daily recommended physical activity and told to walk for 30min/day	Between group differences revealed intervention group increased daily steps significantly (2393, about a mile) more than those in the control group (1101; t_{53}=2.07, P=0.043).	• Available worldwide free of charge. • This app is prescribable to those who are interested in improving their physical activity levels by walking.
Wharton[40] 2014, Pilot	Adults with BMI 25-40 kg/m^2, (n=57, 8 weeks)	Group 1: record food intake using **Lose-It!** app Group 2: record food intake using phone's memo function Group 3: record using paper-and-pencil method		There was no between group differences in weight loss, BMI, and Healthy Eating Index at the end of study. The app group lost a slightly less weight (-3.5 lb) than the other groups (G2 lost -6.5 lb, and G3 lost -4.4 lb).	• Available worldwide. Basic version is free. • This app could be prescribed as food intake recording tool. Larger and longer trials are needed to establish advantage of using this app in weight loss interventions.
Simblett 2016 Systematic review. One relevant RCT out of 39.					
Miner[29] 2016, Pilot	Adults with PTSD symptoms (n=49, 2 months)	**PTSD Coach** app	Waitlist (crossed over after 1 month)	There was no statistically significant between group differences in PTSD scores according to the PTSD Checklist – Civilian (PCL-C). The app was deemed acceptable and the intervention feasible.	• Available worldwide free of charge. • Lack of effectiveness is the barrier to prescribe this app. Larger and longer trials are needed.

*these studies are also included in Payne 2015 systematic review.

^these studies are also included in Schoeppe 2016 systematic review.

TAU: Treatment as usual; CES-D: Center for Epidemiological Studies Depression questionnaire; BMI: body mass index; MET: metabolic equivalent of task; PHQ-9: Patient Health Questionnaire 9; BDI-II: Beck's Depression Inventory Second edition; K-10: The Kessler 10-item Psychological Distress scale; PTSD: Posttraumatic Stress Disorder.

Risk of bias in included systematic reviews

The overall results of risk of bias in the 6 systematic reviews evaluated by the Cochrane Risk of Bias in Systematic Reviews (ROBIS) tool [12] is presented in Table 4. Overall, five of the reviews had high risk of bias and one had low risk. ROBIS assessment has three phases: the first one (optional) assess the relevance of included reviews to the overall review question (not reported here). The second phase evaluates detailed risk of bias in four domains (Table 4). The first domain (study eligibility criteria) revealed that none of the systematic reviews had a published protocol specifying their eligibility criteria and analysis methods. However, the detailed information provided in their methods sections regarding eligibility and analyses, combined with the rest of the domain questions made it possible for us to evaluate the whole domain low risk of bias for all the reviews. The main issue with the second domain (study identification and selection) was limiting the literature search to only English language publications. We considered this to be a serious hurdle in retrieving as many eligible studies as possible because many Spanish and Portuguese speaking countries as well as many European countries are conducting and publishing mHealth research actively. The third domain (data collection and study appraisal) had issues around lack of information about the effort to minimise error in data collection and failure to formally assess the risk of bias in the primary studies. In the last domain of phase 2 (synthesis and findings), the reviews received "no" on reporting of all pre-defined analysis or explaining departures due to lack of published protocols, relating back to domain 1. Also, the risk of bias levels in the primary studies was neither minimal nor sufficiently addressed in the synthesis in all but one review.

Phase 3 assesses the overall risk of bias of the systematic review. The main issue in this summary of risk of bias was with the first signalling question asking if the reviews addressed the concerns identified in the previous four domains in their discussions. All studies failed to recognize and address the potential sources of risk of bias that were identified in the domains of phase 2.

Table 4. Overall results of Risk of Bias in Systematic Reviews (ROBIS) assessment

Review	**Phase 2**				**Phase 3**
	1. Study eligibility criteria	2. Identification and selection of studies	3. Data collection and study appraisal	4. Synthesis and findings	Risk of bias in the review
Bonoto 2017	☺	☺	☺	☹	☹
Firth 2017	☺	☹	☺	☺	☹
Flores-Mateo 2015	☺	☺	☺	☹	☹
Payne 2015	☺	☹	☹	☹	☹
Schoeppe 2016	☺	☹	☺	☺	☹
Simblett 2016	☺	☺	☺	☺	☺

3.5 Discussion

Principal finding

Our overview evaluated six systematic reviews that included 23 RCTs of 22 currently available stand-alone health apps. Eleven of the 23 trials showed a meaningful effect on health or surrogate outcomes attributable to apps (Table 3). However, the overall evidence of effectiveness was of very low quality [43], which hinders the prescribability of those apps. Most of the app trials were pilot studies, which tested the feasibility of the interventions on small populations for short durations. Only one of the pilot trials has progressed on to a large clinical trial [20]. The most commonly trialed apps have been designed to address conditions with the biggest global health burden: diabetes, mental health, and obesity. Although there is widespread acceptance of smartphones and promise of health apps, the evidence presented here indicates few effectiveness trials of health apps. The risk of bias of both the included reviews and the primary studies is high. The reviews lacked sensitivity analyses to integrate the risk of bias results into context. Some of the RCTs also suffered from high attrition rates, sometimes in the intervention groups more than the controls [24, 25], thus compromising the positive results and the conclusions drawn from the studies.

Strengths

Although we set out to do a traditional overview of systematic reviews, it quickly became apparent that in order to ascertain the availability of the stand-alone mHealth apps, which was crucial to our objectives, we needed to investigate the primary trials of the apps. We have provided a window into the body of evidence on currently available stand-alone mHealth apps with a special focus on the "prescribability" in general practice settings, because this is where effective stand-alone apps can benefit both general practitioners and patients. It is also possible for other primary care practitioners, such as diabetes nurses and physiotherapists, to prescribe suitable health apps to patients.

There are a number of previous overviews of systematic reviews in eHealth and mHealth areas that can be comparable to ours in scope and methodology [44-48]. Two of them used the Overview Quality Assessment Questionnaire (OQAQ) and the others used the AMSTAR tool to assess the quality of the included systematic reviews [49, 50]. We chose to use Cochrane's newly developed ROBIS tool, which focuses more on the risk of bias attributes and the quality of the methods compared to AMSTAR [51]. Also, we did not restrict our search to any one language as many of these overviews did. Overviews are often limited by the individual limitations of the included systematic reviews, lack of risk of bias assessments, and challenge of synthesizing the overall results, and ours is no exception [45, 46]. We sought to overcome these limitations by contacting an extensive list of primary study authors to fill in the gaps left by the systematic reviews, and by assessing the risk of bias of included reviews vigorously. Despite the differences, our findings echo the conclusions of all these overviews regarding low quality of evidence in mHealth and eHealth areas they investigated. However, the high heterogeneity of the investigated interventions ranging from text messages, web tools, phone calls to apps, makes their recommendations too general and broad. We aimed to make our study more useful by exclusively focusing on a specific type of mHealth intervention with a vision of practical application in general practice.

LIMITATIONS

Our review was limited by the weaknesses in the systematic reviews we identified. The systematic reviews did not thoroughly adhere to the PRISMA statement [10] by not assessing the included studies' risk of bias or not integrating the risk of bias results into the overall synthesis, thus preventing the reader from recognizing the poor quality of the included studies. The lack of understanding of risk of bias assessment prevented the authors from addressing this limitation in their discussions, as was evident during our ROBIS assessment. In addition, our overview was unable to assess the RCTs of health apps published in the past year because they are yet to be included in any systematic reviews and we specifically aimed to synthesize only systematic reviews. This highlights the necessity of timely updates of high levels of evidence in this field, which is further discussed in the *Implications for research* section.

Furthermore, information regarding app availability was often not available in the primary studies. Thus, to compile the information on practical issues in Table 3 and to determine the current availability of apps, we had to contact primary study authors and search in the app stores. This emphasizes the importance of providing complete and transparent reporting of app interventions [52], as is true of other interventions in health care [53]. We believe that sharing information amongst researchers working in app development is vital to reduce research waste and prevent re-invention of wheels [54]. We also found several cases where, despite the initial trials failing to demonstrate any positive benefit, the apps were still released (Table 3), adding to the 'noise' rather than the 'signal' in this field, and leading to opportunity costs. In other cases, app testing and release were terminated due to lack of ongoing funding as the technology requires constant updates and improvements. Thus, it is important to secure a necessary funding source before engaging in an app development and testing efforts.

IMPLICATIONS FOR PRACTICE

At present, anyone can create and publish health and medical apps in the app stores without having to test them, and patients must experiment with apps by trial and error. If GPs are to prescribe health apps, then they must be confident that the apps are shown to work, have fair privacy and data safety policies, and usable at the very least. However, assessment of individual apps and literature searches on app evidence are highly time-consuming and challenging for doctors to do on their own. Hence, we suggest that an independent and reliable source to carry out the evaluation of apps and to provide a collection of trustworthy mHealth apps is vital in providing practicing doctors with prescribable apps.

Recently re-opened NHS Apps library is a great example of such source of apps for doctors' use despite their initial hurdles with data safety of some of the previously recommended apps [55]. They employ a tool to make app prescribing even easier by collaborating with AppScript app [56]. There have been numerous efforts around the world to provide quality and efficacy assessments of mHealth apps, each devising and using their own app evaluation framework. The challenges and the complexity of those efforts are well summarized by Torous et al [57]. Thus we believe initiatives like NHS App library is the safer and more accountable way to implement digital interventions in real practice. Like clinical guidelines, a recognized national body can decide what framework they want to use and which apps to deem safe for use in practice in that particular country.

IMPLICATIONS FOR RESEARCH

Our overview found a number of methodological shortcomings in evaluation of mHealth apps. Consistent sources of high risk of bias in the primary RCTs were failure to blind participants and personnel to the intervention, and poor reporting of allocation concealment. Although blinding can be challenging in mHealth studies, it is important because of the digital placebo effect [58]. Creating and using a basic static app or sham app for the control groups can help account for digital placebo effect and help establish the true efficacy of the interventions. Allocation concealment in mHealth trials can be done in the same way as in any other RCT by employing personnel who do not have any contact with the participants to handle the app installations; however, hardly any RCTs tried to ensure this. Several studies also noted that the control groups were susceptible to contamination with apps using the same or similar interventions to the tested app, since there are thousands of apps freely available to them outside of the research setting [32, 59]. Without providing controlled smartphones to study participants, it is difficult to identify simple solution to this challenge. Lastly, the only way to establish the effect of an intervention is by demonstrating greater change in one group compared to the other, rather than comparing it to the baseline [60]. Yet, many RCTs did not adhere to the relevant guideline [34] and report their results as between-group differences.

The value of RCTs to evaluate fast-evolving mHealth interventions has been challenged due to their long duration, high cost and rigid designs, and multitude of modifications and alternative methods have been suggested, but widespread consensus is yet to be reached [61-63]. As our overview showed that the effect of apps as health interventions might be marginal, and such small benefits can only be reliably detected by rigorous testing. Thus, RCTs should remain the gold standard, but should be employed with tact: only when the intervention is stable, can be implemented with high-fidelity, and has a high likelihood of clinically meaningful benefit [64].

We also emphasize the value of traditional systematic and other reviews. The role of these higher levels of evidence is not only to assess and summarize the evidence of a field, but also to reveal the gaps and shortcomings in existing research, which our overview has done. If it finds that the base of the evidence pyramid is shaky, that is the trials being done are not of high quality, then we must endeavour to fix it. The traditional reviews are also incorporating new technology. The Cochrane Collaboration's recent advance in the area of living systematic reviews that are "continually updated, incorporating relevant new evidence as it becomes available", offers significant opportunity to reduce the amount of time and effort it takes to update high level evidence [65, 66]. This will be invaluable in digital health research and evidence base building. As the supporting technologies of automation and machine learning continue to improve and become widespread, more time and human effort will be saved, and the easier it will be to update the evidence [67].

Conclusion

Smartphone popularity and mHealth apps provide a huge potential to improve health outcomes for millions of patients. However, we found only a small fraction of the available mHealth apps is tested and the body of evidence is low quality. Our recommendations for improving the quality of evidence, and reducing research waste and potential harm in this nascent field include encouraging app effectiveness testing prior to release, designing better trials, and conducting better reviews with robust risk of bias assessments. Without adequate evidence to back it up, digital medicine and app "prescribability" might stall in its infancy for some time to come.

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participating in an mHealth weight loss program. J Am Med Inform Assoc, 2013. **20**(3): p. 513-8.

60. Bland, J.M. and D.G. Altman, *Comparisons within randomised groups can be very misleading.* BMJ, 2011. **342**.
61. Pham, Q., D. Wiljer, and J.A. Cafazzo, *Beyond the Randomized Controlled Trial: A Review of Alternatives in mHealth Clinical Trial Methods.* JMIR Mhealth Uhealth, 2016. **4**(3): p. e107.
62. Mohr, D.C., et al., *Continuous evaluation of evolving behavioral intervention technologies.* Am J Prev Med, 2013. **45**(4): p. 517-23.
63. Almirall, D., et al., *Introduction to SMART designs for the development of adaptive interventions: with application to weight loss research.* Transl Behav Med, 2014. **4**(3): p. 260-74.
64. Murray, E., et al., *Evaluating Digital Health Interventions: Key Questions and Approaches.* American Journal of Preventive Medicine, 2016. **51**(5): p. 843-851.
65. Elliott, J.H., et al., *Living systematic reviews: an emerging opportunity to narrow the evidence-practice gap.* PLoS Med, 2014. **11**(2): p. e1001603.
66. Elliott, J.H., et al., *Living systematic review: 1. Introduction—the why, what, when, and how.* Journal of Clinical Epidemiology, 2017. **91**: p. 23-30.
67. Thomas, J., et al., *Living systematic reviews: 2. Combining human and machine effort.* Journal of Clinical Epidemiology, 2017. **91**: p. 31-37.

3.7 Supplementary material

Published with article presented in Chapter 3.

Supplementary table 1: Excluded systematic reviews due to Inclusion/Exclusion criteria mismatch

Supplementary table 2: Excluded systematic reviews due to repeated coverage

Supplementary table 3: Excluded systematic reviews due to unavailability of apps

Supplementary material 4. Complete search strategy

Supplementary table 1. Excluded systematic reviews due to Inclusion/Exclusion criteria mismatch

No.	Reference	Reason for exclusion
1.	Al-Durra, M., M.B. Torio, and J.A. Cafazzo, The Use of Behavior Change Theory in Internet-Based Asthma Self-Management Interventions: A Systematic Review. Journal of Medical Internet Research, 2014. 17(4).	This review did not report on the effectiveness of the interventions, but focused only on the theoretical base, guideline adherence and assessment tools.
2.	Arambepola, C., et al., The Impact of Automated Brief Messages Promoting Lifestyle Changes Delivered Via Mobile Devices to People with Type 2 Diabetes: A Systematic Literature Review and Meta-Analysis of Controlled Trials. Journal of Medical Internet Research, 2016. 18(4).	This review did not include any stand-alone app studies.
3.	Bort-Roig, J., et al., Measuring and influencing physical activity with smartphone technology: a systematic review. Sports Medicine, 2014. 44(5): p. 671-86.	None of the primary studies were RCT. They evaluated the feasibility, acceptability, and accuracy of smartphone accelerometers and pedometers.
4.	Chomutare, T., et al., Features of Mobile Diabetes Applications: Review of the Literature and Analysis of Current Applications Compared Against Evidence-Based Guidelines. Journal of Medical Internet Research, 2011. 13(3).	The authors focused on the content of the apps, rather than study design and effectiveness of them.
5.	Dale, L.P., et al., The effectiveness of mobile-health behaviour change interventions for cardiovascular disease self-management: A systematic review. European Journal of Preventive Cardiology, 2016. 23(8): p. 801-817.	Included one app prototype, but it was not stand-alone intervention.
6.	de la Torre-Diez, I., et al., Cost-utility and cost-effectiveness studies of telemedicine, electronic, and mobile health systems in the literature: a systematic review. Telemed J E Health, 2015. 21(2): p. 81-5.	The authors' aim wasn't to evaluate measurable clinical outcomes.
7.	de Souza, A.C.C., T.M.M. Moreira, and J.W.P. Borges, Educational technologies designed to promote cardiovascular health in adults: integrative review. Revista Da Escola De Enfermagem Da Usp, 2014. 48(5): p. 941-948.	The authors' aim wasn't to evaluate measurable clinical outcomes. Only one paper on development of physical activity app was included (not RCT).
8.	DMBaron, J., H. McBain, and S. Newman, The impact of mobile monitoring technologies on glycosylated hemoglobin in diabetes: a systematic review. Journal of Diabetes Science & Technology, 2012. 6(5): p. 1185-96.	The authors specially interested in apps with real-time monitoring and feedbacks, which was our exclusion criterion.
9.	Dute, D.J., W.J. Bemelmans, and J. Breda, Using Mobile Apps to Promote a Healthy Lifestyle Among Adolescents and Students: A Review of the Theoretical Basis and Lessons Learned. JMIR Mhealth Uhealth, 2016. 4(2): p. e39.	Measurable clinical outcome wasn't the aim of this study. They focused on analysing the theoretical mechanisms used in apps.
10.	El-Gayar, O., et al., A systematic review of IT for diabetes self-management: Are we there yet? International Journal of Medical Informatics, 2013. 82(8): p. 637-652.	The app studies included in this review were not stand-alone interventions. Also, measurable clinical outcome wasn't the main aim of this review.
11.	Fanning, J., S.P. Mullen, and E. McAuley, Increasing physical activity with mobile devices: a meta-analysis. J Med Internet Res, 2012. 14(6): p. e161.	This review did not include any RCT of available apps. Other app studies were not RCTs or the apps were discontinued.
12.	Firth, J. and J. Torous, Smartphone Apps for Schizophrenia: A Systematic Review. JMIR MHealth and UHealth, 2015. 3(4): p. e102.	The outcomes reported in this study were of acceptability rating, and patient satisfaction levels, rather than clinically relevant measures.

13.	Fitzner, K.K., et al., Telehealth Technologies: Changing the Way We Deliver Efficacious and Cost-Effective Diabetes Self-Management Education. Journal of Health Care for the Poor and Underserved, 2014. 25(4): p. 1853-1897.	This is more of an overview and did not include effectiveness studies. However, the included systematic reviews were also screened for eligibility.
14.	Free, C., et al., The effectiveness of mobile-health technology-based health behaviour change or disease management interventions for health care consumers: a systematic review. PLoS Medicine / Public Library of Science, 2013. 10(1): p. e1001362.	The only app study included here was not a stand-alone intervention or available.
15.	Fulford, H., et al., Exploring the Use of Information and Communication Technology by People With Mood Disorder: A Systematic Review and Metasynthesis. JMIR Ment Health, 2016. 3(3): p. e30.	They included only qualitative studies (focus group, interview etc.).
16.	Gandhi, S., et al., Effect of Mobile Health Interventions on the Secondary Prevention of Cardiovascular Disease: Systematic Review and Meta-analysis. Canadian Journal of Cardiology, 2016. 13: p. 13.	Included one app prototype, but it was not stand-alone intervention.
17.	Greenwood, D.A., H.M. Young, and C.C. Quinn, Telehealth remote monitoring systematic review: Structured self-monitoring of blood glucose and impact on A1C. Journal of Diabetes Science and Technology, 2014. 8(2): p. 378-389.	Apps that were covered in this review were not stand-alone, and experimental.
18.	Grist, R., J. Porter, and P. Stallard, Mental Health Mobile Apps for Preadolescents and Adolescents: A Systematic Review. J Med Internet Res, 2017. 19(5): p. e176.	This review included 2 RCTs of apps/prototypes, but the apps were discontinued.
19.	Hidalgo-Mazzei, D., et al., Internet-based psychological interventions for bipolar disorder: Review of the present and insights into the future. Journal of Affective Disorders, 2015. 188: p. 1-13.	The outcomes reported in this study were of acceptability rating, retention and patient satisfaction levels, rather than clinically relevant measures.
20.	Holtz, B. and C. Lauckner, Diabetes management via mobile phones: a systematic review. Telemedicine Journal & E-Health, 2012. 18(3): p. 175-84.	Apps that were covered in this review were not stand-alone and experimental.
21.	Hui, C.Y., et al., The use of mobile applications to support self-management for people with asthma: a systematic review of controlled studies to identify features associated with clinical effectiveness and adherence. J Am Med Inform Assoc, 2016.	None of the apps included in this review were available. Most of the studies had web and SMS interventions.
22.	Jackson, B.D., et al., EHealth Technologies in Inflammatory Bowel Disease: A Systematic Review. Journal of Crohn's & colitis, 2016. 10(9): p. 1103-21.	This review included one RCT protocol for an app study, and one non-stand-alone app study.
23.	Joe, J. and G. Demiris, Older adults and mobile phones for health: A review. Journal of Biomedical Informatics, 2013. 46(5): p. 947-954.	This review included two experimental apps (since discontinued) and one non-stand-alone app study.
24.	Karasouli, E. and A. Adams, Assessing the Evidence for e-Resources for Mental Health Self-Management: A Systematic Literature Review. JMIR Mental Health, 2014. 1(1): p. e3.	This review included one discontinued app study and one available app but study was not a RCT.
25.	Levine, D.M., et al., Technology-assisted weight loss interventions in primary care: a systematic review. J Gen Intern Med, 2015. 30(1): p. 107-17.	Only one PDA-based app RCT was included. Eight other primary study authors were contacted for app development and availability, but none were made into an app.
26.	Liang, X., et al., Effect of mobile phone intervention for diabetes on glycaemic control: a meta-analysis. Diabetic Medicine, 2011. 28(4): p. 455-63.	This review included one non- stand-alone app intervention.
27.	Majeed-Ariss, R., 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	The only app study included here was not a stand-alone intervention or available.

	Long-Term Physical Conditions. Journal of Medical Internet Research, 2015. 17(12): p. e287.	
28.	Marcano Belisario, J.S., et al., Smartphone and tablet self-management apps for asthma. Cochrane Database of Systematic Reviews, 2013. 11: p. CD010013.	Reviewed 2 RCTs that used asthma symptom diary type apps which weren't stand-alone and discontinued.
29.	Meurk, C., et al., Establishing and Governing e-Mental Health Care in Australia: A Systematic Review of Challenges and A Call For Policy-Focussed Research. J Med Internet Res, 2016. 18(1): p. e10.	This study did not aim to evaluate effectiveness of eHealth interventions, but to assess the research in regards to informing policy.
30.	Mobasheri, M.H., et al., The uses of smartphones and tablet devices in surgery: A systematic review of the literature. Surgery, 2015. 158(5): p. 1352-71.	This review included one study, which used entertaining apps to distract kids waiting for surgery to reduce their anxiety.
31.	Mosadeghi-Nik, M., M.S. Askari, and F. Fatehi, Mobile health (mHealth) for headache disorders: A review of the evidence base. Journal of Telemedicine & Telecare, 2016. 22(8): p. 472-477.	This review did not include any RCTs. All studies were of app developments.
32.	Nelson, L.A., et al., Patterns of User Engagement with Mobile- and Web-Delivered Self-Care Interventions for Adults with T2DM: A Review of the Literature. Current Diabetes Reports, 2016. 16(7).	This review focused on patient engagement outcomes and associated technology features, but not clinical outcomes.
33.	Pal, K., et al., Computer-based diabetes self-management interventions for adults with type 2 diabetes mellitus. Cochrane Database of Systematic Reviews, 2013. 0(3).	It covered two studies of non-stand-alone apps.
34.	Park, L.G., et al., Mobile Phone Interventions for the Secondary Prevention of Cardiovascular Disease. Progress in Cardiovascular Diseases, 2016. 58(6): p. 639-50.	None of the app interventions are available.
35.	Russell-Minda, E., et al., Health technologies for monitoring and managing diabetes: a systematic review. Journal of Diabetes Science & Technology, 2009. 3(6): p. 1460-71.	This review included one non-stand-alone app study.
36.	Sarno, F., D.S. Canella, and D.H. Bandoni, Mobile health and excess weight: a systematic review. Revista Panamericana De Salud Publica-Pan American Journal of Public Health, 2014. 35(5): p. 424-431.	No real smartphone app studies were included (few PDA based or prototypes that were discontinued since).
37.	Stephani, V., D. Opoku, and W. Quentin, A systematic review of randomized controlled trials of mHealth interventions against non-communicable diseases in developing countries. BMC Public Health, 2016. 16: p. 572.	This review included two studies that involved apps, but the apps were proprietary and discontinued afterwards.
38.	Stephens, J. and J. Allen, Mobile phone interventions to increase physical activity and reduce weight: a systematic review. J Cardiovasc Nurs, 2013. 28(4): p. 320-9.	We contacted the authors of only one app RCT included in this review. However, it was discontinued after the study.
39.	Versluis, A., et al., Changing Mental Health and Positive Psychological Well-Being Using Ecological Momentary Interventions: A Systematic Review and Meta-analysis. J Med Internet Res, 2016. 18(6): p. e152.	This review was aimed at evaluating the ecological momentary interventions usage in mHealth. It wasn't app-specific and no clinical outcomes were reported.
40.	Wesley, K.M. and P.J. Fizur, A review of mobile applications to help adolescent and young adult cancer patients. Adolescent Health Medicine & Therapeutics, 2015. 6: p. 141-8.	The studies included were not RCTs. They analysed contents of 6 applications and included feasibility studies.

Supplementary table 2. Excluded systematic reviews due to repeated coverage

No.	Reference	Reason for exclusion
1.	Aguilar-Martinez, A., et al., Use of mobile phones as a tool for weight loss: a systematic review. Journal of Telemedicine and Telecare, 2014. 20(6): p. 339-349.	Includes one relevant RCT (Turner-McGrievy 2011), which is included in more recent systematic review (Flores-Mateo 2015) that is included on our overview.
2.	Coughlin, S.S., et al., A Review of Smartphone Applications for Promoting Physical Activity. Jacobs J Community Med, 2016. 2(1).	Same search date and same includable studies as Flores-Mateo 2015. FM trumps by publication date.
3.	Cui, M., et al., T2DM Self-Management via Smartphone Applications: A Systematic Review and Meta-Analysis. PLoS ONE [Electronic Resource], 2016. 11(11): p. e0166718.	Trumped by Bonoto 2017 (FTA)
4.	Dallinga, J.M., et al., [Can apps encourage a healthier and more active lifestyle?]. Nederlands Tijdschrift voor Geneeskunde, 2016. 160(0): p. D329.	Trumped by Schoeppe 2017 (Cowdery 2015, Wharton 2014)
5.	David, S.K. and M.R. Rafiullah, Innovative health informatics as an effective modern strategy in diabetes management: a critical review. International Journal of Clinical Practice, 2016. 70(6): p. 434-49.	Trumped by Bonoto 2017 (Diabeo, GB)
6.	Deacon, A.J. and S. Edirippulige, Using mobile technology to motivate adolescents with type 1 diabetes mellitus: A systematic review of recent literature. Journal of Telemedicine & Telecare, 2015. 21(8): p. 431-8.	Includes only one app prototype RCT (Berndt 2014), which was also covered in more recent systematic review (Bonoto 2017) that is included on our overview.
7.	Derbyshire, E. and D. Dancey, Smartphone Medical Applications for Women's Health: What Is the Evidence-Base and Feedback? International Journal of Telemedicine & Applications, 2013. 2013: p. 782074.	Included two relevant studies, which is included in more recent systematic review (Flores-Mateo 2015) that is included on our overview.
8.	DiFilippo, K.N., et al., The use of mobile apps to improve nutrition outcomes: A systematic literature review. Journal of Telemedicine & Telecare, 2015. 21(5): p. 243-53.	As above
9.	Donker, T., et al., Smartphones for smarter delivery of mental health programs: a systematic review. Journal of Medical Internet Research, 2013. 15(11): p. e247.	Includes one app RCT (Watts 2013), which is included in more recent systematic review (Payne 2015) that is included on our overview.

10.	Garabedian, L.F., D. Ross-Degnan, and J.F. Wharam, Mobile Phone and Smartphone Technologies for Diabetes Care and Self-Management. Current Diabetes Reports, 2015. 15(12).	The relevant RCTs were covered in more recent SR (Bonoto 2017), which we included in our overview.
11.	Hamine, S., et al., Impact of mHealth chronic disease management on treatment adherence and patient outcomes: a systematic review. Journal of Medical Internet Research, 2015. 17(2): p. e52.	As above (Kirwan 2013 – Bonoto 2017)
12.	Hood, M., et al., What do we know about mobile applications for diabetes self-management? A review of reviews. J Behav Med, 2016. 39(6): p. 981-994.	Trumped by Bonoto 2017 (FTA)
13.	Hou, C., et al., Do Mobile Phone Applications Improve Glycemic Control (HbA1c) in the Self-management of Diabetes? A Systematic Review, Meta-analysis, and GRADE of 14 Randomized Trials. Diabetes Care, 2016. 39(11): p. 2089-2095.	Trumped by Bonoto 2017 (FTA, GB)
14.	Khokhar, B., et al., Effectiveness of mobile electronic devices in weight loss among overweight and obese populations: a systematic review and meta-analysis. BMC Obesity, 2014. 1: p. 22.	(Carter 2013; Flores-Mateo 2015)
15.	Lindhiem, O., et al., Mobile technology boosts the effectiveness of psychotherapy and behavioral interventions: a meta-analysis. Behavior Modification, 2015. 39(6): p. 785-804.	A-ChESS (Payne 2015), Glucose Buddy – (Bonoto 2017)
16.	Liu, F., et al., The effect of mobile phone intervention on weight loss among overweight and obese adults: A meta-analysis of randomized controlled trials. Circulation, 2014. 130.	Includes one relevant RCT (Turner-McGrievy 2011), which is included in more recent systematic review (Flores-Mateo 2015) that is included on our overview.
17.	McMillan, K.A., et al., A Systematic and Integrated Review of Mobile-Based Technology to Promote Active Lifestyles in People With Type 2 Diabetes. Journal of Diabetes Science & Technology, 2016. 21: p. 21.	Trumped by Bonoto 2017 (FTA)
18.	O'Rourke, L., G. Humphris, and A. Baldacchino, Electronic communication based interventions for hazardous young drinkers: A systematic review. Neuroscience & Biobehavioral Reviews, 2016. 68: p. 880-90.	Only includes Promillekoll study which was covered in Payne 2015
19.	Whitehead, L. and P. Seaton, 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): p. e97.	Trumped by Bonoto 2017.

20.	Wu, Y., et al., Mobile App-Based Interventions to Support Diabetes Self-Management: A Systematic Review of Randomized Controlled Trials to Identify Functions Associated with Glycemic Efficacy. JMIR Mhealth Uhealth, 2017. 5(3): p. e35.	Trumped by Bonoto 2017.

Supplementary table 3: Excluded systematic reviews due to unavailability of apps

No.	Reference	Reason for exclusion
41.	Bassi, N., et al., Lifestyle Modification for Metabolic Syndrome: A Systematic Review. American Journal of Medicine, 2014. 127(12).	Most of the primary studies were of web, SMS and phone call interventions. Only one app prototype study (Spring 2012) was included, hence the app was not available yet.
42.	Faurholt-Jepsen, M., et al., Electronic self-monitoring of mood using IT platforms in adult patients with bipolar disorder: A systematic review of the validity and evidence. Bmc Psychiatry, 2016. 16.	None of the apps are made available yet. RCTs still ongoing.
43.	O'Reilly, G.A. and D. Spruijt-Metz, Current mHealth Technologies for Physical Activity Assessment and Promotion. American Journal of Preventive Medicine, 2013. 45(4): p. 501-507.	Only one app prototype RCT (Spring 2012) was included, hence the app was not available yet.

Supplementary material 4. Complete search strategy

Medline Ovid
exp Cell phones/ OR exp Computers, Handheld/
AND
exp Mobile Applications/ OR (Application OR Applications OR App OR Apps OR Intervention OR Interventions).tw.
AND
exp Self care/ OR exp Life style/ OR exp Patient compliance/ OR exp Patient Care/
OR
(Smartphone OR Smart-phone OR Smart phone OR Smartphones OR Smart-phones OR Smart phones OR Mobile OR Tablet OR Tablets OR iPhone OR Android).tw.
ADJ2
(Application OR Applications OR App OR Apps OR Intervention OR Interventions).tw.
AND
(Utilize OR Utilizing OR Administer OR Administering OR Assist OR Manage OR Management OR Role OR Roles OR Tested OR Increase OR Increased OR Increasing).tw.
AND
exp Patients/ OR (Patient OR Patients OR Population OR Populations OR Public OR Group OR Groups OR Chronic OR Acute OR Behavior OR Behaviors OR Behavioral OR Behaviour OR Behaviours OR Behavioural).tw.
AND
exp "Outcome Assessment (Health Care)"/ OR (Outcome OR Outcomes OR Efficacy OR Effectiveness OR Improve OR Improved OR Improvement OR Improvements OR Reduce OR Reduced OR Reduction OR Reductions).tw.
AND
meta analysis.mp,pt.OR review.pt.OR search.tw. OR searched.tw. OR searches.tw.

Cochrane Database of Systematic Reviews

([mh "Cell phones"] OR [mh "Computers, Handheld"])
AND
([mh "Mobile Applications"] OR (Application OR Applications OR App OR Apps OR Intervention OR Interventions).tw.)
AND
([mh "Self care"] OR [mh "Life style"] OR [mh "Patient compliance"] OR [mh "Patient Care"])
OR
(Smartphone OR Smart-phone OR Smart phone OR Smartphones OR Smart-phones OR Smart phones OR Mobile OR Tablet OR Tablets OR iPhone OR Android):ti,ab
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(Application OR Applications OR App OR Apps OR Intervention OR Interventions):ti,ab
AND
(Utilize OR Utilizing OR Administer OR Administering OR Assist OR Manage OR Management OR Role OR Roles OR Tested OR Increase OR Increased OR Increasing):ti,ab
AND
[mh Patients] OR (Patient OR Patients OR Population OR Populations OR Public OR Group OR Groups OR Chronic OR Acute OR Behavior OR Behaviors OR Behavioral OR Behaviour OR Behaviours OR Behavioural):ti,ab
AND
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Embase
('mobile phone'/exp OR ‘microcomputer'/exp)
AND
'Mobile Application'/exp OR (Application OR Applications OR App OR Apps OR Intervention OR Interventions):ti,ab

AND
('Self care'/exp OR 'Lifestyle'/exp OR 'Patient compliance'/exp OR 'Patient Care'/exp)
OR
((smartphone OR 'smart phone' OR smartphones OR 'smart phones' OR mobile OR tablet OR tablets OR iphone)
NEAR/2
(application OR applications OR app OR apps OR intervention OR interventions)):ab,ti

AND
(Utilize OR Utilizing OR Administer OR Administering OR Assist OR Manage OR Management OR Role OR Roles OR Tested OR Increase OR Increased OR Increasing):ti,ab
AND
'Patient'/exp OR (Patient OR Patients OR Population OR Populations OR Public OR Group OR Groups OR Chronic OR Acute OR Behavior OR Behaviors OR Behavioral OR Behaviour OR Behaviours OR Behavioural):ti,ab
AND
'Outcome Assessment'/exp OR (Outcome OR Outcomes OR Efficacy OR Effectiveness OR Improve OR Improved OR Improvement OR Improvements OR Reduce OR Reduced OR Reduction OR Reductions):ti,ab

AND
meta-analys* OR search:ti,ab OR review:it

Web of Science
Refined by: DOCUMENT TYPES: (REVIEW)

Smartphone OR Smart-phone OR "Smart phone" OR Smartphones OR Smart-phones OR "Smart phones" OR Mobile OR Tablet OR Tablets OR iPhone OR Android
AND
Application OR Applications OR App OR Apps OR Intervention OR Interventions
AND
Utilize OR Utilizing OR Administer OR Administering OR Assist OR Manage OR Management OR Role OR Roles OR Tested OR Increase OR Increased OR Increasing
AND
Patient OR Patients OR Population OR Populations OR Public OR Group OR Groups OR Chronic OR Acute OR Behavior OR Behaviors OR Behavioral OR Behaviour OR Behaviours OR Behavioural
AND
Outcome OR Outcomes OR Efficacy OR Effectiveness OR Improve OR Improved OR Improvement OR Improvements OR Reduce OR Reduced OR Reduction OR Reductions
AND
TOPIC: (meta-analys* OR search OR Searched OR Searches) OR TITLE: (review)

4

Chapter 4. Perspectives of general practitioners and patients

Barriers to and facilitators of the prescription of mHealth apps in Australian general practice: qualitative study

Byambasuren O, Beller E, Hoffmann T, & Glasziou P.

JMIR mHealth uHealth, 2020;8(7):e17447. https://doi.org/10.2196/17447.

PREAMBLE

The previous chapter found that a very small percentage of all available apps has been rigorously tested. We also identified multiple research gaps in testing and reporting of mHealth trials. Despite the thin evidence base, mHealth apps still hold potential as a non-drug intervention.

This chapter will start to explore the perceptions of general practice patients and GPs around mHealth apps and the possibility of app prescription. Barriers and facilitators identified in this study will help inform subsequent studies, especially the development of an intervention to overcome some of the barriers.

Manuscript of this chapter is published in the *Journal of Medical Internet Research mHealth and uHealth*. Work arising from this chapter has been presented at the Higher Degree Research student conference at Bond University in 2018.

4.1 Abstract

Background: The ubiquity of smartphones and health apps make them a potential self-management tool for patients that could be prescribed by medical professionals. However, little is known about how Australian general practitioners (GPs) and their patients view the possibility of health app prescription.

Objective: To determine barriers and facilitators to prescribing mHealth apps in Australian general practice from the perspectives of GPs and patients.

Methods: Semi-structured interviews were conducted in Australian general practice settings. GPs and patients were purposively sampled. Interviews were audio-recorded and transcribed. Transcripts were coded and analysed thematically by two researchers.

Results: Twenty GPs and 15 adult patients were interviewed. From the GPs' perspectives barriers to prescribing apps were: a generational difference in the digital propensity for GPs and patients; lack of knowledge of prescribable apps and trustworthy sources to access them; the time commitment required of GPs and patients to learn and use the apps; and concerns about privacy, safety, and trustworthiness of health apps. Facilitators from GPs' perspectives were trustworthy sources to access prescribable apps and information, and younger generation and widespread smartphone ownership. From patients' perspectives, the main barriers for older patients and the usability of the apps. Patients were not concerned about privacy and data safety issues regarding health app use. The facilitators for patients were the ubiquity of smartphones and apps especially for the younger generation, and recommendation of apps by doctors. Evidence of effectiveness was identified as an independent theme from both GPs' and patients' perspectives.

Conclusion: mHealth app prescription appears to be feasible in general practice. The barriers and facilitators identified from the GPs and patients' perspectives overlapped, though privacy was of less concern to patients. Involvement of HCPs and patients is vital for successful integration of effective, evidence-based mHealth apps with clinical practice.

4.2 INTRODUCTION

The number of smartphones and mobile heath (mHealth) apps has risen globally, with Australians at the forefront of smartphone ownership near 90% of the population [1]. In addition to fitness and wellness, mHealth apps are primarily created for and can benefit patients in managing chronic diseases [2]. More than half of US consumers have downloaded at least one mHealth app [3]. Despite the high initial uptake of apps, user retention rates can be low and the duration of app usage can be short[4, 5]. However, according to the AppScript app prescription platform user data, prescribed mHealth apps have a higher retention rate than the non-prescribed apps [2].

Healthcare professionals prescribe mHealth apps in their practice in varying degrees [6-9]. Although relevant professional organizations provide some guidance on how to prescribe mHealth technology in clinical practice, HCPs are often left to navigate this new area on their own [10-12]. A systematic review by Gagnon et al identified about 180 individual barriers and facilitators to adoption of mHealth by HCPs, about third of which reflects factors directly relevant to their knowledge, attitude and acceptance of mHealth [13]. However, these findings were not specific to general practice.

In Australia, the Royal Australian College of General Practitioners (RACGP) offers limited guidance on mHealth apps. The college also has been collecting basic data on providers' app usage as part of their Annual Technology survey [14]. However, the survey has not explored the barriers to mHealth app adoption in-depth. It is essential to explore the issues around app prescription in general practice in order to devise effective interventions to overcome the barriers perceived by the practitioners. Therefore, the objectives of this study were to determine the barriers to and facilitators of the prescription of mHealth apps in Australian general practice from the perspectives of general practitioners and their patients.

4.3 METHODS

PARTICIPANTS

We conducted one-to-one semistructured interviews with 20 Australian general practitioners (GPs; 8 via telephone and 12 face-to-face) and 15 patients (all face-to-face) in South East Queensland (Australia) general practices between July and December 2017. We recruited the participants using purposive sampling to ensure a diverse range of years of experience and age. Recruitment was done mainly through snowballing via colleagues, organizational contacts, and via initial participants. Participation in the interviews was voluntary and written informed consent was obtained from each participant before the interview. GPs were interviewed in their consultation rooms or over the phone. Patients were interviewed in the waiting area of the clinic if privacy was ensured.

PROCEDURE

We chose semistructured interviews as they allow for flexibility to explore a new subject yet are structured enough to achieve the study aim. The interview questions were developed by the authors, piloted with three academic GPs, and revised before the study. The questions were designed to explore participants' attitudes toward smartphone health apps, their thoughts on the possibility of prescribing health apps, and perceived potential barriers and facilitators to prescribing apps in general practice consultations (Figure 8). Toward the end of the interview, participants were shown (or in the case of phone interviews, apps were named) 9 examples of popular Health & Fitness and Medical apps from the major app stores and 9 examples of tested and effected apps identified through our earlier study on the evidence supporting health and medical apps in order to gauge their general familiarity with mHealth apps [15] (Figure 9). No financial or other incentives were offered to participants.

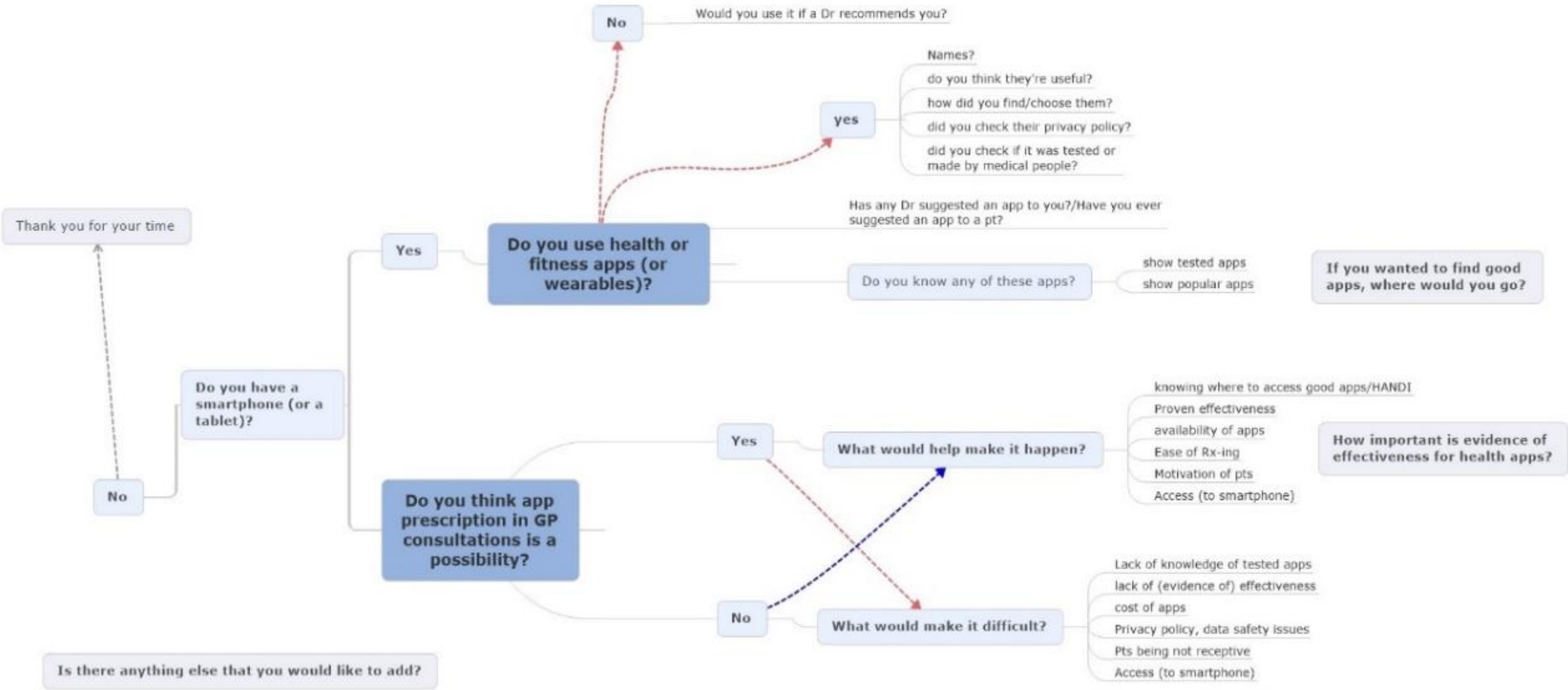

Figure 8. Guide map for the interview

Figure 9. Example apps shown to interviewees to identify their familiarity with evidence-based vs. popular mHealth apps

DATA ANALYSIS

We planned to interview 15-20 GPs and a similar number of patients. Data saturation was fully achieved, ie, no new content emerged after 3 consecutive interviews in both cohorts by the time we interviewed 20 GPs and 15 patients, therefore validating that our sample size was sufficient. All interviews were conducted, audio-recorded, and transcribed verbatim by the first author (OB).

We employed a thematic analysis methodology described by Braun and Clarke [16]. The six phases of analysis were familiarization with the data, coding, generating initial themes, reviewing themes, defining and naming themes, and report writing. Two researchers (OB, RS) familiarized themselves with the interview transcripts and independently coded them. Partially inductive thematic analysis was carried out, and generated themes were reviewed in consultation with the third author (TH). The results are written up by the first author (OB).

We used the Consolidated Criteria for Reporting Qualitative Research checklist to report the details of our study [17], which is provided as Multimedia Appendix 1. Ethics approval was obtained from the Bond University Human Research Ethics Committee (16016).

4.4 Results

We interviewed 20 general practitioners and 15 patients, the demographics of whom are shown in Table 1. Ten additional patients declined to be interviewed, citing that they have never used mHealth apps or do not know anything about them. None of the providers we approached declined to be interviewed. Interviews averaged about four minutes for patients and twelve minutes for GPs.

Table 5. Interview participant characteristics

Groups		**Total n (%)**
General practitioners		**n=20**
Years in practice		
	<10	6 (30%)
	10-20	6 (30%)
	>20	8 (40%)
Gender		
	Female	12 (60%)
Patients		**n=15**
Age (years)		
	18-35	5 (33.3%)
	36-50	5 (33.3%)
	Over 50	5 (33.3%)
Gender		
	Female	10 (66.6%)

General Practitioners' perspectives

The majority of the GPs reported using health apps personally, professionally, and recommending health apps to patients. However, most GPs suggest apps mostly in generic terms in areas such as mindfulness and period-tracking without naming specific apps and let patients make the final choice because they do not know any specific vetted and safe apps.

The GPs were more familiar with popular apps such as MyFitnessPal, Headspace, and Smiling Mind than evidence-based apps. None of the GPs was familiar with five of the evidence-based apps (SuperBetter, MyMealMate, AccupedoPro, Vegethon, Tat). Sources for finding health apps to recommend varied from trusted websites and medical publications to word-of-mouth and app stores.

About half of the participants were unfamiliar with the Handbook of Non-Drug Interventions (HANDI) web resource from the RACGP [18], but upon being introduced to it, they all agreed that HANDI would be a trustworthy resource for evidence-based apps, consistent with those GPs who were already familiar with HANDI.

BARRIERS

We identified four themes around barriers to app prescription in general practice. The most prominent barrier cited was a generational difference in the overall **digital propensity** for both doctors and their patients.

> *Most patients who would benefit from them are elderly and they don't do apps. They don't do smartphones. That's the number one barrier. And most of our patients who are over 70 will be in that category. Most I would say. [GP7]*

> *Well, it's probably my age group more than anything. it's just I'm not as familiar with and as happy around technology as the newer doctors… I do feel it's important to try to learn it because it's part of the future… so it's that technology I think is the main barrier as far as being used to it. I think we need to but it's just hard to do. Can we get away with it? I guess that's what's happening to a lot of older doctors is seeing if we really need to do it or not. [GP5]*

GPs with more than 20 years of experience appeared more likely to find mHealth apps a "gimmick" and less likely to consider using them in their practice.

> *I think it would be [possible to prescribe apps]. The trouble is I think they're a bit of a gimmick. I mean we've always had accessories to health. When I was a young doctor people would bring in their calendars which showed when their next periods are. Now they pull out their phones… you find the phone is slower than the calendar because the calendar… is there and you'd be able to see it visually, whereas a phone, they're pulling it out… trying to find it miss it… then the reception is not good and it takes ages for it to download. So, I don't really find them a step forward. They probably are for the person using them at home. But in the consultation, they're often not a step forward I find. [GP9]*

GPs who primarily work with elderly patients would not consider using apps as potential interventions. The "cut-off age" for recommending apps to patients was around 40-60 years.

> *For somebody like me, there will be obstacles because I don't really use apps. So, if you're not comfortable with that sort of things yourself, you have to overcome that to recommend it... Even when I've learned about them in an education session, I always forget what they are, because I don't use them… In*

fact, the only times I ever recommend apps at all are for young people… they don't have to be young-young, even in their 30s, a young professional… But I never recommend to people older than that. So, there is obviously a generational issue. [GP3]

However, exceptions to the age-based generalization were commonly mentioned, making individual digital propensity a more influential factor than age in deciding to prescribe apps.

I got some elderly patients that don't use an iPhone too often or an app. But there's a lot of savvy oldies there too. It probably depends on the patient, their interests. [GP11]

GPs also recognize that age is a transient barrier as the younger cohort of patients will age and become patients with chronic diseases.

It is a very good idea and something that can be very useful. But I never know which ones are good to use and which population would be good to use them. I'm sure it will come especially as right now the younger population are the ones who are really into the smartphones and they'll get older and have chronic medical conditions in the next 20 years I'm sure it will there's going to be a big space for these apps. [GP16]

Another barrier was a lack of knowledge of prescribable apps and a lack of trustworthy sources to access them.

Probably the only other barrier is knowing which apps. And keeping on top of all the apps they become available, how much they cost and all those kinds of things. [GP20]

I do. I think it's something I'm cautious of simply because if it's not something that I know a lot about then I'm a bit more concerned, you know, I don't really wanna recommend something I don't know the full workings of, especially if I'm gonna ask them to buy. There's so much of me asking them to go on medication until I'm confident that money is money worth spent and the benefit outweighs the cost, then I'm not really willing to do that. [GP2]

I think for education it's really valuable. Ones that I don't use enough of and they all want more information. Otherwise, they'll just Google some unreliable search, and so if I've got a good place to go to that's evidence-based, that's good. [GP18]

Another barrier was the time commitment required to learn about apps and integrating them into consultations as well as the time commitment required of the patients to use the recommended app. Before they were willing to expend time to adopt apps into their clinical practice, GPs described needing to be convinced of the benefits of using apps.

> *And it's time-consuming to learn about these things. It's hard enough just keeping up with what medicine is doing without this app and that app etc. [GP1]*

> *You're so busy doing in medicine there's not a lot of time to go out there and research what might need to be done to create an app or even the ones that are out there. We're so rushed for time. You're competing with lots of other demands for your time and energy as well. So that's a big limiting factor. [GP8]*

> *The patients' motivation would be a big thing. And the time involved in using it would be another big thing for someone who might be busy, for example. I don't think a lot of people have a lot of time to invest in this type of thing. So, I think your time, availability, and the motivation behind a patient. [GP15]*

> *I think for me, it's just when you are consulting, and you're busy. To modify the practice of what I'm doing, I have to have a pretty good reason for doing it. [GP6]*

Another barrier identified was the privacy, safety, and trustworthiness of health apps. The GPs perceived issues around privacy and data safety of health apps as the ultimate responsibility of the patients, since their complete and ongoing safety cannot be guaranteed. Some GPs were aware of how the industry attempts to influence health care.

> *I personally manage my privacy very, very, very carefully. But I think I leave that to the individual patient... and I think that if they're going to be using apps, my perception is that they already have made their own personal decisions upon privacy. [GP4]*

> *I think that's every day now. I mean the number of times you get on Google and then they already go okay well you've got this many children, and I know that already… that's the world we live in. I don't think we're going to stop that by not using an app when we're on the internet all the time. So, if it's demographic information and I think that's being collected by a lot of people, not just an app, I suppose. [GP20]*

> *Also, I guess I'm also very wary of who's paying for it. So, I guess my general approach to most things is to think if you're going to pay for it, then hopefully you are bearing the load of what if it's worth it. If someone else is paying then there's some hidden agenda there, whether it's a drug company or someone else who's gonna benefit of you having their app on your phone and again that comes down to my reticence to recommend something I really don't know*

who's designed it and what's the purpose of it and who's benefiting the most. [GP2]

FACILITATORS

We identified two main themes around facilitators of mHealth app prescription in general practice. One was a **trustworthy source for prescribable apps and information for GPs**. The RACGP was their most preferred trustworthy source to vet, endorse and provide prescribable apps as the majority of the GPs were RACGP members.

> *"Maybe some sort of database of trusted apps that would be recommended for certain conditions or treatment strategies. Having a nice little summary of things that could be used, because of the sheer number of what's on the market, it's hard to really make it part of my regular day-to-day routine... Whereas if some organization was to put together a list of you know tried and tested and reliable apps then it would be much easier to say "look, you're young you'll you've got the time and the patience for it, let's try an app for this problem, and this is the one we trust." (GP15)*

> *"I think we probably need to have them reliably approved and researched by our college. I probably wouldn't be happy to recommend any without the endorsement of the college." (GP11)*

> *"… we need more education on which ones to prescribe and which ones not. We have the NPS which helps us with prescribing medications. So, if there were an organization/body involved with educating GPs on which apps are good and useful and provide the right information and are easy to use, that would be really helpful." (GP16)*

GPs recognized that **near-universal ownership of smartphones, the ubiquity of apps, and younger tech-savvy patients** are enablers of app prescription, as this facilitates information accessibility and can sometimes provide alternatives that are more convenient and lower in cost.

> *"I work in an area where there's a lot of young people and most of these people are … generally pretty switched on. and … I can't imagine a situation where I'm*

not being able to recommend an app so somebody. This hasn't happened yet." (GP12)

"Apps are quite a neat way of showing somebody all that information without having a book to give them. It's often a very low-cost solution if your alternatives are costly. And it's very accessible... you don't need to wait for in-hours care, you can be 10 p.m. at night and do some of the work whether it's treatment or information and knowledge that you're sharing that can all be done at a time that suits a patient. so that's the kind of value of apps I suppose over other resources." (GP20)

PATIENTS' PERSPECTIVES

Two-thirds of the patients have used or use mHealth apps personally. Most commonly used app types were fitness, wellness, and women's health related apps (period, ovulation and pregnancy tracking). Those who did not use any apps said the reason was they do not have any need or significant reason to. People often chose apps through recommendations by friends or family, directly from app stores or through the services they subscribed to such as the local gym. From the list of popular and evidence-based apps, they recognized some of the most popular apps such as MyFitnessPal and 5K runner, but none of the evidence-based apps.

BARRIERS

From the patients' perspectives, a perceived barrier to using mHealth apps in GP consultations was older patients.

"I don't think there'd be any problem. But if we're talking about the elderly, they're not really very computer-savvy. So, they might find it difficult. I have a number of friends, even older than me, they don't wanna use smartphones. It's too much trouble. They just wanna make a phone call and get a text. That's it." (Pt8)

"I guess only with the older generation not having smartphones. They would not use apps. So that would really be the only problem. Yeah, I wouldn't see any other [issue]." (P2)

Another barrier was if the usability of apps was poor.

"I think the ease-of-use has to be paramount. Ease of use is gotta be the big issue. For me, that was the problem. I can't speak for other people. I mean I'm pretty good with technology, but I just found it very tedious… And I just found it was annoying to put data in. That was the issue with it. So, when it becomes difficult, I didn't do it." (Pt12)

Data safety and privacy issues related to health app use were not a barrier described by the patients interviewed. Patients were more concerned about financial information loss than their health-related information.

"I don't worry about it too much, privacy stuff, cause I don't have much to hide. Maybe if someone got on to your phone, they could see your personal information, they usually have like a passcode for private apps anyway." (P13)

"Me personally, no. data safety… it is what it is. I think there are measures in place to keep it safe. Other people probably don't have that opinion. I think honestly it is safe enough." (P15)

"I'm more worried about financial stuff than health that would create a financial loss. if somebody finds out what my blood pressure is, what's the big deal, right?" (Pt8)

"I don't worry about it. well, I'm not really putting anything into an app that is that [important]… I mean I don't know who else in the world cares the day my period came or how big the baby is, I haven't really put in banking details or anything. I haven't used any paid apps." (Pt6)

FACILITATORS

From the patients' perspectives, the ubiquity of smartphones and apps and young patients were perceived facilitators of app prescription.

"I imagine younger people wouldn't have any problems" (Pt11)

"I think it's quite a common thing now. Everyone has smartphones nowadays. So, it's an easy way to access it." (Pt1)

Most patients expressed that they think mHealth apps can be beneficial, especially when recommended by their doctor and that app prescription by GPs is possible, helpful and welcome because it would eliminate the challenge of finding health apps for themselves.

> *"Great idea if they're prescribed from a doctor. I don't think getting them off the net without advice would be a good thing. I think it needs to be advised or prescribed by someone who knows, and then from there, it can only be a good thing, yeah." (Pt15)*

> *"Yeah. If my doctor recommended one, I'd probably go with that rather than trying to go from the recommendations on iPhone, you know, the stars, from the app stores. I mean they are helpful too what other users have found, cause a lot of apps crash and have problems if they're not maintained and upgraded, but yeah if a doctor was recommending one, I'd probably use it." (Pt9)*

> *"if there are multiple people being like "this is really good. This has helped me with this…" then I'll actually go have a look. If I like it for more than a week, then I'll just continue using it. I went through a lot [of apps] before finding the one that wasn't an effort to use, one that was just easy. I went through probably ten to find one I actually liked, which is a bit annoying. It kind of turns you off that. So, if there was one or two that all doctors recommended then people would probably more likely to use them" (Pt1)*

A theme identified from both the GPs and patients' perspectives that could not be clearly categorized as a barrier or facilitator was **evidence of the effectiveness of the apps**. GPs expressed they would not want to prescribe apps without evidence behind it, yet they also feel that simple apps do not need high levels of evidence.

> *"…as it applies to anything in medicine, I think it would need a reasonable degree of efficacy to run with it. You know, you can't just have an app for the sake of having an app." (GP1)*

> *"… [evidence is] pretty important to officially recommend. Some of it is common sense. Like something to log your blood pressure and mood diary is self-explanatory and makes sense. But for some more complex health apps, you sort*

of wanna know if there's good evidence so that it's reasonably well made. Especially if you're going to spend money on it." (GP14)

Most patients viewed the evidence of effectiveness of apps to be important in the same way as the standards required of pharmaceutical interventions. Some were not concerned about the effectiveness and preferred their own evaluations and freedom to make the ultimate decision.

"Very important. It's like anything in health, it's like medication, if a doctor is gonna recommend something, they have to know it works. Cause it might not be suitable for somebody, and if that person is to use something that's not suitable then that could have a bad effect instead of a good one." (Pt13)

"Definitely, yea. I would want one that has references, the app that I use have medical references they've sourced the information. Otherwise, anyone could be sitting home and writing an app." (Pt6)

"I'm not too worried about that. I just get on and try it, if it works for me then that's great. It if doesn't then I'll just delete it if it's not gonna do what I needed it to do for me… I mean as long as it's our choice to use them or not. I mean up to us, they can make a recommendation, but if we find it's not suitable or it doesn't work. and If it does then great if it makes our life easier, it's a fast and busy world, so if they think it can help, it's great." (Pt10)

4.5 Discussion

In this study of the barriers to and facilitators of mHealth app prescription in Australian general practice, all patients and GPs recognized that mHealth apps could be beneficial, and app prescription is achievable. From the GPs' perspective, uptake is hindered by barriers around a generational difference in the digital propensity for both GPs and patients, lack of knowledge of prescribable apps and lack of trustworthy source to access them, time commitments required of the GPs and patients, and privacy, safety, and trustworthiness of health apps.

Both patients and GPs cited the old age of patients as a barrier to app prescription, although also offered examples of exceptions to this age-related division of digital propensity. Annual mobile consumer surveys showing that older age groups have seen the highest increase in smartphone ownership in Australia [19]. Doctors and patients also believed that the ubiquity of smartphones and apps, and young patients are facilitating factors as Australians approach "peak smartphone"—the peak level of usage before the vast majority of consumers to begin actively limiting their phone use [20]. Almost all the interviewed GPs reported using apps personally and professionally; however, they do not recommend specific apps to patients. Instead, they remind patients of the availability of mHealth apps in the general area of focus (eg, mindfulness) should they wish to use them.

The evidence base (weak or strong) for mHealth apps emerged as an important theme as a barrier or facilitator. Patients viewed doctors as a trustworthy source of health apps, and the GPs acknowledged that they needed a trustworthy source for prescribable apps as they have neither the knowledge nor time to find such apps themselves. A national-level professional organization such as the RACGP is well-placed to address this barrier. One of the many resources they provide for GPs is HANDI—a database of effective nondrug interventions, which includes several mHealth apps [18]. However, half of the GPs interviewed in this study were not familiar with or commonly used HANDI, but all agreed that RACGP is the most trusted source for them to access professional and practice-related information and guidance. The majority of participants recognized a few of the most popular apps from app stores and fewer apps from the evidence-based apps list, emphasizing the need for information dissemination about evidence-based apps.

Several comparable studies have explored barriers and facilitators to novel technology adoption in medical practice. Many studies report a lack of education and training as one of the most common barriers that face health care providers in adopting new technology in health care [13,21,22], and our study echoes this. Furthermore, the potential to increase doctors' time strain and workload are universally common factors of poor uptake of new health technologies [23-25]. Brandt et al found that the experiences of GPs with eHealth support for lifestyle changes were an essential factor in recommending it for their patients [26]. Our findings also emphasize the digital propensity of the health care providers and patients would make a big difference in uptake of mHealth apps. Building on this finding and educating and supporting GPs so they understand the value of new technology such as the potential to save consultation time and keep patients connected and motivated between consultations can help mitigate against these barriers and help them recommend apps to their patients with confidence.

Recent research suggests that individuals with poor self-reported health and low rates of physical activity were the least likely to report downloading and using these health tools [27]; however, patients adhere better to prescribed apps [2] beyond the typical one week of usage [4,5]. Thus, the official prescription of apps by trusted medical practitioners might help increase the uptake of effective health apps among such patients who would benefit the most. Future studies should measure the real-world adherence of the patients following app prescription by health professionals.

The present qualitative study appears to be the first of its kind to explore the perspectives of GPs and patients regarding mHealth app prescription in Australian general practice. The barriers identified in this study were added to the mHealth section of the RACGP Annual Technology survey in 2017 to explore further how they would rank among a national sample of GPs [28]. The question about barriers to app prescription gathered over six hundred responses and the top barriers reflected the central theme identified in this study, which was lack of knowledge of effective apps and lack of trustworthy source to access them, further validating the findings of this study.

Limitations of this study include a small sample size that skewed towards relatively healthy patients from high socioeconomic areas and GPs from the metropolitan area. Although we attempted to mitigate this limitation by purposively sampling participants from a variety of age and work experience, future studies should target patients with long-term medical conditions, those from rural and remote areas, and low socioeconomic areas. Other limitations include lack of triangulation of the results, member checking, a reflection of possible interviewer bias about the potential of apps, and not piloting the interview questions with patients.

Conclusions

mHealth app prescription appears to be feasible in general practice. The barriers and facilitators we identified from both GPs and patients widely overlapped. The involvement of all stakeholders of consumer mobile technology, medical professionals, and patients is vital in the successful integration of mHealth apps with clinical practice. The findings of this study will inform the development of effective interventions to overcome the identified barriers and help the adoption of health apps to general practice to patients' benefit.

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Conflict of interest: Authors PG and TH are members of the HANDI project committee at the RACGP.

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5

Chapter 5. mHealth app use among general practitioners

Current knowledge and adoption of mHealth apps among Australian general practitioners: a survey study

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PREAMBLE

The previous study identified several barriers and facilitators to app prescription from the perspectives of both patients and GPs. Main barriers from the GPs' perspectives were a (1) generational difference in the digital propensity for both the GPs and patients; (2) lack of knowledge of prescribable apps and lack of reliable source to access apps; (3) the time commitment required of GPs and patients; and (4) issues around privacy, safety and trustworthiness of health apps.

This chapter reports on the findings of the mHealth section of the 2017 annual technology survey conducted by the Royal Australian College of GPs in 2017 we helped to develop. Questions about GPs' current use of mHealth apps, barriers they perceive, and potential solutions were asked based on the findings of the previous study.

This chapter is published under the title "Current Knowledge and Adoption of Mobile Health Apps Among Australian General Practitioners: Survey Study" in the Journal of Medical Internet Research mHealth uHealth in Jun 2019. Work arising from this chapter has been presented at the GP18 conference, Gold coast, Australia.

5.1 Abstract

Background: Mobile health (mHealth) apps can be prescribed as an effective self-management tool for patients. However, it is challenging for doctors to navigate 350 000 mHealth apps to find the right ones to recommend. Although, medical professionals from many countries are using mHealth apps to varying degrees, current mHealth app use by Australian general practitioners (GPs) and the barriers and facilitators they encounter when integrating mHealth apps in their clinical practice have not been reported comprehensively.

Objectives: The objectives of this study were to (1) evaluate current knowledge and use of mHealth apps of GPs in Australia; (2) determine the barriers and facilitators to their use of mHealth apps in consultations; and (3) explore potential solutions to the barriers.

Methods: We helped the Royal Australian College of General Practitioners (RACGP) to expand the mHealth section of their annual technology survey for 2017 based on the findings of our semi-structured interviews with GPS to further explore barriers to using mHealth apps in clinical practice. The survey was distributed to the RACGP members nationwide between 26 October - 3 December 2017 using Qualtrics online survey tool.

Results: A total of 1014 RACGP members responded (response rate 4.6% [1014/21,884], completion rate 61.2% [621/1014]). The median years practiced was 20.7 years. Two thirds of the GPs used apps professionally in forms of medical calculators and point-of-care references. A little over half of the GPs recommended apps for patients daily (12.9%, n=80/621), weekly (25.6%, n=161/621), or monthly (13.4%, n=83/621). Mindfulness and mental health apps were recommended most often (32.5%, n=337/1036), followed by diet and nutrition (13.9%, n=144/1036), exercise and fitness (12.7%, n=132/1036), and women's health (10%, n=104/1036) related apps. Knowledge and usage of evidence-based apps from the Handbook of Non-Drug Interventions (HANDI) were low. The prevailing barriers to app prescription were lack of knowledge of effective apps (59.9%, n=372/621) and lack of trustworthy source to access them (15.5%, n=96/621). GPs expressed their need for a list of safe and effective apps from a trustworthy source like the RACGP to

overcome these barriers. They reported a preference for online video training material or webinar to learn more about mHealth apps.

Conclusion: Most GPs are using apps professionally but recommending apps to patients sparingly. The main barriers to app prescription were lack of knowledge of effective apps and lack of trustworthy source to access them. A curated compilation of effective mHealth apps or an App library specifically aimed at GPs and HCPs would help solve both barriers.

5.2 Introduction

Over the past decade, smartphones have become an inseparable part of modern living, and mHealth apps have started to establish their place in healthcare [1]. If proven to help achieve measurable clinical improvements in patients' conditions, mHealth apps can be officially prescribed or recommended by general practitioners (GPs) [2]. However, with 350 000 apps available in the medical, and health and fitness categories in the major app stores, it is challenging for GPs to find prescription quality mHealth apps from the app stores themselves to use in their clinical practice [3]. To overcome this issue, a number of initiatives like the NHS App library in the UK [4] and Health Navigator App library in New Zealand [5] have been set up to help doctors. In Australia, official effort to support app prescription does not exist yet, but there are small initiatives such as the Victorian Health Promotion Foundation Healthy living apps guide aimed at the general public [6], and the Handbook of Non-Drug Interventions (HANDI) project by the Royal Australian College of General Practitioners (RACGP) [7], which is a repository of evidence-based non-pharmaceutical interventions for general practitioners (GPs).

Health care professionals' use of mHealth apps and mobile technologies have been explored in several recent reports from the USA [8], UK [9], France [10] and Turkey [11]. At least half of the surveyed GPs, specialists, dieticians and pharmacists reported to recommend mHealth apps to patients, except for the French study of GPs, which reported half that rate. Barriers perceived by the HCPs regarding mHealth integration to their clinical practice include a variety of issues from infrastructure related problems such as Wi-Fi coverage and interoperability with the existing medical software, to more specific data security, content reliability, and a universal lack of awareness of the effective apps to use. These all echo the findings of an earlier systematic review by Gagnon et al [12], which summarized the barriers and facilitators to mHealth adoption by HCPs from around the globe.

Australian GPs' mHealth adoption has been explored only briefly as part of the annual technology survey by the RACGP since 2015. The purpose of this survey is to explore technological innovation and adoption in general practice including mobile technology [13]. Following our qualitative study with GPs on the barriers and facilitators of mHealth app use in general practice, we collaborated with the RACGP to expand the mHealth section for 2017 to better understand the specific barriers to health app use in the wider Australian context. Thus, our objectives for the current study were to: (1) explore knowledge and use of health apps of practicing GPs in Australia in more detail; (2) determine the barriers and facilitators to prescribing health apps in GP consultations in a wider cohort of GPs; and (3) explore potential solutions to some of the barriers.

5.3 Methods

We used the Checklist for Reporting Results of Internet E-Surveys (CHERRIES) as recommended by Journal of Medical Internet Research (JMIR) as a reporting guide for this study [14]. The data for this study collected as part of the 2017 RACGP Technology survey, which was conducted using an online survey tool (Qualtrics, Provo, Utah, USA) between 26 October - 3 December 2017 in Australia [15]. We used convenience sampling and the survey link was emailed to all RACGP members, which include GP trainees, fellows, and vocationally registered GPs, as well as practice managers and clinic owners. Only the GPs currently practicing in Australia were able to advance and answer all questions. For GP registrars and GPs who were not practicing currently or not practicing in Australia, the survey ended after the relevant questions. Ethics approval was obtained from the RACGP National Research and Evaluation Ethics Committee (NREEC).

The previous year's survey contained six questions regarding GPs' use of mobile devices and mHealth apps out of 46 questions [13]. Based on the findings of our semi-structured interview study with 20 GPs that explored the barriers and facilitators to using mHealth apps in practice, we collaborated with the RACGP to expand the mHealth section questions for the 2017 survey making them more specific and informative. The questions were pilot-tested with the co-authors and academic GP colleagues and refined iteratively. This paper reports the analysis of 16 questions pertaining to demographic information, mobile device and health apps usage out of the total 50 questions (Table 6).

Data were extracted from Qualtrics and descriptive statistics were conducted using Microsoft Excel (2016). Answers to the open-ended questions were coded according to their common themes (OB), checked by a second author (EB) and then summarised. Participation in the survey was voluntary and participants who completed the survey were invited to enter a draw to win one of two $50 gift cards.

Table 6. Survey questions analysed as part of this study

		Survey questions analysed
Screening and demographics questions	1.	I am... (a GP, a GP registrar, Other)
	2.	What is your role in the practice?
	3.	Where did you complete your training? (Australia, Overseas)
	4.	Do you currently practice in Australia? (Yes/No)
	5.	For how many years have you worked as a GP? (1-5 years, 5-10 years, 10-20 years, 20-30 years, more than 30 years)
	6.	Please enter the postcode of your current practice location in which you spend the most time
	7.	What is your age group? (Less than 35 years, 35-44 years, 45-54 years, 55-64 years, over 65 years)
mHealth section	8.	Do you use mobile devices in your day-to-day practice for patient related-work? (Yes/No)
	9.	I don't use mobile devices for patient-related work because... (choose all that apply) - I am not confident in how to safely use mobile technology in my day-to-day practice - I don't see how mobile technology can benefit my day-to-day practice - My practice does not allow me to use my own mobile devices - Other (please comment)
	10.	Which health apps do you use for yourself?
	11.	How often do you recommend the use of health apps to patients? (Daily, Weekly, Monthly, Rarely, Never)
	12.	Please share with us which health apps you have recommended:
	13.	Do you ever prescribe any of the following health apps to your patients (choose all that apply): (Quit Now: My QuitBuddy, Quit for you – quit for two, Sleepio, CBT-i Coach, SHUT-I, Ankle, I don't prescribe the apps above)
	14.	Please rate the following barriers for health app integration into your daily clinical practice (where 1 is the most important barrier and 7 is the least important): - lack of knowledge of effective apps - lack of a trustworthy source to access effective apps - lack of patient digital literacy - lack of access to mobile devices - lack of patient interest - lack of practice incentives - lack of understanding about benefits - others (please specify)
	15.	What would help you to recommend health apps to patients more often?
	16.	How would you like to receive training on the use of effective health apps, including on app evaluation? (e.g., webinars, animations, podcasts)

5.4 Results

Of the 39 380 people on the RACGP mailing list who were emailed the survey link, 21 884 were currently practicing GPs and 1,014 of them responded to the survey (4.6%). The survey completion rate was 61.2%. The median age was 51.4 years and the median years practiced was 20.7 years. Age and geographical distribution by state were representative of Australian GP workforce statistics [16]. About a quarter of the survey responders were trained overseas, which was half the rate of the national statistics (Table 7).

Table 7. Survey participants' demographics

Groups		This study Total (n=621) n (%)	National data (n=25 825)
Age (years)			
	< 35	46 (7.4%)	9%
	35-44	126 (20%)	25%
	45-54	196 (32%)	28%
	55-64	174 (28%)	26%
	65+	79 (13%)	12%
Years in practice			
	<5	82 (13%)	NA
	5-10	81 (13%)	NA
	10-20	136 (22%)	NA
	20-30	166 (27%)	NA
	>30	156 (25%)	NA
GP Training			
	Overseas	144 (23%)	51%
	Australia	477 (77%)	49%
Geographic distribution (n=844)			
	NSW	235 (28%)	33%
	VIC	215 (25%)	25%
	QLD	174 (21%)	21%
	WA	78 (9%)	9%
	SA	70 (8%)	7%
	TAS	37 (4%)	2%
	NT	21 (2%)	1%
	ACT	14 (2%)	1%

A half of the GPs reported not using mobile devices for patient related work (n=312; 50%). The main reasons for this included: GPs not seeing how mobile technology could benefit their day-to-day practice (n=136; 39%), not being confident on how to use mobile technology safely in daily practice (n=68; 20%), and the practice they work for did not allow the use of personal mobile devices in practice (n=51; 15%). Other reasons (n=91; 26%) included not wanting to use personal mobile devices in consultations, their desktop computer being sufficient and more convenient, and not needing to use mobile devices altogether. About two thirds of the GPs used health apps themselves (n=440; 64%) mostly in the form of point-of-care references like UpToDate, eTG, Medscape (n=298; 25%), and medical calculators (n=137; 11%).

A little over half of the GPs recommended apps for patients daily (n=80; 13%), weekly (n=161; 26%), or monthly (n=83; 13%). The other half rarely (n=210; 34%) or never (n=87; 14%) recommended apps. Figure 10 shows the app recommendation frequency appears to decrease with the number of years practiced as a GP. GPs most commonly recommended mindfulness and mental health (n=337; 33%), diet and nutrition (n=144; 14%), exercise and fitness (n=132; 13%), and women's health (n=104; 10%) related apps to patients. Examples of the specific apps they use included Smiling Mind, Headspace, MyFitnessPal, and Easy Diet Diary.

The question about evidence-based apps from the HANDI project revealed that smoking cessation apps were reported as prescribed 119 times, insomnia apps 39 times, and the ankle exercise app 7 times. However, the majority of the GPs did not recommend any of the six apps that are currently offered in HANDI (n=417; 72%).

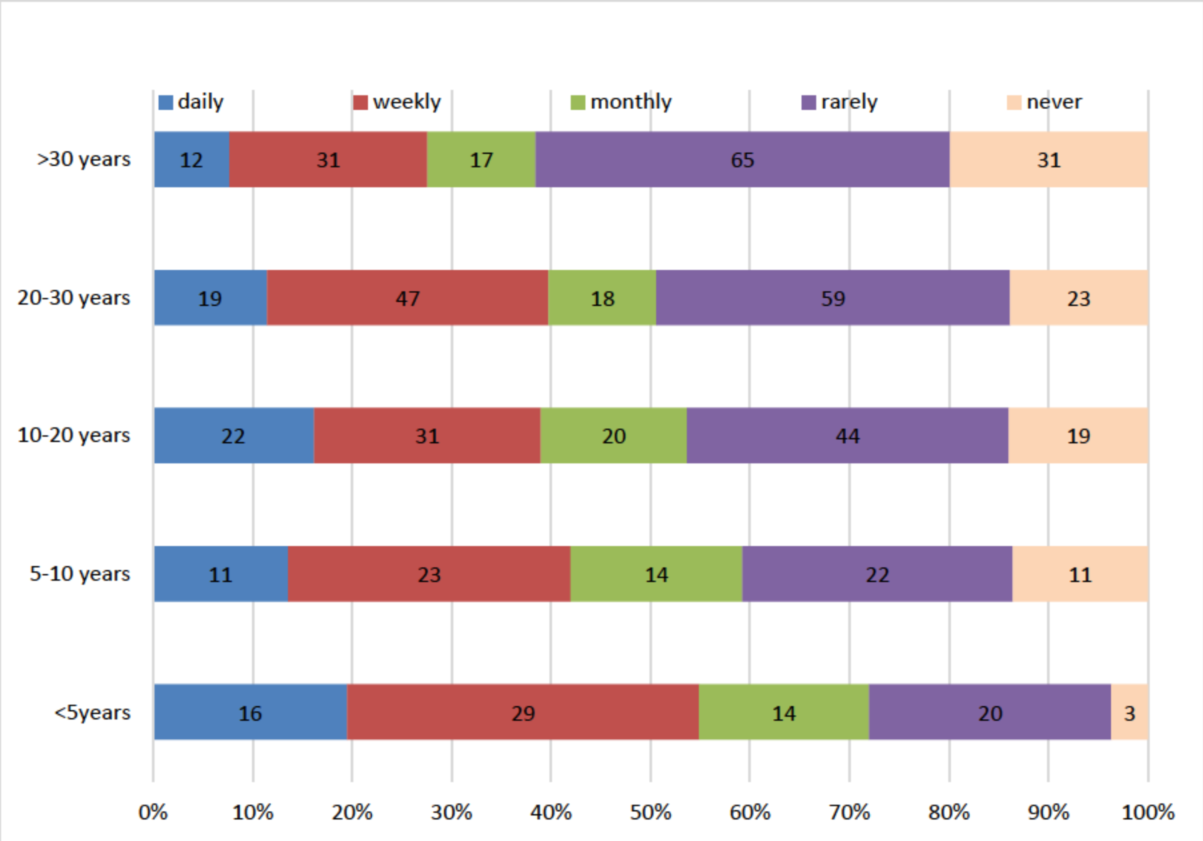

Figure 10. Frequency of health app recommendations stratified by years practiced

GPs also rated the barriers to integrating health apps into their daily practice. The prevailing barriers were lack of knowledge of effective apps (n=372; 60%) and lack of trustworthy source to access them (n=96; 15%). Figure 11 shows the ranking of barriers rated by the combination of the first and second most important barriers. Most of the responders (n=555; 89%) also added their own barriers as other option. Among the additional barriers, consultation time constraint (n=24; 28%) and uncertain benefits of and interests in health apps (n=19; 21%) were the leading reasons as to why use of apps in daily clinical practice would be a challenge, whereas cost (n=3; 3%) was not rated as a major barrier.

When asked what would help them to recommend health apps to patients more often, the top answers were more knowledge, awareness, and training on health apps (n=243; 30%), a list of safe and effective apps provided or endorsed by reliable authority such as the RACGP (n=224; 28%), and quality, benefits and evidence of apps (n=92; 12%). Time, integration into electronic medical software, access to better internet and mobile services, patients' motivation, handouts, and practice incentives were all rated as of the least importance (1-5%) (Table 8).

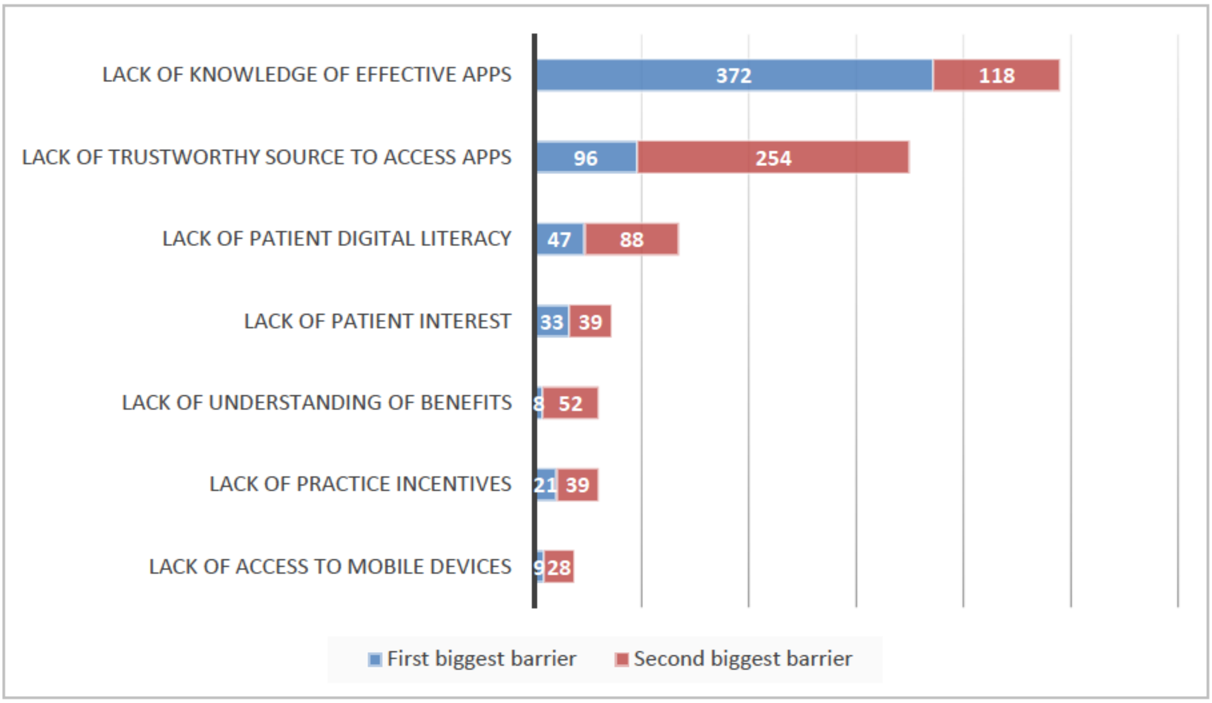

Figure 11. Barriers to app prescription

The preferred ways to receive training on effective apps and app evaluation were permanent online video training material or webinars doctors can watch on their own time and pace (n=303; 33%). Other choices include podcasts (n=137; 15%), animation (n=101; 11%), face-to-face training (n=114; 12%), and other reading materials such as newsletters and articles (n=90; 10%).

Table 8. Facilitators of app prescription as responses to question: "What would help you to recommend health apps to patients more often?"

Theme	**n**	**Example comments**
More awareness/ knowledge/ training	243	*Educate us before we recommend to patients.* *Myself getting more familiar about it & for me to learn what it is all about.*
List of approved/vetted apps	224	*A clear directive, guideline about which are validated safe and useful,* *"recommendation from respected advisors e.g. RACGP, NPS"*
Evidence/benefits/ quality	92	*evidence for its use - case in the field*
Nothing	44	*Nothing. I recommend to my patients that they get away from screens and go and do some exercise, appreciate nature and breathe some fresh air and RACGP should do the same instead of apparently trying to encourage everyone, doctors and patients to increase their screen time.*
More time	39	*More time during a consult to discuss benefits...however it starts to make us a 'Telstra* shop' and not a GP practice.*
Practice incentive	29	*Incentives - costs involved in recommending the apps - the ones I do recommend I research myself and spent time and money to do so.*

Integration with practice software	26	*If the health information software used could pick up on coded diagnoses in patient's clinical information system and recommend a trustworthy app for the relevant medical conditions, it would be most beneficial.*

Note: n=683 replies were coded into n=800 answers. All other themes (n=9) had less than 25 answers each to support them. *Telstra is an Australian telecommunications company.

5.5 Discussion

This study provides insights into the current adoption of smartphone health apps by Australian GPs. We found that two thirds of the GPs use apps professionally, and at least half are recommending apps to patients. Mindfulness and mental health apps were most commonly suggested. The majority of the GPs were not aware of, and thus not using, evidence-based health apps that are included in the free RACGP resource HANDI. The biggest barriers to app prescription were lack of knowledge of effective apps and lack of trustworthy source to access them. To overcome these barriers, GPs expressed their need for a list of safe and effective apps from a trustworthy source and more training on health apps in the form of permanent online video training material or webinar that they can watch in their own time and pace.

The 2017 RACGP Technology survey results were similar to the preceding year's in terms of smartphone health app usage, most commonly used and recommended apps, and barriers to technology adoption in practice in general, thus validating the trends [13]. Studies from several other countries report that anywhere between 20-75% of HCPs use mHealth apps for their patients [8-11], which is comparable with the 50% use by Australian GPs. The main barriers we identified were also reflective of the barriers HCPs face around the world. The surveys indicate that HCPs recognize the potential benefit of smartphone health apps for self-management of health conditions and would like to use them in their work. However, they lack the knowledge, time, and skills to evaluate, find and recommend evidence-based apps, and therefore, they need help and guidance from the professional organizations and policy makers to overcome these barriers.

It is important that solutions to the barriers are unique to each country's healthcare structures and HCPs' demands. For example, New Zealand's Health Navigator website hosts a health app library set up by a GP organization and healthcare providers who use the apps can curate and provide feedback [5]. UK's NHS not only provides web-based Apps library for doctors, but also introduced an app prescription platform for the GPs [17]. Similarly, for Australia, there is an opportunity for a professional organization such as the RACGP to lead the way to address the major barriers identified in this study. Although the inclusion of mHealth apps in the HANDI project is a starting place, more work needs to be done to raise awareness and profile of this initiative. Furthermore, integration of approved apps into the electronic medical systems to streamline the usability as well as providing continuing professional development trainings for up-to-date information on mHealth apps would enhance the use of evidence-based apps in clinical practice.

The strengths of this study include expanding on and improving previous year's mHealth questions with more specific questions regarding evidence-based app adoption and barriers in general practice based on our qualitative research on GPs to get obtain more comprehensive data on a nationally representative sample. Our response rate of 4.6% was similar to that of other mHealth app surveys undertaken on HCPs [9, 10]. The completion rate of the mHealth section was uniformly high although skipping questions was allowed.

The limitations of our survey study are the selection bias inherent in survey studies, and the low response rate. However, the median age, median years practiced, and geographical distribution data of the GPs in our study were comparable to those of the national GP workforce data [16], thus supporting the demographic representativeness of our study population. A reason for the low response rate could be survey fatigue due to the fact that the mHealth questions analysed here were a part of a larger survey on technological innovation in general practice [18]. The challenge for conducting survey studies on medical professionals is a balancing act between conducting a dedicated survey only focusing on single topics and the burdening of GPs with yet another survey. To increase the response rate of surveys that involve medical professionals, certain strategies could be undertaken such as offering more attractive incentives to participate and randomly sampling the cohort to send surveys and other study offers sparingly.

mHealth apps have a unique niche in the future of healthcare. However, the evidence of their effectiveness, safety and usability issues are challenged by both the fast-evolving nature of the software and commercial aspects of the technology that can be easily exploited. HCPs need guidance on the quality of mHealth apps to assist in their adoption into clinical practice. In the absence of notable initiatives from government or private sectors to regulate app quality and safety, professional organizations must take the lead to address this challenge.

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Conflict of interest: Authors declare no relevant conflict of interests.

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Chapter 6. mHealth app prescription in general practice

mHealth app prescription in Australian general practice: a pre-post study

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PREAMBLE

The previous chapters identified the most important barriers facing GPs in using mHealth apps in their practice. The one barrier we were able to address was the lack of knowledge of prescribable apps and lack of trustworthy source to access them.

This chapter reports on the details of our feasibility study to increase the uptake of mHealth app prescription by Australian GPs. The timeline of the study is shown in Figure 12.

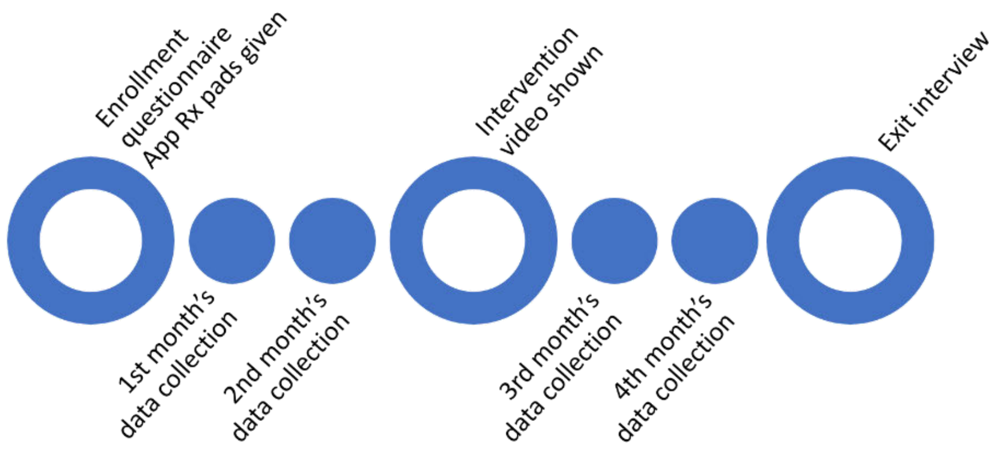

Figure 12. Timeline of App prescription study: four data collection points interjected halfway by app video introduction, bookended by enrolment survey and exit interview.

The manuscript of this study is published in the Journal of Medical Internet Research mHealth uHealth. Work arising from this study has been presented by invitation at the Northern Territory Primary Health Network's learning and teaching conference COMPASS in Aug 2019 and at the National Health and Medical Research Council's annual symposium in 2019.

6.1 ABSTRACT

Background: The evidence of effectiveness of mobile health (mHealth) apps and their usability as non-drug intervention in primary care are emerging around the globe.

Aim: This study aimed to explore the feasibility of mHealth app prescription by general practitioners (GPs) and to evaluate the effectiveness of an implementation intervention to increase app prescription.

Methods: A single-group, before-and-after study was conducted in Australian general practice. GPs were given prescription pads for 6 mHealth apps and reported the number of prescriptions dispensed for 4 months. After the reporting of month 2, a 2-minute video of one of the apps was randomly selected and sent to each GP. Data were collected through a prestudy questionnaire, monthly electronic reporting, and end-of-study interviews. The primary outcome was the number of app prescriptions (total, monthly, per GP, and per GP per fortnight). Secondary outcomes included confidence in prescribing apps (0-5 scale), the impact of the intervention video on subsequent prescription numbers, and acceptability of the interventions.

Results: Of 40 GPs recruited, 39 commenced, and 36 completed the study. In total, 1324 app prescriptions were dispensed over 4 months. The median number of apps prescribed per GP was 30 (range 6-111 apps). The median number of apps prescribed per GP per fortnight increased from the pre-study level of 1.7 to 4.1. Confidence about prescribing apps doubled from a mean of 2 (not so confident) to 4 (very confident). App videos did not affect subsequent prescription rates substantially. Post-study interviews revealed that the intervention was highly acceptable.

Conclusion: mHealth app prescription in general practice is feasible, and our implementation intervention was effective in increasing app prescription. GPs need more tailored education and training on the value of mHealth apps and knowledge of prescribable apps to be able to successfully change their prescribing habits to include apps. The future of sustainable and scalable app prescription requires a trustworthy electronic app repository of prescribable mHealth apps for GPs.

6.2 INTRODUCTION

More than 350,000 apps exist in the Medical and Health and Fitness categories in major app stores [1], with downloads and revenues in the billions [2]. Their popularity and potential to influence health-related behaviors make their integration to medical practice imminent [3]. Pragmatic studies of app prescription in primary care have been emerging around the world with varied interventions and results [4-6]. To assist the integration of apps into clinical practice, mobile health (mHealth) app repositories have been created, including the National Health Service App library in the United Kingdom [7], Health Navigator in New Zealand [8], and other private entities such as AppScript [9] and the Organization for the Review of Care and Health Applications [10].

Given the potential of mHealth apps to help improve the self-management of chronic conditions, we explored their value in general practice. Previously, in an overview of systematic reviews, we explored the possibility of simple integration of mHealth apps into the general practice setting and proposed a concept of "prescribable" mHealth apps. These were defined as proven effective (that is, shown to help achieve measurable clinical improvements in patients' conditions), in addition to being standalone and currently available in the app stores [11].

We also explored the potential barriers to app integration in Australian general practice [12]. Patients expressed their preference for doctor-recommended apps; however, doctors were overwhelmed by the sheer number of available apps and faced 2 major barriers: not knowing of many prescribable apps and the lack of trustworthy source to access such apps. To address these barriers, we developed a brief implementation intervention. Objectives of this study were to explore the feasibility of app prescription by general practitioners (GPs) and to evaluate the effectiveness of an implementation intervention to increase uptake of app prescription.

6.3 METHODS

STUDY DESIGN AND SETTING

We employed a single group, before-and-after design. Our study was conducted in Australian general practice setting. Ethics approval was obtained from the Bond University Human Research Ethics Committee (#OB00017).

PARTICIPANTS AND RECRUITMENT

GPs currently working in Australia at least two days a week were eligible to participate in our study. Information about the study was distributed at GPDU2018 and GP18 conferences and posted to a closed Facebook group called GPs DownUnder (GPDU). Recruitment occurred from June through to November 2018 and data collection from September 2018 until May 2019. Upon the completion of the study, GPs were thanked with AUD$ 50 gift cards.

INTERVENTION

There were two parts to the intervention. Firstly, prescription pads for 6 apps were developed (Figure 13). These apps were chosen because they address conditions relevant in general practice, have either direct trial evidence (This Way Up: Managing Depression (St. Vincent's Hospital Sydney Ltd) [13], Tät – Pelvic floor exercises (Umeå University, Sweden) [14], Lose-It! (FitNow Inc.) [15, 16], CBT-i Coach (US Department of Veteran's affairs) [17]) or indirect evidence from trials of similar apps (Smiling Mind (Smiling Mind Pty Ltd) [18-20], and Quit Now: My QuitBuddy (Australian National Preventative Health Agency) [21]). The apps also had to have stable content, created or backed by trustworthy not-for-profit organizations, and are available for both Apple and Android phones. Five of the apps were freely available and one (This Way Up: Managing Depression) had a one-time purchase price of AUD $59.99. The cost of apps was not an exclusion criterion as it will help assess if the cost is a barrier to app prescription.

The app prescription pads had individually numbered pages with tear-off design. Each app prescription page included the app's full name and logo, download instruction, space for the patient's name, the reason for prescription, and a disclaimer. Prescription pads were assembled onto an A4 display stand and mailed to participating GPs. A letter outlining the study timelines and procedures along with a short introduction to each app was included in the shipment.

Figure 13. The six app prescription pads. (A) the front of the prescriptions. Note script number in the bottom right corner. (B) the back of the prescriptions with download instructions and costs.

The second part of the intervention was aimed at enhancing uptake. Short videos (2 min) demonstrating the content, functions, and features of the apps in detail were created for each app. A YouTube link to the video randomly selected for each participant was emailed following their second month's reporting.

Our study aimed to change the prescribing behavior of GPs. Evidence suggests that behavioral interventions are more effective and sustainable when guided by behavior change techniques. Our prior research helped to identify the target behaviors [12]. We based our intervention on the Capability, Opportunity, Motivation and Behavior model [22]. Capability to prescribe apps was addressed through the list of evidence-based apps and the introductory videos demonstrating the content, features, and function of the apps; opportunity was enabled through the purposefully designed stand with the prescription pads; and motivation was harnessed through the GPs' expressed interest in the study that demonstrates their belief that app prescription would be a good thing to do [23].

PROCEDURES

At the beginning of the study, participants signed consent forms and answered the prestudy questionnaire via the web-based SurveyMonkey (SurveyMonkey Inc, San Mateo, CA) tool. The survey collected demographic data, contact details, current app prescription rate in the preceding 2 weeks (self-reported in ranges: 0, 1-5, 6-10, >10 times), and level of confidence around app prescription.

The official commencement dates for the study were recorded as the date that each participant reported they started using the pads. Every 4 weeks following commencement, participants were asked to send a photo of the prescription pads electronically to the research team to provide details of the number of prescriptions for each app within that month. If participants took leave from work, the reporting dates were adjusted to allow for a full 4-week reporting period.

Qualitative semistructured interviews (10-15 minutes) were conducted and audio recorded at the end of the study, either face-to-face or by telephone, to gather feedback on the intervention. GPs were asked about their knowledge of other apps and relevant resources outside the study, including the Handbook of Non-Drug Interventions (HANDI) project by the Royal Australian College of General Practitioners, which includes a number of mHealth apps. Interviews were transcribed verbatim, coded by the lead researcher (OB), and thematically analyzed to determine the feasibility of the interventions, barriers, and solutions to the scalability of the intervention to Australian GPs. The thematic analysis was done in consultation with a second author (TH).

SAMPLE SIZE

Prior data [12] indicated that the difference in the response before and after is normally distributed with a standard deviation of 10, and a baseline mean of 2 apps prescribed per month per GP. We calculated that we needed 24 participants to have 80% power (with alpha=0.05) to detect an increase of app prescription by at least 6 per month. Taking attrition into account, we planned to recruit 30 GPs for the study.

OUTCOMES

Data on app usage were collected for the 2-week period prior to study commencement and then every month for 4 months. The primary outcome of the study was the number of app prescriptions dispensed in total, as an average per month, per GP, and per GP per fortnight. We calculated the median number of apps recommended by a GP per fortnight using the following formula:

$$m=l + (w(n/2-c))/f$$

where l is the lower limit of the bin (range) containing the median, w is the width of the bin, n is the total population, c is the cumulative count (frequency) up to l, and f is the count in the median bin.

Prestudy raw numbers are provided in Table 1 (m=1.7 [1 + (5(39/2-17))/19]). Poststudy numbers are given in the Results section (m=4.1 [1 + (5(39/2-0))/31]).

Secondary outcomes were confidence around prescribing apps (measured on a 5-point Likert scale; pre-study and poststudy); the number of intervention video views and their impact on the subsequent prescription numbers; and attrition rate. In addition, the acceptability of the interventions to GPs and their feedback on the interventions were explored in semi-structured interviews. Descriptive statistics were used to report the frequency of app use at each time point and confidence in app prescription. Qualitative data were analyzed thematically.

To conduct an overall analysis of the effect of video exposure on prescription rates the 6 separate outcomes (1 for each app) were considered as one overall global outcome (individual monthly counts were not aggregated). Initially, a Poisson model was fitted with the (categorical) explanatory variables specified being a month (1 to 4), exposure to the video (yes/no), video (1 to 6) as well as the interaction between exposure and video. To account for the 24 repeated measures collected on each GP (4 time points by 6 apps) a random intercept was fitted. Over-dispersion was assessed using the generalized Chi-square divided by degrees of freedom. Due to evidence of over-dispersion for the Poisson model (Gener. Chi-Square / DF = 2.13), a negative binomial model was fitted and showed no evidence of over-dispersion (Gener. Chi-Square / DF = 0.98).

6.4 Results

A total of 40 currently practising Australian GPs were recruited for this study. One GP dropped out before the beginning of the study due to personal health issues, 3 GPs dropped out after the second and third data collection due to relocation and change of jobs. Thirty-six GPs completed the full 4 months of the study and we analysed the data as intention-to-treat (ITT). The median age of participants was 40, median years in practice was 8.5 years, and participants worked a median of 4 days a week (Table 9).

Table 9. App prescription study participants' demographics and pre-study characteristics

Groups		Total (n=39) n (%)
Age (years)		
	< 35	11 (28%)
	36-45	20 (51%)
	46-55	5 (13%)
	56+	3 (8%)
Years in practice		
	<10	23 (59%)
	11-20	12 (31%)
	21<	4 (10%)
Gender		
	Female	28 (72%)
Geographical distribution		
	Queensland	21 (54%)
	New South Wales	9 (23%)
	Victoria	4 (10%)
	South Australia	2 (5%)
	Western Australia	2 (5%)
	Tasmania	1 (3%)

Days worked in a week		
	Two	8 (21%)
	Three	9 (23%)
	Four	13 (33%)
	Five or more	9 (23%)
Number of apps prescribed in the two weeks prior to study		
	None	17 (44%)
	1-5	19 (49%)
	5-10	3 (8%)
Confidence level with app prescribing		
	Not at all (1)	7 (18%)
	Not so (2)	12 (31%)
	Somewhat (3)	19 (49%)
	Very (4)	1 (3%)
	Extremely (5)	0

In total 1,324 app prescriptions were dispensed over 4 months, with a mean of 331 a month. Figure 14 illustrates the number of individual app prescriptions within the monthly totals. The number of apps prescribed per GP per fortnight increased from an imputed pre-study median of 1.7 to 4.1. Overall, the Smiling mind app was the most frequently prescribed (533; 40%), followed by CBT-i Coach (242; 18%), Managing Depression (167; 13%), Lose-It! (155; 12%), Quit Now: My QuitBuddy (134; 10%) and Tät Pelvic floor exercises (93; 7%).

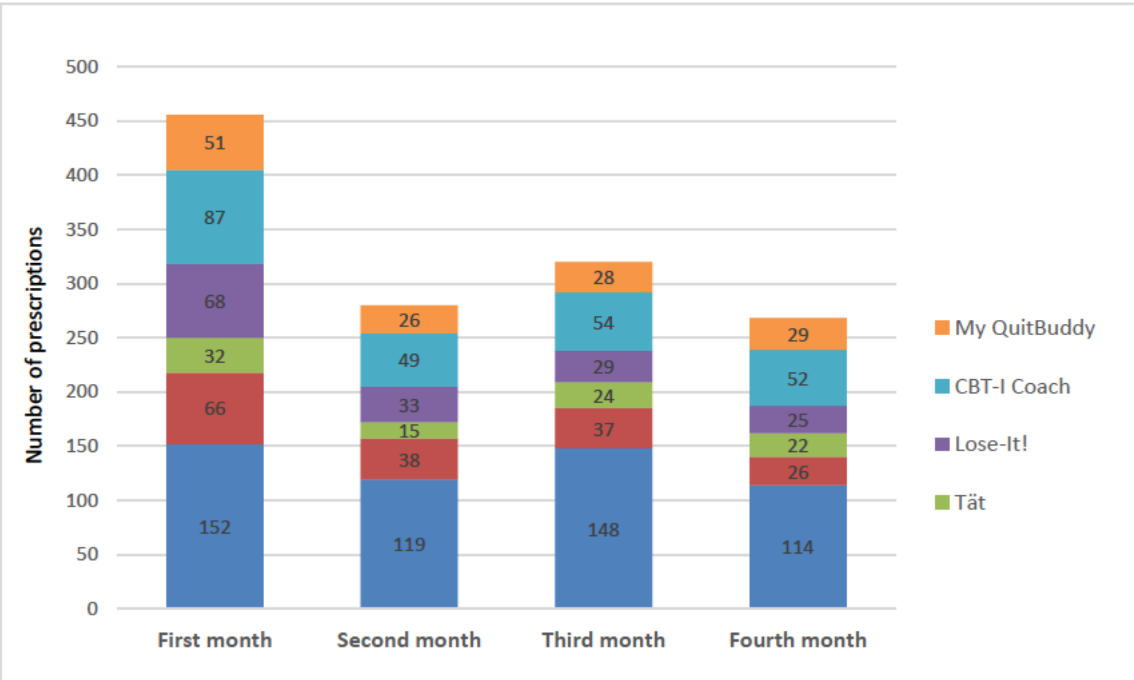

Figure 14. Number of individual app prescriptions are shown in the monthly total

Figure 15 illustrates the distribution of the total app prescription per GP. According to the ITT analysis, a median of 30 apps (range 6-111 apps) was prescribed per GP over the 4 months. Every GP prescribed at least one app per fortnight, 31 (31/39, 80%) GPs prescribed 1-5 apps, 7 (7/39, 18%) prescribed 6-10 apps, and 1 GP prescribed more than 11 apps. The GPs' confidence around prescribing apps doubled from a mean of 2 (not so confident) before the study to 4 (very confident) at the end of the study: 0/39, not confident at all; 1/39 (3%) not so confident; 12/39 (31%) somewhat confident; 25/39 (64%) very confident; 1/39 (3%) extremely confident.

At the end of the study, the My QuitBuddy app video was viewed 8 times; the Smiling mind, Managing Depression, and Lose-It! app introduction videos were viewed 9 times each; the Tat-Pelvic floor exercise video was viewed 19 times; and the CBT-i Coach video was viewed 21 times. We were not able to track whether every GP watched the video sent to them. The effects of exposure to app videos are shown in Figure 16. Only two of the app videos had a significant effect on the subsequent app prescription numbers following the exposure to the video: Smiling Mind app prescription increased from 3-4 times per month to 6 times per month, and Lose-it app prescription increased by one time. The full analysis is provided in Multimedia Appendix 1. A global test for the interaction between exposure and video showed strong evidence of heterogeneity (P<.001) indicating the treatment effects were different across the 6 apps. Therefore, we did not report an overall effect of the video.

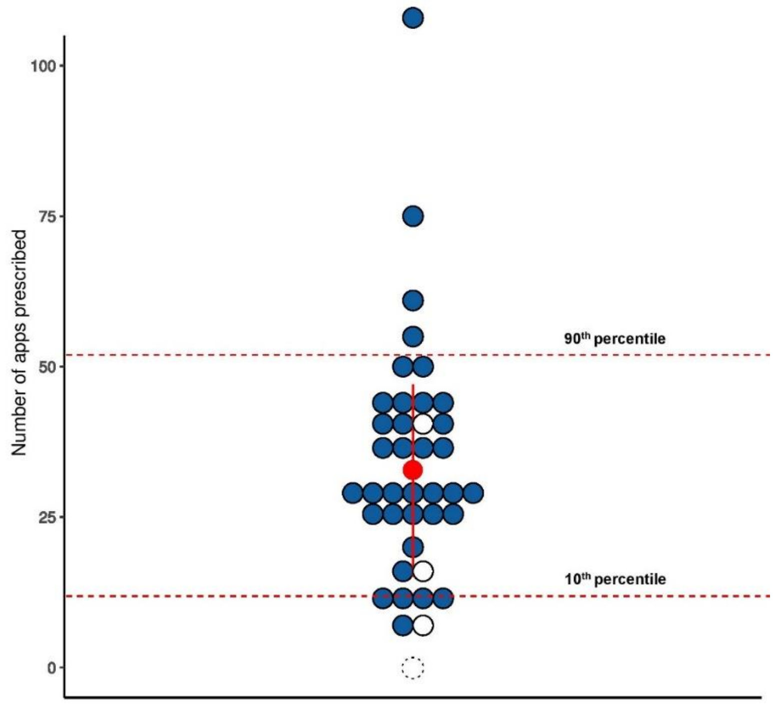

Figure 15. Distribution of total app prescription per GP. The red dot indicates the median (30). White dots are the participants who dropped out. The dashed circle is the participant who never commenced.

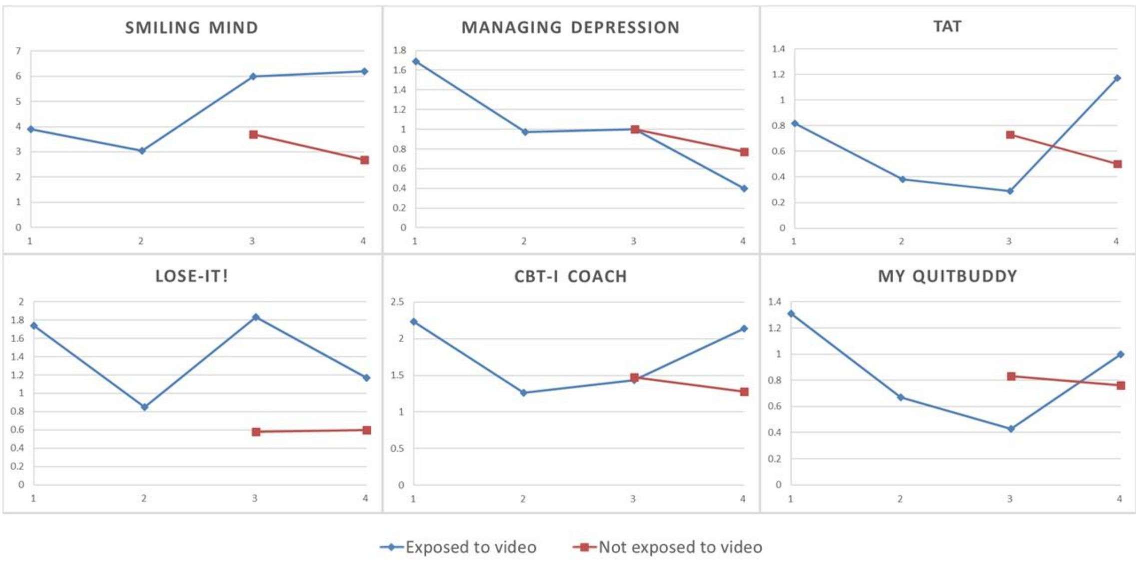

Figure 16. Mean number of app prescription per GP before and after the intervention video exposure at each month. Only Smiling Mind and Lose-It! videos show a significant effect of the subsequent prescription numbers.

QUALITATIVE INTERVIEWS

Thirty-nine GPs were interviewed at the conclusion of their participation in the study as per ITT analysis. Participants expressed their overall experience of prescribing apps as overwhelmingly positive. They liked the size of the prescription pad, the information included on it, ease of use and integration into the workflow, with the most useful feature identified as the visual cue aspect of the stand. They also liked the short length of the videos, yet that they contained sufficient details about the apps. Most GPs reported not downloading and interacting with the apps themselves. Although most reported having watched the allocated video, many did not recall the contents during the post-study interviews.

Two of the 6 study apps were well known to the GPs: 28/39 GPs were already familiar with Smiling Mind, and 12/39 GPs with Managing Depression. They had been recommending these apps to their patients even before the study and appreciated having a formal prescription to give out during the study. Among the other apps that GPs recommended, mindfulness and meditation apps (Calm, Headspace) were common. Mental health–related apps were the most frequently prescribed, and all GPs reported that the overall number of apps they prescribed is a reflection of the demographics of their patients and the prevalence of conditions encountered.

GPs reported that they might have prescribed the weight loss and pelvic floor exercise apps more frequently. Instead, they habitually referred patients to dieticians and physiotherapists or to programs and tools already compiled as the first line of intervention. None of the GPs except for one had watched, read, or received any other app-related content apart from the study intervention. Knowledge of HANDI was low, especially that apps were included in some HANDI entries. However, upon learning this, they all agreed that HANDI would be a reliable evidence-based app repository for GPs in Australia. The main barriers and facilitators to app prescription in general practice are shown in Table 10 along with the illustrative quotes.

Table 10. Key themes and illustrative quotes around barriers and facilitators of mHealth app prescription in general practice

Theme	Illustrative quotes
Barriers	
Poor knowledge and familiarity of prescribable apps	*"I think from a doctor, it's purely just knowledge of health apps."*
	"From the GP point of view, thinking about it, knowing which ones are good and which ones aren't."
	"challenging because I wasn't necessarily familiar myself with the details of the app in terms of using them myself or actually being able to really coach patients with using them. I guess that takes time to sit down and actually go through the apps."
Prescribing habit	*"Getting into the habit of having those things available was part of the process, trying to trigger the idea that I can do this was part of it."*
	"I think trying to, in a busy consultation, trying to remember that as an option that we could recommend to people, because often you're so busy going, here, have this, do this, have this medication and then you often - adding some sort of self-help app into this is just part of getting more used to thinking about it as being an option."
Cost of apps	*"The depression one was quite an expensive app, that was quite prohibitive to a lot of people."* *"I guess I think cost definitely is a barrier for some patients, especially those that are in financial difficulty because they even ask for a referral to a bulk-billing psychologist."*
Patients' capability and attitude towards mHealth apps	*"I think they're probably for me the two big factors, is (one, the doctor's knowledge of them and) two, the patient perception of how important it is or the value of these health apps in terms of part of their management plan."*
	"A lot of my main issue was the demographic of my patients. I didn't realize how much I would struggle to incorporate it because I actually have a huge percentage of elderly patients who don't even have smartphones and some of them that do, don't know how to use the apps properly."
Consultation time	*"time constraints, a lot of the time we're running behind and the app prescription is a slightly luxury, but when we have time and we're able to be thorough, of course, we can do it, but we don't always have that luxury of time"*
	"Time is just such a big issue because we're so time-pressured."
Facilitators	

Tailored education, face-to-face training, and information dissemination to increase knowledge of prescribable apps	*"it's one message consistent and persistent. So if you've got a list that you're confident in, then why are you confident in it, what's the message behind and then you get it out as many ways as you can because none of us is looking at everything all the time. So if there's some way to get it out to the colleges, is there some way to get it out of the journals, is there somewhere to put it online somewhere that's an authoritative source, is there some way to get it out through the universities? Word of mouth is always good, influencers, social media…*
	"Coming and meeting us and going through face to face, maybe demonstrating some, a bit like the drug reps do"
	"I mean getting doctors early, so getting them through their training programs, getting them as GP registrars and making it part of there, I think that's where you're going to really get significant change."
Meaningful familiarity with apps	*"GP's own familiarity with the app, that if you're familiar with it, it's going to be much easier to prescribe than something that you have just head about or read about. "*
	"I think certainly the more hands-on you can get, I've done a couple or participated in a couple of webinars from the e-mental health stuff probably a year or two ago and that helped with my awareness of things, but my confidence I don't think improved too much. I think you've got to do them. You've either got to… Use it yourself or see it being used or at least be familiar with what it looks like."
Trustworthy source of vetted prescribable apps	*"I think having somebody external to narrow down the pool of apps and say this is a decent product, then you don't mind recommending them in that way."*
	"if it's coming from a reliable source like the university and say these are the apps we think are good quality apps to recommend, then I feel comfortable because there is so much information on the internet and app world, we don't know which is good quality and which is fake."
Integration with existing software and workflow	*"I think it would be brilliant to have an app that I could use for chronic disease management that actually was integrated, that the patients could potentially put data into that will then be integrated with my software, that would be fantastic."*
	"Certainly, would help to have them integrated into our - the fact that we've prescribed them, into our software, medical software, so that we can just click a button to say recommended whichever app."
Visual reminder or cue for prescribable apps	*"having those pads in front of me made me think about it, the reminders and having a resource to go to."*

	"I think having something like you did that makes it easy to give them out, that makes it easier and not having too many, just having a few that is quite good."
Patients' capability and attitude towards mHealth apps	*"most of the current population, the phone is the one thing that they carry around that they have with them all the time. Instead of - especially them being able to use it as an extra tool, they're useful in the way of treating patients."*
Proof of benefits of apps as an alternative and or adjunct treatment	*"sometimes the apps were very useful for patients who I was aware weren't able to afford other options. So for example, the pelvic floor exercises app would sometimes occur to me when I was talking to patients about the difficulties of accessing physiotherapy due to the cost and it would then prompt me to think, oh yes, actually I have an app that you could try at home without cost."*
	"maybe some data showing that they are received well by patients, I guess. apps showing patient receptiveness and patient engagement"

6.5 Discussion

This study demonstrated that it may be possible to increase the uptake of mHealth app prescription by providing an implementation intervention in the Australian general practice setting. The results demonstrated a total of 1324 app prescriptions by 39 GPs over 4 months and positive feedback from GPs about the intervention. The fortnightly number of apps prescribed per GP more than doubled compared to the prestudy level. However, identified barriers to app prescription uptake were poor knowledge of prescribable apps and insufficient familiarity with the apps to foster confident prescribing habits. Participants identified a need for a reliable prescribable app repository, preferably integrated with their electronic medical systems, and consistent and persistent messaging to increase the knowledge and familiarity of such apps.

The variation in the total individual tally of apps prescribed by participants may reflect differences in their personal digital propensity and flexibility in altering prescribing behavior. The reduction in the monthly app prescriptions after the first month could be related to the timing of the second and third reporting for about half of the participants. These occurred during the Christmas, New Year, and summer holidays in Australia, during which acute conditions dominate GP visits more than chronic conditions, which were the focus of the apps in the intervention.

The app explanation videos had varying effects on app prescription numbers. The results from the qualitative interviews showed that app prescription numbers are primarily dependent on the patient cohort and the prevalence of the conditions for which the intervention apps were intended. Thus, the short explanatory videos were informative but unlikely to be sufficient to influence complex behaviors such as prescribing. Perhaps, it would be more beneficial if video introduction and instructions for mHealth apps were developed for patients and given as part of the app prescription.

This is the first study to test the feasibility of an intervention to increase app prescription in Australian general practice. The overall attrition rate was low, and we analyzed the data as ITT, including those who dropped out of the study. Limitations include lack of access to electronic medical record data of the GP clinics to correlate the prevalence of conditions with the frequency of app prescription within the patient cohort. We aimed to recruit a sample of GPs representative of the national GP cohort; however, our participants' median age of 40 years was younger than the national average of 50-55 years. Other limitations include a single-group pre-post study design, possible volunteer bias of the participants, and short time frame (4 months). Ideally, a randomized controlled trial should be conducted to establish the long-term effectiveness of the intervention with a large and representative sample for a longer duration. Due to the restrictions of available time and resources, we were unable to achieve this. Future studies should also opt for an electronic version of app prescription to improve sustainability and scalability. Another limitation is the analysis of qualitative data by a single researcher; however, the qualitative data result was a small part of our secondary outcome to primarily answer if the intervention was acceptable and feasible for practicing GPs.

There are few comparable studies of app recommendation in a primary care setting. A trial for an app prescription platform, AppSalut, in Spain involved 32 doctors who made 79 app recommendations in 5 months. Of the three apps they used, a medication adherence app was the most prescribed [4]. It sends the prescribed app to patients as text messages and can monitor and receive data on patients' use and adherence to the system. In the United States, the Cambridge Health Alliance network of primary care clinics implemented a mental health app dissemination program, in which they evaluated mental health apps, selected 7 apps, and recommended these 7 apps in 12 primary care clinics [5]. Similar to the finding of our study, app prescriptions for anxiety and stress were the most frequently prescribed. An Australian study tested the feasibility of integrating mHealth apps into dietetic practice by asking 5 dietitians to use one chosen app for 12 weeks [6].

All of these studies provided training to the participating health care professionals to educate them about the study apps as well as the electronic systems they needed to use. The qualitative feedback from our participants also included the need for such training. However, because GPs often report being overworked, time-poor, and inundated with different information and offers, it would be challenging to organize out-of-hours training involving many GPs or train dedicated personnel to visit GP clinics during lunch hours, which was suggested by the GPs as a solution. The scalability of such an intervention would pose funding and logistical challenges.

One way to promote the sustainability and scalability of mHealth app integration into clinical practice is to provide an electronic repository of vetted and curated apps for health care professionals. In Australia, the Victoria Department of Health [24], Black Dog Institute [25], and HANDI project by the Royal Australian College of General Practitioners [26] offer small repositories of mHealth apps, but these organizations function under different jurisdictions with no national guideline in place. GPs in our study emphasized the need for a nationally accessible repository of a select few prescribable apps that are relevant to general practice that is safe, reliable, and easy to navigate.

We found that mHealth app prescription is feasible in a general practice setting in Australia by addressing previously identified practical barriers to mHealth app prescription. Our implementation intervention was effective in increasing app prescription. However, the future of app prescription depends on efforts to increase GPs' knowledge of prescribable apps as well as a dedicated trustworthy app repository for GPs.

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Conflict of interest: Authors declare no relevant conflict of interests.

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7

Chapter 7. General Discussion

Preamble

This chapter summarises the findings and novel contributions of all four studies within the broader scope of the overarching thesis aim. It also discusses the implications of these findings for clinical practice, policymaking, and future research.

7.1 DISCUSSION OF THE MAIN FINDINGS

The overall aim of this thesis was to evaluate the evidence of effectiveness of patient-facing stand-alone mHealth apps and to explore the interest and feasibility of mHealth app prescription in Australian general practice. This aim was achieved by undertaking a series of connected studies: by assessing the evidence of effectiveness of mHealth apps (**Chapter 3**), determining the barriers and facilitators to prescribing mHealth apps in Australian general practice (**Chapters 4-5**), and by testing the feasibility of an implementation intervention to overcome the identified barriers and increase app prescription by GPs (**Chapter 6**).

This thesis provides a window into the body of evidence on currently available stand-alone mHealth apps with a special focus on their "prescribability" in general practice settings. The focus is here - because that is where effective stand-alone apps can be easily integrated into clinical practice and help both patients and doctors. However, it is possible for other primary care practitioners, such as diabetes nurses, dieticians, and physiotherapists, to prescribe suitable health apps to patients [1]. The perspectives of patients and practicing GPs have been invaluable in achieving the objectives of the thesis and addressing the barriers to app prescription.

EVIDENCE OF EFFECTIVENESS OF MHEALTH APPS

In **Chapter 3** (Study 1), the concept of "prescribable" health apps was proposed and defined as: currently available, proven effective and preferably stand-alone. Due to the high number of available apps in app stores, a systematic review of RCTs of prescribable apps was needed. However, a preliminary search revealed several systematic reviews of RCTs of apps in specific disease areas and since general practice deals with a variety of conditions, it was appropriate to conduct an overview of systematic reviews to find relevant apps.

Study 1 found that a very small percentage of all available apps had been rigorously evaluated (Figure 7). From the overview, only 11 trials of apps showed a meaningful, yet small to medium effect on health or surrogate outcomes attributable to apps were identified (Table 3). However, the overall evidence of effectiveness was hampered by pilot studies, small sample size, high risk of bias, and high attrition rates, thus making the evidence very low quality according to GRADE approach [2].

In turn, this hinders the prescribability of those apps. Furthermore, one of the main purposes of Study 1 was to identify prescribable apps that can be used to test the concept of app prescription in general practice (Study 4) provided that they remain available in Australian app stores, and stay stable in terms of content and features. Ultimately, we were able to use four apps identified during the conduct of this study in our final study.

Any intervention that claims to improve health should be supported by evidence of effectiveness. Rigorous standards of quality and safety must not be relaxed because of the allure of technology. Currently, mHealth apps are shown not to be the panacea that 'Silicon Valley' makes them out to be. Furthermore, one of the main purposes of Study 1 was to identify prescribable apps that can be used to test the concept of app prescription in general practice (Study 4) provided that they remain available in Australian app stores, and stay stable in terms of content and features. Ultimately, we were able to use four apps identified during the conduct of this study in our final study.

BARRIERS TO AND FACILITATORS OF PRESCRIBING MHEALTH APPS IN AUSTRALIAN GENERAL PRACTICE

Following the evaluation of the evidence base, two interconnected studies, Studies 2 and 3 (**Chapters 4 and 5**), were conducted to explore the barriers to and facilitators of mHealth app prescription in Australian general practice. These were - an interview study with patients and GPs (Study 2), and a national survey study with GPs (Study 3). The interviews with patients and GPs found that mHealth apps prescription is perceived as inevitable and achievable. Both patients and GPs are aware of and overwhelmed by the sheer number of apps available and identified the need for a more trustworthy source of health apps other than the app stores. For patients, their GPs represent a trusted source.

However, the interview analysis showed that main barriers from the GPs' perspectives were a (1) generational difference in the digital propensity for both the GPs and patients; (2) lack of knowledge of prescribable apps and lack of reliable source to access apps; (3) the time commitment required of GPs and patients; and (4) issues around privacy, safety and trustworthiness of health apps. From these barriers, the lack of knowledge of prescribable apps and lack of reliable source to access them was shown to be the most prominent concern in the survey results (Figure 11). This was also the one that could be influenced by implementation interventions that were possible within the scope of this thesis. Further comments from the participating GPs also hinted at potential solutions to this barrier: a need for an education and training on mHealth apps, app prescription skills, and most importantly trustworthy source of prescribable apps at their fingertips.

This barrier of lack of knowledge and resources can be addressed by behaviour change interventions. It can be mapped onto the COM-B model for understanding behaviour to assist with intervention development [3]. Education, training, enablement, and incentivization are the strategies identified by COM-B that can provide GPs with the knowledge, skills, and tools to integrate mHealth apps into their practice. Lack of education and training is one of the most common barriers that HCPs face in adopting new technology in healthcare [4-6] and this study also reflects this essential element. Furthermore, the potential to increase HCPs' time strain and workload are common factors of poor uptake of new health technologies [7, 8]. However, understanding the value of new technology, such as the potential to save consultation time and keep patients engaged and motivated in between consultations, can help mitigate against perceived barriers.

FEASIBILITY OF MHEALTH APP PRESCRIPTION IN AUSTRALIAN GENERAL PRACTICE

Study 4 tested the feasibility and effectiveness of an implementation intervention we developed to overcome one barrier we chose from the preceding studies with an aim to increase the uptake of mHealth app prescription in Australian general practice (**Chapter 6**). Due to time and resource constraints of the PhD, we were unable to conduct a RCT. Instead we conducted a single group before-after study with pre-study survey and post-study interviews. The implementation intervention was shown to be highly acceptable and successful in achieveing the study aim of increasing uptake of prescribable apps.

The variation in the total individual tally of apps prescribed by participants was wide (Figure 15). This may reflect differences in their personal digital propensity and flexibility in altering prescribing behaviour, as well as the trust they placed on the study team's vetting process and credibility. The app introduction videos intended to serve as additional education and training to enable the GPs to develop knowledge and familiarity with the apps. However, because only one app video was sent to each GP midway through the 4-month study, many GPs did not gain or retain much information from them. Also, it would take more detailed information and sustained exposure than watching a 2-minute video on one occasion, to develop a meaningful familiarity with the apps. For example, the most frequently prescribed app Smiling Mind was the most well-known app among GPs and patients alike because it has been created and advertised in Australia for a number of years and is also used in many Australian schools.

The feedback interviews conducted at the end of the study revealed insights into the intervention and GPs' prescribing behaviour. The prescription pads provided a visual cue and physical tool, which was found to be important in guiding GPs' prescribing behaviour. The prescription pads seem to be more influential than the app introduction videos. The interviews also provided more depth into the barriers to app prescription uptake, such as personal familiarity with the apps is likely as important as knowing the app's name and credibility to foster confident prescribing habits. It was also suggested that integrating the much needed repository of prescribable apps with the electronic medical systems of GP practices would further enhance the adoption of app prescription by reducing friction and streamlining the process.

Changing GPs' prescribing behaviour is complex [9]. Tailored interventions that were developed based on identified barriers to implementation are shown to be more effective in changing clinician's practice [10]. This thesis aimed to achieve that by using step-by-step exploration of the barriers to and facilitators of app prescription, and successfully developed and tested a tailored implementation intervention. Recommendations arising from this thesis and future unanswered research questions are discussed later in this chapter.

7.2 Further perspectives on mHealth apps

mHealth apps make up a considerably small part of the new technology landscape that are crossing over into healthcare, so it is important to zoom out and consider the bigger picture of these technologies and their evolution. Gartner Hype Cycle helps us to see that every new technology-based tools that enter healthcare come with a big bubble of hype around them, which bursts open upon close scrutiny and the real value they may offer to healthcare is then eventuates [11]. At the start of this PhD in 2016, mHealth apps were at around the Peak of Inflated Expectations (Figure 17). Daily headlines with lists of top apps for many different conditions were the norm, but the literature did not reflect that as evidenced by Study 1. Then, their popularity slowly declined, and they were mostly replaced by Artificial Intelligence (AI) and other new technologies entering healthcare as the new "disruptors". Currently, mHealth apps are undergoing major disillusionment that they are not and have never been the panacea we all hope every new technology to be. Most mHealth apps fail to demonstrate clear health improvements, we need to re-evaluate the design to improve the second- and third-generation apps and to enhance testing to improve the relevance, maturity, and benefit of the apps. Only then we can hope to ascend onto the Slope of Enlightenment.

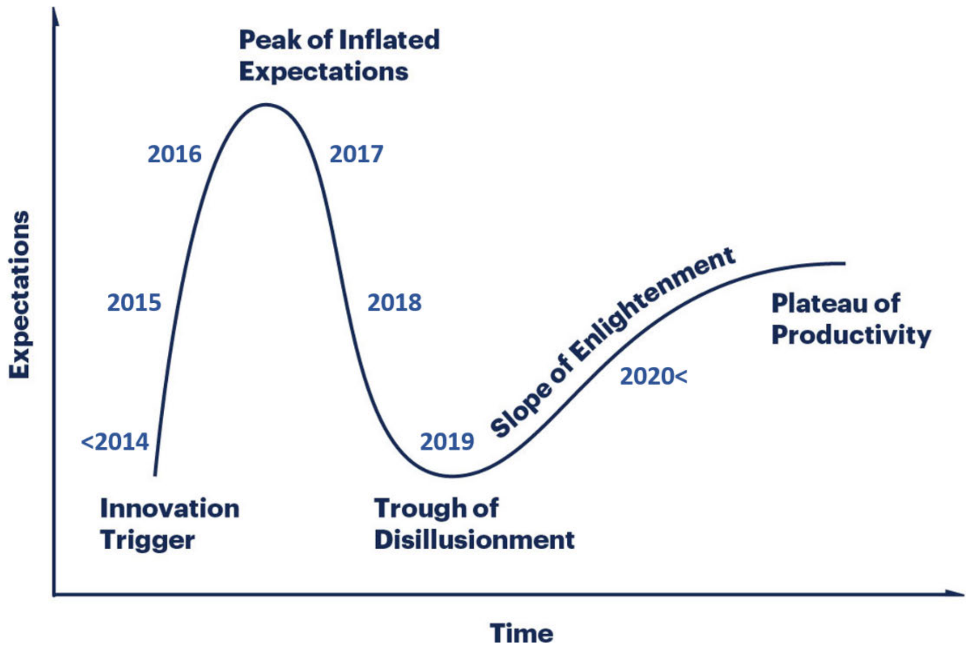

Figure 17. Gartner Hype Cycle showing relative position of mHealth apps during the conduct of this thesis. (Gartner Inc. Gartner Hype Cycle 2020 [Available from: https://www.gartner.com/en/research/methodologies/gartner-hype-cycle.[11])

Furthermore, the new and improved models of smartphones and smartwatches are also integrating many health-related functions and sensors such as step-counting, sleep tracking, calorie expenditure calculation and mindfulness as native smartphone functions. So, the need to download extra apps or buy separate fitness trackers are rapidly declining especially in areas of health and fitness. Thus, perhaps the main area of impact of mHealth apps will be the Medical category apps, which has a significantly smaller market than Health and Fitness yet requires more serious level of regulation, making mHealth apps not a very profitable area of health tech, but this decline in scope will in turn be favorable to the regulatory opportunities.

7.3 Strengths and Limitations

The strengths and limitations of the individual studies have been discussed in the relevant chapters and are summarised in Table 11. The key strength of this thesis lies in its pioneering exploration of mHealth app prescribability in general practice and the evidence it contributes to the body of knowledge in the applied mHealth research field. The use of rigorous study methodologies, reporting guidelines, and risk of bias tools further adds to the strength of the research in this thesis. All four studies are published in peer-reviewed open-access journals.

Another strength is that all of the primary studies were conducted in a 'real-world' setting and involved practicing GPs in Australia. This was important for helping to understand contemporary barriers and facilitators, and to use this understanding to develop feasible and acceptable solutions. The studies also achieved an acceptably representative sample of participants from all ages, work experience and geographical location in Australia through a highly targeted recruitment strategy and purposive sampling. Nevertheless, it is still important to recognize the effect of selection bias on the results due to the self-selection of participants in the studies.

Interconnectedness of the studies was also a big strength of this thesis (Figure 2). The concept of "prescribable apps" and the mHealth apps that are identified during the first study were used in all three subsequent studies. Congruence between Studies 2 and 3 - the findings of main barriers to app prescription as determined by Australian GPs - ultimately made it possible to design the final study within the scope of this thesis. However, this thesis could have had a clearer theoretical grounding such as the Theoretical Domains Framework and Behaviour Change Wheel to better unify the studies into a gestalt. A particular limitation is that the earlier studies lacked a stronger theoretical framework that could have further strengthened their findings and subsequently the development of the final implementation intervention.

Table 11. Summary of key strengths and limitations of individual studies in this thesis

	Strengths	**Limitations**
Study 1 Prescribable mHealth apps identified from an overview of systematic reviews	• Proposed concept of "prescribable" apps for general practice setting • First study to evaluate the evidence behind prescribable apps • Broad search strategy and inclusion criteria • Contacted extensive number of authors to obtain missing information • Robust risk of bias assessment • Two researchers conducted screening and bias assessment	• Poor reporting of methodology, intervention, and risk of bias among included studies • Lack of high-quality evidence of effectiveness of prescribable apps • Lack of comparable overviews • Data extraction by a single researcher
Study 2 Barriers and facilitators to using mHealth apps in general practice	• One of the first attempts at an in-depth exploration of barriers to mHealth app prescription in general practice • Purposive sampling to include all ages and GP experience levels • Identified and compared barriers to app prescription from both GPs and patients' perspectives	• Small sample size skewed towards healthy patient cohort and metropolitan GPs • Lack of triangulation of data and member checking • Possible lack of reflexivity
Study 3 Current knowledge and adoption of mobile health apps among Australian GPs	• National reach • Representative sample	• Low response rate • Selection bias • Part of a larger survey, possibly survey fatigue
Study 4 mHealth app prescription in Australian general practice	• First study to test the feasibility of implementation intervention for app prescription in general practice • Low attrition • ITT analysis	• Pre-post study design • Relatively young GP cohort • Selection bias • Lack of triangulation of the app prescription numbers with the prevalence of conditions among patient populations • Analysis of qualitative data by a single researcher

7.4 Recommendations and Implications

This section outlines five recommendations that are being proposed based on the findings of this thesis. The first three recommendations focus on improving the quality of mHealth app research. The last two recommendations address implementation issues, such as creating a national-level evidence-based app repository and regulatory framework for mHealth apps for Australia.

1. More pragmatic trials on the comparative effectiveness of mHealth apps against other proven interventions and different modalities of interventions are needed

"We need less research, better research, and research done for the right reasons"

Doug Altman

When it comes to mHealth app research, the late Doug Altman's famous words need a slight modification [12]. Right now, we need 'more research' into the effectiveness and safety of mHealth apps to evaluate their potential in improving care and health. **Chapter 3** (Study 1) identified that a very small proportion of all available apps have undergone testing. Most RCTs tested mHealth apps against treatment as usual, but the comparator interventions were often multifaceted, therefore hindering the interpretation and attribution of treatment effect to the use of apps (Table 3). Simple comparative studies of the app version of interventions with the other established interventions (such as paper diary, text message reminder, educational pamphlets, phone calls, or web-version of the interventions) will produce more practical results.

Most importantly, trial results should be reported as between-group differences [13], which many RCTs did not. The only way to establish the effect of an intervention is by demonstrating a greater change in the intervention group compared to the comparison group, rather than change from baseline within each group.

The studies also should be pragmatic in design so that they can directly answer whether the intervention app actually works in real life [14]. Many mHealth apps failed to demonstrate the same effectiveness in real-world settings as they did in pilot studies or the full explanatory RCTs [15]. Therefore, pragmatic trials conducted in the specific environment that the app will be used will increase the rigorousness of future studies and their generalizability.

2. To help improve the quality of evidence of effectiveness of mHealth apps, trials of mHealth apps need to improve methods and adhere to reporting guidelines

Chapter 3 (Study 1) also identified several gaps in the quality of research in testing and reporting of mHealth apps. Consistent sources of high risk of bias in the RCTs were lack of blinding of participants and personnel to the intervention and lack of allocation concealment. While blinding can be challenging in mHealth studies, it is important because of the digital placebo effect, which could be overcome by using sham or 'placebo' apps [16].

The completeness and quality of the reporting of the included systematic reviews and RCTs was poor. Many of the RCTs did not include sufficient descriptions of their interventions to allow replication, and the availability of their study apps beyond the study period was uncertain. Sharing information among researchers working in app development and testing is vital to reduce research waste and prevent unnecessary duplication. Despite the low number of effectiveness studies, digital health interventions are already plagued by a reproducibility crisis [17]. Hence, we must promote the importance of providing complete and transparent reporting of app interventions, as is true of other interventions in health care. This can be achieved by following the guidance provided by TIDieR [18].

Existing systematic reviews in this area also do not adhere to the PRISMA statement [19] in their reporting. Many did not conduct risk of bias assessments of the included studies or integrate the risk of bias results into the overall synthesis, thus preventing the readers of the reviews from recognising the poor quality of the included studies.

Risk of bias issues at every level of evidence are compromising the quality of the evidence of effectiveness of mHealth apps.

3. Establishing a repository of trustworthy prescribable mHealth apps for GPs is crucial in the uptake of effective mHealth app prescriptions in general practice; a national-level professional organisation should take the lead in the provision of this repository

Findings of Studies 2-4 provide the basis for this recommendation. The GPs who participated in these studies expressed the need for a national, accessible, and trustworthy repository of selected prescribable apps that are relevant to general practice, that is safe, reliable, and easy to navigate. Study 4 used app prescription pads printed on paper, akin to traditional prescription pads. The tangible and familiar way that the doctors perceive prescription appeared to be the biggest appeal of the printed app prescription pads. However, it is not sustainable and practical to produce prescription pads for the many different apps that are useful in general practice, keep them updated as apps change, and supply them to GPs around Australia on an ongoing basis.

One of the most promising ways to promote the sustainability and scalability of mHealth app integration to clinical practice may be to provide an electronic repository of apps for GPs. Currently, in Australia, the Victoria Department of Health [20], Black Dog Institute [21], and Health Direct consumer web resource [22] offer small repositories of mHealth apps. However, none have transparent vetting processes and evaluations.

Studies 2 and 4 also found that the most trusted source of professional and practice-related information and guidance for GPs is the RACGP. One of the many resources that the RACGP provides for GPs is HANDI, which already includes a small number of mHealth apps [23]. Upgrading, re-organising, and consistent and prominent branding and messaging of HANDI as also containing an app repository may be one of the most efficient ways to assist Australian GPs to learn about and potentially use and adopt mHealth apps. The RACGP is also well-placed to coordinate the opportunities to integrate app repositories with the most common electronic medical record software that is used in Australian general practices.

The RACGP recently released their renewed research priorities [24]. Many items in the top 20 priorities offer opportunities to integrate mHealth apps – these include consumer focus, mental health, avoiding hospitalisations, use of technology in primary care delivery, obesity, health promotion and illness prevention, and non-pharmacological treatments. There are numerous apps available for the top ten most commonly presented medical problems in general practice: hypertension, immunisation, upper respiratory tract infection, depression, diabetes, lipid disorder, general check-up, osteoarthritis, back complaint, and prescription request [25]. Evaluating and including mHealth apps according to such areas of importance further improve the usefulness of mHealth app repositories.

4. The establishment of national mHealth app regulation framework is essential in integration of mHealth apps into clinical practice

All issues around mHealth app prescription are impacted by the fundamental lack of comprehensive app regulation and evaluation in Australia. This is an important challenge for Australian digital health governance due to its impact on patient safety [26]. mHealth apps regulation requires a multifaceted approach as the existing volume of apps and a multitude of stakeholders involved in the development, marketing, and consumerisation of apps span a wide variety of jurisdictions [27].

App store requirements for health and medical apps have never been, and continue to not be, sufficiently rigorous. Apple's introduction of a "physical harm" clause under safety requirements in 2016 has been a step forward. It states that "medical apps that could provide inaccurate data or information, or that could be used for diagnosing or treating patients may be reviewed with greater scrutiny" [28], but the who, what, when and how of the "greater scrutiny" is unclear. Google Play currently does not have any special requirements for publishing apps in mHealth categories.

In the US, the Food and Drug Administration (FDA) has decided to regulate mHealth apps using a risk-based approach like other medical devices. Apps that satisfy the definition of “software as a medical device” and poses a potential risk to human health have to go through the FDA approval process [29]. The Federal Trade Commission (FTC) keeps the low-risk mHealth apps accountable, which makes up the vast majority of apps in the app stores. The FTC also released best practice guidance for mobile health app developers that is mainly geared towards data safety, privacy and security issues, rather than health safety or efficacy [30].

In the UK, the NHS Digital offers an app library for patient-facing mHealth apps. It outsources the app evaluation to private organisations that specialises in vetting mHealth apps, such as the Organisation for the Review of Health Apps (ORCHA) [31], before issuing its stamp of approval. ORCHA itself offers a highly searchable large repository of vetted apps that contains over 5000 mHealth apps in 24 categories evaluated by three main areas: data privacy, clinical assurance, and user experience. However, they must comply with the National Institute for Health and Care Excellence’s Evidence standards framework for digital health technologies [32].

In Australia, the Therapeutic Goods Administration takes a similar approach to the FDA and regulates medical apps that classify as software as a medical device [33]. The Australian Digital Health Agency developed the National Digital Health Strategy, but it is not yet involved in the regulation of mHealth apps, their safety, privacy and efficacy. A recent report on national digital health safety governance in Australia concluded that Australia cannot delay the creation of national digital safety measures because patient safety is the ultimate outcome that needs to be achieved [34]. This fifth of the thesis is in agreement with the findings and recommendations of this report.

7.5 Unanswered questions for future research

1. ***How should we evaluate the prescribability (the effectiveness, safety, and usability) of mHealth apps in a sustainable and timely manner?***

To be prescribed, apps should, at the very least, be shown to work and to be safe and usable [35]. Safety and usability issues are challenged by the fast-evolving nature of the operating systems and commercial aspects of the technology. Pham *et al* argue that the average 2 years that it takes for an RCT to be conducted is far too long to evaluate fast-evolving technology-based interventions [36]. The challenge of ever-changing operating systems and app software and funding issues support this argument. However, given that Study 1 (**Chapter 3**) showed that the effect of apps as health interventions might be small, marginal benefits can only be reliably detected by rigorous testing.

There are a couple of approaches that can help solve this problem of time-intensive traditional way of conducting RCTs. Murray et al suggested that full RCTs should only be conducted once the intervention app is stable, can be implemented with high fidelity, and there is a reasonable likelihood of clinically meaningful benefit of the intervention shown in initial testings [37]. Additionally, the sustainability and timeliness of app evaluations can be improved by first conducting a pilot study, which includes user feedback to assess potential benefits prior to further development and testing [38].

Another emerging approach is to conduct app RCTs online. Bindhim et al conducted an online double-blind RCT of a smoking cessation app. Participants were recruited internationally through the app store downloads, which helped save time and resources for recruiting compared to traditional in-person approach [39]. They used a simpler version of the intervention app as a control, thus mitigating for a potential digital placebo effect. Although, online recruitment saves time, it also introduces self-selection bias to the study. However, app developers should explore similar options and opportunities when testing mHealth apps.

Timely synthesis of the research in mHealth app effectiveness is highly important yet time-intensive, as demonstrated by the conduct and conclusion of Study 1. Contemporary approaches to evidence synthesis, such as living systematic reviews as suggested by Elliot et al, may be particularly well-suited to keeping up evidence syntheses for fast-paced technology-based interventions such as mHealth apps up to date [40]. The Clinical Trials Transformation Initiative created a program for Mobile Clinical Trials and an online database of feasibility studies for mobile and wearable technologies [41]. More initiatives like these are needed to improve the sustainability and timeliness of mHealth research.

2. ***What are the factors that impact patient adherence rates to prescribed mHealth apps?***

This thesis primarily examined the possibility of mHealth app prescription from the GPs' perspective, although Study 2 did interview a small number of patients. Future studies should further explore barriers to and facilitators of long term adherence to apps from patients' perspectives because low levels of use after app recommendations is a big challenge in digital health [42, 43]. Real-world app adherence and engagement levels have been shown to be low: drop out from studies can be as high as 80% and sustained use of apps can be as low as 0.5% [44, 45]. Most user experience studies show that consumers and patients stop using apps actively within a week [46, 47]. The exponential growth of apps since the origin of app stores, which were mostly available for free or for a one-off price of less than AUD$3, likely contributes to the perception of apps as being low value and dispensable.

Some of the theories that explain the low adherence to apps are a lack of user-centric design and low usability of apps [48]. It is important to involve the end-users whether they are pateints or HCPs in every stage of app development, from conception, design, testing, through to implementation is important in creating safe, effective, and useful apps [49]. An example of a successful solution is the iBobbly suicide prevention app, which was designed for indigenous youth of Australia. It involved the end-users in every step of the app development and achieved 85% of adherence during the trial period [50]. For some apps and settings, HCPs are also one group of users and therefore their input into the intricacies of the management of specific conditions and health service settings is valuable and needed.

Accountability and personalised care appear to be important contributors to app adherence. A growing number of app studies show that human connection and follow-up, in addition to app prescription, increase app adherence. Potentially this increased adherence may also be a contributor to improved patient outcomes, particularly in mental health and weight loss studies [44, 51, 52]. Therefore, it is important to explore the impact of patient involvement in app development, feasibility and effects of different modalities of intervention delivery and follow-up (such as face-to-face, telephone, video calls or SMS) on long-term app adherence and patient outcomes.

3. ***What are the potential or real harms and detriments mHealth apps can cause, contribute to, or have caused in real-world?***

Technology use can be a double-edged sword. It is a tool that is inherently neither bad nor good. It is what we do with it or how we choose to use that gives it the positive or negative attributes. mHealth apps are inseparable part of smartphones and other smart devices and thus closely linked with the larger contexts and circumstances in which these devices are used. Therefore, harms associated with mHealth apps can be categorized as:

- app-related: incorrect or non-evidence-based content [26], harms arising from inaccurate measurement (e.g. blood pressure) [53], lack of timely escalation (e.g. worsening depression, exacerbation of eating disorders [54]), false or misleading claims of health benefit [55], anxiety associated with constant quantification of life, food, sleep, and weight [56], or unintended reverse effects such as app designed for moderating alcohol use instead increasing alcohol intake[57].

- smartphone and its wider use related mental, physical and social effects: smartphone or app addiction [58], data breach [59], loss of privacy [60, 61], financial scamming (e.g. making it hard to unsubscribe from the service) will all erode trust, and hinder adoption of technology and adherence to beneficial digital interventions.

These harms need to be studied and measured for us to understand consumer usage and behaviour, and to develop safer apps and better evaluation and regulatory frameworks.

4. ***What is the effectiveness of mHealth apps with additional personal support and what are the feasibility and cost-effectiveness of implementing them primary care compared to stand-alone apps?***

The primary focus of this thesis was the effectiveness of stand-alone mHealth apps. However, mHealth apps that are 'not stand-alone' and designed to be used in conjunction with support from HCPs, health coaches or even chatbots are a major part of the mHealth app world and there are some evidence to show that they perform better than stand-alone apps [51]. The additional supports can be personalised goal setting, real-time or regular feedbacks, and individualised communication provided through built-in app features or add-on services such as phone call, periodic intensive counselling, face-to-face follow ups, or text messages in-between the consultations. Such additions could make mHealth app implementation into clinical practice more resource-intensive and costlier than stand-alone options, but how exactly these apps compare with stand-alone apps and what the effective "doses" for each support are also priority research questions in digital health.

7.6 Conclusion

The research in this thesis evaluated the evidence of effectiveness of patient-facing stand-alone mHealth apps and explored the feasibility of prescribing them as a non-drug intervention in general practice. From an overview of systematic reviews, it was concluded that the evidence of effectiveness for mHealth apps is emerging. From the interviews with patients and GPs and survey of GPs, it was found that both groups accept that app prescription is possible, inevitable, and acceptable, although GPs are currently not sufficiently knowledgeable or resourced to optimally prescribe apps. The future of app prescription in Australian general practice appears to be likely influenced by efforts to increase GPs' knowledge of prescribable apps as well the creation and maintenance of a dedicated app repository for GPs.

It is a challenge for 21st-century HCPs to keep up with the soaring number of mHealth apps, which are also of variable quality. The research in this thesis had the underlying philosophy of desiring HCPs to be able to use these new tools in their clinical practice with a positive impact on patients. To safeguard patient safety, as HCPs, and researchers, we must drive the push to ensure that the potential of this new technology is evaluated rigorously and harnessed without inappropriate hype. The sustained involvement of stakeholders in consumer mobile technology, HCPs, patients, and policymakers will be vital in the successful integration of mHealth apps in clinical practice.

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