Prescribable mHealth using built-in device sensors: a mixed methods exploration of a respiratory therapy app for smartphones

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This work is dedicated to the memory of my parents

Ronald & Galina Baxter

and to my family

Keywords

eHealth; mHealth; smartphone; cell phone; mobile apps; pulmonary rehabilitation; respiratory; atelectasis; COPD exacerbations; cystic fibrosis; respiratory Infections; pneumonia; SARS-CoV-2; instrumentation; microphone; digital simulation; virtual reality; gamification; serious game; exergame; health care evaluation; health care quality; medical informatics; consumer health informatics; physician patient relations; prescriptions; patient participation; patient-generated health data; self-evaluation; self-care; self-management; usability

Abstract

Clinicians are cautious about embracing prescription of health and well-being (i.e., mHealth) smartphone apps to patients, citing a lack of evidence regarding safety, reliability and clinical validity as barriers to wider adoption. This doctoral thesis presents an exploration of a new smartphone mHealth app (QUT Inspire) which virtualises a longstanding respiratory therapy technique called Incentive Spirometry (i.e., ISy); this new app detects inspired breath sounds using the built-in phone microphone and displays responsive animated on-screen graphics to encourage engagement, effort and persistence with virtualised ISy therapy.

In this mixed methods research, a systematic survey of curated (i.e., trusted) health app libraries was first conducted to assess availability of "prescribable" smartphone mHealth apps using built-in phone sensors. A paucity of apps using built-in sensors (n=18) was identified in the libraries examined, with no available respiratory therapy apps offered by the libraries surveyed. As a precursor to clinical studies, the technical validity and reliability of the new QUT Inspire app was first demonstrated using (non-human) acoustic simulations of inspiration. Optimal parameters for sound detection including mouth diameter, inspiratory flow rate and detection range for inspiratory sound were documented. A mixed methods randomised usability study using disease-free participants (n=24) compared the QUT Inspire app with a conventional ISy device. The QUT Inspire app was demonstrated to be both effective and efficient in terms of technical usability, with participants reporting high levels of satisfaction with the app compared with a conventional clinical ISy device.

This research contributes original knowledge in the fields of smartphone mHealth app development, evaluation and interface refinement and offers evidence supporting broader adoption of mHealth for prescription to patients concerning a virtualised respiratory therapy technique. Improvements in health may be realised by leveraging ubiquitous, low-cost sensor and smartphone app technology now available globally, particularly in geographically, socially or economically marginalised groups.

Publications

Study 1 (Chapter 4): Baxter, C., Carroll, J.-A., Keogh, B., & Vandelanotte, C. (2020). Assessment of Mobile Health Apps Using Built-In Smartphone Sensors for Diagnosis and Treatment: Systematic Survey of Apps Listed in International Curated Health App Libraries. *JMIR mHealth and uHealth*, *8*(2), e16741. doi:10.2196/16741 https://eprints.qut.edu.au/137019/

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Conference Abstracts

Baxter, C., Carroll, J.-A., Keogh, B., & Vandelanotte, C. (2018, November). *Incentive spirometry & smart phones: Performance validation & user impressions.* In Proceedings of the 57th Australian Society for Medical Research National Scientific Conference. Australian Society for Medical Research, Adelaide, Australia. https://eprints.qut.edu.au/125166/

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Peer reviewer activities for international journals

The candidate completed 54 verified peer reviews for 21 international journals between 2020 and 2022. (Number of reviews completed in parenthesis)

Year(s)	Journal
2021	Adolescent Health, Medicine and Therapeutics (1)
2022	Archives of pulmonology and respiratory care (2)
2020	BMJ Open (2)
2021	Clinical Interventions in Aging (1)
2021-2022	Digital Health (3)
2022	Interactive Journal of Medical Research (1)
2021-2022	International Journal of General Medicine (3)
2022	International Journal of Human-Computer Interaction (12)
2022	International Journal of Women's Health (1)
2022	Journal of Medical Internet Research (2)
2021-2022	JMIR Formative Research (4)
2022	JMIR Medical Informatics (1)
2022	JMIR mHealth and uHealth (7)
2021-2022	JMIR Public Health & Surveillance (3)
2021-2022	JMIR (5)
2021	Journal of Multidisciplinary Healthcare (2)
2021	Medical Devices: Evidence and Research (1)
2022	NPJ Schizophrenia (1)
2022	Patient Preference and Adherence (1)

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2022	Risk Management and Healthcare Policy (1)
2021	Smart Homecare Technology and Telehealth (1)
2021	Telemedicine Reports (1)

See Peer reviews at: https://www.webofscience.com/wos/author/record/2057212

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Epigraph

No air (Air, air...)

Jordin Sparks, 2008

Chapter 1: Introduction

Mobile health apps and the use of built-in smartphone sensors to augment diagnostic and therapeutic applications are introduced as the focus of this research in sections 1.1 and 1.1.1 respectively. Barriers to wider adoption of this technology in medical practice are considered in section 1.1.2. The aims of this doctoral research program, research questions and a brief synopsis of the research studies conducted are presented in sections 1.2, 1.3 and 1.4. Section 1.5 describes the structure of this thesis and the remaining chapters. Section 1.6 presents a contribution statement concerning stakeholders in this research. This introductory chapter concludes with a brief description of the significance of this research (section 1.7).

1.1 BACKGROUND

According to recent World Health Organisation (i.e., WHO) estimates, seven billion mobile phone subscriptions exist worldwide, with more than 70 % found in low and middle-income countries (WHO, 2021). Beyond simple telephony and messaging, these devices offer potential for healthcare transformation and realising improvements in health using downloadable apps to extend device functionality (WHO, 2021). An estimated four and a half million applications (i.e., apps) are available to smartphone users for download from Google and Apple application stores and pertaining to a vast array of topics (Statista A, 2022). Over a million of these apps relate to health and wellbeing, with those using mobile computing, mobile sensors, or communication technologies for healthcare collectively termed mHealth (i.e., mobile health) apps (WHO, 2011). A recent review identified a subset of 350,000 of these mHealth apps as potentially prescribable by clinicians to patients (Byambasuren et. al., 2019). A lack of evidence demonstrating the safety and efficacy of mHealth apps has hindered broader adoption of app prescription by clinicians, which has languished in comparison to widespread self-prescription of apps by health consumers; some apps may be potentially ineffective or dangerous if used without medical guidance (Rowland et. al., 2020; WHO (A), 2019; Wykes & Schuller, 2019).

A simple taxonomic distinction can be drawn between mHealth apps which are “passive” - displaying static health-related text information or accepting manually

keyed input – and mHealth apps which are “active” - using smartphone sensors to generate health data for diagnosis or treatment (Herron, 2016). This research contributes to the evidence base regarding active mHealth apps, focusing on a novel app using the built-in smartphone microphone sensor to virtualise an existing respiratory therapy by means of inspiratory sound detection.

1.1.1 SMARTPHONE SENSORS

Each of the billions of smartphones in use today encapsulate a variety of built-in sensors for detecting environment (e.g. microphone, camera) and position (e.g. accelerometer, gyroscope, GPS, touchscreen) (Stankevich et. al., 2012). In addition to native telephony-related uses for these sensors (i.e., sound for voice, accelerometer to determine phone orientation and trigger screen re-sizing), novel uses for these sensors in health-related applications have emerged (Majumder & Deen, 2019). Sound detection by smartphone microphones can act as a stethoscope, analyse and diagnose types of respiratory illnesses based on patterns of coughing sounds or count the respiratory rate of neonates for monitoring purposes (Karlen et. al., 2014; Lu & Wu, 2015; Porter et. al., 2019). Camera images from phones may assist in diagnosis of liver dysfunction or pancreatic cancer by detecting yellow discolouration in the eye associated with jaundice or to superimpose measurements of the dimensions and progression of the size of wounds in the management of diabetic ulcer lesions (Outlaw et., al., 2019; Ploderer et. al., 2018).

Great potential for improving global health exists by leveraging built-in sensors and processing power available in smartphones, aided by obviating the need for often costly external add-on sensor components. (Bastawrous & Armstrong, 2013; Onodera & Osei & Mashamba-Thompson, 2021; Onodera & Sengoku, 2018). Capitalising on this technology may result in new and novel ways to deliver health care, empower patients and potentially reduce health inequalities by increasing access to otherwise unavailable technologies for both clinicians and patients alike (Baldwin et. al., 2017). Smartphone adoption and access to mHealth tools has grown in developed and developing countries and across socioeconomic strata (Osei & Mashamba-Thompson, 2021).

1.1.2 BARRIERS TO WIDER mHEALTH ADOPTION

In contrast to widespread popularity of mHealth apps among health consumers as evidenced by the multitude of mHealth apps available for download, clinicians demonstrate reticence in incorporating apps in clinical practice (Byambasuren et. al., 2019; Kao & Liebovitz, 2017). Health professionals cite "app overload" when confronted by millions of apps of unknown provenance and indeterminate quality to choose from, a lack of information regarding how best to prescribe available apps to patients and a paucity of peer-reviewed clinical evidence regarding efficacy and safety as barriers to wider adoption of mHealth for prescription (Hempel et. al., 2018). Search engines offer listings of apps based on keyword searches including user ratings or reviews that may not necessarily reflect the accuracy or quality of a given app (Paglialonga et. al., 2018, Stoyanov et. al., 2015). App stores offer more focused searches on health topics, but the trustworthiness of listed apps and ratings is also questionable, as limited disclosure is given as to how apps are screened for safety and effectiveness before inclusion in each store (Gan et. al., 2016). Third party curated web portals such as the free NHS Apps Library, MyHealthApps, AppScript libraries and the subscriber-only Australian Digital Health Guide offer curated lists of mHealth apps which have undergone varying degrees of quality assessment before inclusion in "trusted" lists for prescription by clinicians or for self-prescription by health consumers (Wykes & Schueller, 2019). A gap in current research exists as to the representation of mHealth apps using built-in smartphone sensors for diagnosis or treatment of health conditions available for selection from these third-party curated mHealth app libraries.

1.2 AIMS OF THIS RESEARCH

This doctoral research program explored the emergent field of mHealth with special reference to smartphone mHealth apps using built-in phone sensors. Better understanding of offerings in this field may assist clinicians and health consumers in app selection and adoption, and to identify research gaps amenable to future study. The remainder of this research program concerns development of suitable methodology and evaluation of a novel mHealth app which virtualises a longstanding respiratory therapy using the built-in smartphone microphone for inspiratory sound

detection. Techniques developed for this research may be applicable to evaluation of other emergent mHealth apps.

1.3 RESEARCH QUESTIONS

1. RQ1: What curated information is currently available to inform and guide clinician-initiated prescription and health consumer self-prescription of mHealth apps using built-in sensors for diagnosis or therapy?

2. RQ2: How reliable and clinically valid is the new QUT Inspire virtual ISy app for detection of audible inspiratory sound using the built-in smartphone microphone for sound detection?

3. RQ3: How does the performance of the new app compare with conventional clinical modalities in cohorts of disease-free participants?

1.4 SYNOPSIS OF RESEARCH STUDIES CONDUCTED

This research program consists of three studies, designed to address the aforementioned research questions:

- Study 1 surveys the availability of potentially prescribable mHealth apps using built-in smartphone sensors offered by selected international curated third-party mHealth app libraries, addressing research question 1, namely “What curated information is currently available to inform and guide clinician-initiated prescription and health consumer self-prescription of mHealth apps using built-in sensors for diagnosis or therapy”. This systematic survey offers insight into available contemporary mHealth offerings for clinicians and consumers including any mHealth apps that use the built-in smartphone microphone to virtualise respiratory therapy.

- Study 2 investigates the reliability and clinical validity of a new mHealth app for respiratory therapy (QUT Inspire) using non-human simulation of inspiratory sounds to investigate the influence of simulated mouth diameter (10-25mm) and the distance separating the sound source (i.e., user’s mouth) on the amplitude of

inspiratory sound detected by the QUT Inspire mHealth app. Study 2 contributes information addressing research question 2 (i.e., "How reliable and clinically valid is the new QUT Inspire virtual ISy app for detection of audible inspiratory sound using the built-in smartphone microphone for sound detection?"). This a quantitative acoustic simulation study designed to assert reliability and clinical validity of the new QUT Inspire app without risking harm to human subjects. The methodology developed for Study 2 may also be amenable for use in evaluating other sound-based mHealth apps.

- Further to research question 3 (i.e., How does the performance of the new app compare with conventional clinical modalities in cohorts of disease-free participants?), Study 3 compares the usability of the new QUT Inspire app with a clinical ISy device in a cohort of healthy participants. Multiple dimensions of usability were compared by participants in this study including effectiveness, efficiency and satisfaction. There is potential to use these quantitative and qualitative useability measures for evaluation of other virtualised mHealth apps compared with respective conventional clinical tools.

1.5 THESIS STRUCTURE

This thesis is comprised of seven main chapters. Chapter 1 offers a brief overview of the research area and describes the structure of this thesis document. Chapter 2 presents a narrative review of literature relevant to mHealth using built-in smartphone sensors and an introduction to incentive spirometry as a respiratory therapy technique potentially amenable to virtualisation as a smartphone mHealth app. Chapter 3 outlines the methodology for this research program, including research questions defined for investigation and theoretical frameworks selected to underpin and inform this research. Chapter 4 presents findings from the first study where three international curated mHealth app libraries were surveyed to ascertain availability of mHealth apps using built-in smartphone sensors. Chapter 5 documents the results of the second study which applied simulated inspiratory sounds to assess the reliability and clinical validity of the novel QUT Inspire virtual incentive spirometry app. Chapter 6 presents the results of the third study, a randomised usability study using a cohort of healthy participants (n=24) comparing the QUT inspire app with a clinical incentive

spirometer device. Chapter 7 presents a general discussion of the results, synthesis of the findings and recommendations for future research.

1.6 CONTRIBUTION STATEMENT

Clarence Baxter designed, conducted and analysed all of the research studies presented in this thesis, and wrote the original drafts of each manuscript. Dr Julie-Anne Carroll, Dr Brendan Keogh and Professor Corneel Vandelanotte contributed to study design and participated in review and refinement of all manuscripts prior to submission for publication.

1.7 SIGNIFICANCE OF THIS RESEARCH

This research program contributes original knowledge regarding the modest number of vetted (i.e., trusted) sensor-based mHealth apps offered by curated mHealth app libraries and identified an absence of mHealth apps using built-in microphone sensors offered for respiratory therapy (i.e., ISy). Regarding the new QUT Inspire virtual ISy app, simulated inspiratory sounds were employed to demonstrate the reliability and clinical validity of the new app compared with clinical reference devices. The usability of this new app was compared with a clinical ISy device by a cohort of healthy participants yielding valuable insights regarding user interactions with the app. This research may inform new and emergent mHealth app developments by demonstrating techniques and providing reference data pertinent to mHealth and breath sound detection. Engagement with apps requiring motivation and persistence may benefit from implementing lessons learnt from the usability studies presented here, such as the utility of creating app interface designs which impart a clinical look-and-feel to the app interface and display of responsive animations to engage users.

Chapter 2: Literature review

In the preamble to this narrative review chapter, the emergence and growth in engagement with mobile health apps is framed in the context of rapid change arising from technological development (section 2.1). Smartphones and downloadable mHealth apps are introduced (section 2.2), including taxonomies for describing these apps (section 2.2.1), government policy and regulation (2.2.2), mHealth app prescription (2.2.3), digital disruption and mHealth prescription (2.2.4) and sources of information on mHealth apps (2.2.5). Usability and app interface design are considered in section 2.2.6. A longstanding respiratory technique for preventing respiratory infections and pneumonia called incentive spirometry is then introduced (section 2.3), with potential for virtualisation of this therapy as a smartphone mHealth application using the built-in smartphone for inspiratory breath sound detection. Origins of this therapy are presented (2.3.1) followed by description of available devices for incentive spirometry (2.3.2) and discussion of contention regarding this technique (2.3.3). Breath sound analysis is outlined (2.3.4) prior to introducing the new QUT Inspire virtual incentive spirometry app evaluated in this research program (section 2.4).

2.1 PREAMBLE

A certain impetus pervades uptake and adoption of some seemingly unrelated emergent technologies. While reflecting a zeal to realise and capitalise on benefits arising from new and insightful ideas, a sense of urgency in technology adoption may have counterintuitive consequences or result in unforeseen harm. It has been argued that the 15th century introduction of Gutenberg's movable type printing press not only heralded broader access to print media (and thus knowledge) for the masses, but it also challenged existing power and hierarchy structures which in turn fuelled the Enlightenment (Roth & Bruni, 2021; Topol, 2015). Some identify early examples of "fake news" resulting from Gutenberg's publishing innovation; English pamphleteers were reported to have mass-published "scurrilous" accusations about Marie Antoinette for the purpose of blackmailing King Louis XVI, arguably contributing to violence and death arising from the French Revolution (McKee et. al., 2019).

Revolutions mark milestones in history which are noteworthy for heralding radical changes in established orders. Parallels have been drawn between the transformative effects of Gutenberg's press and contemporary computers, internet connectivity and smartphone technology in the context of health (Benson & Grieve, 2021). Four evolutionary stages have been identified as contributing to the impetus in employing digital technologies for health care (McLuhan, 1962; Roth & Bruni, 2021). In the first stage, knowledge was held in the mind of a clinician and exchanged verbally with patients; an enduring process which is still at the very heart of medical practice. The development of handwritten records that extend spoken engagements with patients beyond the memory of a given clinician constitute a second iterative stage, allowing comparison of notes on a given patient's condition over time in addition to exchange and sharing of health knowledge with other clinicians. The emergence of Gutenberg's press in 1452 reflects a third stage in health information handling, providing a low cost means for wide dissemination of medical knowledge by printing. Finally and most recently, technological developments in electronics arising from the second world war provided a foundation for the current digital revolution, brokering new relationships between health consumers and clinicians and "democratising" medicine in a way not dissimilar to the democratisation of reading afforded to us by Gutenberg's press (Roth & Bruni, 2021).

Quarantine and isolation requirements imposed during the recent SARS-Cov-2 pandemic illustrate how rapidly the digital revolution facilitated rapid adaption to new and unfamiliar circumstances (Jeffrey Reeves et. al., 2021). Once only possible as face to face exchanges, audio-visual telehealth consultations made the very same essential verbal exchanges between clinicians and patients possible at safe distances due to (1) wide availability of devices for patients to connect to telehealth services, (2) availability of Medicare rebates for clinician reimbursement encouraging participation in telehealth and (3) acceptance of this re-brokering of consultations between doctors and patients. Replacement of handwritten records with electronic medical records and prescriptions facilitated timely sharing of health and vaccine history in addition to contactless prescription dispensing (Taylor et. al., 2021). Mass dissemination of public health information such as contact, and exposure information was made accessible to many by means of internet connectivity and smartphone apps. Finally, health consumers were able to independently research and leverage public health

interventions such as vaccinations and check-in history in a manner previously unavailable to individuals before the advent of smartphones and mHealth apps (Garfan et. al. 2021).

Gutenberg's printing press was a platform for change in more ways than one. When considering contemporary emergent technology such as computers, smartphones and the internet, Gillespie posits that platforms may be considered in 4 contexts (Gillespie, 2010). In terms of printing infrastructure pioneered by Gutenberg, (1) computational platforms nowadays represent (competing) technologies such as offset printing versus digital printing. Computational platforms for technologies such as smartphones include competing offerings from Apple IOS and Google Android operating systems. (2) The design (architecture) of these devices extends beyond the phone itself. Competing smartphone offerings use dedicated app store or application store platforms to offer apps for download and update programs (i.e., apps) to extend the functionality of a given smartphone in realms such as health. (3) Figurative platforms imply a foundation or a basis for an action or condition. Smartphone apps which implement behaviour change as part of a broader suite of interventions (e.g. exercise, diet etc) constitute a figurative platform for health improvement. (4) Gutenberg's printing press exerted political forces well beyond it's intended use of producing facsimiles of documents. Similarly, use of smartphone health apps may occur outside longstanding doctor-patient relationships, necessitating a re-brokering of the relationship between these (and other) health care stakeholders (Barta & Kneff, 2016; Ruckstein & Schüll, 2017).

Self-tracking of health parameters became a viable pursuit with the advent of wearable computers and sensors made possible by advances in semi-conductor and integrated circuity and resulting in robust portable devices of small size with modest power consumption requirements (Feng et. al., 2021). In 2007, Wolf and Kelly coined the term "quantified self" to describe "self-knowledge through numbers" afforded by rapidly evolving health technology converging with an emergent audience of willing "quantified selfers" (Barta & Kneff, 2016). Calorie intake, weight loss and running distance were among the pararmeters monitored and shared between ardent followers (Wolf, 2010). Some sought behaviour changes from monitoring health parameters (Maturo, 2015). This technology has been described as acting like an "invisible"

personal drone for curation of a potentially continuous stream of health data on physical activity, mental state and physiology (Dobkin & Dorsch, 2017). Interest in this type of technology burgeoned with the release of smartphones such as the Apple iPhone and phones from competing manufacturers such as Google (Android) from 2007 onwards (Mehra et. al., 2022).

Following the inception of modern smartphones, acceptance of these devices by health consumers far exceeds adoption by clinicians for prescription to patients. Evidence is needed to encourage confidence and greater use of mHealth in traditional patient care, and in investigating the efficacy and safety of apps with special reference to virtualising longstanding clinical instruments as apps. It is in this space that this dissertation resides.

2.2 SMARTPHONES AND mHEALTH

Early smartphone devices such as the 1992 IBM "Simon" Personal Communicator offered "untethered" mobile telephony, including a "smart" suite of modular apps (i.e., applications) extending basic telephone functionality by addition of calendar, diary and drawing apps (Ali et. al., 2016; Reid, 2018). The advent of the Apple iPhone in 2007 and offerings from competing smartphone vendors using the Google Android operating system saw the emergence of platform-specific application stores offering downloadable apps to extend the phone's functionality for a multitude of purposes (Paglialonga et. al., 2018). Three billion people worldwide use these devices, with more than 70% of all mobile phones used in low and middle-income countries (Statista B, 2022, WHO, 2021). Cost and availability remain as barriers to wider adoption of these devices in more impoverished areas, including costs of updating phones to the latest models or acquiring add-on components to extend phone functionality (Bastawrous & Armstrong, 2013; Osei & Mashamba-Thompson, 2021). In the context of mobile device use in Australia, a survey conducted by the Australian Telecommunications and Media Authority (i.e., ACMA) in found that 99% of adult Australians had reported using a mobile phone during the first six months of 2021, and that 94% owned a smartphone (ACMA, 2021 A). Regarding internet connected devices and app use, a more recent survey (following commencement of the COVID19

pandemic) by the ACMA found that almost all Australians (99%) had accessed the internet during the six months up to June 2021, and that during that period Australians each had an average of 4 internet connected devices (ACMA, 2021 B).

2.2.1 TAXONOMIES FOR mHEALTH APPS

An estimated 4.5 million apps are available for smartphone users to download from the Apple App and Android Play stores, with more than one million (22 %) pertaining to health, wellbeing, nutrition and diet (Statista A, 2022). In 2011, the World Health Organisation (WHO) acknowledged growing interest in this field, defining mHealth as "medical and public health practices supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices." (WHO, 2011). While health consumers demonstrate great enthusiasm for self-prescription and self-initiated engagement with mHealth apps, health professionals have been reticent to widely embrace mHealth app prescription for their patients (Byambasuren et. al., 2019; Kao & Leibovitz, 2017). A lack of evidence regarding safety and efficacy, difficulty in identifying suitable candidate apps and "app overload" regarding multiple apps available for some health conditions are all cited as contributing to this reluctance by clinicians to prescribe mHealth (Hempel et. al., 2018; Martin et. al., 2018). The WHO reflected on the state of mHealth research and adoption in 2019, nearly a decade on from acknowledging this field of medical pursuit, cautioning that "rigorous evaluation is necessary to generate evidence regarding benefits" and that reduction in health inequalities are required in the use of digital technologies such as mHealth apps (WHO A, 2019).

Three categories of mHealth apps based on app functionality are identified by the US Food and Drug Administration, namely administrative, health management and medical device applications (Cortez et. al., 2014). mHealth apps may be more simply categorised as either passive or active, based on function, (Herron, 2016). Passive mHealth apps include static health information pages, symptom logs, diaries and calendar reminder systems that involve manual input of data (Stankevich et. al., 2017). In contrast to passive mHealth apps, active mHealth apps use built-in smartphone sensors (*Figure 1*) to generate health data, (e.g. heart rate, oximetry measuring blood oxygen saturation and spirometry for detecting breath) (Herron, 2016). It is in this realm of active mHealth apps that use of built-in smartphone sensors reside (*Figure*

1). Smartphone sensors may be categorised according to the physical property being sensed (e.g. optical sensors for light images or acoustic microphone sensors for sound) (Daponte et. al., 2013). The context in which sensors are employed for detection offers a further simple dichotomy in sensor functionality between those that sense the environment (e.g. microphone, camera, barometer) in contrast to those which measure position (e.g. GPS, gravitometer, accelerometer, proximity sensor, touch screen) (Stankevich et. al., 2012). mHealth apps using built-in phone sensors for diagnosis or treatment of health conditions address a range of health concerns including arthritis, diabetes, sleep conditions, cardiovascular, cerebrovascular, respiratory, neurological and psychological conditions (Anderson & Emmerton, 2016; Majumder & Deen, 2019).

Figure 1: **Built-in smartphone sensors**

(Majumder & Deen, 2019)

Apps are developed as software programs which are designed to operate on particular smartphone operating system platforms, most commonly Apple IOS or Google's Android operating systems. Popular application stores limit app availability to those which are compatible with one operating system or another (Bindhim & Trevena, 2015). Differences between sensor types used in competing popular smartphone brands pose challenges to software developers in situations where one brand or model of smartphone offers (sensor) features unavailable or implemented differently on other phones (Frank, 2013). Apple iOS device manufacture is controlled solely by Apple, with relative homogeneity in hardware components such as sensors

potentially offering app developers more stable or predictable target platforms for app development (Kamel Boulos et. al., 2014). In contrast, Android devices may originate from multiple hardware vendors with disparate hardware components, potentially adding complexity to development of apps catering for a wider range of target device hardware and sensors (Daponte et. al., 2013; Kamel Boulos et. al., 2014). Use of built-in sensors capitalises on components already available in popular smartphones and obviates the need to purchase additional external sensor components which may be costly, potentially incompatible with subsequent smartphone upgrades or result in excessive phone battery consumption (Bastawrous & Armstrong, 2013). Applications for built-in sensors in smart devices evolve as technology improvements yield more reliable and accurate sensors (Daponte et. al., 2013).

2.2.2 POLICY AND REGULATION OF mHEALTH APPS

Government administration of medicines and therapies in Australia is legislated at the commonwealth level by means of Australia's National Medicines Policy (NMP), enacted in 1999 and based on United Nations initiatives for improvement in health by co-ordination of health resources and services (DoH, 2019; WHO B, 2019). This policy mandates the creation and operations of both the Pharmaceutical Benefits Scheme (PBS) for subsidised availability and prescription of medicines and the Therapeutic Goods Administration (TGA) for administering the regulation of medicines, therapeutic goods and medical devices (McEwen, 2007).

The NMP remains unchanged since its adoption in 1999, and does not reference mHealth apps, nor does the Pharmaceutical Benefits Scheme offer subsidised access to mHealth apps; there are calls to update the NMP, and for future revision to encompass emergent mHealth technologies (Shaw & Chisolm, 2019). The National Disability Insurance Scheme (NDIS) offers subsidy for "assistive" apps (NDIS, 2021). The TGA regulates mHealth apps as "software as a medical device" (SaMD), requiring regulatory approval for any app which transforms a device (smartphone, watch etc) such that it functions as a medical device, or when an app offers diagnostic or treatment advice (TGA, 2021). Apps are classified by level of risk from low (class I) to high risk (class III), requiring substantiation of efficacy and safety for TGA approval for use with patients (TGA, 2021).

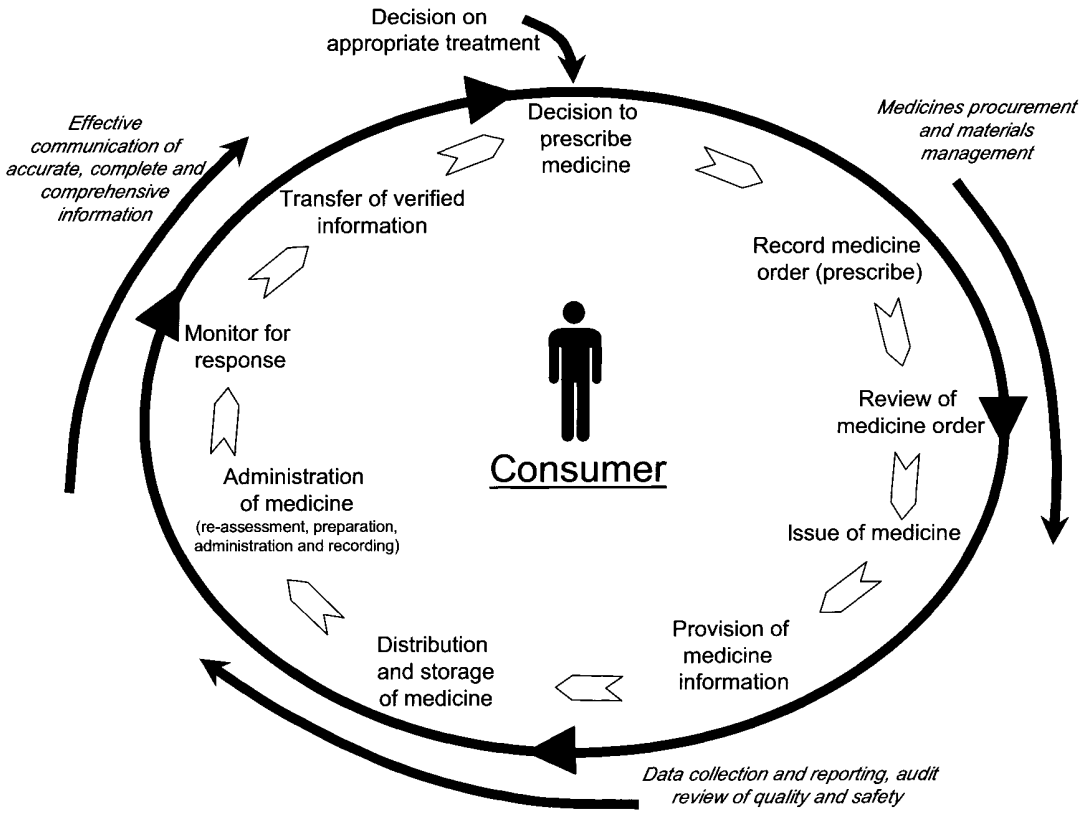
The TGA recently updated its regulatory position regarding SAMD in smart devices (e.g., smart phones, tablets) and computers, namely:

- Where the data collection components (such as sensors) are integrated into a smart device, the smart device is a finished consumer product (e.g. smart phones, tablets and laptops). In this circumstance, the smart device is not required to be included in the Australian Register of Therapeutic Goods (ARTG).
- In order to demonstrate compliance with the essential principles, it is a requirement that the SaMD is validated against the data collection component(s) and/or smart device. The data collection components or smart device must also be validated for the intended use of the SaMD to ensure it is safe and fit for purpose.
- It should be expected that the level of scrutiny applied to such data collection component(s) would be commensurate with the level of risk associated with the intended use. For example, a Class III SaMD which provides a diagnosis of a life-threatening disease or condition should expect a high level of scrutiny applied to the validation of any sensors used to perform its intended use, such as a camera.

In summary, SaMD must be included in the ARTG for supply in Australia, with evidence of validation against the data collection component(s), using applicable state of the art testing; the data collection component(s) themselves are not required to be included in the ARTG if integrated into a finished consumer smart device (TGA, 2021).

'Grey' areas exist in regulations where mHealth apps may utilise sensors in an ancillary role, such that sensor use is not the main function of the app, or the app is branded as "for entertainment or recreation purposes only" to attempt circumventing regulation (Herron, 2016). Examples of this include anxiety management apps that use camera-based heart rate or microphone-based breathing rate monitoring as an adjunct to the main stated purpose of these apps (e.g. anxiety or stress management).

Figure 2: **Medicines prescription and management pathway**



(Stowasser et. al., 2014)

Traditional prescription by health professionals involves diagnosis based on examination and consideration of a patient's history (Stowasser et. al., 2014). While multiple decision management models exist regarding how health professions prescribe, no single model accurately predicts prescription decision-making by clinicians (Ali Murshid & Mohaidin, 2017). Pharmacopeia or prescription guides are published to guide prescription of medication, including indications for use, contraindications and dosing information. Dispensing traditional medication prescriptions (*Figure 2*) involves a trusted source for the treatment, dispensed and verified by a trusted independent third party (i.e., pharmacy). (Stowasser et. al., 2014). No such vetted independent prescription regime exists for mHealth apps.

The Royal Australian College of General Practitioners report that relatively few Australian doctors are formally prescribing mHealth apps to patients, citing a lack of

an evidence base for their use and absence of trustworthy sources for prescribing information. However, weight management, exercise and chronic disease management apps are among those apps where such an evidence base exists (RACGP, 2016). A recent survey of 1014 Australian General Practitioner's found that only 12.7 % of GP recommended apps for patients daily (Byambasuren et. al., 2019). It is not known whether informal suggestion of mHealth app use or a "prescriptive" recommendation to patients to use an mHealth app constitutes such clinician recommendations (Kao & Liebovitz, 2017).

Peer reviewed evidence-based research is a foundational process for asserting safety and efficacy of medicines and medical devices contributing to regulatory approval and guidance for prescription; universities and research institutions play pivotal roles in mHealth app regulation by vetting and ethical selection of suitable candidate mHealth app research programs for approval (Hempel et. al., 2018).

Diagnostic and therapeutic apps are described as inhabiting a "contested and ambiguous site of meaning and practice", lacking in evidence-based guidelines to allow patients to therapeutically manage conditions with mHealth apps respectively (Lupton & Jutel, 2015; Glance, 2014). This whole emergent field has been described as a "wild west" and as a "jungle" (Lobelo et. al., 2016; Rijcken, 2019). Clinicians report that an evidence base must be established to assert the efficacy and safety of mHealth interventions in order for more widespread adoption of these tools to occur (Lobelo et. al., 2016; Rijcken, 2019).

An overview of systematic reviews considered evidence concerning the efficacy of potentially prescribable mHealth apps. Byambasuren et. al. examined 318,000 mHealth apps from contemporary app marketplaces, finding only 23 published randomised controlled trials (RCTs) (Byambasuren et. al, 2018). Only 11 of these apps demonstrated meaningful health effects (Byambasuren et. al, 2018). Use of built-in phone sensors in these apps is not stated in this study. Byambasuren et. al. concluded that the 'prescribability' of health apps is limited by the paucity and quality of evidence regarding benefits of using mHealth, citing small sample size, short duration of RCTs and methodological issues such as inadequacy of blinding and potential for a digital placebo effect as contributing to risks of bias in evaluating mHealth apps

(Byambasuren et. al, 2018). Reviews of consumer mHealth applications for diagnosis and treatment reiterate that lack of evidence as to safety and efficacy present barriers to wider adoption of this technology (Millenson et. al., 2018).

The WHO recently updated recommendations regarding digital health interventions (including mHealth), noting proliferation of short-term interventions in the absence of rigorous evidence gathering, and limited understanding of impacts of mHealth interventions on health systems and people's wellbeing (WHO A, 2019).

2.2.3 PRESCRIPTIONS FOR USE OF mHEALTH APPS

Prescription medicines and medical devices are dispensed with comprehensive instructions including indications and contraindications for use, safety information and manufacturer contact details (Ferguson et. al., 2018). Further, the TGA in Australia regulates the naming of medications to reduce the risk of "Look alike sound alike" errors due to like-sounding names that describe different products (TGA, 2013). "Tall man" lettering is an example of a regulatory requirement where capitalisation of particular letters in a TGA registered medication name is used to differentiate potentially confusing similar medication names to reduce ambiguity or prevent prescription error (TGA, 2013).

No such regulations currently exist concerning naming mHealth apps or presenting prescription information to app users (Albrecht et. al., 2019; Paglialonga et. al., 2018). Descriptive information may be provided by app developers for display in Apple or Google application store listings or presented in text-based or instructional video-based instruction materials embedded in individual apps (Escalada-Hernández et. al., 2019). As apps developed in one country may be available in other international jurisdictions, prescriptions recommended in one country may not be applicable in other countries. Comprehension of prescription instructions by users may be influenced by presentation method and user literacy.

2.2.4 DIGITAL DISRUPTION AND mHEALTH PRESCRIPTION

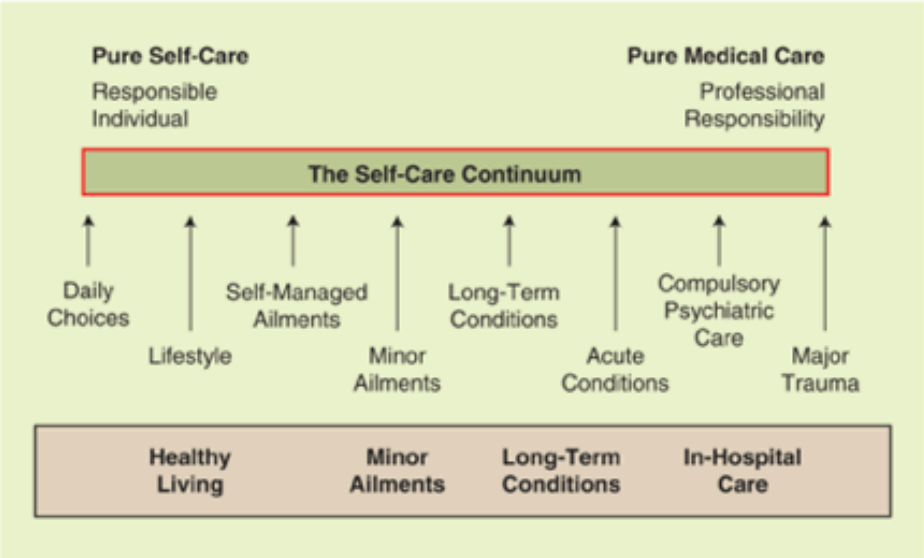
In 1995, Clayton Christensen and Joseph Bower coined the term “Disruptive Technology” (a term later revised as “Disruptive Innovation” by Christensen) to describe creation of new markets in response to novel emergent technologies, based on values which are different to that of existing markets (Bower & Christensen, 1995; Christensen, 2013; Skog et. al., 2018). Innovation is a hallmark of developments in medical technology, with a rich pedigree that long precedes contemporary ”digital disruption” such as that attributable to mobile telephones and related technologies (Garge et. al., 2018). Ubiquity, accessibility and familiarity with smartphone technology, combined with increasing general interest in health and the rising cost of clinician-led health care may all contribute to the emergence of one such new “disrupted” market, namely in the context of mHealth (Garge et. al., 2018). Health consumers may now independently seek out mHealth apps to assist with diagnosis or management of health conditions (IMS, 2015). Smartphone camera apps for wound care and microphone apps for sleep apnoea management are examples of smartphone mHealth apps using built-in sensors where diagnostic or treatment procedures once restricted to the realms of formal medical consultation are now accessible to lay persons for download and “self-prescription”, constituting potential disruption which circumvents traditional clinician-initiated care and supervision (Kao & Liebovitz, 2017).

Rapid uptake of mHealth technology by lay smartphone users is in stark contrast to caution exercised by clinicians before embracing such emergent technology, (Byambasuren et. al., 2019). While some apps may be amenable for prescription by physicians for patients, most are self-selected by smartphone users (Millenson et. al., 2018; Morgan, 2016). Self-initiated prescription of mHealth apps for health conditions in the absence of medical guidance is characterised by some as the “Dr Google” effect, citing potential risks to health (Millenson et. al., 2018). Others cite self-selection of mHealth apps as a “democratisation of information control” (Bull & Ezeanochie, 2016).

Self-care in a healthcare context has been described as the actions taken by people to recognise and manage their own health, be it independently or in partnership with health care systems (Garge et. al., 2018). A Self-care continuum (*Figure 3*) has been proposed, describing a spectrum of health concerns spanning daily life choices

to chronic conditions and an escalated necessity for medical care with increasing severity of given health conditions; a distinction is made between self-care and self-management where the former pertains to acute illnesses or injuries and the latter concerns a wider range of long-term conditions (Garge et. al. 2018).

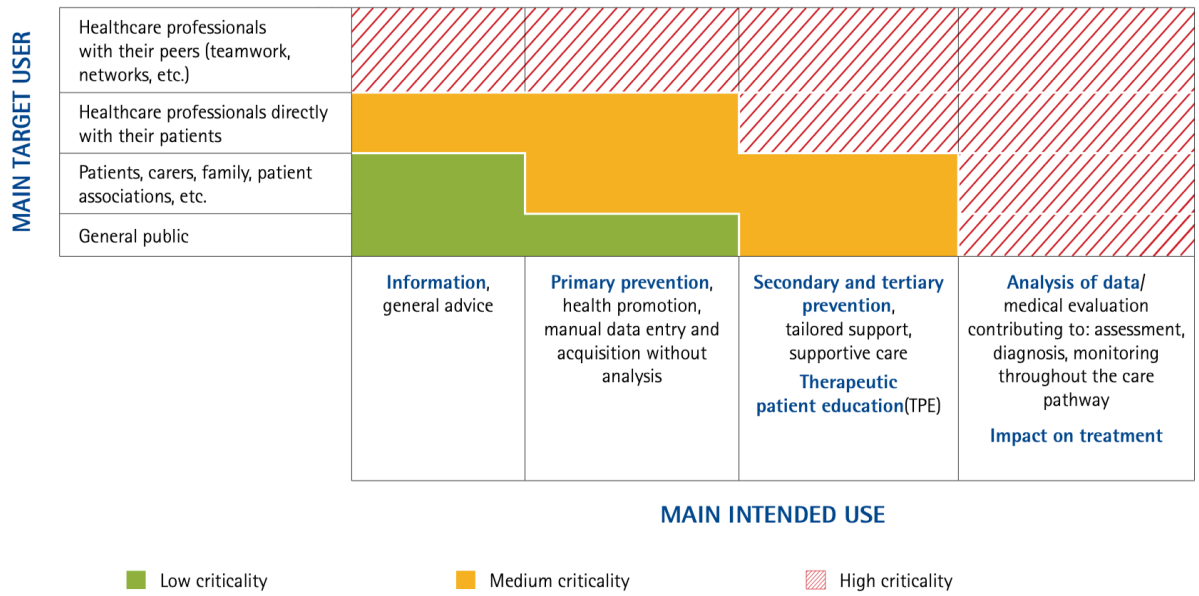
Figure 3: **Self-care/self-management continuum**



(Garge et. al., 2018)

Risks are implicit in using any mHealth app across the spectrum of health app consumers (e.g.. the general public, patients and healthcare professionals). The criticality for mHealth apps to function reliably and correctly has been assessed by the French National Authority for Health (Haute Authorite` de Sante, 2016). The most critical mHealth apps which must function correctly were rated as those relied on to assess, diagnose, monitor or treat health conditions (Haute Authorite` de Sante, 2016). Information and primary prevention apps were rated as being of low relative criticality in contrast to apps used for secondary and tertiary prevention (*Figure 4*). Apps used in the analysis of data by health professionals where potential risks impacts on patient treatment (diagnosis or monitoring thru the care pathway) were rated as of higher criticality (Haute Authorite` de Sante, 2016).

***Figure 4*: Criticality of mHealth apps by intended use**



(Haute Authorite` de Sante, 2016)

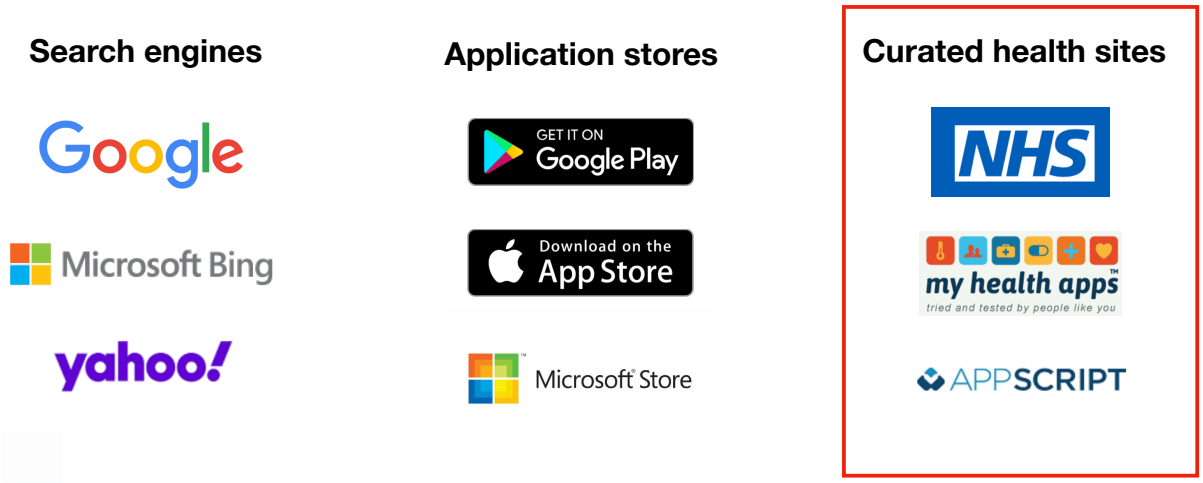
2.2.5 SOURCES OF INFORMATION ON mHEALTH APPS

Searching for apps related to particular health topics or medical concerns pose challenges for health professionals and consumers alike. “App overload” is described as occurring where the sheer volume of available apps of indeterminate quality makes app selection or recommendations difficult (Hempel et. al., 2017). Search engines such as Google and Bing index available apps based on keyword search algorithms, often yielding large volumes of uncurated search results for a given health topic (Gan et. al., 2016; Mandl et. al., 2015; Parker et. al., 2017; Stoyanov et. al., 2015). While Apple and Google application stores categorise submitted apps for more focused searching (e.g. “Health and well-being”), those searches can still return an overwhelming result list of indeterminate quality (Paglialonga et. al., 2018; Gan et. al., 2016). Search engines and application stores display star ratings and reviews to indicate popularity of given apps, but these may not be reliable measures by which listed mHealth apps can be “trusted” (Albrecht et. al., 2019; Torous et. al., 2016; Wicks & Chiauzzi, 2015).

Distinct from application stores such as the Apple App Store and Google Play Store, independent third party mHealth app repositories have emerged, with the intent

of providing curated "trusted" lists of health apps for users to review, and to guide the selection of safe and effective mHealth apps (Jones et. al. 2018; Wykes & Schueller, 2019). Also known as health app clearinghouse websites, these libraries are online portals that do not host apps per se' but offer information and links to a range of vetted apps which have satisfied selection criteria required for inclusion in the respective repository (Yetisen et. al., 2014; Boudreaux et. al., 2014; Haute Autorite de Sante, 2016Rijcken, 2019). Examples of such libraries include the government funded NHS Apps Library in the United Kingdom and two privately funded repositories (*Figure 5*), namely AppScript in the United States and MyHealthApps in Europe/UK (Appscript, 2022; MyHealthApps, 2022; NHS, 2022).

***Figure 5*: Sources of information regarding mHealth apps**



Curation of apps submitted to these libraries consists of varying degrees of scrutiny (Jones et. al. 2018) Submissions to the NHS Apps Library and Appscript repositories require app developers to respond to questions regarding app quality and safety which are evaluated by curators of these libraries using proprietary scoring methodologies, while the MyHealthApps site incorporates reviews from patients (IMS, 2015; Wicks & Chiauzzi, 2015, Ashurst & Jones, 2017). Intended audiences for such curated apps include clinicians (with the intent to prescribe an app for use by a patient) as well as lay persons seeking to self-manage their health. In addition to high level categorical grouping, third-party curated mHealth libraries offer more detailed sub-categories and lists for specific health conditions and medical specialties.

In the absence of a prescribing guide for apps, use of third party mHealth app libraries are advocated by some as an important step in identification and prescription of such apps (Paglialonga et. al., 2018; Rijcken, 2019, Wykes & Schueller, 2019). The range and type of sensor-based mHealth apps offered by third party curated mHealth libraries is not known and needs to be examined.

2.2.6 USABILITY AND APP DESIGN

Modern smartphones are marketed to consumers with inducements including better built-in cameras, improved microphones and other technological innovations designed to compel acquisition of newer, faster (and often more expensive) devices. Factors motivating upgrading to newer devices are complex and include performance, compatibility and price considerations (Mehra et. al., 2022). Expectations of health improvement may fail to be realised if mHealth apps are difficult to use or readings from built-in sensors in old, contemporary or emergent phones are marred due to inability for users to comply with manoeuvres required to operate a given app as intended by developers. Standards developed by the International Organisation for Standardisation (i.e., ISO) exist for guiding application design for usability (ISO 9241-12) and for conducting usability testing for apps (ISO 9241-11) (Geuens et. al., 2016; Maramba et. al., 2019). According to the ISO, usability involves learnability, operability, understandability and attractiveness contributing to the achievement of specified goals with effectiveness, efficiency and satisfaction within a specific context of use (Zapata et. al., 2015). More succinctly, usability describes how users can achieve a particular goal using a technological item (Zapata et. al., 2015). Considering dimensions of usability, effectiveness measures the outcomes of interactions between people and systems (such as mHealth apps), efficiency describes completeness in achievement of goals and satisfaction relates to positive attitudes and comfort when using technology such as mHealth apps (FrØkjaer et. al., 2000).

Questionnaires, interviews and logs (collectively termed empirical user testing) based on impressions from real app users are the most frequently employed means by which mHealth usability is assessed; this is in contrast to technical usability inspection which involves experts and designers (Zapata et. al., 2015). Measures of mHealth app quality such as the Mobile Applications Ratings Scale (MARS) assess aspects of usability in quality dimensions such as ease of use, reliability, quality, scope

of information, and aesthetics (Stoyanov et. al., 2015). The System Usability Scale (SUS) is a longstanding questionnaire-based usability measure, applying ten core questions originally developed to evaluate office equipment; detractors from this simple usability measure claim that the SUS is dated and generalist in nature and fails to address nuances in complex contemporary mHealth apps (Arthurs et. al., 2022; Hamilton et. al., 2021; Neal et. al., 2022). In contrast to measures of usability per se`, the NASA Task Load Index provides insight into perceived workload when a user interacts with a user interface; assessment of workload demand may be best suited to assess changes in interface design or layout (AHRQ, 2022; Sauro, 2019).

Notwithstanding an app possessing all the right content to achieve a certain goal, a poorly designed user interface may render an app unusable (Katusiime & Pinkwart, 2019). mHealth app use may be challenging for persons of certain age groups, literacy levels or in different contexts (Anderson & Emmerton, 2016). Older persons may be less familiar and dexterous with app control and operation, with complex navigation systems posing an additional barrier to app use (Cunha et. al., 2016). Numeracy and literacy may influence comprehension and compliance with screen designs or information flows; use of pictograms over tabular presentation of on-screen data may improve comprehension (Hawley et. al., 2008; Shabir et. al., 2015). Larger phone screen sizes may also improve reading time and ability to recall information (Al Ghamdi et. al., 2016).

In the following sections, focus shifts from description of mHealth apps in general to discussion regarding an established clinical therapy device and potential for virtualising the functions of this instrument as a smartphone mHealth app using built-in smartphone sensors.

2.3 INCENTIVE SPIROMETRY

Incentive spirometry (ISy) is a longstanding respiratory therapy technique which encourages gradual maximal inhalation (Craven et. al., 1974). Purposeful inflation of the lungs over and above normal inhalation is postulated to promote mucus clearance by coughing, reducing respiratory complications during post-surgical recovery and in the management of some chronic respiratory conditions including COPD (Holland &

Button, 2006; Restrepo et. al., 2011; Rodman, 2014). COPD is a progressively debilitating condition which ranks fourth in Australia as the greatest combined cause of death and disability, and sixth as a cause of premature mortality (Institute for Health Metrics and Evaluation, 2022). In COPD and other health contexts, ISy is employed to prevent mucus build-up which can occlude airflow or result in infections such as pneumonia (Craven et. al., 1974).

2.3.1 ORIGINS OF INCENTIVE SPIROMETRY

Ancient Egyptian papyrus dated from 1,554 BC depict vaporisation and inhalation of alkaloids from a plant called black henbane over a fire to treat disease (Sanders, 2007). Populations in South and Central America, China and India also practiced such therapies. European physicians in the seventeenth- and eighteenth-century fashioned inhalers for combustion and delivery of a bewildering array of materials to the lungs by means of inhalation for treatment of respiratory maladies such as cough and asthma (Sanders, 2007). In addition to prescription of substances for inhalation (including opium and tobacco), designs for inhalation therapy devices were also pursued vigorously, particularly given the growing incidence of tuberculosis and resultant lung damage caused by bullous sponge-like lung lesions causing mucus accumulation and infection (Jackson, 2010).

Given widespread popularity of such inhalation therapies in the eighteenth and nineteenth centuries (commonly referred to as Pneumotherapy), it is no accident that a physician called Francis Ramadge directed his attention to the design and dimensions of tubes for inhalation therapy (Murnane et. al., 2017. In 1834, Ramadge pioneered the first successful medical treatment for pneumothorax (i.e., air entrapped in the chest cavity resulting in partial or full deflation of the lungs). His contribution to inhalation therapy follows on from this pedigree in respiratory medicine, with development of inhalation pipes for combustion of tar and other substances which imposed inspiratory back pressure on patients with consumption (i.e., tuberculosis) while they used his inhalation device (Murnane et. al., 2017). These “Ramadge tubes” were described as being up to six feet long, with an internal diameter no greater than the one-sixth the diameter of a human airway (Murnane et. al., 2017).

In 1915, a British surgeon called John MacMahon was caring for World War One troops who were convalescing following surgery. MacMahon reported decreased post-surgical morbidity and mortality in convalescing troops when regular breathing exercises were incorporated as part of their recovery (MacMahon, 1915). Surgical techniques and methods for anaesthesia were improved over the ensuing decades, but morbidity and mortality remained a risk arising during recovery from surgery due to respiratory complications following surgical anaesthesia and convalescence (e.g. alveolar atelectasis or alveolar collapse) (Craven et. al., 1974; Randtke et. al., 2015).

Responding to the risks arising from post-surgical complications at the time, a device designed to "re-inflate" collapsed alveoli was developed by Bartlett and Edwards in the early 1970s. Called an incentive spirometer, the device was designed to encourage repeated inspiratory efforts mimicking inspiratory inflows akin to sighing or yawning (Bartlett et.al., 1970; Narayan et. al., 2016). It was postulated that such inspiratory manoeuvres might create negative intrathoracic pressure sufficient to "re-inflate" collapsed alveoli and dislodge mucus from the airways for expulsion by coughing (Bartlett et. al., 1973). Bartlett is said to have quipped that the device was a bedside reminder to convalescing patients to breathe deeply to avoid respiratory complications (Craven et. al., 1974)

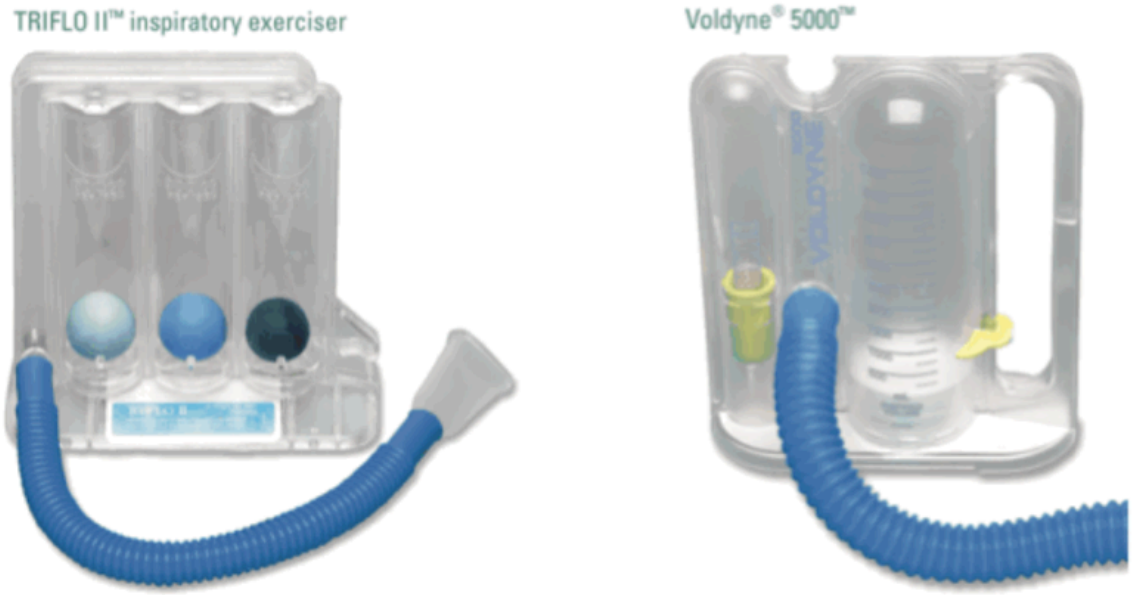
2.3.2 TYPES OF CLINICAL INCENTIVE SPIROMETER DEVICES

Bartlett and Edward's original incentive spirometer design consisted of a piston encased in a cylinder attached to a breathing hose. As the patient inhaled using the breathing hose, a rod would rise at the top of the device as the embedded piston rose in respond to a vacuum created by the patient's inspiratory effort. A single light activated to indicate that sufficient inspiratory flow had been achieved (Craven et. al., 1974). Later iterations of this device replaced displacement of a piston with an array of LED lights in a more compact case, with lights activating when inspiratory flow was detected by a flow meter coupled to the device (Frea, 2012). Two types of ISy device are in common clinical use today (*Figure 6*). Flow-based ISy devices today (e.g. Triflo II incentive spirometer) use balls encased in a clear plastic case to display inspiratory airflow rate. Vertical deflection of these spheres triggered by inspiration using an attached breathing tube equates to a calibrated flow rate, for example 600, 900 or 1200 cc/sec (Loh et. al., 2005). Volume-based ISy devices (e.g. Voldyne 2500 or

5000) deflect a single piston in response to an inspiration, with a graduated scale embedded in the device's clear plastic case to indicate the inspiratory volume achieved for a given inhalation attempt. An additional small flow meter is embedded in the volume-based device to check for adequate inspiratory flow rate.

Age, height and body mass index have been identified as predictors for inspiratory capacity and flow; inspiratory capacity for normal adults and children is of the order of 2 - 3 litres in adults and 0.6 - 2 litres in children (depending on the child's age) (Tantucci et. al., 2006; Robert et. al., 2008).

***Figure 6*: Types of clinical incentive spirometer devices**



(Teleflex, 2018)

Recumbent positions have been found to reduce pulmonary volumes, including inspiratory capacity (Naitoh et., al., 2014). Contemporary 'prescriptions' for post-surgical and chronic care incentive spirometry commonly involve ten repetitions of slow gradual maximal inhalations, with a 3 to 5 second breath hold at maximal inspiration. This regimen is repeated hourly (Armstrong, 2017; Eltorai et. al. A, 2018; Heydari et. al, 2015; Narayanan et. al., 2016; Queensland Health, 2021). Incentive spirometry is contraindicated where deep breathing may cause pain to a patient, or

where there maybe pre-existing lung hyperinflation (e.g. asthma) (Restrepo et. al., 2011).

2.3.3 CONTENTION REGARDING EFFICACY OF INCENTIVE SPIROMETRY

Post-operative pulmonary complications in a range of cardiac, thoracic and abdominal surgeries have been reviewed, to assess the efficacy of ISy in preventing complications. One such review found that physiotherapy and respiratory therapy techniques such as intermittent positive pressure breathing devices were as effective as ISy in minimising complications (Overend et. al., 2001). Methodological flaws in available studies were found to significantly reduce the range of studies considered as eligible for the review. Another review cited lack of standardisation in ISy practice as problematic in assessing efficacy in patients post-surgery (Carvalho et. al., 2011). A systematic review of ISy for the prevention of post-operative pulmonary complications in abdominal surgery found low quality evidence of the lack of effectiveness of ISy in preventing complications post-surgery, compared with physiotherapy (Do Nascimento et. al., 2014). Poor methodological quality was also cited in this review, with inadequate data on compliance with therapy grossly reducing the sample pool of studies available for review (Do Nascimento et. al., 2014). Notwithstanding conflicting results in reviews of studies conducted (Cattano et. al, 2010; Katsura et. al., 2015; Marques & Faria, 2009; Neto et. al., 2017), ISy remains widely used in clinical settings (Carvalho et. al., 2011, Eltorai et.al. B, 2018; Eltorai et.al. C, 2018; Rodman, 2014).

A potential role for incentive spirometry has recently been identified in pulmonary rehabilitation following acute respiratory distress syndrome (i.e., ARDS) related to COVID-19 infection (Navas-Blanco & Dudaryk,2020; Sheth et. al., 2021; Wang et. al, 2020; Seyller et. al., 2021).

2.3.4 ACOUSTICS AND DETECTION OF INSPIRATORY BREATH SOUNDS

Inhalation sounds are a mixture of both respiratory sounds and sounds created from turbulence as air enters the mouth, and a relationship between the volume of respiratory sounds and airflow has been established (Holmes et. al., 2013). Smartphone microphone detection of breath sounds has been demonstrated in the context of peak expiratory flow (PEF) measurement using a calibrated mouthpiece and used to quantitate airflow reduction with maximal expiration for asthma monitoring

(Nam et. al., 2016; Natarajan et. al., 2014). Early works in this field employed tracheal and chest microphones to detect breath sounds (Holmes et. al., 2013; Reyes et. al., 2014; Roche & Dekhuijzen, 2016). Inspiratory breath sound detection has been used in smartphone app to coach optimal metered aerosol inhalation technique for delivery of respiratory medication (Zubaydi et. al., 2020).

Two types of smartphone apps implementing sound-based breath detection are found in the literature. Meter-type apps detect breath flow and display a reading or graphic display. Several strategies have been implemented in these apps to minimise spurious background or environment sounds triggering aberrant sound measurements. Spacer devices act to constrain, direct and focus respiratory sound for detection by smartphone microphones (Larson et. al., 2013) Vortex whistles transform respiratory air flows into higher pitched sound proportional to the flow rate applied (Michelson, 1955). Calibrated whistles have been applied in apps for asthma monitoring and for management of chronic lung conditions (Kaiser et. al., 2016). Signal post-processing of detected sound is also employed in some apps to filter extraneous noise (Andrès et. al., 2018). In contrast to meter-style apps, game-based apps use detected breath sounds to control game play in the context of goal-oriented sequences (Chacon et. al., 2016; Laamarti et. al., 2014; Mazzoleni et. al., 2014). The latter have been termed “therapeutic exergames”, in that motivation to persist with, and repeat (breath) behaviours is consolidated by the game play itself (Pirovano et. al., 2016).

Acoustic calibration of flow rate readings for devices with microphones has been performed using recordings of breath sounds (Holmes et. al., 2013; Larson et. al, 2012; Seheult et. al., 2014). Assessment of the efficacy of medication delivery via a dosed inhaler device has also been assessed using breath sounds detected by a phone-coupled microphone (Seheult et. al., 2014). Timings of breath components may be extrapolated from such analysis and used to access adequacy of inhalation in the context of medication delivery. Modern smart phone microphones are engineered with voice control in mind, and this may impact on sound processing algorithms. Apple phones are reported to use selective filtering of low frequency sound to optimise voice detection (Brown & Evans, 2011; Danaher et. al., 2015); this may contribute to differences in microphone performance between Apple and Android phones.

2.4 THE QUT INSPIRE VIRTUAL INCENTIVE SPIROMETER APP

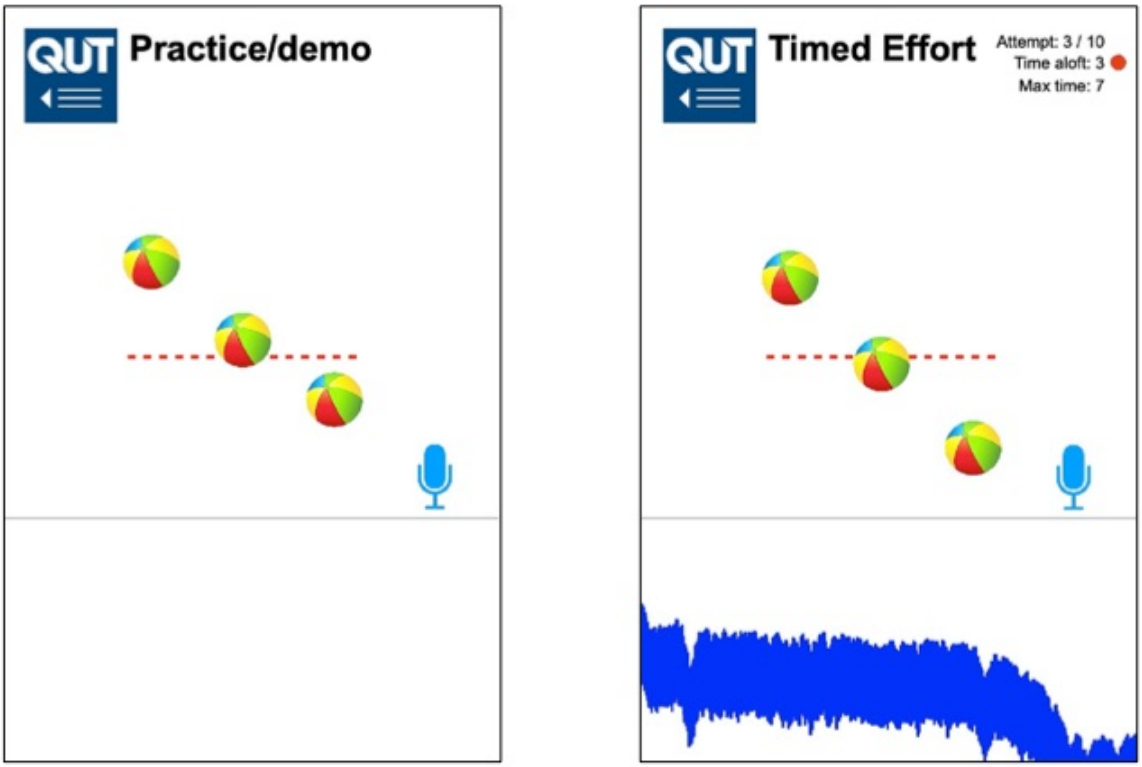
In 2018, the author of this thesis evaluated the performance of a prototype smartphone microphone app called QUT Inspire as part of a Master of Public Health dissertation (Baxter, 2018). The performance of this app was evaluated using audio samples of mechanically simulated inspirations and found to be comparable to a flow-based incentive spirometer device (Baxter, 2018). Impressions regarding the app were sought from healthy users (n=19) who used the app to perform several non-maximal inhalations; animated and responsive display layouts were preferred by users to depict inhalation effort (Baxter, 2018).

The QUT Inspire app is a cross-platform HTML 5 app compatible with popular internet browsers (e.g. Chrome, Firefox and Safari) running on Apple IOS and Android smartphones and tablet devices (*Figure 7*). It was developed using Construct 3 (www.scirra.com), a 2D platform gaming integrated development environment. Apps developed using Construct can be deployed as native IOS or Android apps (using Apache Cordova) or can be deployed on a web server and executed as a HTML 5 apps for use with smartphone browsers.

Clinical incentive spirometers display a graphic incentive to motivate patients to persist with slow gradual maximal inspiration for therapeutic benefit. Early designs used a levitating mechanical piston to indicate effort. Later models used arrays of LED lights to provide feedback on inspiratory effort, with more recent incarnations of this device using encased spheres or a piston to display inspiratory flow or volume inspired respectively. The new QUT Inspire app detects inspiratory sound using the built-in smartphone microphone as an uncalibrated pressure sensor. The app implements a skeuomorphic design to “virtualise” levitating spheres akin to that of a traditional clinical flow based ISy device. The app detects the presence of sustained inspiratory sound. As flow rates are not measured, representation of volume-based incentive spirometry is not feasible using this new app. As the user holds their phone close to their mouth while inspiring, the top two-thirds of the screen is dedicated to displaying animation activity. The lower third of the screen displays a frequency histogram of the sound detected, but in practice may be considered as dead space during use of the app as it is too close to focus on.

A practice/demo mode of operation is offered to practice reducing mouth shape (diameter) to generate audible inspiratory noise for detection (akin to pursing ones lips to whistle and inspiring). Home or hospital wards where this app may be used can be noisy environments. The effect of background or extraneous sounds can be damped to prevent spurious triggering with a sliding control displayed when the blue microphone icon is tapped. By default, a threshold sound level of 50 dB A is required to start elevating the spheres, and the animation is sustained only while continuous sound above this threshold is detected. In addition to a practice mode, QUT Inspire offers a timed mode, where the duration of each inspiration is timed, and a count of breaths attempted is displayed.

Figure 7: **QUT Inspire virtual incentive spirometer app**



Performance evaluation of the original QUT Inspire prototype app was conducted using audio samples of mechanically simulated (non-human) inhalations at 4 flow rates, using a peak inspiratory flow meter (designed for asthma medication inhaler training and possessing limited accuracy) to quantitate inspiratory airflows. The next

stage in investigation of this app required more accurate comparison of its performance with that of a clinical incentive spirometer device when used by healthy participants. Addition of gamification elements to the app may improve motivation to comply and persist with repeated gradual maximal inhalations using the app. There is potential for this app to be used in prevention of respiratory complications due to mucus build up in the airways, potentially saving the cost of a clinical incentive spirometer device and making this type of respiratory therapy more widely accessible.

2.5 SUMMARY AND IMPLICATIONS

In less than fifteen years since the inception of modern smartphones (as heralded by the earliest iteration of the Apple iPhone in 2007), smartphone users worldwide are now counted in their billions. Millions of downloadable apps are offered by Apple and Google application stores, giving this multitude of smartphone users unfettered access to a myriad of apps for a variety of purposes. Smartphone ownership, familiarity with app technology and app availability have all grown at a phenomenal pace. Popularity of apps concerning health have also flourished, coinciding with growing interest in health and wellbeing, and greater accessibility of online (generalist) health information to health consumers.

In 2011, the WHO acknowledged the emergent field of mHealth as medical and public health practice using devices such as smartphones, lauding health improvement and reduction in health inequality that might be realised with implementation of apps addressing health concerns (WHO, 2011). The WHO took stock in 2019 and reflected on a decade's progress in this field, concluding that a lack of evidence regarding the safety and efficacy of many mHealth app initiatives presented risks to realising potential health benefits arising from this smartphone "revolution" (WHO A, 2019).

Digital disruption is acknowledged as presenting challenges and inducing changes to traditional systems as a consequence of emergent technologies, with creation of new markets with values different to existing ones (Bower & Christensen, 1995). With mHealth, clinicians are presented with opportunities to prescribe and deliver health care to their patients in new and innovative ways, with potential to reduce

direct health care costs of medical equipment, realise savings by reducing morbidity arising from health conditions and to reduce health inequality by improving access to tools for health improvement in some socioeconomic contexts. Peer-reviewed evidence and clinical experience are the foundations upon which health professional make decisions to prescribe medicines and treatments for patients. A lack of such evidence (as identified by the WHO) is cited by clinicians as a barrier to capitalising on this opportunity.

In contrast, health consumers have embraced emergent and previously unheralded access to mHealth apps, often self-prescribing use of apps in the absence of medical advice. This has been termed by some as a democratisation of information control, potentially disrupting traditional doctor patient relationships (Bull & Ezeanochie, 2016). Given growing interest in health and well-being, many adopters of mHealth embrace the technology with zeal (Bull & Ezeanochie, 2016). Other users may be unwilling or financially unable to engage with or capitalise on re-brokered clinician-patient health care relationships afforded by mHealth (Turrell & Mathers, 2000).

Clinicians and health consumers alike are “overloaded” with a large volume of mHealth apps to choose from. Searching for apps using search engines and app stores may yield many results, but app listings and recommendations may be of indeterminate quality. Curated third-party mHealth app libraries offer “trusted” lists of mHealth apps for selection which have been vetted before inclusion. No data currently exists as to the nature and availability of mHealth apps using built-in smartphone sensors offered by these curated libraries. Fostering growth in clinician-initiated prescription of mHealth is contingent on development and evaluation of new apps, such that they meet both government and regulatory requirements, in addition to satisfying quality criteria for inclusion in, and are accessible to clinicians and health consumers alike from trusted repositories such as curated mHealth app libraries.

An example of a therapeutic mHealth app using built-in smartphone sensors is considered in this review. QUT Inspire uses the smartphone microphone to detect breath sounds and displays inspiratory effort. Quantitative validation of app performance and qualitative assessment of usability both contribute evidence

regarding the suitability of the app for use. Usability, or the ability to complete app-related tasks with ease is a design consideration equal in importance to technical accuracy, as it may determine a health consumer's willingness or ability to use an app successfully to improve their health. A common catch cry heard frequently today is that "there is an app for that", but is that app safe and is it suitable for its intended use?

Chapter 3: Methodology

In this methodology chapter, two theoretical frameworks informing the design of this research program are introduced (section 3.1). Research gaps identified in the preceding narrative literature review chapter are then summarised (section 3.2) prior to presentation of an overview of this research program, including links between the research studies conducted and underlying research questions (section 3.3). Sections 3.3.1 – 3.3.3 provide detailed descriptions of the constituent studies in this doctoral research program.

3.1 THEORETICAL FRAMEWORKS GUIDING THIS RESEARCH

Likened to the "blueprints" defining a building project, theoretical frameworks provide structure and order to guide research using an established coherent explanation of certain phenomena and relationships (Grant & Osanloo, 2015). Theoretical frameworks assist in definition of problems and research questions and selection of feasible approaches to answer those questions (Ledermann & Ledermann, 2015).

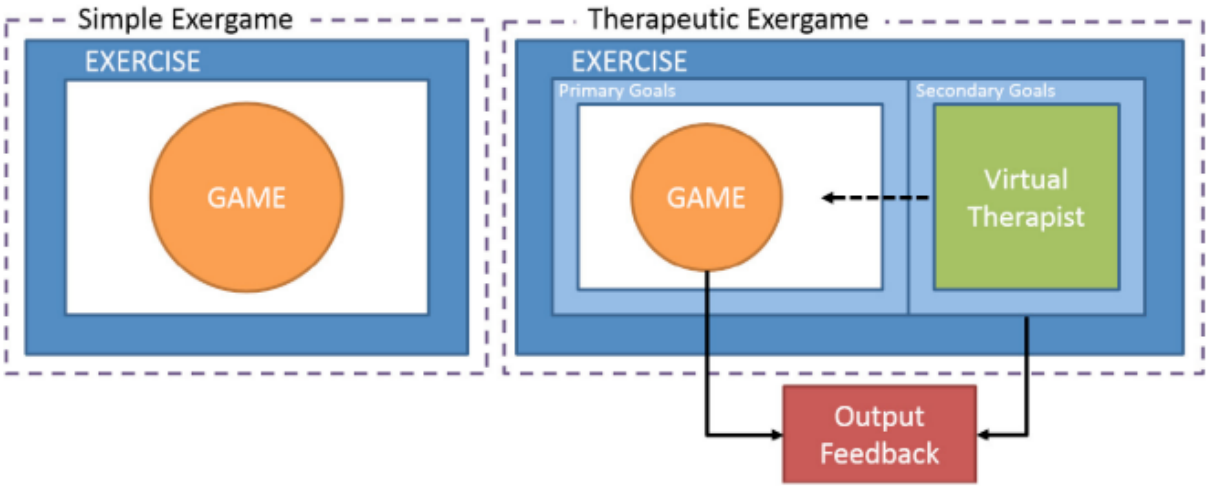
Contemporary mHealth app developments have been criticised for failure to incorporate theoretical frameworks when designing apps to motivate users and to improve app usability (Bull & Ezeanochie, 2016; Vollmer Dahlke et. al., 2015). Many theoretical models have been proposed to underpin mHealth app developments, particular where motivation is a requisite feature for a new app or where behaviour change is the desired outcome (Cho, 2016). The Technology Acceptance Model (TAM), Health Information Technology Acceptance Model (HITAM) and Unified Theory of Acceptance and Use of Technology Model (UTAUT) describe technological acceptance factors such as perceived usefulness, ease of use and intent to use as driving considerations for uptake and continued use of mHealth apps (Anderson et. al., 2016). In contrast, Self Determination theory identifies intrinsic motivations over extrinsic factors in soliciting enduring motivation and change, particularly where extrinsic motivations such as the necessity to engage with an app may thwart autonomy perceived by an app user (Johnson et. al., 2016). Some mHealth app developers have adopted an alternative strategy, mapping individual mHealth app

features and goals to subsets, discrete attributes or an amalgam of one or more theoretical models to suit requirements for a given app using dyadic lenses of motivational design (Geuens et. al., 2016). Apps have been developed to navigate selection of theoretical models for mHealth app design based on desired structural or functional app attributes or vice versa where requisite app attributes list potentially applicable theoretical models (www.lensesofmotivationaldesign.com) (Geuens et. al., 2016.

3.1.1 THERAPEUTIC EXERGAMING

Gamification is described as the use of game elements in a non-game context and can be a "motivational affordance" built into an app to encourage persistence in app use (Deterding et. al., 2011). The term "Exergame" has been coined to describe an exercise that has a game built into its structure (*Figure 8*) (Pirovano et. al., 2016). Exergames are a subset of "serious games" or games with a purpose, distinguishing their intent as distinct from pure recreational gaming (Deterding et. al., 2011). Therapeutic exergames have been defined as those which support all primary (therapeutic) and secondary goals (e.g. compliance, technique) defined for an exercise (Pirovano et. al., 2016). A spirometry app displaying motivational animations, timings, scores or progressive goals or objectives is an example of a therapeutic exergame.

***Figure 8*: Therapeutic exergaming**



(Pirovano et. al., 2016)

In applying a therapeutic exergaming framework to development of a new app, the following require consideration:

- Exercise definition - primary goal of ISy are repeated gradual maximal inspirations to encourage mucus dislodgement and clearance by coughing

- Defining the primary goal of virtual exercise to address primary goal - elevate the spheres in response to inspiration

- Design of exergame - clear display of primary goal

- Handling secondary goals - Additional game components such as a timer for duration of each inspiration and an attempt counter are adjuncts that support the primary goal

(Pirovano et. al., 2016)

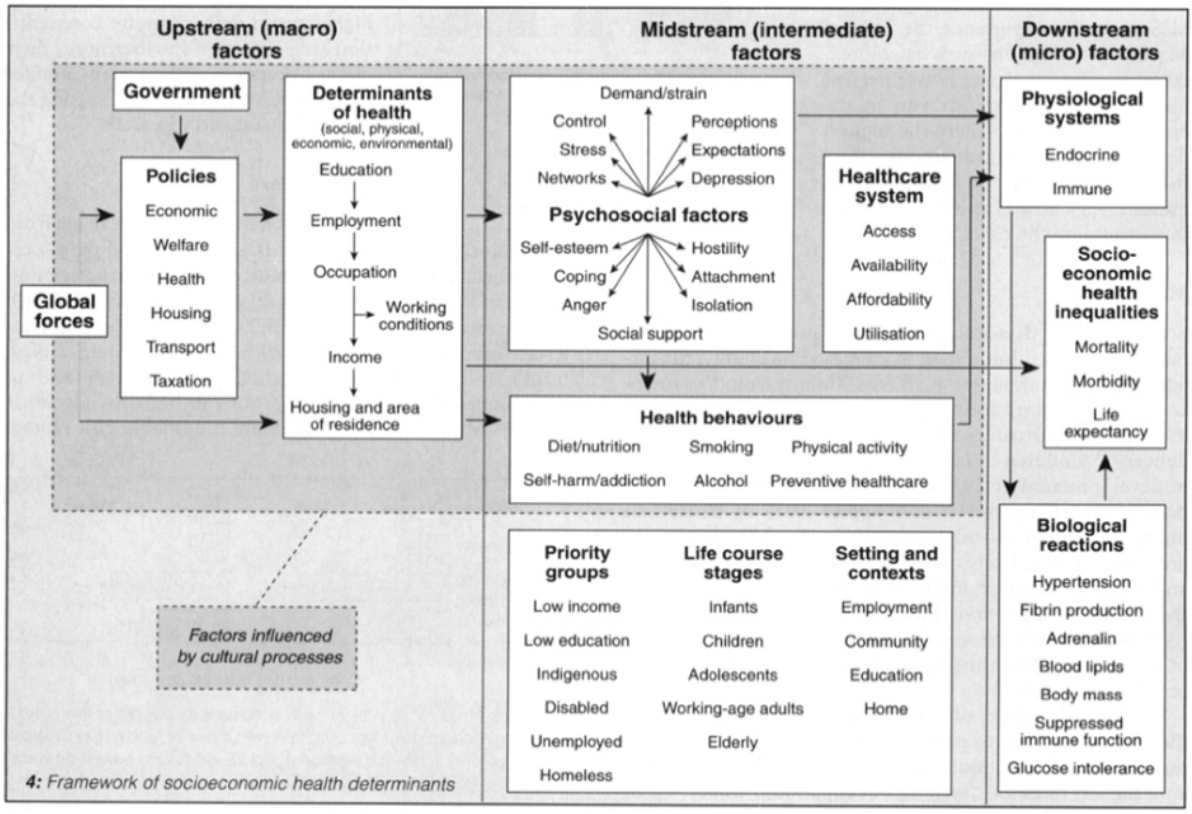
In this research program, ISy devices (physical or virtual ISy) are designed with a primary motivational goal (i.e., elevation of spheres) and a secondary underlying therapy goal (i.e., promoting repeated gradual maximal inspirations) to promote mucus clearance from airways.

3.1.2 SOCIOECONOMIC STATUS AND HEALTH

Socioeconomic factors influence health improvement and health outcomes based on broader societal influences. Concerning mHealth, the ability to afford a smartphone device or have access to the internet to download apps may depend on government policy, geographic constraints, income levels or education. A model for socioeconomic status and health (*Figure 9*) proposed by Turrell and Mathers describes “big picture” societal and government influences as “upstream factors” that may be expressed as positive or negative “downstream” health outcomes (Turrell & Mathers, 2000). In this model, mortality, morbidity or life expectancy may also be influenced by “midstream” factors such as health and psychosocial behaviours, life course (e.g. age) or living contexts.

Insufficient income to afford a smartphone, lack of familiarity of confidence regarding use of this type of technology arising from limited education or old age may present barriers to some realising health benefits from use of smartphone mHealth apps for health improvement. (Bauer et. al., 2014; Carroll et. al., 2017; Joe & Demiris, 2013). Availability of apps on competing smartphone platforms is a further example whereby some health consumers may be disadvantaged if compatible apps are not available for cheaper phones (Kao & Liebovitz, 2017; Lechner & Strahonja, 2017).

***Figure 9*: Socioeconomic status and health**



4: Framework of socioeconomic health determinants

(Turrell and Mathers,2000)

3.2 RESEARCH GAPS IDENTIFIED

In the preceding chapter, mHealth was introduced as an emergent health discipline, with detailed consideration given to apps using built-in phone sensors for diagnosis and treatment. Little published evidence exists regarding the availability of sensor-based mHealth apps for prescription by clinicians or self-prescription by health consumers (Heron, 2016, Paglialonga et. al., 2018). In contrast to the vast selection of unverified (i.e., untested) app offerings available for download for smartphones, estimates based on surveys of app stores or published systematic reviews suggest that only a modest number of potentially prescribable apps exist (Byambasuren et. al., 2018, Gan et. al., 2016).

A longstanding respiratory therapy technique called Incentive spirometry was then outlined. A new incentive spirometry app developed for this research (QUT Inspire) was described. While some prior studies describe detection of breath sounds using the smartphone microphone for quantitation of respiratory airflows using mouthpieces or other spacer devices, no published research could be found regarding virtualisation of incentive spirometry as a smartphone app using the built-in microphone sensor without any spacers or mouthpieces to detect inspiratory breath sounds (Kaiser et. al., 2016; Larson et. al, 2013).

3.3 OVERVIEW OF THE RESEARCH PROGRAM

This research program explored smartphone mHealth apps using built-in sensors for diagnosis or treatment, with particular reference to a new mHealth app for respiratory therapy using built-in phone microphones for inspiratory sound detection. Conducted in three stages, this research is presented as a thesis by publication.

Table 1: ***Overview of the research program***

Study 1 Chapter 4	**Objective:** Conduct a systematic survey of mHealth apps using built-in sensors available from curated international third-party health app libraries **Design:** Systematic survey **Mapped to:** RQ1: Research question 1 **RQ1:** What curated information is currently available to inform and guide clinician-initiated prescription and health consumer self-prescription of mHealth apps using built-in sensors for diagnosis or therapy?
	Citation Baxter, C., Carroll, J.-A., Keogh, B., & Vandelanotte, C. (2020). Assessment of mobile health apps using built-In smartphone sensors for diagnosis and treatment: systematic survey of apps listed in international curated health app libraries. *JMIR mHealth and uHealth*, *8*(2), e16741. https://eprints.qut.edu.au/137019/
Study 2 Chapter 5	**Objective:** Evaluate the reliability and clinical validity of the new QUT Inspire app using simulated inspiration sounds (Calibration study) **Design:** Quantitative study - using calibrated simulated inspirations **Mapped to:RQ2:** Research question 2 **RQ2:** How reliable and clinically valid is the new QUT Inspire virtual ISy app for detection of audible inspiratory sound using the built-in smartphone microphone for sound detection?
	Citation Baxter, C., Carroll, J.-A., Keogh, B., & Vandelanotte, C. (2021). Seeking Inspiration: examining the validity and reliability of a new smartphone respiratory therapy exergame app. *Sensors (Basel)*, *21*(19), 6472. https://eprints.qut.edu.au/213592/

Study 3 Chapter 6	**Objective:** Compare the usability the QUT Inspire app with a conventional ISy device in cohort of healthy participants **Design:** Mixed methods - randomised usability study **Mapped to:** RQ3: Research question 3 **RQ3:** How does the performance of the new app compare with conventional clinical modalities in cohorts of disease-free participants?
	Citation Baxter, C., Carroll, J.-A., Keogh, B., & Vandelanotte, C. (2022). Virtual respiratory therapy delivered through a smartphone app: a mixed methods randomised usability study. *BMJ Open Respiratory Research*, *9*(1), e001221. https://eprints.qut.edu.au/232718/

3.3.1 STUDY 1: SYSTEMATIC SURVEY OF mHEALTH APPS USING SENSORS

Clinicians report that a paucity of information regarding safe, effective and trustworthy mHealth apps is a barrier to wider prescription of mHealth apps to patients. Third-party mHealth app libraries offer recommendations regarding vetted or screened apps, acting as “sources of truth” to inform selection and prescription of quality mHealth apps. A gap in the literature exists regarding the representation of built-in smartphone sensors in mHealth apps offered by these “trusted” libraries for clinician-initiated prescription to patients or selection and self-prescription by health consumers.

Before embarking on evaluations focusing on a new respiratory mHealth app in this research program, contemporary mHealth app offerings in this field were surveyed to better understand the number of available apps using built-in smartphone sensors offered by curated mHealth app libraries (i.e., diagnostic or therapeutic). Findings arising from this survey provide insights into the availability of curated apps described in research question 1 (see 1.6.1 Research Question 1) and inform the scope and design of subsequent studies in this research program.

In Study 1, a selection of popular international third-party mHealth app libraries were identified based on usage (e.g. NHS Apps Library, AppScript, MyHealthApps). These libraries were selected as examples of government-funded (NHS Apps Library) and privately funded curated mHealth app repositories (AppScript and MyHealthApps). The latter two privately funded libraries differ in that MyHealthApps incorporates patient reviews in the curation process, whereas AppScript uses a proprietary scoring process.

Apps using external or add-on sensors and non-smartphone wearable device apps were excluded from this survey; external components may impose additional cost, complexity, or excessive battery consumption and may potentially reduce availability or accessibility to smartphone mHealth users. Exercise, general activity, and accessibility apps were also excluded, as only apps used in diagnosis or treatment of specific health conditions were in scope of this survey. For each library, the number and type of smartphone mHealth apps using built-in sensors offered for diagnosis or treatment of health conditions were documented. Cross-platform app compatibility, types of built-in smartphone sensor used, and the range of health conditions addressed by apps recommended by these libraries were also noted for each curated app library examined. All apps addressing health conditions using built-in mobile phone sensors to generate health data were identified using the publicly accessible search interfaces offered by each repository. As no search criteria were offered by these sites for filtering and identifying sensor-based apps, manual screening of the descriptions of all individual apps listed by each website was performed to confirm use of built-in mobile phone sensors.

Curated library descriptions for identified apps were inspected to categorize the purpose of the app as solely diagnostic, therapeutic, or a combination of both. Diagnostic apps were defined as those that identify the nature of a health condition, in contrast to treatment apps offering features for health condition management. Health conditions addressed by included apps were classified based on the description provided by each repository.

3.3.2 STUDY 2: EVALUATION OF THE QUT INSPIRE APP - CALIBRATION

QUT Inspire is a virtualised incentive spirometer app which detects inhalation sounds using the phone microphone, displaying a graphical animation depicting inhalation effort while inspiration is sustained. Incentive spirometry is a respiratory therapy technique used in post-surgical recovery and some chronic respiratory conditions to prevent complications such as pneumonia by dislodging mucus from the lungs for expulsion by coughing (Graybill et. al., 2012). Previously developed as a prototype for this author's Master of Public Health dissertation in 2018, the QUT Inspire app was redeveloped to incorporate user impressions gained from that earlier study.

As a precursor to clinical testing of a new mHealth app such as QUT Inspire, demonstration of robust and reliable app performance warrants preliminary non-human simulation as it is nether ethical, feasible nor safe to ask people to supply literally dozens of reproducible inspirations for calibration testing. Modelling the influence of distance from the phone microphone on detected sound levels and assessing the influence of mouth diameter on attenuating inspiratory sound further contributed to the need for considerable volumes of data to assess the reliability and clinical validity of the new app and making human testing unviable to achieve this. Cross-platform testing of the new app on both Apple and Android smartphone was incorporated into the study design to assert compatibility with commonly used smartphones devices, and to demonstrate scope for broader adoption of this virtual therapy.

Performance of the redeveloped QUT Inspire app was evaluated in Study 2 in this research program using audio samples (loops) of mechanically simulated inhalations generated by a 3-litre calibration syringe (See 1.6.2 Research Question 1.6.2). Testing of the app was conducted at increasing distances between microphone and sound source and using increasing source nozzle diameters to model mouth size during inhalation. Study 2 aimed to examine performance of the new QUT Inspire app using mechanical and acoustic simulations of inspirations to assess the reliability and clinical validity of the new app.

Reproducible inspiratory air inflows were mechanically simulated using a 3 L calibration syringe (Welch Allyn Model: 7034803). The rate of withdrawal of the

syringe plunger was timed using a counting sequence spoken out loud to generate high, medium and low simulated inspiratory flow. The clinical validity of these air inflows was assessed by (1) measuring inspiratory flow rates using a clinical incentive spirometer device (Triflo II incentive spirometer Model: 8884717301) and (2) a Fleisch Type 2 pneumotachograph (Vitalograph Micro Model: 6300) (*Figure 10*).

Figure 10 **Clinical Incentive Spirometer and Pneumotachograph**

(a) Triflo II Incentive Spirometer (b) Vitalograph Micro Pneumotachograph

(Teleflex, 2018; Vitalograph, 2022)

A 10 mm flow nozzle coupling connected the distal end of the hose to the Triflo II device, as this device offers a fixed 10 mm hose connection. Syringe actuations (n=15) were repeated for each flow rate. Measurement of peak inspiratory flow rate using the Vitalograph flow meter was performed by coupling flow nozzles of decreasing diameter (25, 20, 15 and 10 mm) to the calibration syringe to model the effect of reducing mouth diameter on the resultant airflows produced. These flow reduction couplings used hard neoprene washers, with a central hole of known diameter. Syringe actuations (n=15) were repeated for each flow rate and mouth diameter combination.

Sound levels generated by mechanically simulated inspirations were measured with a digital sound meter (i.e., DSM) (Digitech Model: QM1591). Flow nozzles of reducing diameter (25, 20, 15 and 10 mm) were clamped to a 1.5 m tall stand separated from another stand holding the DSM. Sound level measurements were repeated at increasing distances separating the flow nozzle and digital sound meter (1, 2, 5, 10, 20, 50 cm). Audio samples were recorded as loops for playback via an external speaker (UE Roll Model:991-000105) for detection using the QUT Inspire application at increasing distances (1, 2, 5, 10, 20, 50 cm).

Two contemporary smartphones were selected for evaluation of the new QUT Inspire app, an Apple iPhone XR (IOS 13.5.1) and Samsung Galaxy (Android 9.0 Pie). The smartphones were less than twelve months old. A separate test was conducted to assess the influence of phone orientation on detected simulated inspiratory sound, Both Apple and Android phones were oriented flat (horizontally) at 45° and 90° to the audio to compare the range of detection of inspiratory sound by the QUT Inspire application at distances ranging from 1 to 50 cm separation between phone and audio source.

IBM SPSS Statistics (version 26.0.0.1) was used to collate statistics and generate plots. Error bars on plots indicate 95% confidence intervals. Multiple linear regression was performed to model the influence of distance, flow rate and mouth diameter of mechanical syringe-generated inspirations on observed variability in PIFr and sound levels. Natural log transformations of variables (e.g., PIFr and sound level) were performed where exponential decay was observed over the distances investigated.

3.3.3 STUDY 3: QUT INSPIRE APP - RANDOMISED USABILITY STUDY

In progressing to clinical studies regarding the new QUT Inspire app, participant safety was the primary consideration. In deference to testing in a cohort of persons with diseases amenable to ISy therapy, healthy people were recruited to compare the usability of the new virtual respiratory therapy app with a traditional ISy device (Study 3). Insights from the earlier simulation study (Study 2) were applied to the design of Study 3 including assessment of user interactions with their phones (e.g. distance from

mouth and mouth shape during inspiration) as contributing towards usability assessment.

In Study 3, disease-free human participants (n=24) took part in a mixed methods randomised usability study, comparing the new QUT Inspire app with an existing (Triflo II) clinical ISy device (see 1.6.3 Research Question 3). Participants were randomly allocated to an order of device testing (i.e., those who first used the app then tested the Triflo II clinical device and vice versa), and the order in which on-screen text and video instructions were offered for perusal.

In this study, effectiveness, efficacy, and user satisfaction were considered as dimensions of usability. Duration of inspirations (seconds) sustained with both the app and clinical device and the distance users held their phones away from their mouths for sound detection (cm) were used as measures of effectiveness and efficacy respectively. In addition a post-test questionnaire, satisfaction using the app was explored using a post-test questionnaire and semi-structured interviews to glean participants insights regarding interface design elements, instructional materials (i.e., video or on-screen text) and additional features such as gamification.

Approval to conduct Study 3 was granted by the Queensland University of Technology Human Research Ethics Committee (UHREC Ethics Approval Number: 1900000919).

Chapter 4: Assessment of mobile health apps using built-In smartphone sensors for diagnosis and treatment: systematic survey of apps listed in international curated health app libraries (Study 1)

This manuscript presents the results of the first study of the research program. The aim of this systematic survey was to evaluate availability of diagnostic and therapeutic smartphone mHealth apps using built-in phone sensors available from curated health portals for prescription by clinicians or self-prescribed by health consumers.

This manuscript pertains to Research Question 1:

What curated information is currently available to inform and guide clinician-initiated prescription and health consumer self-prescription of mHealth apps using built-in sensors for diagnosis or therapy?

This paper has been published in the peer reviewed journal: Journal of Medical Internet Research (JMIR) mHealth and uHealth.

Citation:

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Statement of Contribution of Co-Authors

The authors listed below have certified that:

1. they meet the criteria for authorship and that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
5. they agree to the use of the publication in the student's thesis and its publication on the QUT's ePrints site consistent with any limitations set by publisher requirements.

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Assessment of Mobile Health Apps Using Built-In Smartphone Sensors for Diagnosis and Treatment: Systematic Survey of Apps Listed in International Curated Health App Libraries (published 3/2/2020)

Contributor	Statement of contribution*
Clarence Baxter	(eg. wrote the manuscript, experimental design, conducted experiments, and data analysis)
12/08/2022	
Julie-Anne Carroll	(eg. aided experimental design, data analysis, reviewed manuscript)
Brendan Keogh	(eg. aided experimental design, data analysis, reviewed manuscript)
Corneel Vandelanotte	(eg. aided experimental design, data analysis, reviewed manuscript)

Original Paper

Assessment of Mobile Health Apps Using Built-In Smartphone Sensors for Diagnosis and Treatment: Systematic Survey of Apps Listed in International Curated Health App Libraries

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Abstract

Background: More than a million health and well-being apps are available from the Apple and Google app stores. Some apps use built-in mobile phone sensors to generate health data. Clinicians and patients can find information regarding safe and effective mobile health (mHealth) apps in third party–curated mHealth app libraries.

Objective: These independent Web-based repositories guide app selection from *trusted* lists, but do they offer apps using ubiquitous, low-cost smartphone sensors to improve health? This study aimed to identify the types of built-in mobile phone sensors used in apps listed on curated health app libraries, the range of health conditions these apps address, and the cross-platform availability of the apps.

Methods: This systematic survey reviewed three such repositories (National Health Service Apps Library, AppScript, and MyHealthApps), assessing the availability of apps using built-in mobile phone sensors for the diagnosis or treatment of health conditions.

Results: A total of 18 such apps were identified and included in this survey, representing 1.1% (8/699) to 3% (2/76) of all apps offered by the respective libraries examined. About one-third (7/18, 39%) of the identified apps offered cross-platform Apple and Android versions, with a further 50% (9/18) only dedicated to Apple and 11% (2/18) to Android. About one-fourth (4/18, 22%) of the identified apps offered dedicated diagnostic functions, with a majority featuring therapeutic (9/18, 50%) or combined functionality (5/18, 28%). Cameras, touch screens, and microphones were the most frequently used built-in sensors. Health concerns addressed by these apps included respiratory, dermatological, neurological, and anxiety conditions.

Conclusions: Diligent mHealth app library curation, medical device regulation constraints, and cross-platform differences in mobile phone sensor architectures may all contribute to the observed limited availability of mHealth apps using built-in phone sensors in curated mHealth app libraries. However, more efforts are needed to increase the number of such apps on curated lists, as they offer easily accessible low-cost options to assist people in managing clinical conditions.

(JMIR Mhealth Uhealth 2020;8(2):e16741) doi: 10.2196/16741

KEYWORDS

telehealth; mHealth; smartphone; mobile apps; instrumentation; health care quality; health care access; and health care evaluation; medical informatics; consumer health informatics; physician-patient relations; prescriptions; patient participation; patient-generated health data; diagnostic self evaluation; self-care; self-management; medical device legislation

Introduction

Background

With origins in the early 1990s and the inception of devices such as the IBM *Simon* Personal Communicator, early smartphone devices offered *untethered* mobile telephony, augmented by a humble suite of modular apps to extend basic phone functionality, hence the *smart* moniker in *smartphone* [1,2]. Nearly 3 billion people worldwide now use smartphones [3]. The release of the Apple iPhone in 2007 and subsequent competing Android smartphone offerings from Google and other vendors saw the emergence of platform-specific app stores, offering downloadable apps for a myriad of purposes [4]. Of the estimated 4.5 million apps available in the Google and Apple app stores, a million collectively pertain to health, fitness, nutrition, and well-being in general [5,6]. A subset of 300,000 of these apps may be regarded as *bona fide* mobile health (mHealth) apps, some of which may be potentially prescribed to patients for the diagnosis or treatment of health conditions [7]. Acknowledged by the World Health Organization in 2011, mHealth is defined as medical and public health practices supported by mobile devices, such as mobile phones, patient-monitoring devices, personal digital assistants, and other devices such as wearables [8]. More than 500 million people worldwide are believed to have downloaded one or more mHealth apps to their mobile phone [9].

Digital Disruption, Prescription, and Self-Prescription of Apps

Innovation is a hallmark of developments in medical technology, with a rich pedigree that long precedes contemporary *digital disruption* such as that attributable to mobile telephones and related technologies [10]. In 1995, Christensen and Bower [11,12] coined the term *disruptive technology* (later termed *disruptive innovation*) to describe the creation of new markets in response to novel emergent technologies based on values that are different from that of existing markets. Ubiquity, accessibility, and familiarity with mobile phone technology, combined with increasing general interest in health and the rising cost of clinician-led health care, may all contribute to the emergence of one such new *disrupted* market, namely, in the context of mHealth [10]. Health consumers may now independently seek out mHealth apps to assist with the diagnosis or management of health conditions [13]. Mobile phone camera apps for wound care and microphone apps for sleep apnea management are examples of mHealth apps using built-in sensors where diagnostic or treatment procedures once restricted to the realms of formal medical consultation are now accessible to laypersons for download and *self-prescription*, constituting potential disruption, which circumvents traditional clinician-initiated care and supervision [14,15].

Self-management of health conditions without adequate medical guidance (colloquially termed the *Dr Google* effect) is viewed by some as a *disruption* to traditional doctor-patient relationships, with potential risks of delayed (or incorrect) diagnosis or inadequate treatment because of the selection of malfunctioning and ineffective or inappropriate mHealth apps [16,17]. On the contrary, others cite the emergence of the *Quantified Self* movement in the 1970s and ensuing developments in areas such as Precision Medicine as offering patients the opportunity to leverage mobile phone technology to improve health, heralding a *democratization of information control* in health care [18-21]. In contrast to self-initiated engagement with mHealth, some apps may be prescribed to patients under the guidance of health professionals [7,15]. *Badly behaving* mHealth apps pose regulatory challenges regarding the evidence of app quality, safety, and efficacy and present risks to human health by potential misdiagnosis and inadequate or ineffective treatments, or by delaying face-to-face medical consultations [7,15,22,23].

Taxonomies for Mobile Health App Sensors

Several taxonomies exist for describing mHealth apps; one simple method categorizes them as either passive or active [23]. Passive mHealth apps display static health information pages or acquire hand-keyed input of health information. In contrast, active mHealth apps generate some form of health data [13,23]. It is in this latter active realm that sensor-based mHealth apps reside. Built-in smartphone sensors are readily accessible in the devices owned by billions of mobile phone users worldwide. Smartphones have evolved to incorporate environment and position sensors to augment and enhance device functionality [24]. In addition to sound detection by the phone microphone, cameras document the visual world [25]. Touch screens facilitate flexible display presentation and command initiation [25]. Accelerometers sense device orientation and adjust screen display layout in either portrait or landscape modes accordingly, whereas GPS locates devices geographically [25].

Regulation and Compliance Issues

The utility of such a trove of sensors has not gone unnoticed by clinicians and app developers alike [24,26]. Pedometer apps have been coded to count steps based on accelerometer monitoring [27]. Photoplethysmography apps leverage mobile phone cameras to detect changes in skin color with blood flow, estimating respiratory rate, heart rate (and heart rate variability), blood pressure, and blood oxygen saturation [28-31]. Examples abound as to innovative uses of sensor information for gathering health data [26]. In contrast, examples also exist highlighting deficiencies in some sensor-based mHealth apps. For example, blood pressure values based on pulse estimates from a particular camera-based smartphone app were demonstrated to be erroneous, potentially exposing hypertensive persons to harm with spurious readings [32]. Oximetry readings from another camera-based app were found to be inaccurate, with the potential for incorrect blood oxygen saturation readings to put users at risk [33]. Regulatory authorities worldwide seek to mitigate

this risk by deeming any app that attempts diagnosis or treatment to be a medical device, requiring rigorous evaluation, testing, and regulatory control [4]. Given the impost this places on app developers, some have sought to circumvent regulation by defining some apps as for entertainment or recreation or by using sensor-generated data as an adjunct to an app's operation as opposed to its main purpose [23,34].

Searching for Apps Using Curated Libraries

App stores such as those offered by Apple and Google present literally millions of results in response to searches on health topics [4,35]. A 2016 review of clinical and health care–related apps in the Google and Apple app stores found 36 apps for clinical diagnosis and 44 patient health monitoring apps, with the mobile phone camera identified as the predominant built-in sensor used [35]. Mobile phone camera apps offered for image-based diagnosis of eye and skin conditions, or photoplethysmographic monitoring of pulse and estimated blood pressure, and sleep apnea diagnostic apps using mobile phone microphones are examples of sensor-based apps offered by major app stores [15,34,35]. Information regarding vetting procedures for the inclusion of apps in these vendor stores is not publicly available [36]. For example, Apple is reported to have introduced additional requirements for developers regarding the measurement accuracy of apps, but details of these requirements remain undisclosed [37]. The quality and safety of mHealth apps offered by these vast stores are questioned by some, as is the utility of listed app descriptions in facilitating informed use of apps in a prescription context [37,38]. App listing and availability are also tempered by emergent government medical device regulatory requirements in Europe, the United States, and elsewhere [4,36,39].

Distinct from app stores such as the Apple App Store and Google Play Store, a number of independent third-party mHealth app repositories have emerged, with the intent of providing curated *trusted* lists of health apps for users to review and to guide the selection of safe and effective mHealth apps [39]. Also known as health app clearinghouse websites, these libraries are Web-based portals that do not host apps per se but offer information and links to a range of vetted apps that have satisfied selection criteria required for inclusion in the respective repository [40-42]. Examples of such libraries include the government-funded National Health Service (NHS) Apps Library in the United Kingdom and two privately funded repositories, namely, AppScript in the United States and MyHealthApps in Europe and the United Kingdom [43]. Curation of apps submitted to these libraries consists of varying degrees of scrutiny [39]. Submissions to the NHS Apps Library and AppScript repositories require app developers to respond to questions regarding app quality and safety, which are evaluated by curators of these libraries using proprietary scoring methodologies, whereas the MyHealthApps site incorporates reviews from patients [13,22,44]. Intended audiences for such curated apps include clinicians (with the intent to prescribe an app for use by a patient) as well as laypersons seeking to self-manage their health. In contrast to reviews regarding the availability of mHealth apps in popular Google and Apple app stores (including those using built-in smartphone sensors), there is a paucity of information regarding sensor-based mHealth apps offered by third party–curated mHealth app libraries [4,16,35].

Objective

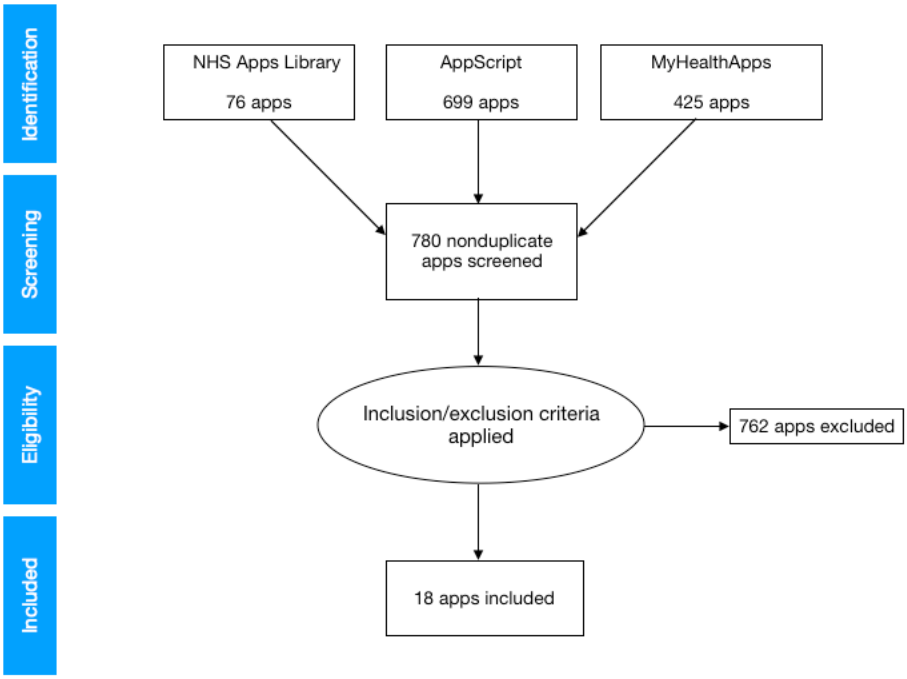
Given the potential for health improvement arising from the availability and utility of built-in sensors in billions of smartphones worldwide, the purpose of this systematic survey was to identify smartphone mHealth apps using built-in sensors, offered by three popular contemporary international curated mHealth app repositories, and to assess which health conditions these apps address and whether they are available across different platforms [39,43,45].

Methods

Libraries Selected for Survey

This survey, conducted in October 2019, considered all mHealth app listings in the NHS Apps Library, AppScript, and MyHealthApps–curated mHealth app repositories (Figure 1) [46-48]. These libraries were selected as examples of government-funded (NHS Apps Library) and privately funded curated mHealth app repositories (AppScript and MyHealthApps) [4,15,36,41]. The latter two privately funded libraries differ in that MyHealthApps incorporates patient reviews in the curation process, whereas AppScript uses a proprietary scoring process [22,41,44].

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram for survey.



Identification of Apps for Inclusion

All apps addressing health conditions using built-in mobile phone sensors to generate health data were identified using the publicly accessible search interfaces offered by each repository. As no search criteria were offered by these sites for filtering and identifying sensor-based apps, manual screening of the descriptions of all individual apps listed by each website was conducted by the lead researcher to screen for the use of built-in mobile phone sensors. Curated library descriptions for identified apps were inspected to categorize the purpose of the app as solely diagnostic, therapeutic, or a combination of both. Diagnostic apps were defined as those that identify the nature of a health condition, in contrast to treatment apps, which offered features for health condition management. Health conditions addressed by included apps were classified based on the description provided by each repository.

Exclusion Criteria

Apps using external or add-on sensors and nonsmartphone wearable device apps were excluded from this survey, as external components may impose additional cost, complexity, or excessive battery consumption, potentially reducing availability or accessibility to smartphone mHealth users [49]. *Propeller* is an example of an asthma therapy coaching app using an external Bluetooth sensor, which was excluded from this study [47]. Exercise, general activity, and accessibility apps were also excluded, as only apps used in diagnosis or treatment of specific health conditions were in scope of this survey. *Runkeeper* is an example of a GPS running tracker designed for monitoring exercise but excluded from this study, as no specific health condition was indicated for its use [47].

Availability of Apps

Mobile phone operating systems supported by included apps were noted, assessing the availability of these apps by users of the Apple iOS and Google Android phone types. The availability of included apps on advertised platforms was confirmed by following links advertised by each repository to inspect the Apple and Google app store app listings for apps. Apps were not downloaded or tested. App listings included as in scope by the lead researcher were then reviewed by the research team.

Low numbers across result groups precluded rigorous statistical analysis. Descriptive statistics were used where appropriate to illustrate results and to allow comparison between different libraries proportionate to respective library size.

Results

Overall Findings

A total of 1200 apps listed in the three selected curated mHealth app repositories were identified (Figure 1). Of 1200 apps, 780 nonduplicated apps were screened for eligibility. A total of 18 mHealth apps using built-in smartphone sensors were found in the three repositories surveyed. These represented 1.1% (8/699) to 3% (2/76) of the total app count across respective curated libraries (Table 1).

Table 1. Built-in sensor smartphone apps found in surveyed mobile health app libraries.

Curated mobile health app library	Total apps identified (n=1200), n	Built-in sensor apps included (n=18), n (%)
NHS[a] Apps Library	76	2 (3)
AppScript	699	8 (1.1)
MyHealthApps	425	8 (1.9)

[a]NHS: National Health Service.

Included Apps

Details of smartphone mHealth apps using built-in sensors included from each respective curated mHealth library in this survey are presented in Multimedia Appendix 1. Listings include app type (ie, diagnostic, therapeutic, or both), sensor type used, app name, description, mobile phone operating system, and health concern addressed by each app.

Cross-Platform Availability

Half (9/18, 50%) of all apps inspected were offered solely for use on the Apple iOS platform, with a further 11% (2/18) dedicated to the Android operating system (Table 2). Only about one-third (7/18, 39%) of the identified apps across all surveyed libraries were available for cross-platform use on Apple iOS and Android operating systems. The MyHealthApps repository offered the greatest cross-platform app availability, with 5 of the 8 (63%) identified apps in this library compatible with Apple iOS and Android operating systems. Most AppScript listings identified (6/8, 75%) were compatible only with Apple iOS.

Table 2. Operating systems for apps using built-in mobile phone sensors.

Operating system	Curated mobile health app library			Total, n (%)
	NHS[a] Apps Library	AppScript	MyHealthApps	
Apple iOS only	1	6	2	9 (50)
Android only	0	1	1	2 (11)
Both	1	1	5	7 (39)
Total	2	8	8	18 (100)

[a]NHS: National Health Service.

Purpose of the Apps

Almost one-fourth (4/18, 22%) of all included apps were dedicated entirely to the diagnosis of health conditions (predominantly available in MyHealthApps), whereas half were solely treatment oriented (Table 3). The AppScript and MyHealthApps libraries offered comparable numbers of combined diagnostic and therapeutic apps using built-in sensors, whereas more apps dedicated to treatment were available in AppScript compared with the other libraries.

Table 3. Purpose for mobile health apps identified using built-in mobile phone sensors.

Purpose	Curated mobile health app library			Total (n=18), n (%)
	NHS[a] Apps Library (n=2)	AppScript (n=8)	MyHealthApps (n=8)	
Diagnostic (Dx)	0	1	3	4 (22)
Therapeutic (Rx)	2	5	2	9 (50)
Both	0	2	3	5 (28)

[a]NHS: National Health Service.

Mobile Phone Sensors Used

Camera (7/18, 39%) and touch screens (6/18, 33%) were the most frequently identified smartphone sensors used (Table 4). Microphones and accelerometers (and mobile phone speakers) were found to be less frequently used sensors in the identified apps. No GPS-based mHealth apps were identified in this survey. MyHealthApps offered more camera-based apps than the other libraries combined, whereas AppScript listed more apps using touch screens and microphones.

Smartphone cameras assessed pulse rate using photoplethysmography in an anxiety treatment app (Beat Panic), a respiratory therapy app (HeartRate+ Coherence), and a cardiac app (Instant Heart Rate). Beat Panic and Heart Rate+ Coherence are examples where smartphone pulse rate sensing is a secondary function to support a main therapy, namely, anxiety management and breathing exercise, respectively. Camera images were also used for automated skin cancer diagnosis (SpotMole) and in capturing images for dermatological diagnosis (UMSkinCheck, iDoc24, and MyPso).

In addition to capturing responses to speaker-generated tones in audiology testing, touch screens were used in vision training (Vision training 1 and Visual Attention Therapy Lite), neurological tremor assessment (pdFIT and Dexteria), and anxiety management (Chill Panda and Antistress Chromotherapy). Microphone sensors were used in several respiratory therapy apps (Breathing Zone, SnoreLab, and SnoreMonitor SleepLab). The use of a mobile phone accelerometer sensor was identified in a single app for neurological tremor assessment (LiftPulse).

Table 4. Sensor types found in curated mobile health app libraries.

Sensor	Curated mobile health app library			Total (n=18), n (%)
	NHS[a] Apps Library (n=2)	AppScript (n=8)	MyHealthApps (n=8)	
Camera	1	2	4	7 (39)
Touch screen	1	3	2	6 (33)
Microphone	0	3	0	3 (17)
Accelerometer	0	0	1	1 (6)
Speaker	0	0	1	1 (6)

[a]NHS: National Health Service.

Health Conditions Addressed

Respiratory (4/18, 22%), dermatological (4/18, 22%), neurological (3/18, 17%), anxiety (3/18, 17%), and visual health (2/18, 11%) were the predominant health concerns addressed by the identified apps (Table 5). MyHealthApps and AppScript libraries listed more apps addressing a wider range of health conditions than the NHS Apps Library. The AppScript repository presented more apps for respiratory-related conditions, concerning snoring (n=2) and breathing exercises (n=2). Both the apps using built-in sensors in the NHS Apps Library addressed the management of anxiety.

Table 5. Summary of health conditions where built-in mobile phone sensors were used.

Health condition	Curated mobile health app library			Total (n=18), n (%)
	NHS[a] Apps Library (n=2)	AppScript (n=8)	MyHealthApps (n=8)	
Respiratory	0	4	0	4 (22)
Dermatology and skin cancer	0	1	3	4 (22)
Anxiety	2	0	1	3 (17)
Neurology	0	1	2	3 (17)
Visual acuity	0	2	0	2 (11)
Audiology	0	0	1	1 (6)
Cardiology	0	0	1	1 (6)

[a]NHS: National Health Service.

Sensor Types and Health Conditions

Mobile phone cameras are employed in addressing the broadest range of health issues (Table 6). For example, skin cancer assessment camera apps are available in MyHealthApps and AppScript repositories. Diagnostic pattern-matching algorithms analyze acquired camera images of skin lesions in one app in the MyHealthApps library, whereas another from AppScript captures photos for later analysis by a physician. General dermatology apps using smartphone cameras to capture images are listed in the MyHealthApps library. In addition, two apps for the assessment of tremor were identified in the AppScript and MyHealthApps libraries, using the touch screen to assess touch accuracy in Parkinson disease symptom assessment and accelerometer sensors to detect tremor-induced movements, respectively.

Table 6. Sensors, health conditions, and methodologies identified.

Sensor and health condition	Measure	Methodology used
Camera		
General anxiety disorder	Heart rate	Photoplethysmography
Cardiac	Heart rate	Photoplethysmography
Dermatology (n=2)	Photography	Clinician inspection
Respiratory (breathing exercise)	Heart rate variability	Photoplethysmography
Skin cancer	Photography	Steganographic pattern matching from photo
Skin cancer	Photography	Clinician inspection
Touch screen		
Panic attacks	Screen image display	Images displayed to reduce panic
Visual acuity (n=2)	Touch accuracy	Eye-hand coordination assessment and coaching
Parkinson disease	Touch accuracy	Fine motor skill assessment and coaching
Microphone		
Respiratory (sleep; n=2)	Snoring sound level and frequency	Snoring and apnea detection
Respiratory (breathing exercise)	Breath sound detection	Feedback to encourage slow purposeful breaths
Accelerometer		
Neurology	Tremor detection	Calculates tremor frequency
Speaker and touch screen		
Audiology	Calibrated sound generation	Self-administered hearing test

Discussion

Principal Findings

Curation activities offered by third-party mHealth libraries, which are underpinned by medical device regulation, contribute to informing and protecting mHealth consumers. In this study, we surveyed three popular curated libraries regarding a specific subset of mHealth apps, namely, those using built-in mobile phone sensors for diagnosis or treatment of health conditions. Key aims of this survey included determining app availability, mobile phone operating system compatibility, intended purpose (diagnosis or therapy), types of sensors employed, and the range of health conditions where built-in smartphone sensors are used. First, this survey yielded a relatively small number of apps across the libraries examined, with differences found in the number of apps available between libraries. Second, more apps were available for the users of Apple iOS smartphones than for those of Android devices; cross-platform availability differed between the libraries surveyed. Third, the majority of apps offered treatment and combined diagnosis and treatment, with a smaller proportion offering dedicated diagnostic functionality. Fourth, cameras, touch screens, and microphones were the most frequently used mobile phone sensors in these apps. Finally, the range of health conditions addressed by these apps included respiratory, dermatological, anxiety, and neurological conditions.

Finding Trusted Mobile Health Apps

Searching for apps related to particular health topics or medical concerns pose challenges for health professionals and consumers alike. Search engines, such as Google and Bing, which index available apps based on keyword search algorithms, often yield large volumes of uncurated search results for a given health topic [35,36,50,51]. Although the Apple and Google app stores categorize submitted apps for more focused searching (eg, *Health and well-being*), those searches can still return an overwhelming result list of indeterminate quality [4,35]. Search engines and app stores display star ratings and reviews to indicate the popularity of given apps, but these may not be reliable measures by which listed mHealth apps can be *trusted* [22,45]. In addition to high-level categorical grouping, third party–curated mHealth libraries offer more detailed subcategories and lists for specific health conditions and medical specialties.

No studies could be found that quantify the prevalence of mHealth apps using built-in sensors in curated mHealth app libraries. A 2016 review of health care–related apps available from the Google and Apple app stores identifies 80 clinical or health care–related mHealth apps for diagnosis or health monitoring [35]. Of the apps described in this review, mobile phone cameras are the most frequently employed sensor type, with camera images used by some apps for dermatological and ophthalmological diagnosis. Camera imaging is also employed in apps for blood flow monitoring by means of photoplethysmographic monitoring of pulse rate and estimation of blood pressure [35]. Emergent problems with blood pressure estimation received wide publicity when found to be unreliable in the case of at least one app [32]. In a number of health care contexts, app availability has been termed *volatile*, where apps may be removed from app stores in response to the revision of the underlying evidence base of an app or for medicolegal reasons [52].

Critics highlight a lack of transparency in standards applied to the screening of submitted apps before inclusion and hosting in popular app stores and search engines, resulting in mHealth app offerings, which may vary in quality or safety [7,45,51]. Measures of mHealth app quality have been developed (but not widely applied), including the (now defunct) Happtique Health App Certification, EU Kitemark certification, Intercontinental Medical Statistics (IMS) Score, and Mobile Application Rating Scale (MARS) [39,51]. For example, MARS evaluates mHealth app quality in five areas: aesthetics, functionality, engagement, information quality, and subjective quality [39,53]. Curated mHealth app libraries offer *trusted* sites for health consumers to select mHealth apps, constituting more detailed and specialized search portals than the aforementioned search engines and app stores [4,13]. Varying degrees of (proprietary) vetting are conducted to assert the safety and efficacy of curated apps, thereby imbuing search results with trust; detailed app scoring methodology and the incorporation of app quality measures, such as MARS, into the vetting process are not disclosed by these sites [40,54].

Primary and Supporting Roles for Sensors

In contrast to a million health and well-being apps on offer to mobile phone users from popular app stores, only 18 mHealth apps using built-in smartphone sensors are identified in this survey, representing 1.50% (18/1200) of all mHealth apps collectively offered by the three curated libraries examined here (Table 1). A key consideration in the curation process is that medical device regulatory requirements may preclude listing of some apps in these libraries to prevent harm to app users [50]. Active mHealth apps (ie, those using sensors to gather health data) may be at greater risk of causing negative health impacts because of potential harm from inaccurate or incorrect data, demanding more rigorous curation and potential exclusion from curated libraries [23]. Regulatory authorities may require the assessment and accreditation of mHealth apps that offer diagnostic or therapeutic recommendations or those that transform the functionality of the mobile phone into that of a medical device [23,54]. Some sensor-based mHealth apps may use sensors as a secondary or supporting measure and thus not be regarded as medical devices per se [23]. Overall, two such examples are identified in this survey: anxiety and breathing exercise apps that use camera sensors for pulse detection as a secondary or indirect health data measure.

Availability on Competing Mobile Phone Platforms

The respective smartphone market shares for Apple and Android devices are comparable [55,56]. In contrast, not all the apps identified in this survey are available across both popular mobile phone platforms, potentially disadvantaging some mHealth consumers. Half (9/18, 50%) of the apps identified in this survey are dedicated solely to Apple iOS, a further 11% (2/18) specific to Android, and only about one-third (7/18, 39%) available for both operating system platforms (Table 2). Apple iOS device manufacture is controlled solely by Apple, with relative homogeneity in hardware components such as sensors potentially offering app developers more stable or predictable target platforms for app development [56]. In contrast, Android devices may originate from multiple hardware vendors with disparate (sensor) hardware components, potentially adding complexity to the development of apps catering for a wider range of target device hardware and sensors [55,56].

Half of the identified mHealth apps (9/18, 50%) offer dedicated treatment features, with further about one-fourth (4/18, 22%) dedicated to diagnosis (Table 3). The imperative to seek (traditional doctor-patient) medical consultation regarding definitive diagnosis, potential risk of self-misdiagnosis, and regulatory restrictions may all contribute to the smaller proportion of purely diagnostic sensor-based apps offered by the libraries surveyed [57]. Dermatology and skin cancer diagnostic apps using the mobile phone camera constitute 4 of the 5 dedicated diagnostic apps identified.

Health Concerns and Sensor Types

Cameras and touch screens are the most frequently used sensors in the identified apps, followed by microphones and accelerometers. Apps using camera sensors are most prominent in the MyHealthApps library, whereas AppScript lists more microphone and touch screen apps (Table 4). Notwithstanding contemporary research studies regarding the use of GPS for activity tracking in mental health conditions such as bipolar disorder and general depression, no examples of translating this research into GPS-based sensor apps were found in any of the libraries surveyed [20,26]. Anxiety therapy was the sole focus of both apps identified in the NHS Apps Library. Respiratory concerns were the most frequently addressed health conditions in the AppScript library, whereas apps related to dermatology and neurological conditions were more prevalent in the MyHealthApps library (Table 5). Cameras are employed in a wider range of health conditions compared with other sensors (Table 6). Photoplethysmography is used to measure heart rate and heart rate variability in three camera apps, whereas photo capture for later inspection by a clinician is offered by two dermatology and skin cancer diagnostic apps. A single camera app performs steganography (pattern matching) for skin cancer diagnosis.

Conclusions

This survey found that mHealth apps using built-in sensors for diagnosis and treatment represented but a modicum of all apps found in the curated mHealth libraries examined. The nature and rigor of the curation process go some way to explain this observation, including the constraints of regulatory requirements for software deemed as medical devices. This may also help explain the smaller proportion of dedicated diagnostic apps observed in these libraries. Some health consumers may be disadvantaged by differences in the availability of apps on competing mobile phone platforms. Cameras, touch screens, and microphones were used most frequently in the surveyed apps. A limited range of health concerns were addressed by the surveyed apps.

Further efforts are needed to increase the availability of ubiquitous, low-cost mobile phone sensor technology in curated lists to assist with health conditions.

Authors' Contributions

CB conceptualized the survey, developed methodology, and collected data for the survey. He categorized and evaluated the results and prepared the draft manuscript. JC supervised the overall work. BK and CV contributed to discussing and revising the manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix 1

Details of mobile health apps using built-in mobile phone sensors in surveyed curated libraries.
[PDF File (Adobe PDF File), 144 KB-Multimedia Appendix 1]

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Abbreviations

MARS: Mobile Application Rating Scale
mHealth: mobile health
NHS: National Health Service

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Chapter 5: Seeking Inspiration: examining the validity and reliability of a new smartphone respiratory therapy exergame app (Study 2)

This manuscript presents the results of the second study of the research program. The objective of this simulation study was to evaluate the reliability and clinical validity of calibrated simulated inspiratory sound samples detected by popular smartphone types running the QUT inspire virtual incentive spirometry app.

This manuscript pertains to Research Question 2:

How reliable and clinically valid is the new QUT Inspire virtual ISy app for detection of audible inspiratory sound using the built-in smartphone microphone for sound detection?

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The authors listed below have certified that:

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Brendan Keogh	(eg. aided experimental design, data analysis, reviewed manuscript)
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sensors

MDPI

Article

Seeking Inspiration: Examining the Validity and Reliability of a New Smartphone Respiratory Therapy Exergame App

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Abstract: Background: Clinically valid and reliable simulated inspiratory sounds were required for the development and evaluation of a new therapeutic respiratory exergame application (i.e., QUT Inspire). This smartphone application virtualises incentive spirometry, a longstanding respiratory therapy technique. Objectives: Inspiratory flows were simulated using a 3 litre calibration syringe and validated using clinical reference devices. Syringe flow nozzles of decreasing diameter were applied to model the influence of mouth shape on audible sound levels generated. Methods: A library of calibrated audio inspiratory sounds was created to determine the reliability and range of inspiratory sound detection at increasing distances separating the sound source and smartphones running the app. Results: Simulated inspiratory sounds were reliably detected by the new application at higher air inflows (high, medium), using smaller mouth diameters (<25 mm) and where smartphones were held proximal (≤5 cm) to the mouth (or at distances up to 50 cm for higher airflows). Performance was comparable for popular smartphone types and using different phone orientations (i.e., held horizontally, at 45° or 90°). Conclusions: These observations inform future application refinements, including prompts to reduce mouth diameter, increase inspiratory flow and maintain proximity to the phone to optimise sound detection. This library of calibrated inspiratory sounds offers reproducible non-human reference data suitable for development, evaluation and regression testing of a therapeutic respiratory exergame application for smartphones.

Keywords: telemedicine; mHealth; respiratory; smartphone; cellphone; digital simulation; microphone; gamification; serious game; exergame

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1. Introduction

At rest, normal human breaths are barely perceptible. Vigorous respiration produces audible sound at the mouth by means of turbulence created at higher air flow rates and greater air pressure changes [1,2]. Designed primarily for telephony and the capture of spoken voice sounds, built-in microelectromechanical (i.e., MEMS) microphones in contemporary smartphones can be repurposed to sense changes in air pressure arising from breath sounds. Diagnostic and therapeutic mHealth (i.e., mobile health) applications detect breath sounds and sound components for a variety of innovative health improvement purposes including respiratory rate monitoring in children, cough diagnostics, sleep apnoea detection, asthma inhaler technique training and respiratory function testing. [3–9].

Some mHealth apps infer respiratory flow rates by means of calibrated vortex whistles to produce sound of a known pitch for microphone detection, or by constraining and controlling mouth shape as a potential variable influencing the respiratory sounds generated;

others may employ external microphones to improve sound detection [10,11]. Add-on components such as external microphones, whistles or spacers may add cost and complexity to mHealth apps or limit what phone types or models may be used, potentially limiting accessibility to patients, particularly in resource-poor or impoverished settings [12]. Built-in microphones are available in all smartphones and offer a single, easy to use encapsulated means for sound detection.

Serious gaming techniques (i.e., gaming for purposes other than entertainment) have been applied to mHealth application design in contexts such as disease detection and treatment, monitoring, health education and rehabilitation [13]. Gamification of mHealth apps offers an "attention shift" for users experiencing unpleasant or negative sensations such as breathlessness or fatigue [14]. Patients may be distracted from the repetitive nature of therapeutic exercise by engaging with engrossing and motivational game play [15].

This study concerns development and use of methodology for evaluating the validity and reliability of a new respiratory therapy exergame application for smartphones (i.e., QUT Inspire or Queensland University of Technology Inspire), using clinically valid and reproducible calibrated (non-human) simulated inspirations. This new smartphone application virtualises incentive spirometry (i.e., ISy), a longstanding respiratory therapy technique for mucus clearance from airways commonly employed in clinical contexts such as post-operative convalescence and in the management of certain chronic respiratory conditions such as chronic obstructive pulmonary disease (i.e., COPD) and cystic fibrosis [16].

From its inception, incentive spirometry was designed as a motivational affordance to encourage mucus clearance from the airways using repeated slow gradual maximal inspirations (Figure 1) [16]. An emergent role for ISy therapy has recently been proposed in pulmonary rehabilitation for convalescing SARS-CoV-2 (i.e., COVID-19) patients. [17]. In contrast to existing clinical incentive spirometer devices that levitate spheres or pistons in response to maximal inspiration, the new QUT Inspire smartphone application is an exertion-type exergame for the detection of inspiratory sound generated at the mouth using the smartphone microphone (without the need for any mouthpieces or other add-on components) [18]. The application displays an animated graphic on the screen to provide a responsive, visual incentive to persist with gradual, sustained, repeated inspirations (Figure 2). QUT Inspire is an exemplar of an exergame where a game is built into the interface, with a primary goal of keeping animated balls aloft by means of detecting inspiratory sound, and a secondary goal of encouraging sustained gradual maximal inhalation for mucus dislodgement from the airways and expulsion by coughing [19]. It has been argued that a safe and effective exergame must support primary and secondary goals defined for a therapeutic exercise to be safe and effective for patients [19].

Widespread availability of smartphone technology affords opportunities to leverage sensors built into these ubiquitous devices as a low cost, accessible means for improving health. However, risks to health exist where sensors in "badly behaving" apps may malfunction or misread physiological parameters, or where variations in application performance may be introduced by unintended or unforeseen user interactions with their phones while using a given app, or with updates to phone models, sensors or software that may affect application functionality [20]. This study aims to develop a library of reproducible, calibrated non-human simulated inspiratory audio samples representing a clinically valid range of inspiratory flow rates and mouth diameters, suitable for application development, testing and re-testing. The resultant audio library is applied to evaluation of the reliability and range of sound detection of the new QUT Inspire respiratory therapy exergame app.

Figure 1. A Triflo II clinical incentive spirometer (image: iStock by Getty Images).

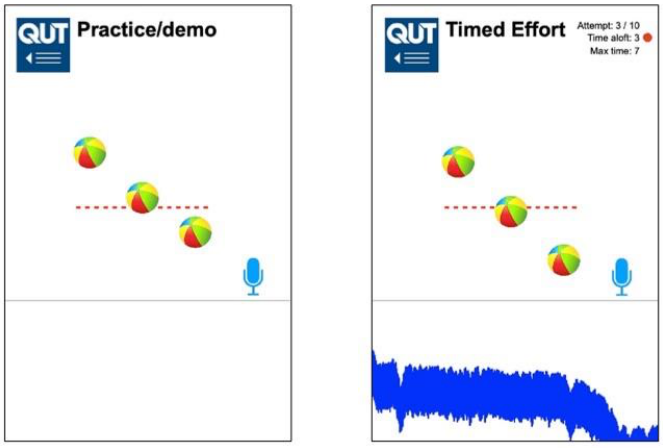

Figure 2. QUT Inspire incentive spirometer application—practice and timed modes.

2. Inspiratory Air Flow and Sound Generation

Mouth-throat modelling indicates that air flow near the mouth becomes turbulent at flow rates ranging from 15–45 L/min (i.e., approx. 250–750 cc/s) [21]. Sound levels greater than approximately 50 dBA become audible at the mouth as the inspiratory flow rate approaches 60 L/min (i.e., approx. 1000 cc/s) [22]. Inspiratory sounds are generally louder than those arising from exhalation [23]. Turbulent (and thus more audible) air flow requires a sustained air pressure difference between the outer atmosphere and mouth, proportional to the square of the flow rate [24,25]. Air flow resistance at the mouth contributes to sustaining this audible turbulence by constraining the diameter available for air exchange and increasing air pressure across the lumen of the mouth, with the resultant sound amplitude proportional to the square of the air flow at the mouth [26,27]. This is best demonstrated by pursing one's lips (e.g., as in preparing to whistle) and noting an

increase in audible mouth noise with boisterous inspiration. Respiratory sound amplitude diminishes as the distance between the sound source (i.e., mouth) and monitoring device is increased [27].

2.1. Sound Detection and Modern Smartphones

Only a small number of smartphone apps using built-in phone microphones meet international standards for sound level measurement, with fewer standards-compliant sound metering apps offered for Android smartphones compared with Apple devices [28]. This may be attributable to application development challenges arising from potential disparities in microphone architecture between multiple manufacturers of Android phones compared to a reported relative homogeneity of components in Apple devices [29,30]. The age of a given phone microphone may also influence monitored sound levels [29]. Sound detection in modern smartphones now encompasses voice-activated command features such as Siri which may implement sound-level filtering or attenuation to support voice detection when the phone is held proximal to, or at a distance from the mouth [31,32]. Potential variations in microphone performance between phone brands and between existing and emergent models highlight the need for analysis and benchmarking of sound detection, particularly where this is implemented in mHealth apps.

2.2. Limited Respiratory Application Availability for Improving Health

Several broad categories of smartphone respiratory monitoring apps have been identified including breathing pattern detection, cough sound analysis, sleep and snoring analysis, spirometry and lung function assessment [33,34]. Surveys of popular application stores (e.g., Apple App Store, Google Play Store) and curated mHealth application libraries (e.g., AppScript, MyHealthApps) yield a relative paucity of sensor-based respiratory mHealth apps translated from the research lab to offerings made available for prescription by clinicians or self-prescription by smartphone users [35,36]. Nevertheless, respiratory therapy apps may have application in both short- and long-term patient engagement, ranging from short hospital stays to protracted outpatient use for chronic conditions; treatment outcomes that previously required dedicated, and sometimes costly equipment may be realised by use of widely available smartphone technology [37,38]. Quality measures such as MARS (i.e., Mobile Application Rating Scale) for evaluating mHealth apps are gaining more widespread acceptance, particularly when vetting apps for inclusion in curated application libraries [39]. Technical validation of apps and clinical studies regarding application performance are requisite steps in building an evidence base supporting use of a given app, and in some countries such validation is a requisite for satisfying requirements for medical device registration [40]. Wider adoption of such mHealth apps may be contingent on rigorous evaluation and building an evidence base which demonstrates safety and effectiveness for an app, potentially contributing to the paucity of such apps offered by popular application stores [36,41].

2.3. Air Flows for Testing Respiratory Apps

It would be both unfeasible and unethical to expect human subjects to produce the considerably large number of reproducible breaths necessary to assert that new and emergent respiratory apps are both reliable (i.e., reproducible) and clinically valid when compared with reference devices [42]. Non-human generation of airflows for respiratory application testing has previously drawn on techniques used in the calibration of equipment in clinical respiratory laboratories settings [4,43]. Decompression calibrator devices and flow delivery pumps (for ventilator calibration) are specialist devices used in clinical respiratory laboratory settings to discharge air at pre-determined flow rates [44]. However, calibration syringes deliver known volumes of air by manual actuation of the syringe plunger to simulate inspiration or expiration. Syringes for generating air flows are relatively inexpensive compared with specialised devices, widely accessible and are a mainstay in

clinical respiratory function testing settings for evaluating performance of respiratory function testing equipment (e.g., spirometers, flow meters, plethysmographs) [45,46].

Computerised respiratory sound analysis (i.e., CORSA) provides a foundation catalogue of abnormal respiratory sounds using standardised sound samples in apps for diagnosis or therapy [23,33]. Playback of sound recordings of inspiratory or expiratory air flows captured at known flow rates offers a reproducible means for assessing application performance, including the range (i.e., distance separating the phone from the sound source) and reliability of sound detection afforded by a given application [9,47]. Vortex whistle and other add-on devices have been employed in some apps to constrain mouth shape and translate airflow into sound of a known pitch, facilitating quantitating of air flows in peak flow measurement, metered dose inhaler medication training for asthma and in assessment of lung function [11,48,49]. A paucity of literature exists regarding the contribution of reduced mouth diameter to sound production during simulated inspiration, suitable for detection by smartphone microphones.

3. Incentive Spirometry and Respiratory Therapy

Incentive spirometry is a respiratory exercise intended to encourage repeated gradual maximal "purposeful" inspirations which result in intrapleural air pressure changes to precipitate mucus dislodgement and expulsion by coughing; the objective of this therapy is prevention of morbidity and mortality arising from respiratory infections and pneumonia [10,50]. ISy is employed in post-surgical convalescence (where anaesthesia or protracted periods of bed rest may result in mucus accumulation in the airways) and in management of some chronic disease conditions where mucus overproduction may occlude airways or increase the risk of respiratory infections such as COPD or cystic fibrosis [51]. In the presence of COPD, low inspiratory flow rates may also be a predictor for hospital re-admission following initial hospital admission for COPD [52,53]. Low inspiratory flow rates have been identified as a possible biomarker for COPD, offering a potentially inexpensive and accessible means for COPD screening [52,54].

ISy therapy has also recently been proposed for post-COVID-19 respiratory therapy and convalescence [17]. In the modern incarnation of this device, spheres or a piston embedded in a clear injection-moulded plastic chassis are attached to a breathing tube (Figure 1) [52]. The patient gradually and maximally inhales via the tube, creating a vacuum in the device chamber and levitating the spheres or piston. Flow-based and volume-based ISy devices are available for respiratory therapy, using either flow-rate calibrated levitation of a sequence of spheres or a graduated scale to report deflection of a piston and the volume of air inspired respectively [55].

3.1. QUT Inspire—A Virtual Incentive Spirometer

QUT Inspire is a virtualised incentive spirometer application for smartphones. It is a HTML5 web application developed using Construct 3 (scirra.com, Scirra Ltd., London, UK, accessed 17 September 2021) and designed for cross-platform compatibility with a range of popular smartphones using Apple IOS and Google Android operating systems, executed using the smartphone web browser.

The new application (Figure 2) detects inspiratory breath sound above a pre-determined threshold, using the built-in MEMS smartphone microphone as an uncalibrated pressure sensor. The lower part of the application screen displays sound frequency sampling as an indicator to the user that sound detection is active. The sound of inspiration triggers a three-ball animation (akin to the clinical flow-based ISy device depicted in Figure 1) in response to sustained inhalation effort. This animation is maintained while sound levels are sustained above a pre-determined threshold (i.e, 50 dBA). The height (i.e., elevation) of the spheres is a pre-set animation sequence of fixed magnitude; this does not reflect the actual flow rate values detected but instead reports to the user that sustained inspiratory sound is maintained and detected by the phone microphone. The sound level threshold

can be altered using a slider control to minimise spurious triggering due to background noise.

Inspiratory air inflows were mechanically simulated using a 3 L calibration syringe (Welch Allyn Model: 7034803). The rate of withdrawal of the syringe plunger was timed using a counting sequence spoken out loud (Table 1) to generate a range of simulated inspiratory flow rates (high, medium and low).

Table 1. Counting sequence for syringe withdrawal.

Flow Rate	Counting Sequence
High	One, two, three
Medium	One, one hundred, two, one hundred
Low	One, one hundred thousand, two, one hundred thousand

3.2. Inspiratory Flow Rate (IFr)—Clinical Incentive Spirometer

To assess the clinical validity of the range of air inflows generated by this timed counting sequence, simulated inspiratory flows were applied to a clinical incentive spirometer device (Triflo II incentive spirometer Model: 8884717301), coupled to the syringe via a 3 m length of 25 mm internal diameter PVC hose. This hose length was selected to minimise any spurious audio artefacts arising from mechanical syringe actuation in the subsequent audio sampling of simulated inspirations.

A 10 mm flow nozzle coupling connected the distal end of the hose to the Triflo II device, as the device offers a fixed 10 mm hose connection. For each flow rate, syringe-generated simulated inspirations (n = 15) were applied to the Triflo II device. Levitation of spheres in the device in response to syringe actuations was noted and compared with an inspiratory flow rate (i.e., IFr) scale embedded in the device chassis, indicating clinically significant air inflows (i.e., 600, 900 and 1200 cc/s).

3.3. Peak Inspiratory Flow Rate (PIFr)—Pneumotachograph

Reliability of mechanically simulated inspirations was assessed by attaching the calibration syringe to a Fleisch Type 2 pneumotachograph (Vitalograph Micro Model: 6300) and measuring peak inspiratory flow rate (i.e., PIFr). To model the effect of reduction in mouth diameter on the simulated inspiratory flow rates generated, flow reduction couplings of decreasing diameter (25, 20, 15 and 10 mm) were attached to the distal end of the PVC hose attached to the syringe (n = 15 syringe actuations at each flow rate and mouth diameter combination). These flow reduction couplings were hard neoprene washers, with a central hole of known diameter.

3.4. Sound Level of Syringe Inflows (dBA)—Digital Sound Meter

Sound levels generated by the mechanically simulated inspirations were measured with a digital sound meter (i.e., DSM) (Digitech Model: QM1591). Flow nozzles were clamped to a 1.5 m tall stand separated from another stand holding the DSM. Sound level measurements were repeated at increasing distances separating the flow nozzle and digital sound meter (1, 2, 5, 10, 20, 50 cm).

3.5. Acoustic Sampling for Smartphone Testing

To eliminate variability in flow rates generated, the sound produced by mechanically simulated inspirations was sampled with a digital sound recorder (i.e., DSR) (Sony Model:ICDPX470). Recordings were performed at a distance of 1 cm separation between the flow nozzle and the DSR to prevent spurious vibration of the recorder. The flow nozzle and sound recorder were clamped to individual stands at a height of 1.5 m above floor level. Audio frequency spectra for these digital sound samples were inspected (https://academo.org/demos/spectrum-analyzer/ accessed on 17 September 2021). A single audio sample was selected as representative for each flow rate and mouth diameter

combination for application testing. For each sound sample, an audio loop of 15 iterations of a single audio sample inspiration was created to investigate the reliability of inspiratory sound detection. Five seconds of blank sound was interspersed in the audio loop between each simulated inspiration.

3.6. QUT Inspire Smartphone Application Testing

Audio sample loops were played back using a MacBook Pro computer via an external speaker (UE Roll Model:991-000105) for detection with the QUT Inspire application at increasing distances (1, 2, 5, 10, 20, 50 cm). Separating the speaker and smartphone. Sound level output from the speaker was checked and set to the same volume as that of the source sound generated by the syringe using the digital sound meter. Phones were oriented flat (horizontally) with the phone microphone pointed towards the speaker. Two contemporary smartphones were selected for evaluation of the new QUT Inspire app, an Apple iPhone XR (IOS 13.5.1) and Samsung Galaxy (Android 9.0 Pie). The smartphones were less than twelve months old. A separate test suite was conducted to assess the influence of phone orientation on detected simulated inspiratory sound, Both Apple and Android phones were oriented flat (horizontally) at 45° and 90° to the audio source respectively, to compare the range of detection of inspiratory sound by the QUT Inspire application at distances ranging from 1 to 50 cm separation between phone and audio source.

3.7. Statistical Analysis

IBM SPSS Statistics (version 26.0.0.1) was used to collate statistics and generate plots. Error bars on plots indicate 95% confidence intervals. Multiple linear regression was performed to model the influence of distance, flow rate and mouth diameter of mechanical syringe-generated inspirations on observed variability in PIFr and sound levels. Natural log transformations of variables (e.g., PIFr and sound level) were performed where exponential decay was observed over the distances investigated [56].

4. Results

4.1. Syringe-Generated Inspirations by Flow Rate—Triflo II Clinical ISy Device

When mechanically simulated inspiratory flows were applied to the Triflo II ISy device at decreasing flow rates, inspiratory flow rates of 1200, 900 and 600 cc/s were reliably reported by this device (n = 15 of 15 simulated inspirations at each flow rate) (Figure 3). These syringe-simulated inspiratory flow values were within the range of clinically valid inspiratory flow rates the Triflo II clinical incentive spirometer device is designed to monitor.

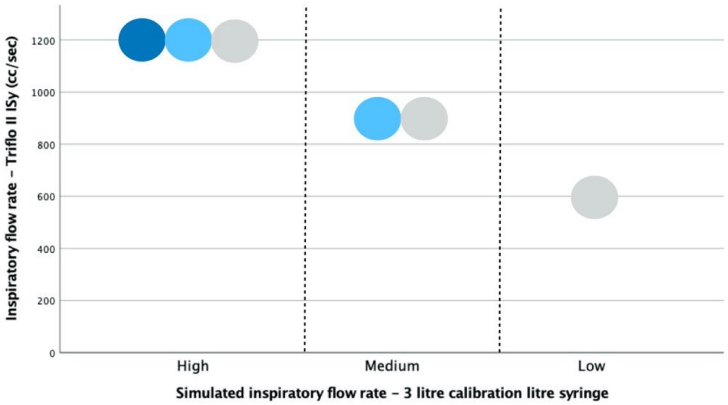

Figure 3. Triflo II ISy device—sphere(s) deflected with increasing inspiratory flow.

The Triflo II device offers a fixed 10 mm aperture for coupling to a breathing hose; only the 10 mm flow restriction nozzle was applied to the calibration syringe for the generation of simulated inspirations.

4.2. Peak Inspiratory Flow (PIFr) of Simulated Inspirations by Flow Rate and Mouth Diameter

The highest PIFr values recorded by a Fleisch Type II Pneumotachograph were observed for high simulated inspiratory flow rates and larger mouth diameters (e.g., 2000 cc/s at 25 mm mouth diameter) (Figure 4). Considering the fixed 10 mm aperture in the Triflo II Isy device, PIFr values measured by the pneumotachometer for the 10 mm mouth diameter yielded mean PIFr values of 1100, 900 and 800 cc/s for high, medium and low simulated inspiratory air flows respectively (n = 15 iterations at each flow rate and mouth diameter combination). These results are comparable to the clinically valid range of inspiratory flow rates displayed on the calibrated scale in the Triflo II Isy device (Figure 3).

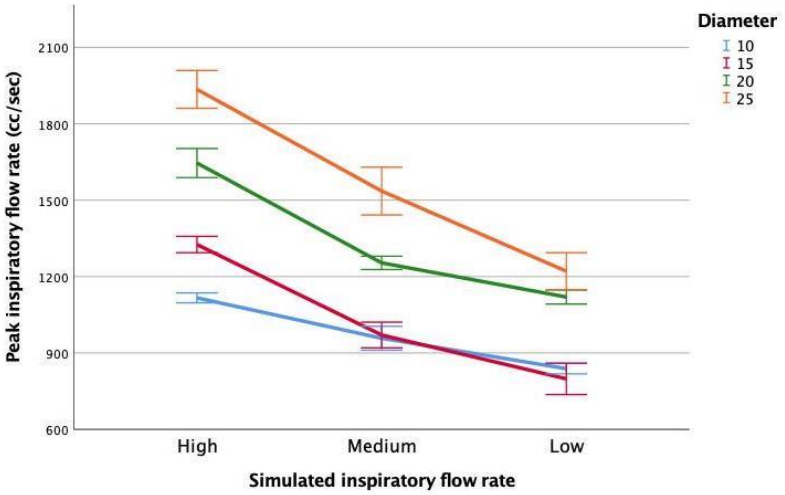

Figure 4. PIFr measured by pneumotachometer for syringe generated. Inspiratory flows by flow rate and mouth diameter.

Low simulated inspiratory flows measured as 600 cc/s by the Triflo II device, compared with 800 cc/s reported by the pneumotachometer. At medium and high simulated inspiratory flow rates, the simulated inspirations produced by timed withdrawal of a calibrated 3 L syringe plunger generated PIFr comparable to the clinically significant range by the calibration scale reported by Triflo II device. As the mouth diameter was increased beyond 10 mm, the PIFr also increased, with the highest PIFr values observed for the largest mouth diameter (25 mm).

The association of flow rate and mouth diameter with the observed peak inspiratory flow values was found to be significant ($F_{2,177}$ = 553.381, $p < 0.01$), explaining 86.1% of the observed variability in peak inspiratory flow rate (adjusted R^2 = 0.861). Both flow rate ($ß_{\text{flow rate}} = -0.623$, $p < 0.01$) and mouth diameter ($ß_{\text{mouth diameter}} = 0.689$, $p < 0.01$) contributed to the variability observed in this model. See Supplementary Materials file for the regression model. The highest simulated peak inspiratory flow rates were produced using higher mechanical syringe-simulated inspiratory flow rates (e.g., high) and application of larger mouth diameters (e.g., up to 25 mm).

4.3. Sound Levels of Syringe-Simulated Inspirations by Distance, Flow Rate and Mouth Diameter

The sound generated by syringe-generated inspirations was measured using a digital sound meter for each flow rate and mouth diameter combination (Figure 5). Sound levels

were monitored at increasing distances (separation) between syringe nozzle (simulated mouth) and DSM, akin to holding a phone further away from the mouth. In contrast to PIFr measurements where the largest mouth diameter generated the greatest flow rate, the highest sound levels (95 dBA) were measured where mouth diameter was small (i.e., 10 mm) (Figure 5). This may reflect turbulent, audible airflow where the lumen of the simulated mouth (nozzle) is small. Higher flow rates resulted in louder inspiratory sound. Sound levels detected by the DSM decreased as the distance separating the flow nozzle and the DSM was increased. The lowest sound levels (75 dBA) were observed where the largest mouth diameter (i.e., 25 mm) was used; no detectable sound was produced for this large mouth diameter at distances greater than 1 cm from the audio source.

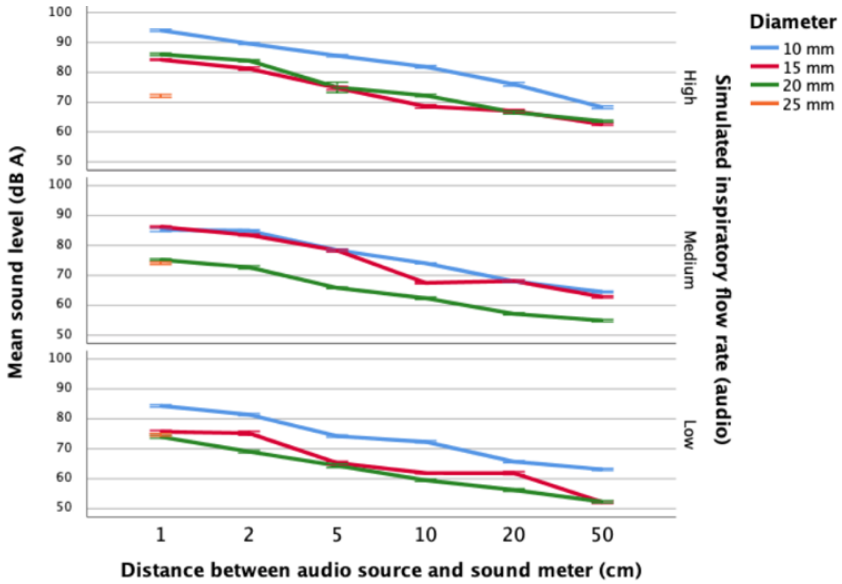

Figure 5. Sound levels of syringe-simulated inspirations by distance, flow rate and mouth diameter.

The association of distance, flow rate and mouth diameter with sound levels arising from simulating inspirations using the calibration syringe was significant ($F_{3,851}$ = 835.231, $p < 0.01$), accounting for 74.6% of the observed variability in sound levels (adjusted $R^2 = -0.746$). See Supplementary Materials file for the regression model.

Distance ($ß_{distance} = -0.706$, $p < 0.00$) explained more than twice the variability in sound levels compared with either flow rate ($ß_{flow\ rate} = -0.374$, $p < 0.01$) or mouth diameter ($ß_{mouth\ diameter} = -0.398$, $p < 0.01$). The highest peak inspiratory flow rates were measured when large mouth diameters (e.g., up to 25 mm) were applied using the pneumotachograph (Figure 4). Conversely, the highest sound levels arising from syringe-simulated inspirations were detected where the smallest mouth diameters (e.g., 10 mm) were used (Figure 5). Minimising the distance from the simulated "mouth" nozzle contributed more to producing higher and more audible inspiratory sound, with high syringe-simulated inspiratory flow rates and small mouth diameters also contributing to louder inspiratory sound for detection.

4.4. Sounds Level of Audio Samples of Syringe-Simulated Inspirations

Measured using a digital sound meter, sound levels for audio recordings of syringe-generated inspiratory sound were comparable with sound levels measured during syringe-simulated inspirations. (Figure 6).

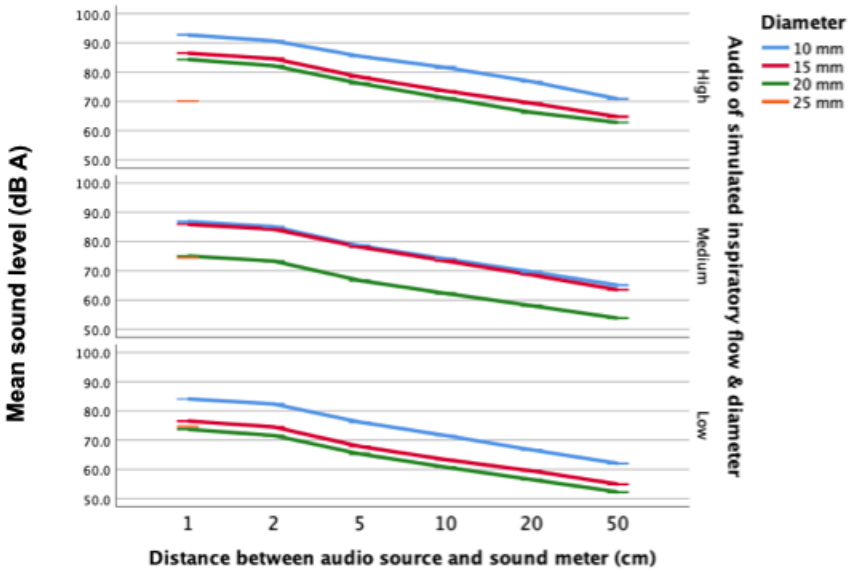

Figure 6. Sound levels of audio samples by distance, flow rate & mouth diameter.

The highest sound levels were recorded for high flow rate and small mouth diameter combinations (93 dB). Sound levels decreased as the distance between the audio source and digital sound meter increased. At each distance sampled (1, 2, 5, 10, 20 and 50 cm), higher airflows produced greater sound levels.

4.5. Audio Frequency Spectra for Simulated Inspirations

Audio spectra were generated for audio samples of each mechanically simulated inspiratory flow rate and mouth diameter combination, at a 1 cm distance from the audio source (Figure 7). Spectral peaks were greatest where mouth diameter was small (i.e., 10 mm) and the simulated inspiratory flow rate was high. Sound levels and resultant spectral peaks dissipated as flow rate was reduced, and as mouth diameter was increased.

Considering the largest simulated mouth diameters (i.e., 20 and 25 mm), a clearly delineated spectral peak (or perceptible sound) was difficult to identify. A representative sample of each mechanically simulated flow rate and mouth diameter combination was selected for testing the new QUT Inspire app.

4.6. QUT Inspire Application Testing with Audio Samples

Table 2 summarises investigations regarding the range of inspiratory sound detection of audio samples by Android and Apple smartphones running the new QUT Inspire application according to the increasing distance between the audio source and the smartphone. Results indicate that high and medium flows using mouth diameters of less than 25 mm were reliably detected at distances of up to 50 cm from the audio source. Low inspiratory flows were detectable at distances up to 5 cm using 10 or 15 mm mouth diameters for inspiration and up to 50 cm where mouth diameter was 10 mm.

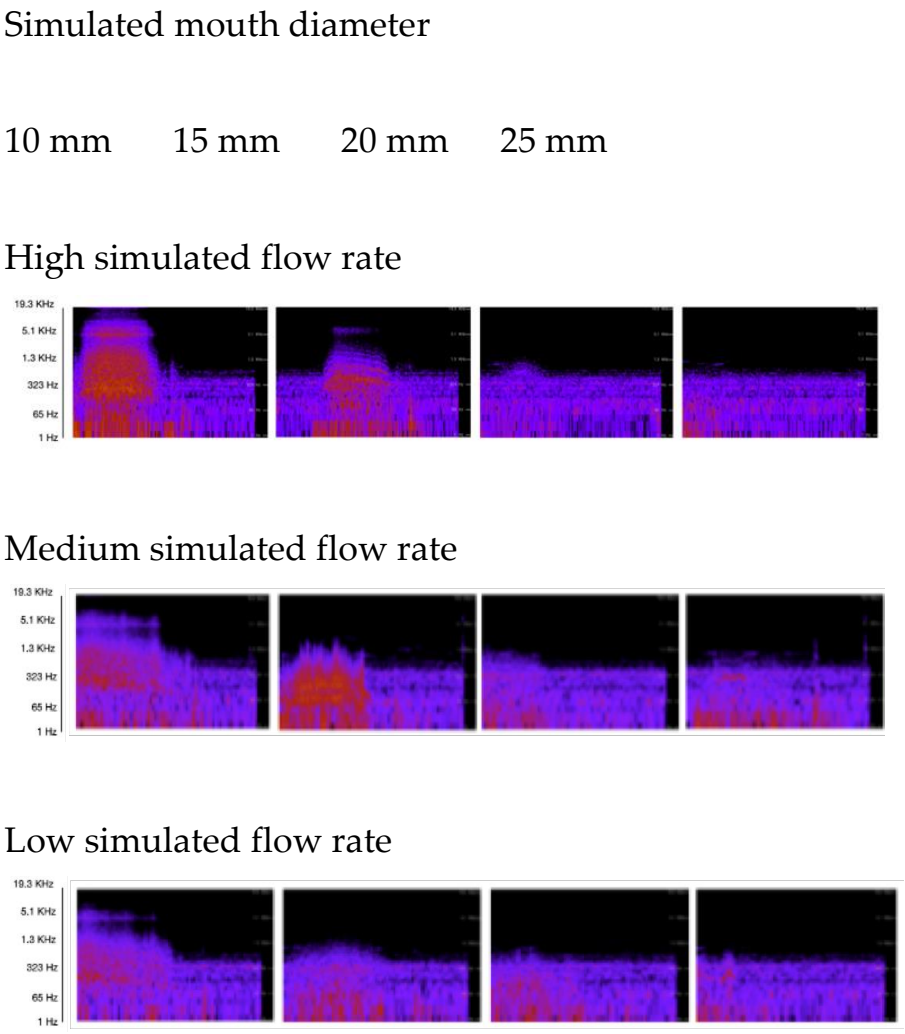

Figure 7. Audio frequency spectra for audio samples of simulated inspirations.

Inspirations simulated with the largest mouth diameter (25 mm) were not detected at any of the distances examined. The range of detection of inspiratory sounds by the QUT Inspire application was unchanged when the phone orientation relative to the sound source was rotated from horizontal to 45° and 90°, respectively.

Table 2. QUT Inspire application—range of inspiratory sound detection by flow rate and mouth diameter. When the following symbols are shown it means sound was detected using the corresponding simulated mouth diameter.

	Distance Between Smartphone and Audio Source					
	1 cm	**2 cm**	**5 cm**	**10 cm**	**20 cm**	**50 cm**
High flow audio						
Apple iPhone XR	●○○	●○○	●○○	●○○	●○○	●○○
Samsung Galaxy S10	●○○	●○○	●○○	●○○	●○○	●○○
Medium flow audio						
Apple iPhone XR	●○○	●○○	●○○	●○○	●○○	●○○
Samsung Galaxy S10	●○○	●○○	●○○	●○○	●○○	●○○
Low flow audio						
Apple iPhone XR	●○	●○	●○	●	●	●
Samsung Galaxy S10	●○	●○	●○	●	●	●

● = 10 mm; ● = 15 mm; ○ = 20 mm; ○ = 25 mm.

5. Discussion

The need for rigorous evaluation of mHealth apps has been mandated by the World Health Organisation and other stakeholders in light of the proliferation and popularity of health apps, and a paucity of evidence regarding application safety and efficacy. [20,39–41]. Widespread adoption of sensor-rich smartphones offers potential for generating and leveraging health data for health improvement purposes, notwithstanding the need for scrutiny to assert the validity and reliability of these emergent tools [34,36].

Complex sensor data can be simplified and presented to users in the form of exergames, using on-screen avatars or animations to respond to body movements (i.e., limb movements, respirations) in virtual or augmented environments designed to motivate engagement with a game and achieve some form of health improvement goal by engaging with game play [57]. In the context of exergaming, evidence is required to assert that both the primary and secondary goals for a given therapeutic exergame are achieved when using a new app, and that efficacy and safety are maintained when translating a conventional longstanding exercise technique or therapy to a virtualised implementation of that therapy [19]. In this study, a new smartphone respiratory therapy mHealth application for virtualising incentive spirometry (QUT Inspire) was investigated using non-human airflows generated with a calibration syringe to assess the reliability of inspiratory sound detection and validity compared with clinical reference measures.

This study contributes knowledge regarding the primary goal for this new application, namely reliable detection of inspiratory sound to trigger the display of an animation at a range of distances between phone and user, and with the application of different air inflow rates and simulated mouth diameters. Demonstration of the reliable triggering of the motivational animation at a range of distances contributes information regarding the safety of the new application. While the primary goal for this therapeutic exergame application is engaging and "distracting" the user to keep animated spheres aloft using the smartphone microphone to detect breath sounds, the secondary (and therapeutic) goal is the encouragement to persist with and to repeat gradual maximal inspiration to promote mucus clearance from the airways. The next step in these investigations are clinical studies to demonstrate the comparative efficacy of the new smartphone application compared with clinical devices in disease-free human subjects, and then in patients with disease.

Key insights arising from this research include highlighting the importance of sustaining a sufficiently high inspiratory flow rate and maintaining a small mouth diameter during inspiration to generate the largest, most audible sound levels. Further, the benefit of keeping the phone close to the mouth to maximise inspiratory sound detection was

also demonstrated. As a precursor to in vivo trials of this new app, insights gained from these studies inform enhancements to the application interface design such as instructional on-screen prompts to coach users to maintain a small mouth diameter and minimise the distance between the user's mouth and the phone microphone to optimise sound detection. Performance of the new application was comparable on examples of both Apple and Android smartphones, with no difference found in the range of simulated inspiratory sound detection when smartphone orientation was varied (i.e., held flat or horizontal, at 45 or at 90 degrees from the sound source).

Contemporary clinical incentive spirometers are robust mechanical devices that utilise a vacuum created by gradual maximal inspiration to levitate spheres (i.e., flow-based) or deflect a piston (i.e., volume-based) in a transparent plastic chassis, motivating compliance and persistence with repeated inspiratory efforts for therapeutic benefit by dislodging mucus from the airways for expulsion by coughing [16,53]. Debate exists as to the comparative clinical efficacy of these two types of ISy device; both device types are employed in clinical respiratory therapy [16,52]. Previous studies of incentive spirometry in healthy subjects suggest that higher inspiratory flow rates may be a more significant determinant of chest wall expansion than the type of incentive spirometry device [58].

In contrast to vacuum-triggered ISy devices such as the Triflo II, the new QUT Inspire virtual ISy application detects inspiratory sound using the built-in smartphone microphone displaying a levitating sphere animation on the screen (Figure 2), akin to the Triflo II flow-based ISy device (Figure 1). Turbulent airflows have been recorded at the mouth, with inspiratory flow becoming audible from 250 to 750 cc/s [21,22]. Acoustic recordings of breath sound components have been employed in the evaluation of smartphone mHealth apps previously, with respiratory sound components played back in contexts as diverse as cough sound analytics, snoring and sleep apnoea diagnosis; post-processing and complex analytics applied to sound samples yield diagnostic or therapeutic information without the need for accurate quantitation of respiratory flow rates per se [6,7,34,43].

Unlike classification of patterns of coughs or snoring, apps for performing respiratory function testing require the ability to quantitate flow rates, both for reporting clinically significant respiratory flows and for estimation of lung volumes (i.e., calculating flow over time). For example, a smartphone respiratory function testing application called Spirosmart was evaluated using playback of sound recordings of expirations captured from 52 subjects, comparing results with formal clinical respiratory function testing for each subject [9]. To improve measurement accuracy, users breathed through a plastic spacer mouthpiece device at the time of sound capture to constrain and standardise the diameter and shape of the mouth (for flow rate calculation) [9,48]. The investigators in this study reported successful sound detection by this application at distances up to arm's length separating the phone from the mouth [47]. Respiratory rate estimation has also been performed using smartphone microphone recordings [41]. Breath sounds were recorded at tracheal and nasal sites using built-in and headset smartphone microphones [46]. Nasal sound monitoring was found to be superior to sound sampling at the trachea in this study with respiratory rates accurately estimated at distances of up to 30 cm separating the nose from the smartphone microphone [46]. A separate investigation of cough sounds demonstrated a reliable range of detection for expiratory cough sounds at distances up to 30 cm separation [27].

Add-on devices such as spacers, whistles and headset microphones may present barriers to wider adoption of mHealth apps due to factors such as cost, compatibility and availability [12]. For the purpose of detection of gradual maximal inspiration in the context of ISy therapy, the QUT Inspire application does not quantitate respiratory airflows. The new application detects inspiratory sound and sustains a display animation while sound persists. The range of sound detection for the new application was comparable to results of previous studies reporting breath sound detection up to an arm's length separating user and phone for respiratory function testing, respiratory rate estimation or cough detection [9,27,47]. In this study, high and medium airflows using smaller mouth

diameters were detected up to 50 cm from the sound source by the Android and Apple smartphones tested.

The simulation equipment and testing environment present several limitations to the applicability of these study results to use in human subjects. The calibration syringe used in these simulations has a capacity of 3 L; this may not be representative of reduced lung capacities encountered with some respiratory conditions. Smaller syringes are available for regression testing to mitigate this risk. The flow reduction nozzles used for modelling changes in mouth diameter were neoprene washers, each possessing a single central circular hole of known diameter. Characteristics of turbulent air inflows (and audible sound) generated using these symmetrical apertures may differ when more complex (i.e., non-circular) mouth shapes may be formed when humans reduce their mouth shape. A smartphone held in the hand may distort the sound detected by a built-in microphone (e.g., if the hand is cupped around the phone producing an echo or sound attenuation effect). Background noise such as that encountered in hospital wards or shared living environments may also affect the detection of inspiratory sound. The QUT Inspire application displays a sliding onscreen volume control for suppression of background noise. Testing this background noise suppression feature was outside the scope of this research. While both smartphones selected for this study (i.e., Apple and Android) were less than 12 months old at the time of testing, newer phone models are often released. It is envisaged that audio samples such as those produced for this research may be amenable for regression testing newer phones to assess performance in light of advances in phone hardware and software.

Smartphones contain additional sensors that may complement or enhance future iterations of respiratory therapy mHealth apps such as the new QUT Inspire app. Built-in proximity (or approach) sensors measure the distance between a phone and user to unlock or brighten the phone screen as the phone is moved closer to the head, a feature that may be used to alert the user if the phone is too far away from the mouth and optionally prompt the user to bring the phone closer to their head to improve sound detection [3]. Advanced camera sensor technology in modern smartphones (e.g., Apple Face ID) is capable of measuring mouth diameter [59]. This measurement could prompt the user to adopt a smaller mouth shape to maximise sound production. These ancillary sensors may contribute to addressing limitations to the range of detection and effect of mouth diameter identified in this research. Recent research in gait analysis using built-in accelerometer sensors in smartphones shows promise in estimating a subject's lung capacity based on elements derived from their walking pattern [21]. These estimates could be used to customise respiratory effort required for inspirations or to display the normal range of respiratory values calculated for a given user (i.e., prediction of total lung capacity based on height, as inferred by gait) as part of the screen display of apps such as QUT Inspire.

6. Conclusion

A methodology for the acoustic sampling of mechanically simulated inspirations is presented here, with inspirations generated by a calibrated syringe at a range of clinically valid flow rates using a selection of mouth diameters of decreasing size (25–10 mm) to model conditions for audible inspiratory sound generation. Audio of these inspirations is used to evaluate the reliability and range of inspiratory sound detection for a new smartphone mHealth app that virtualises incentive spirometry. This methodology may also be amenable for evaluating other types of diagnostic or therapeutic respiratory mHealth apps. Results from this study inform new and emergent application design requirements such as the addition of screen prompts to remind users to maximise inspiratory flow rate, to reduce mouth diameter to maximise audible inspiratory sound production and to minimise the distance between the user and their phone to optimise inspiratory sound detection. Opportunities exist to incorporate other built-in phone sensors (e.g., camera, proximity and accelerometer sensors) as adjuncts to improving detection and display of inspiratory sound.

Supplementary Materials: Regression models—Model 1 (Section 4.2) and 2 (Section 4.3). https://www.mdpi.com/article/10.3390/s21196472/s1.

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Chapter 6: Virtual respiratory therapy delivered through a smartphone app: a mixed methods randomised usability study (Study 3)

This manuscript presents the results of the third study of the research program. The aim of this mixed methods study was comparison of the QUT Inspire virtual ISy app with a clinical ISy device using quantitative measures of usability (i.e., including effectiveness and efficiency) and qualitative usability insights (i.e., satisfaction), assessed using a cohort of healthy participants (n=24).

This manuscript pertains to Research Question 3:

How does the performance of the new app compare with conventional clinical modalities in cohorts of disease-free participants?

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Statement of Contribution of Co-Authors

The authors listed below have certified that:

1. they meet the criteria for authorship and that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
2. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
3. there are no other authors of the publication according to these criteria;
4. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit, and
5. they agree to the use of the publication in the student's thesis and its publication on the QUT's ePrints site consistent with any limitations set by publisher requirements.

In the case of this chapter:

Virtual respiratory therapy delivered through a smartphone mHealth app: a mixed methods randomised usability study (submitted 27/06/2022)

Contributor	Statement of contribution*
Clarence Baxter 12/08/2022	(eg. wrote the manuscript, experimental design, conducted experiments, and data analysis)
Julie-Anne Carroll	(eg. aided experimental design, data analysis, reviewed manuscript)
Brendan Keogh	(eg. aided experimental design, data analysis, reviewed manuscript)
Corneel Vandelanotte	(eg. aided experimental design, data analysis, reviewed manuscript)

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Virtual respiratory therapy delivered through a smartphone app: a mixed-methods randomised usability study

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ABSTRACT

Introduction A new smartphone app (QUT Inspire) has been developed to detect inspiratory sound and deliver virtual incentive spirometry (ISy), a respiratory therapy technique used in postoperative recuperation, management of some chronic conditions and with potential applications in SARS-CoV-2 rehabilitation. The aim of this study was to compare the usability of this new app with a clinical ISy device as measured by effectiveness, efficiency and satisfaction.

Methods In this mixed-methods randomised usability study, healthy volunteers (aged 39.2±12.2 years, n=24) compared inspirations using the QUT Inspire app and a Triflo II clinical ISy device. A post-test questionnaire and a semi-structured interview explored dimensions of usability regarding the new app.

Results The duration of inspirations performed using the QUT Inspire app (7.3±2.0 s) were comparable with use of the Triflo II ISy device (7.5±2.3 s). No artefacts arising from the order of device testing were identified. App users held their phones adjacent but not proximal to their mouths (13.6±6.4 cm), notwithstanding instructions to keep the phone less than 5 cm away for optimal breath sound detection. The use of onscreen text or video instructional materials did not result in a significant reduction in this distance. Participants reported clear preferences for the app (100%, n=24) to motivate persistence with repeated inspirations. App gamification features such as a timer (75%, n=18) and breath counter (83.3%, n=20) were well regarded. Analysis of semi-structured interviews identified four main themes arising from this study: visual reward from responsive app animations, clinical look and feel influencing credibility, perceived effort affecting engagement and selective adoption of gamification features.

Conclusion This study demonstrates that a virtual ISy app can be effective, efficient and have high satisfaction. Improvements informed by this research include use of additional phone sensors to optimise sound detection and minimising the distance that phones are held from the user's mouth. Further research in randomised controlled trials are needed to evaluate performance of this app in clinical contexts where ISy is currently employed.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Virtual incentive spirometry (ISy) is a novel emergent mHealth technology but little is known about the usability of apps compared with longstanding clinical devices for this respiratory therapy?

WHAT THIS STUDY ADDS

⇒ This study contributes knowledge regarding the usability of a new virtual ISy app compared with a clinical incentive spirometer device.

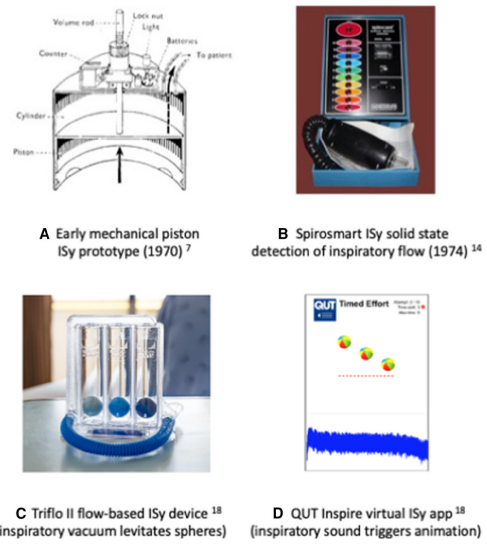
HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE AND/OR POLICY

⇒ A paucity of evidence regarding safety and efficacy presents barriers to more widespread adoption of mHealth apps for prescription by clinicians to patients. Evidence from this study may contribute to broader adoption of ubiquitous smartphone technology for health improvement.

INTRODUCTION

Developed in the 1970s, incentive spirometers are motivational devices designed to engage patients to persist with repeated gradual maximal inspirations for respiratory therapy.[1 2] The original purpose for this therapy was encouragement to produce inspirations which mimicked a yawn or a sigh, intended to reinflate collapsed alveoli (ie, alveolar atelectasis) arising as a side effect from surgical anaesthesia or protracted periods of postoperative recuperation in bed.[3 4] Designed as a 'bedside reminder' for patients to practice deep inhalations, applications for incentive spirometry (ISy) therapy now encompass prevention of chest infections and pneumonia due to mucus build-up in the airways, including chronic conditions such as chronic obstructive pulmonary disease and cystic fibrosis.[5–8] Recent reports also indicate a potential emergent role for ISy in rehabilitation for SARS-CoV-2 patients.[9–12] ISy therapy may decrease ventilation/perfusion mismatch and atelectasis in patients with mild to moderate SARS-CoV-2 related acute respiratory distress syndrome.[13]

While early ISy devices coupled a breathing hose to an enclosed mechanical piston levitated by means of a vacuum created with



A Early mechanical piston ISy prototype (1970) [7]

B Spirosmart ISy solid state detection of inspiratory flow (1974) [14]

C Triflo II flow-based ISy device [18] (inspiratory vacuum levitates spheres)

D QUT Inspire virtual ISy app [18] (inspiratory sound triggers animation)

Figure 1 Mechanical, electronic, inspiratory vacuum and sound detection incentive spirometry (ISy) devices.

purposeful inspiration (figure 1A), later ISy incarnations employed flow meter with LED displays (figure 1B) and more recently encased plastic spheres (figure 1C) or pistons to display and motivate inspiratory effort.[5–8 14 15] Contemporary flow-based ISy devices levitate spheres at calibrated inspiratory flow rates (IFR) while volume-based ISy devices deflect a piston to indicate inspired volume.[16] Annual prescription costs of ISy used for postoperative patients in the USA alone are estimated to be of the order of US$1.04 billion, reflecting widespread contemporary use of ISy.[17] Implementing ISy therapy (including device purchase, initial education and nursing reminders) costs between US$65.30 to US$240.96 depending on the length of stay as an inpatient.[17]

We have previously described a virtual ISy app for smartphones (QUT Inspire) which detects inspiratory sound at the mouth using the built-in phone microphone as an uncalibrated pressure sensor (figure 1D).[18] The QUT Inspire app is an HTML5 web app using the built-in smartphone microphone to detect inspiratory sounds, sustaining a responsive animated graphic display for as long as detectable breath sound is sustained. The app runs using the web browser on popular Apple and Android smartphones. A microphone volume control (Microphone icon) offers adjustment of sound sensitivity to eliminate background noise or increase the inspiratory sound volume required to trigger and sustain the onscreen animation. While reliable detection of high simulated IFR was demonstrated for the app at distances of up to 50 cm separating smartphones from a calibrated sound source, optimal sound detection for high, medium and low flow rates was established at distances of 5 cm or less.[18]

The QUT Inspire ISy app offers a low-cost, widely accessible means to increase access to ISy for health improvement. A paucity of literature exists regarding the usability of respiratory mHealth apps using the built-in phone microphone sensor for detection of inspiratory sound for display as a virtual incentive spirometer, and comparison of usability with clinical ISy devices. As a new virtualised incarnation of a longstanding respiratory therapy device, it would be negligent and potentially dangerous to conduct early usability studies on the QUT Inspire app using people with diseases amenable to treatment with ISy therapy without first deriving a better understanding of the app's performance in a relatively lower risk setting, namely by using a cohort of healthy persons to compare the traditional and virtual ISy devices. Should the app be found to be usable and perform well for healthy people (ie, encourage inspirations of adequate and comparable vigour and duration compared with traditional ISy devices and without any adverse events occurring during testing), studies in more vulnerable groups with relevant disease conditions may be indicated.

In this study, we compare the usability of the new QUT Inspire virtual ISy app (figure 1D) with a flow-based Triflo II clinical ISy device (figure 1C) in healthy subjects, considering effectiveness, efficiency and satisfaction as dimensions of usability.[19] While the reliability and clinical validity of this app has previously been demonstrated using calibrated acoustic simulation studies, assessment of interactions between people and the app are needed to further refine its design and functionality prior to prospective studies assessing the efficacy of virtual ISy therapy in cohorts with relevant diseases.[18]

METHODS

The usability of the new QUT Inspire virtual incentive spirometer mHealth app was investigated in this study using a mixed-methods randomised usability approach. Usability was measured according to effectiveness, efficiency and user satisfaction.[19] Effectiveness and efficiency were measured in the initial quantitative study phase, and satisfaction in a latter qualitative component. In the first phase, a cohort of healthy participants compared gradual maximal inspirations performed using the new app and the clinical incentive spirometer (Triflo II Model: 8884717301) in a randomised cross-over approach to control for any device testing order effects. Effectiveness was compared by monitoring duration of sustained inspiratory effort with both devices. Efficiency was assessed using the distance that participants held their phones from their mouths. At the completion of device testing, participant satisfaction was canvassed in the second phase using semi-structured interviews.

Patient and public involvement

The design of this research was informed in part by insights gained from an earlier Master of Public Health dissertation by Clarence Baxter in 2018 regarding user impressions concerning an initial design prototype of the app. Users in this earlier study reported a preference for more responsive graphic animations in response to inspiratory effort. The app was updated based on feedback received.

Participant recruitment procedure

The SARS-CoV-2 global pandemic presented constraints in recruitment of participants for this study and due caution on the part of the Ethics Committee regarding participant safety; approval was granted on conditions including (1) receipt of informed consent by disease-free adult participants over 18 years of age, (2) that participants use their own phones for testing (to minimise cross infection risk) and (3) that testing must not impose excessive repetitive inspiratory exertion on the part of participants over and above that required to experience use of, and then comment on app usability compared with a traditional ISy device. Testing was conducted with a rest period interspersed between each of three slow gradual maximal inspiration attempts performed with each device tested.

Email and social media advertising targeting potential participants were employed to garner interest in this research. Healthy people were recruited from a Queensland university and members of the public affiliated with community organisations between May and June 2021, using opportunistic and snowballing recruitment strategies. Using sample size methodology published by the *BMJ* and assuming two-sided α=0.05 and β=0.10, an approximate sample size (n) of 25 was calculated as required for this study (ie, $n=16*\sigma^2/d^2$ where a clinically valid difference in inspiratory duration of 4 s (d) and between-subject variability of 5 s (σ) were assumed).[20] Further, saturation and triangulation of data were achieved in the qualitative study component using this cohort, thus removing a need for further recruitment in this phase.

Testing was conducted face-to-face in office settings at several urban locations in South-East Queensland, Australia. Participants were excluded from the study if any pre-existing medical condition prevented gradual maximal inspiration. Participants were also excluded if unable to provide a sustained inspiratory flow of 600 cc/s using the clinical ISy device or unable to trigger the app's display animation due to insufficient sound from inspiratory flow. To minimise risk of SARS-CoV-2 cross-infection, participants used their own Apple or Android smartphone internet browser to run and test the app. Written informed consent to take part in this study was obtained from all participants.

Phase 1: randomised usability study

Figure 2 presents a Consolidated Standards of Reporting Trials diagram for this study. To control for potential

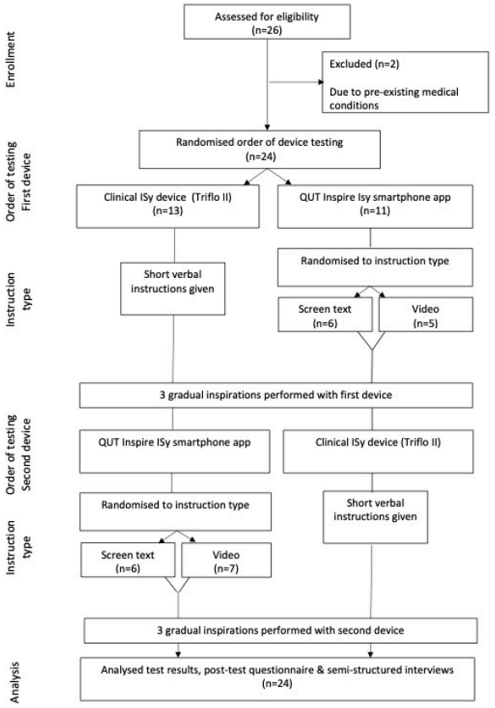


Figure 2 Consolidated Standards of Reporting Trials diagram for study.

device testing order effects, participants were randomly assigned (using a random number table) to use either the Triflo II ISy device or the new QUT Inspire app first, and then to use the other device. Prior to testing the app, participants were randomly assigned to view onscreen text or a short instructional video describing how to use the app (including the need to minimise distance between their mouths and phone for optimal sound detection). In keeping with standards for the performance of clinical spirometry, only the data from the highest of three comparable inspirations using each device were recorded.[21] The duration of inspirations using the devices were measured using a stopwatch. When testing the app, the distance separating the phone and user's mouth was measured with a ruler. Quantitative measures were calculated using IBM SPSS Statistics (V.28.0.0.0.190). A self-administered questionnaire was completed by participants following device testing (see online supplemental appendix 1). A 5-point Likert scale captured responses to questions regarding the user-friendliness, layout and ease of use of the new app in addition to breathing effort required in completing inhalations using the devices. Participants were also asked to rate the utility of instructions for the app, and whether gamification features such as a timer and an attempt counter were helpful to keep track of

Table 1 Participant demographics

Gender	n (%)
Female	14 (58%)
Male	10 (42%)
Age and age distribution	39.2±12.2 years
Under 25	1 (4%)
25–34	8 (33%)
35–44	2 (8%)
45–54	11 (46%)
55–64	2 (8%)
65 and above	0 (0%)
Education	n (%)
High school	14 (58%)
Undergraduate degree	6 (25%)
Postgraduate degree	4 (17%)
Phone type	n (%)
Android	10 (42%)
Apple	14 (58%)
Internet browser used	n (%)
Chrome	8 (33%)
Firefox	4 (17%)
Safari	12 (50%)

inhalations. Questionnaire responses were consolidated as 'agree' where 'agree' or 'strongly agree' was reported by respondents, or 'disagree' where 'neutral', 'disagree' or 'strongly disagree' was reported.

Phase 2: qualitative usability study

Semi-structured interviews were conducted with participants after completion of the quantitative testing phase. All interviews were digitally recorded. Using a set of starter questions, participants were asked about their device preferences for motivating inhalations and whether gamification features such as a timer and breath counter provided additional motivation (see online supplemental appendix 2). Interview recordings were transcribed and inductive thematic analysis was performed using axial coding.

RESULTS

Of 26 initial respondents to email or social media invitations to participate in this research, 2 were excluded due to screening for pre-existing medical conditions precluding repeated maximal inspirations (figure 2). Of the remaining participants (n=24), all completed quantitative testing and post-test qualitative studies (table 1). No adverse events were reported during or after testing, and all participants were able to supply adequate inspirations.

Statistical analysis and findings

Participant demographics are presented in table 1. Participants were aged between 21 and 64 years of age, with equivalent numbers of users having Apple or Android smartphone types. More than two-thirds of study participants (70.8%, n=17) had no prior knowledge of ISy, while under a third (29.2%, n=7) had seen or used a clinical ISy device.

No significant difference was found between the duration of inspirations (seconds) generated using the QUT Inspire app compared with the Triflo II clinical ISy device (table 2A). Inspiratory durations when using the app were comparable regardless of device testing order. A device order effect was identified regarding measurement of inspiratory flow rates (IFR_{max}) using the Triflo II device; the mean IFR_{max} was found to be higher (1176.9±83.2 cc/s) if this device was used first, with lower mean IFR_{max} observed (1036.4±156.7 cc/s) when the Triflo II was the second device tested (p=0.018). As the QUT Inspire app

Table 2 Comparison of quantitative usability measures—effectiveness and efficiency

(A) Effectiveness: duration of inspirations (s) by device testing order (QUT Inspire and Triflo II)			
	Order of device testing		**Significance**
Inspiration duration	QUT Inspire app	Triflo II ISy	
Tested first (s)	7.3±2.0	7.5±2.3	p=0.787
Tested second (s)	7.2±2.1	7.4±2.2	p=0.732
(B) Efficiency: distance between mouth and phone (cm) by testing order (QUT Inspire only)			
	Order of QUT Inspire app testing		
Mouth↔phone	QUT Inspire App tested first	QUT Inspire App tested second	
Distance (cm)	13.6±6.4	9.2±5.7	p=0.088
(C) Efficiency: distance between mouth and phone (cm) by order of instructions (QUT Inspire only)			
	Order of presenting app instructions		
Mouth↔phone	On screen text shown first	Video instructions shown first	
Distance (cm)	10.4±5.4	12.1±7.2	p=0.529

Table 3 Questionnaire responses

Question	Agree	Disagree
I think the app is user friendly	24 (100%)	0
I like the overall layout of the app	24 (100%)	0
I was easily able to complete 3 inhalations using the app	24 (100%)	0
Similar effort was required for me to inhale using the app and the plastic device	20 (83.3%)	4 (16.7%)
I could easily understand the screen instructions displayed by the app	21 (87.5)	3 (12.5%)
The attempt counter displayed by the app is useful for tracking inhalations	20 (83.3%)	4 (16.7%)
The timer displayed by the app gave me motivation to persist	18 (75.0%)	6 (25.0%)

does not measure or display IFR_{max}, no comparison of this measure with the Triflo II device was possible.

The distance that participants held their smartphones away from their mouths for inspiratory sound detection was comparable and independent of device testing order (QUT Inspire app tested first: 13.6±6.4 cm and: 9.2±5.7 cm when tested second). Few participants held their phones at distances less than 5 cm (optimal for sound detection) away from their mouths (table 2B). This distance was not minimised significantly when either onscreen text or video instructional materials were presented to the user prior to app testing (table 2C). While users held their phones at distances greater than recommended, no instances were observed where the app failed to detect inspiratory sound.

Post-test questionnaire

Table 3 presents participant responses to a post-test questionnaire; all agreed that the app was user friendly, that they liked the app layout and that they were easily able to complete three inhalations using the app.

While most participants (83.3%, n=20) agreed that similar effort was required to inhale using the app and the clinical ISy device, four participants (16.7%) reported that less effort was required to use the app. Most participants (87.5%, n=21) reported that they understood the screen and video instructions. Three-quarters of participants (75.0%, n=18) agreed that the timer provided motivation to persist with inspirations, and that the attempt counter was useful for tracking inhalations (83.3%, n=20).

Qualitative findings

The average time taken for semi-structured interviews was 15 min, ranging from 11 min to 17 min. Interview transcripts were analysed using thematic analysis and axial coding to identify emergent concepts related to participant satisfaction in the context of app usability. Four main concepts and themes were identified in this analysis:

- Visual reward from responsive app animations.
- Clinical look-and-feel influencing credibility.
- Perceived effort affecting engagement.
- Selective adoption of additional gamification elements.

Theme: visual rewards from responsive app animations

Most participants preferred the new virtual app as best for displaying inspirations. Responsiveness of the app screen display and compactness when using the app on a smartphone were reported as advantages of the virtual ISy device:

> The phone … [app] responded quicker … worked when I breathed in …. it jumped up and stayed up … [gestures upwards movement of balls using hand]. (Participant 4, male, aged 21 years)

Most users favoured the smartphone app for maintaining inspiratory effort with some noting more rapid responsiveness to inspiratory sound compared with the clinical ISy device:

> The app definitely … I could see it change as soon as I started breathing in. (Participant 16, male, aged 29 years)

Theme: clinical look-and-feel influencing credibility

Of those participants with a preference for the virtual app, several noted similarities in the appearance of the clinical device and virtual app display:

> I was impressed by the smartphone [app]. It looks like the medical one and shows my breaths on the screen. (Participant 18, female, aged 58 years)

In contrast, one participant preferred the clinical device display, likening the app display to a trivial game:

> The Triflo one …The app looked like a bit of a game. (Participant 22, male, aged 35 years)

Participants were offered onscreen text instructions and an instructional video guiding use of the app. Ten participants expressed a clear preference for on-screen text instructions while six preferred video instruction:

> The on-screen help spelled it all out. The video took extra time to watch. (Participant 4, male, aged 21 years)
> Video. I think I understand better with pictures… so I can go back and check it again. (Participant 13, female, aged 31 years)

Use of both onscreen text and video instruction were favoured by eight participants.

Theme: perceived effort affecting engagement

Some participants reported that it was easier to trigger and maintain elevation of the spheres with the app compared with the Triflo II device, and preferred the app for this:

> The app worked best. It was harder breathing in using the plastic tube …. I didn't like it [gestures towards Triflo device]. (Participant 14, male, aged 34 years)

In contrast, four participants described a preference for the Triflo II clinical ISy device due to greater inspiratory effort needed to elevate spheres using the clinical device:

> The plastic one was more of a workout. I had to inhale harder to get the plastic balls in the phone to jump. (Participant 17, male, aged 26 years)

Theme: selective adoption of additional gamification elements

Participants were allowed to discover gamification features such as an on-screen timer to measure the duration of each inspiration, and an inspiration counter. More than half of the participants reported that gamification features afforded some degree of additional incentive, with some tempering their views due to the small number of inhalations required during the study. Some others reported that they were too pre-occupied with the app's main display to make use of gamification features:

> Yes, the counter was good for to keeping track of your breathing. (Participant 7, female, aged 49)

Nine participants reported no additional incentive from the app's timer and breath counter:

> I looked at the timer … less so with the counter … I was looking at the balls. I was too busy keeping the balls up in the air and making sound to look. (Participant 3, female, aged 61)

DISCUSSION

In its many incarnations, ISy embodies key tenets of 'serious gaming' (ie, a game for a non-recreational purpose such as healthcare) called therapeutic exergaming.[22 23] A therapeutic exergame engages a patient in a primary exercise goal using inspiratory effort to keep real or virtual spheres aloft (or by levitating an encased piston), with a secondary therapeutic goal built into the activity, namely performing repeated gradual maximal inspirations for dislodgment of mucus from the airways for expulsion by coughing.[24] Traditional ISy devices are simple in design and easy to use, with inhalation via a breathing tube offered as the sole manoeuvre required for therapy. The new QUT Inspire app is a skeuomorphic design which presents a virtualised representation of a traditional clinical flow-based ISy device.

A recent review noted that usability is not fixed, and that evaluations of 'technical usability' (ie, quantitative assessments, scale-based questionnaires) and qualitative usability insights are only relevant in the context where they are applied.[25 26] Technical usability has been further defined as the capability for a technology to be understood, learnt, used and attractive to the user when used under specified conditions.[27] It has been (boldly) suggested that up to 80% of usability problems can be identified by using as few as five subjects and further, that almost all of high-severity usability problems can be uncovered with usability assessment by only three subjects.[28] The International Standards Organisation (ie, ISO) has proposed and revised standards for quality assessment of health and well-being apps.[29] The ISO defines usability as the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.[29] Critics claim that the most recent ISO standards lack nuance regarding the diversity of app users and contexts for use.[29] For the purposes of this study, effectiveness measures the outcomes of interactions between people and systems; the primary comparative measure of effectiveness in this study was the duration of inspirations sustained when using each device.[19] Participants in this study produced inspirations of similar duration using both the new QUT Inspire app and a Triflo II clinical incentive spirometer. This was independent of the order of device testing.

Clinical ISy devices such as the Triflo II connect users to the device by means of a breathing tube of fixed length and a mouthpiece of fixed diameter. Given these dimensions are known for the Triflo II, IFR_{max} can be displayed on the device chassis (600, 900 or 1200 cc/s, respectively) and represented with sequential levitation of spheres. A device testing order effect was noted in this study where lower IFR_{max} was observed where the Triflo II device was the second device used. This may be attributable to fatigue arising from the first round of testing or familiarity with the app in the first round of testing influencing the amount of effort expended by participants when subsequently testing the Triflo II device.

Detection of breath sounds using smartphones has been demonstrated previously, including use of external add-on microphones for attenuation of sounds arising from tracheal airflows or by adding plastic tube-like spacer devices of known dimensions to constrain mouth shape and facilitate flow rate estimates for smartphone-based respiratory function testing.[30 31] In contrast to vacuum-induced levitation of spheres, the new QUT Inspire app uses the smartphone microphone as an uncalibrated pressure sensor for detection of sustained inspiratory sound, triggering and maintaining a levitating ball animation while sound is sustained over and above an adjustable threshold sound level. Several users (n=4) reported that the app required less effort to use than the Triflo II

device. Inspiratory workload can be increased for the app by adjusting the microphone sound level (Microphone icon) and raising the sound level threshold for triggering the display animation (not evaluated in this study).

The second quantitative dimension of usability examined in this study concerns efficiency. Efficiency relates to completeness in achievement of goals.[19] The distance that a phone user holds their phone away from their mouth when using the QUT Inspire app can be considered as an indicator of efficiency in this study. Participants held their phones between 9 and 13 cm away; neither onscreen or video instructional materials resulted in a significant reduction in this distance. While screen readability may be a barrier to holding the phone extremely close, distances measured in this study were within the range of detection for medium and high inspiratory flow sounds (up to 50 cm) identified in a previous QUT Inspire acoustic simulation study.[18]

Satisfaction was investigated as a third component of usability arising from qualitative studies using this cohort, reflecting positive attitudes and 'comfort' when using the app.[19] Favourable comments were made concerning the app's portability, display animations and responsiveness. The clinical 'look and feel' of the app display was generally well regarded. Some participants expressed preference for the Triflo II device because they felt more inspiratory work was required, while others expressed the converse view. Satisfaction reported by a healthy cohort such as this study group does not directly equate to a likelihood to use or persist with virtual ISy therapy, as the needs of people with health conditions may compel compliance (or attempt to comply) for treatment purposes. While gamification features were generally well received, several users commented that they were too busy keeping the animated balls aloft to look at the timer and attempt counter features. Traditional ISy devices do not offer attempt counters or inspiration times. While remembering a count of three inspirations may be straightforward, the ability for the app to count up to a prescription of 10 inspirations for therapeutic benefit may help some users keep track of progress. There may be additional benefit in inspecting inspiratory performance to analyse duration of inhalations performed. Enhancements to the display animations were suggested, including a windmill-style display which spins faster with higher airflows and use of avatars which move with breathing effort.

Strengths and Limitations

Apps such as QUT Inspire offer a low-cost means of improving health by leveraging built-in microphone sensors available in all smartphones to perform ISy. Given the app runs as an HTML5 web app on any Android or Apple device with a web browser, QUT Inspire is compatible with most contemporary smartphone devices. While smartphones are widely adopted and used, older app users may require training if unfamiliar with such virtual technology, not unlike training currently required to use a traditional ISy device. Following on from this usability study, evaluation of this new app using subjects with relevant health conditions potentially amenable to ISy therapy is a logical next step in asserting that the app is safe and effective.

Participants in this study only performed three inhalations using each device, in contrast to clinical 'prescriptions' for ISy therapy which commonly involve 10 slow gradual maximal inspirations, with this set of ten repetitions performed hourly.[24] Coughing induced by disease conditions or as a therapeutic byproduct resulting from ISy therapy may present additional challenges (eg, potential spurious noise generation) particular to virtual ISy use but not encountered in healthy subjects.

This study cohort was skewed towards adults and more mature persons, and represented those with (at a minimum) some experience with smartphone technology. Neither children nor adolescents were represented in the study cohort, and future clinical studies will need to factor in usability among younger persons with conditions such as cystic fibrosis where ISy therapy may be indicated.

Future research

Key observations arising from this study concern compliance required from app users regarding minimising the distance separating the user and their smartphone. Modern smartphones possess proximity or approach sensors which can measure the distance between phone and user; an enhancement to the app could warn if the phone is too far from the user's head for optimal detection of inspiratory sound. As some users commented that less work was needed to use the app, inspiratory effort or work can be increased when using the app by adjusting the microphone sound level control to raise the threshold sound level required to trigger the display animation. The default preset sound threshold may warrant being increased, but this was not examined in the current study.

Suggestions from study participants will be included in refinements to the app design. Larger font sizes, additional animation styles and making the app available for use on smartwatches will be considered among design refinements. Regression testing of the enhanced app using an additional cohort of healthy subjects would be warranted. Following implementation of enhancements arising from this research, clinical studies regarding safety and efficacy are the next step in evaluating the QUT Inspire app.

CONCLUSION

Development of an mHealth app such as QUT Inspire is an iterative process. App prototyping involving bench testing provides formative evidence of functionality. Simulations contribute additional data under controlled conditions with opportunities to apply rigorous test sequences not possible when using human subjects. In this study, usability testing with healthy subjects contributes further

insights into the operation of this app 'in the wild'. These insights contribute to improvements in the app, with particular reference to optimising distance between the user and their phone for inspiratory sound detection and improving the user interface.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Queensland University of Technology Human Research Ethics Committee (Ethics Approval Number: 1900000919). Participants gave informed consent to participate in the study before taking part.

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Supplemental Appendix 2 - Post-Test Questionnaire

USABILITY QUESTIONNAIRE

IF49 QUT Inspire - Incentive spirometry study

QUT Ethics Approval Number 1900000919

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Participant ID Number: _____

Date/Time: _____

Questions regarding usability of the QUT Inspire app:

Please consider the following questions and circle your chosen response.

1. **I think the QUT Inspire app is user-friendly**

1	2	3	4	5
strongly disagree	disagree	neutral	agree	strongly agree

2. **I like the overall layout of the QUT Inspire app**

1	2	3	4	5
strongly disagree	disagree	neutral	agree	strongly agree

3. **I was able to easily complete 3 inhalations using the QUT Inspire app**

1	2	3	4	5
strongly disagree	disagree	neutral	agree	strongly agree

4. **I was able to easily complete 3 inhalations using the plastic device**

1	2	3	4	5
strongly disagree	disagree	neutral	agree	strongly agree

5. **Similar effort was required for me to inhale using both QUT Inspire and the plastic device**

1	2	3	4	5
strongly disagree	disagree	neutral	agree	strongly agree

6. **I could easily understand the on-screen prescription instructions displayed by QUT Inspire**

1	2	3	4	5
strongly disagree	disagree	neutral	agree	strongly agree

7. **The attempt counter displayed by QUT Inspire was useful in keeping track of my inhalations**

1	2	3	4	5
strongly disagree	disagree	neutral	agree	strongly agree

8. **The timer displayed by QUT Inspire gave me motivation to persist with inhalations**

1	2	3	4	5
strongly disagree	disagree	neutral	agree	strongly agree

THANK YOU FOR YOUR ASSISTANCE WITH THESE QUESTIONS

Supplemental Appendix 3 - Semi-structured interview: List of starter questions

SEMI-STRUCTURED INTERVIEW GUIDE

IF49 QUT Inspire - Incentive spirometry study

QUT Ethics Approval Number 1900000919

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Participant ID Number: _____

Date/Time: _____

List of starting questions:

1. Have you ever seen or used an incentive spirometer before?
2. Which instrument did you like the best for displaying inspiration and why?
3. Which instrument do you think provides the most encouragement to maintain effort and why?
4. Did the timer or attempt counter on the app provide additional incentive for your inspirations?
5. Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?
6. Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Chapter 7: Discussion and conclusion

In this discussion and conclusion chapter, section 7.1 summarises why this research matters. Section 7.2 presents a discussion of the principal findings arising from the research program comprising this thesis. The strengths and limitations of the constituent studies are itemised in section 7.3. Sections 7.4 and 7.5 consider practical applications of this research and recommendations for further research respectively, followed by a conclusion (section 7.6) which restates the outcomes of this doctoral research.

The multitude of apps available to contemporary smartphone users is testament to the fervour with which this emergent technology has been embraced by literally billions of people worldwide. In the context of health, many apps provide health-related information, others support behaviour change and a further subset leverage built-in sensors in smartphone devices for diagnostic or therapeutic purposes (Paglialonga et. al., 2018). Smartphone sensors such as the phone microphone may be useful when repurposed in contexts such as breath sound detection in respiratory medicine, with potential to virtualise the functionality of established clinical devices to improve accessibility to health improvement at low cost by leveraging smartphone technology already possessed by many people (Andrès et. al., 2018; Majumder & Deen, 2019). Notwithstanding a veritable trove of mHealth apps offered to health professionals and patients alike, clinicians have demonstrated reticence in adopting mHealth app prescription, citing challenges in identifying suitable candidate apps and scant evidence regarding app safety and efficacy as barriers to wider adoption in clinical practice (McCay, 2020). Gaps in current research exist concerning the availability of prescribable smartphone mHealth apps using built-in sensors. Evidence is needed to determine the suitability and the potential for prescribability of emergent mHealth apps such as the new QUT Inspire app (the focus of this thesis) for virtualising a longstanding respiratory therapy technique. It is in these realms that the current thesis resides, contributing original knowledge regarding mHealth apps using built-in smartphones and evaluation of a novel app for respiratory therapy.

7.1 WHY THIS RESEARCH MATTERS?

There is a risk that potential benefits from emergent mHealth technology may not be realised if confidence in the performance of apps fails to meet expectations or worse, if harm is caused by unsafe or ineffective apps particularly where smartphone sensors are used to gather health data. The potential reach of low-cost, widely accessible apps for health improvement may be stymied if clinicians are not satisfied with the evidence base underpinning justification for prescription of apps to patients or health consumers fail to achieve health benefits. Further, some health consumers may need protection when self-selecting or relying on unproven apps by rigorous evaluation of safety and efficacy before making apps available. Two prescient examples illustrate this:

Examples 1: Natural Cycles is an example of a contraception planning app using an algorithm to calculate days of the month a woman is likely to be fertile using body temperature readings and menstrual cycle information (Lowe & Hartley, 2018). Predictions made by this 'passive' app (i.e., requiring keyed data entry) have been demonstrated to be variable in accuracy resulting in multiple unplanned pregnancies (Kalampalikis et. al., 2022).

Example 2: Risks to health have also been reported in 'active' mHealth apps using built-in smartphone sensors to gather health data, which may be incorrectly captured or reported in the absence of rigorous testing. 148,000 people downloaded a malfunctioning smartphone blood pressure monitoring app using the phone camera and photoplethysmography to detect blood flow at the fingertip and infer blood pressure based on pulse, later found to report inaccurate measurements and posing a potential risk to patients with hypertension (Chanpimol et. al., 2017; Plante et. al., 2016).

Legions of COPD sufferers worldwide and others for whom ISy therapy is a mainstay of contemporary (or future) inpatient and outpatient treatment may potentially benefit from a low cost virtual ISy app to improve health accessible from smartphone devices which many already own. Akin to any other medical device or treatment,

demonstration of app safety and efficacy demands scrutiny before considering prescription to health consumers.

7.2 PRINCIPAL FINDINGS

Table 13 presents a summary of research questions, gaps in knowledge and contributions related to this research program.

Table 13: ***Summary of the research program***

Study 1 Chapter 4	**Research Question 1:** What curated information is currently available to inform and guide clinician-initiated prescription and health consumer self-prescription of mHealth apps using built-in sensors for diagnosis or therapy? **Gaps in knowledge:** Availability of potentially prescribable apps using built-in phone sensors for diagnosis or therapy; availability of respiratory therapy apps using built-in microphone for inspiratory breath sound detection. **Action:** Conducted a systematic survey of mHealth apps using built-in sensors available from curated international third-party health app libraries **Contribution:** A paucity of prescribable apps found in a sample of curated mHealth app libraries; no respiratory therapy apps were offered by any of the curated libraries surveyed

Study 2 Chapter 5	**Research Question 2:** How reliable and clinically valid is the new QUT Inspire virtual ISy app for detection of audible inspiratory sound using the built-in smartphone microphone for sound detection? **Gaps in knowledge:** Need to determine optimal mouth diameter, flow rate and range of detection of inspiratory breath sound for the QUT Inspire app. **Action:** Evaluated the reliability and clinical validity of the new QUT Inspire app using simulated inspiration sounds (Calibration study) **Contribution:** Demonstrated reliable detection of high and medium inspiratory airflow sounds at distances up 50 cm separating the sound source and smartphones running the QUT Inspire app
Study 3 Chapter 6	**Research Question 3:** How does the performance of the new app compare with conventional clinical modalities in cohorts of disease-free participants? **Gaps in knowledge:** Need to assess performance and usability of the QUT Inspire app compared with a conventional clinical ISy device. **Action:** Compared the usability the QUT Inspire app with a conventional ISy device in cohort of healthy participants (n=24). **Contribution:** The new QUT Inspire app demonstrated usability comparable with that a conventional clinical ISy device in terms of effectiveness, efficiency and satisfaction as reported by a cohort of healthy users.

The first study (Chapter 4) was a systematic survey of three selected popular international third party curated mHealth app libraries designed to establish the availability of potentially prescribable smartphone mHealth apps using built-in smartphone sensors for diagnosis or therapy. The major finding of this study was identification of a paucity of apps using built-in smartphone sensors (n=18 from 1,200 apps surveyed) for diagnosis or therapy listed in these libraries where vetting or screening for safety and efficacy is conducted. This is in agreement with previous research which found that 11 apps from an estimated pool of 325,000 potentially prescribable mHealth apps demonstrated meaningful health benefits based on an overview of systematic reviews; built-in sensor use was not considered in this prior work (Byambasuren et. al., 2018). Earlier studies also report modest representation of clinical apps in offerings from Google and Apple app stores, but prior point-in-time search results need to be tempered by consideration that apps can be added or removed from app stores over time, and that investigation of sensor use was not documented in these works (Gan et. al., 2016; Kao & Liebovitz, 2017; Paglialonga et. al., 2018).

A disparity was found in the number of sensor-based smartphone apps available from the surveyed curated libraries for diagnosis (22%, n=4), therapy (50%, n=9) or combined diagnostic and therapeutic functionality (28%, n=5). This observation supports earlier findings regarding app store offerings where disease management apps represented a quarter of all mHealth offerings, with a smaller proportion offering diagnostic functions (Kao & Liebowitz, 2017). It may be that regulatory constraints and rigorous curation activities conducted by the surveyed libraries may have excluded a higher proportion of diagnostic apps (Baldwin et. al., 2017). From the perspective of a software developer, it may be more lucrative to code and sell apps that are used on an ongoing basis for ongoing therapy, in contrast to diagnostic apps which may be single use only for detection or diagnosis of a particular health condition (Keutzer,& Simonsson, 2020; Lupton & Jutel, 2015). While potential risks to health from ineffective or unsafe therapy apps are serious, harm arising from type I (false positive) or type 2 (false negative) errors in diagnosis may further discourage risk-adverse developers from offering diagnostic apps. (Millenson et. al., 2018, Muro-Culebras et. al., 2021).

Study 1 also highlights limited cross-platform availability of mHealth apps using built-in sensors in the curated libraries surveyed. More apps were found to be dedicated to use solely on Apple (50%, n=9) devices compared with Android specific apps (11%, n=2). Fewer apps compatible with both phone types (39%, n=7) were identified. Differences in sensor components and heterogeneity in app offerings for competing smartphone manufacturers have been described previously as presenting challenges to development of cross-platform sensor-based mHealth apps (Boulos et. al., 2011; Daponte et. al., 2013). Android devices are more prevalent (particularly in low to middle income countries) and health inequalities may exist where device compatibility constraints may preclude access to potentially valuable mHealth tools (Osei, E., & Mashamba-Thompson, 2021; Royston et. al, 2015; Sedrati et. al., 2016).

A limited range of health conditions were addressed by the sensor-based apps identified in Study 1. The phone camera was the most frequently used built-in sensor (39%, n=7), employed in apps for dermatology, cardiology and visual acuity. Past reviews report a wider range of health conditions where smartphone sensor use has been researched, but these reviews encompass research studies of apps not yet translated into commercial app products amenable to listing in curated app libraries (Cornet & Holden, 2018; Majumder & Deen, 2019). Pertinent to Studies 2 and 3 in this research program, no respiratory therapy apps were identified in the curated libraries investigated, but microphones (17%, n=3) were used for breath detection in apps addressing anxiety and snoring analysis.

Study 1 yielded novel insights into the availability and nature of sensor-based mHealth apps available for prescription to patients and self-selection by health consumers in a sample of trusted mHealth app libraries. Regulatory approval of software as a medical device, listing in curated mHealth app libraries and more generally garnering acceptance by clinicians is contingent on gathering evidence to support adoption of any potential app for prescription (Wickes & Chiauzzi, 2015). Moving from the diaspora of sensor-based apps considered in the first study, the remainder of this research program focused on contributing original knowledge regarding a specific respiratory therapy app using the built-in phone microphone to detect inspiratory sound (QUT Inspire), a type of app notably absent as an offering from the curated libraries surveyed. The objective of this new app was virtualisation

of incentive spirometry, a widely employed respiratory technique which currently uses longstanding clinical instruments triggered by an inspiratory vacuum to levitate spheres in a plastic case as encouragement to repeat slow gradual maximal inspirations. In virtualising this device, key steps in the evaluation of QUT Inspire first required pre-clinical non-human simulation studies to first assert the reliability and clinical validity of a virtualised variant of an ISy device without risk of harm to human users (Study 2 Chapter 5) as a precursor to clinical studies (Study 3 Chapter 6). Comparison of the new app with the traditional clinical device was required to assert equivalent performance. As a learning from Study 1, evaluation of the cross-platform performance of the app on both Apple and Android smartphones was an additional requisite, acknowledging the imperative to reduce health inequality by catering for the widest group of potential app users possible.

In Study 2 (Chapter 5), the reliability and clinical validity of detected airflows and range of inspiratory sound detection for the new QUT Inspire app were evaluated. This virtual respiratory therapy app detects breath sound with the phone microphone in contrast to inspiratory vacuum needed to levitate encased spheres in contemporary clinical devices. Before comparing performance of QUT Inspire with a traditional clinical ISy device, considerable effort in Study 2 was devoted to modelling, generating and validating a calibrated library of audio samples suitable for playback and detection by the QUT Inspire app at flow rates in a clinically valid range compared with a traditional clinical ISy device. This type of audio calibration methodology for breath sound components has been reported previously, in contexts such as measurement of peak expiratory airflow rate to assess airway constriction and in training the correct use of metered aerosol asthma medication administration (Natarajan et. al 2014; Seheult et. al., 2014). Two key novel features differentiate the acoustic modelling performed in Study 2 from earlier studies. First, different mouth shapes were modelled (in addition to a range of inspiratory flow rates) to assess the effect of a wide or narrow mouth shape on resultant mechanically simulated inspiratory sound levels. Secondly, detection of inspiratory sound using the QUT Inspire app was assessed in this study at increasing distances between the phone and sound source, using a range of simulated mouth diameters to reflect real-world use of the app. Use and evaluation of the QUT Inspire app in the absence of any mouthpiece, spacer device or vortex whistle to control for mouth shape is a further differentiating feature of this research compared

with earlier studies (Holmes et. al., 2013; Larson et. al, 2012). Obviating the need for add-on mouthpiece components may broaden the audience for such an app, particularly in low resource and socioeconomic contexts (Bastaworus & Armstrong, 2013)

The key findings arising from Study 2 demonstrate that the QUT Inspire app performed reliability in using the built-in smartphone microphone as an uncalibrated pressure sensor to detect sound from sustained calibrated simulated inspiratory flow rates in a clinically valid range of flow rates comparable to the contemporary Triflo II flow-based clinical incentive spirometer device (i.e., from 600 to 1,200 cc/sec). Flow rates approaching 1,000 cc/sec have previously been reported as an approximate threshold for audible sound generation, corresponding to a sounds level of 50 dB A (Forgacs et. al., 1971). Simulated inspiratory sound was detected using mouth diameters up to 20 mm (i.e. optimal at 10mm akin to pursing one's lips to whistle and then inspiring), responding to sound levels from 50 to 95 dB A and above. Successfully tested on both Android and Apple phone types, QUT Inspire reliably detected inspiratory sound at distances up to 50 cm (i.e., equivalent to holding the phone at arm's length). Additional findings from Study 2 pertain to multiple linear regression modelling of simulated sound levels in the audio library constructed for testing. Distance explained more than twice the observed variability in sound levels compared with flow rate or mouth diameter. Previous reports confirm diminished sound levels detected as distance between phones and sound sources is increased (Umayahara et. al., 2018).

The third and final study (Study 3 Chapter 6) was a mixed methods randomised usability study comparing the new QUT Inspire app and a Triflo II clinical incentive spirometer device using a cohort of healthy participants (n=24). When attempting to virtualise a longstanding clinical respiratory device, the onus is placed on those proposing a new and innovative "take" on a trusted tool to ensure that virtualised technologies such as apps maintains functionality and usability which is faithful to and comparable with that of the traditional incumbent device. Technical performance comparable with that of a traditional Triflo II clinical ISy device was demonstrated in Study 2 by means of non-human simulation of calibrated inspiratory airflows. Further exploration of the new QUT Inspire app was warranted to examine the "in the wild"

human experience using the app by comparing both traditional and virtual incarnations of this respiratory therapy device. Erring on the side of caution, healthy participants were chosen for Study 3, given the potential risks to health in cohorts with relevant diseases in the event that the app malfunctioned. This can be likened to to a phase 1 clinical trial to assert safety and functionality, albeit on a smaller scale. In Study 3, participants were randomised to control for any device testing order effects given that each participant tested both the longstanding vacuum-based and new virtualised device types.

Following on from additional learnings from Study 2 where inspiratory sound detection was found to be contingent on holding the phone close to the mouth for optimal sound detection, the display order for on-screen text or video instructions for using the app was examined in Study 3 as an additional randomised strata to investigate potential benefits from two alternate means of presenting instructional materials to guide use of the app to minimise distance separating users and their phones for optimal inspiratory sound detection. The comparisons performed in Study 3 were both quantitative and qualitative in nature. The dimensions of usability investigated included effectiveness and efficiency as quantitative usability measures, in addition to qualitative exploration of participant satisfaction (FrØkjaer et. al., 2016). Customised questionnaire and interview topics were applied in this research, in deference to standardised tools such as the System Usability Scale, given this research pertained to specific usability aspects pertinent to respiratory therapy and interactions concerning breath rather than a more generalist approach offered by tools such as the SUS.

ISy therapy encourages gradual maximal inspiration which differs from normal unconstrained breathing. Study 3 demonstrated that no significant difference was observed in effectiveness as measured by the duration of inspirations sustained using the app (7.3±2.0 sec) compared with the clinical ISy device (7.5±2.3 sec), and that no adverse events were reported during or subsequent to testing. Normal resting inspirations occur at a rate of approximately 15 per minute, equating to a duration around 4 seconds per inspiration; chronic conditions such as COPD may prolong inspiratory times due to non-communicating airspaces in lung tissue in addition and loss of lung elasticity due to this condition resulting in reduced airflow (Cretikos et. al.,

2008; Oliveira & Marques, 2014; Wang et. al., 2020). Both the traditional and virtual ISy devices investigated in this study were found to encourage slow gradual maximal inspiration of comparable durations, sustained for greater period of time than in normal resting breathing. All participants reported preference for using the app to motivate persistence with slow gradual maximal inspirations (100%, n=24), and that it was easy to complete 3 inspirations using the app (100%, n=24), Most reported that similar effort was required to complete inspirations using the app compared with the traditional clinical ISy device (83.3%, n=20). A majority appreciated additional gamification features including a timer for the duration of each inspiration (75%, n=18) and a breath counter (83.3%, n=20).

Notwithstanding that the majority of participants in Study 3 reported that screen and video instructions where easy to follow, most held their phones at distance greater than 5 cm from their mouths (mean distance 13.6±6.4 cm). Despite this observed discrepancy in efficiency (even with screen and video instructions coaching users to keep their phones close to their mouths) , the app reliably detected all inspirations delivered by participants during testing and within the range of detection suggested by the simulation studies (up to 50 cm away from the phone) in Study 2. It may be that distancing requirements stipulated for app use may warrant relaxation in light of these findings, or alternate means found to assert minimal separation from one's phone when using the app.

In terms of technical (i.e., empirical or quantitative) usability, the app performed well by demonstrating effectiveness and efficiency. Defined by positive attitudes and feelings of comfort when using the app, Participants in Study 3 expressed a high level of satisfaction with the app. Four main concepts and themes were elicited from semi-structured interviews conducted at the completion of testing. Participants reported visual reward from responsive app animations, a feature which may be capitalised on in future QUT Inspire app refinements by reimagining display animations offered by the app to improve engagement. Intended to look like a traditional ISy device, the skeuomorphic design of the new app was appreciated by participants who reported the app's clinical look and feel in terms of providing more credibility towards the app's value as a virtualisation of a real-world medical device.

Differences in perceived effort required to use the app compared with the traditional device was reported by several (n=4) study participants. A built-in a microphone sound damping control is incorporated into the app design to reduce the influence of background noise and prevent spurious animation; this control can be adjusted to increase the threshold amount of inspiratory sound (i.e., effort) required to trigger display animation. This additional feature was not evaluated in Study 3. Participants also reported selective adoption of additional gamification elements such as timers and counters for additional motivation, with many reporting they were too busy keeping spheres aloft with inspired breath components of the app to make full use these ancillary display components.

7.3 STRENGTHS AND LIMITATIONS

A fundamental strength of this research pertains to its contribution to original knowledge regarding availability of vetted or trusted mHealth apps using built-in sensors amenable to prescription by clinicians and self-prescription by health consumers. Previous studies scrutinised uncurated repositories such as the Google Play Store and the Apple App Store, reporting on counts of health apps of unknown provenance that may not be safe or appropriate to prescribe (Gan et. al., 2016; Kao & Liebovitz, 2017). Little information is available regarding representation of apps using built-in sensors from curated sources. Other studies have reviewed research literature on app protypes that await translation from the research lab to offerings potentially amenable for potential prescription (Majumder & Deen, 2019). By focusing on curated information sources where health professionals and consumers may turn to for trusted advice on currently available apps, this systematic survey offers valuable contemporary insights which may inform and contribute to managing the expectations of health professional and health consumers regarding available apps leveraging built-in sensors and identify potential areas of need to guide future developments in the field. A further strength of this research is identification of potential health inequalities in terms of a lack of cross-platform support for potentially prescribable apps and an underrepresentation of diagnostic apps compared with those for therapy. Clinicians need to be made aware of available and prescribable app offerings and purposes, and to highlight that not all apps may be available to all smartphone users.

A further strength of this research concerns developing and evaluating a respiratory therapy mHealth app that requires no add-on components such as mouthpieces or whistles to operate. This reduces cost and dependency on components that may only be compatible with particular phone makes or models and means the app may be more widely accepted in low resource or socioeconomic contexts.

The small number of curated mHealth app libraries surveyed in Study 1 (n=3) and the currency of the information listed therein are potential limitations to the utility and applicability of these findings. Due to regulatory constraints, not all apps may be available in different countries; some may have functionality partially limited or restricted for medico-legal or compliance reasons in some jurisdictions. Apps are constantly being added to and removed from these repositories. Updates to phones may also result in variations in available listed apps. Immediately following the publication of Study 3, a new subscriber-only Australian Digital Health Guide website was released, specifically targeted towards offering information on mHealth apps intended for use by health professionals (HCS, 2022). The three international mHealth app libraries selected for Study 1 were chosen based on their popularity and free-to-use status; emergent curated repositories may differ in representation of apps using built-in sensors and the vetting criteria they use to include apps.

Considering Study 2, a core strength of the observations made therein is vested in the rigorous modelling and calibration procedures performed in preparing audio samples for testing the QUT Inspire app. While prior studies have demonstrated detection and quantitation of sounds emanating from respiratory airflows in contexts such as peak flow measurements, no literature could be found where mouth shape was incorporated as a variable when simulating inspiratory airflows for smartphone detection of sound at increasing distances and increasing flow rates. Assessing the influence of flow rate, mouth shape and distance from the phone contributes original knowledge which may benefit future research, with the calibrated sampling methodology and audio sample production potentially amenable to a variety of research contexts.

A by-product of creating a library of calibrated audio files in Study 2 for testing, creation of a suite of sound flies suitable for future regression testing of the QUT Inspire app is an additional strength of this research. In the event of code changes, bug fixes or upgrades to phone models and software , regression testing using these calibrated sound loops can easily be performed to verify that functionality is maintained.

A limitation of the testing conducted in Study 2 concerns evaluation of the influence of background noise (such as that encountered in noisy hospital ward environments) on the reliability of sound detection by the QUT Inspire app. The app has a built-in sensitivity control the alter the sound threshold at which the display animation is triggered, but this was not evaluated in Study 2.

A further potential limitation concerns the calibration methodology used in Study 2. A 3-litre calibration syringe was used to mechanically generate inspiratory flows. Larger and smaller lung capacities represented by different syringe volumes were not simulated in the audio samples produced for testing. Nozzles of decreasing diameter were affixed to the syringe to model different mouth diameters and the influence of mouth diameter on inspiratory sound generation. These nozzles had circular lumens to approximate mouth diameter in contrast to oblong mouth shapes formed by humans which may generate different simulated inspiratory sound levels.

The phone brands and models tested represent contemporary Android and Apple smartphone offerings. Inability to test every phone type on the market is a limitation pertinent to Study 2. Regression testing of new devices (with potentially heterogeneous microphone components) using the calibrated audio library applied in Study 2 may mitigate this, facilitating future testing when needed.

A strength implicit in Study 3 is demonstration of an iterative progression from pre-clinical research in Study 2 as an exemplar for pre-clinical evaluation of a sensor-based mHealth app, building on preliminary characterisation and demonstration of the reliability and clinical validity of the QUT Inspire app by means of inspiratory sound simulation. Application of key learnings to clinical studies included the importance of

minimising distance and mouth shape to maximise inspiratory sound generation for detection using the app informed the design of Study 3.

Study 3 demonstrates comparable ISy effectiveness (i.e., duration of inspirations sustained) using QUT Inspire compared with the Triflo II clinical ISy device when tested by healthy people. An absence of adverse events reported by participants during or after Study 3 is an additional key strength of this research, asserting the safety of the QUT Inspire app when used under controlled test conditions. Notwithstanding many study participants holding their phones at distances further than recommended, the app demonstrated efficiency in reliably detecting all inspirations performed during Study 3 and confirmed observations regarding the range of sound detection (up to 50 cm) gleaned from simulation studies in Study 2.

An additional limitation of the Study 3 methodology relates to selection of healthy participants to evaluate the app. This research constitutes early phase clinical research, and it was deemed inappropriate to subject people with health conditions to the risk of adverse events for the conduct of this usability study. While a statistically valid sample size was used for the statistical analyses performed, the modest sample size used in Study 3 (n=24) limits the applicability of those results to the broader population. The study cohort comprised mainly middle-aged people who had some degree of familiarity with smartphone technology. The cohort used in Study 3 does not represent people with health conditions, younger persons or those unfamiliar with, or adverse to the use of smartphones. Some health conditions may result in excessive coughing or breathlessness, limiting inference of how people with health conditions amenable to ISy therapy might perform in comparison to healthy persons. Further, the study protocol for Study 3 stipulated that only 3 breaths were performed by each participant using each device to prevent exhaustion. Common prescriptions for ISy dictate performance of a set of 10 inspirations using an ISy device, with each set of 10 breaths repeated hourly. This more vigorous regiment further precludes inferring how people with disease may perform compared with healthy persons in this study.

The COVID19 pandemic posed an additional and significant limitation regarding the recruitment and conduct of human studies required for this research. Study 3 was conducted over a two-month window between lockdown periods, and opportunities for

participant recruitment and testing were limited, resulting in a modest sample size (n=24). Clinical studies in cohorts of participants with relevant health conditions were not possible to perform given constraints due to the pandemic and the timeframe available for conduct of this research program.

7.4 PRACTICAL APPLICATIONS OF THIS RESEARCH

This research has highlighted the need to foster growth in the availability of evidence-based prescribable mHealth apps where built-in smartphone sensors are used for health improvement. Emergence of curated third party mHealth libraries is symptomatic of the imperative to critically assess and build an evidence base regarding the safety and effectiveness of potentially beneficial apps. Practical applications arising from this research include:

For researchers:

- Demonstration of the utility of surveying and interrogating curated third-party mHealth app libraries as a data source for researchers to focus research on apps that are commercially available vetted for safety and quality and are prescribable. This under-utilised strategy may benefit researchers and health professionals by offering more potent “distilled” lists of trusted prescribable apps offered by such repositories for research or prescription purposes

- Offering the QUT Inspire app developed for this research program for evaluation or enhancement by other researchers

- Offering the novel audio simulation methodology developed for these investigations to researchers to adapt for evaluation of other smartphone mHealth apps where the built-in smartphone microphone is used for detection of clinically relevant sounds

For operators of curated mHealth app libraries:

- Providing impetus to urge existing and emergent curated third-party mHealth app libraries to incorporate search or filtering features for identify apps using sensors in mHealth apps. At present, individual app listings in curated libraries require manual interrogation to establish what, if any sensors are used in listed apps

For clinicians and health consumers:

- Increasing awareness and more informed selection of prescribable apps by clinicians and health consumers, alerting them the pitfalls of dealing with a multitude of potentially unsafe uncurated apps offered by app stores or via "Dr Google"

- Fostering growth in mHealth app prescription among clinicians by highlighting the current paucity of offerings in this space and encouraging the gathering and dissemination of evidence regarding suitable potentially prescribable apps

7.5 RECOMMENDATIONS FOR FURTHER RESEARCH

This thesis presents novel insights in the field of prescribable mHealth using built-in phone sensors and virtualised incentive spirometry not published elsewhere at the time of thesis submission. Avenues for further research following on from this research program are many and varied. First, learnings from Studies 2 and 3 warrant incorporation into an updated prototype of the QUT Inspire app. An updated version of the app can then be applied to more rigorous prospective randomised clinical trials to determine the efficacy of the app in cohorts of people with relevant diseases.

In updating the design of the QUT Inspire app, consideration is needed to minimising distance between the phone user and their smartphone to maximise sound detection. Built-in proximity sensors in smartphones are used to deactivate the screen and prevent spurious activation of the phone screen during phone calls. This sensor could be repurposed to warn the user if their phone was being held too far away for optimal sound detection. There may also be merit in employing the forward-facing camera to

display mouth shape and coach users to minimise mouth diameter while using the app to further increase detectable inspiratory sound.

ISy is a motivatory tool and compliance with prescribed therapy may be enhanced by adding nudge messaging such as scheduled email or SMS reminders to assist with compliance. The app could be redesigned to be encapsulated in a behaviour modification style app, setting and tracking schedules of therapy tasks and gamifying rewards for achieving set milestones. Compliance monitoring and reporting could be incorporated into the app, allowing clinicians to inspect performance metrics and intervene if inspiratory duration is insufficient, or frequency of use is inadequate for therapeutic efficacy.

The codebase for QUT Inspire is written as a HTML5 web app for execution via common web browsers. The Construct 3 integrated development environment used for coding the app has a simple deployment tool that supports porting of the app code to other platforms. QUT Inspire could easily be redeployed in devices such as smart watches, suitable for evaluation as an alternate means for interacting with the app using the built-in microphone in modern smart watches for detection of inspiratory effort, albeit with a simplified interface given the smaller dimensions offered by watch screens.

7.6 CONCLUSION

A frequently heard catch cry proclaims that “there is an app for that”. Contrary to this missive, many clinicians stop and do a double take, rightly asking where is the evidence that a given app is safe and effective? Health consumers may accept claims regarding a given health app at face value, without questioning its quality or any potential to cause harm. Risks to health are exacerbated where mHealth apps rely on sensors to generate health data, with potential for malfunctioning, unreliable or clinically invalid sensor readings to cause harm or delay a patient from seeking medical advice.

This thesis provides evidence which contradicts the commonly held belief among many health consumers that apps are the panacea for most maladies. The findings highlight the relative scarcity of potentially prescribable apps using built-in smartphone

sensors represented in curated mHealth app libraries which apply rigour to assessing evidence concerning the safety and efficacy of such apps before inclusion. The reliability and clinical validity of the new QUT Inspire virtual incentive spirometry app were asserted in pre-clinical studies using inspiratory simulation. Clinical usability studies comparing QUT Inspire with a clinical incentive spirometry device in a cohort of healthy subjects found the app to be effective and efficient, with a high degree of satisfaction as reported by a cohort of healthy study subjects.

In conclusion, it may very well be the case that “there is an app for that”. It pays to understand that this needs to be more of a nuanced retort. It is an invitation to study and characterise emergent mHealth apps and apply scrutiny to ensure “that” app behaves in a safe, reliable and effective fashion and that it really does what it claims to do.

Chapter 8: Postscript

Back in the late 1970s, this author was one of a group of bright-eyed high school students regularly transported by bus to the QIT (now QUT) Computing Centre at Gardens Point Brisbane to exercise our (then) newfound Fortran programming skills. We would diligently color in our mark sense cards using pencils to program instructions for calculation of areas in non-normal geometric shapes and similar vexing educational programming tasks. Stacks of mark-sense cards were submitted by each eager programming student for processing by a skilled operator with the (then) state-of-the-art DEC PDP8, a wonderous and very expensive mainframe computer shared by the university with multiple schools in southeast Queensland. We would return the following week with soaring expectations only to have our spirits crushed when handed reams of dot matrix printed error output indicating a looping error in our code; no results to take back home but a collective resolve to debug our code and resubmit.

As a clinical measurement scientist practicing in public hospitals in the mid-1980s, this author saw the promise of technological development realised in microcomputers. An early Sigma Oki 8-bit personal computer was a mainstay of our clinical measurement laboratory, regularly seizing up midway through a 10 minute sub-maximal exercise stress test much to the chagrin of clinicians and patients alike who then had to repeat the testing after a reboot. It also malfunctioned during lung function testing using whole body plethysmography. We received one of the first IBM PCs in Queensland bundled for use with a Morgan Lung Function analyser, and with subsequent iterations (IBM XT, AT etc) the reliability of these remarkable adjuncts to clinical practice improved as did the range of diagnositic and therapeutic functions they were applied to. The need to reboot and apologise diminished as the technology was refined.

We are now in an age where personal digital devices offer unprecedented opportunities to augment and facilitate patient-centred care. As with earlier iterations of technology in clinical contexts, improvements in reliability, validity and efficacy are vested in research, evidence gathering and refinement. Who knows what bright-eyed students in the futute may accomplish in further advancing this pedigree?

Clarrie Baxter

Chapter 9: References

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Chapter 10: Appendices

Appendix A presents the participant information sheet used in Study 3

Appendix B presents transcripts of semi-structured interviews conducted with 24 participants in Study 3

Appendix A Participant information sheet - Study 3

PARTICIPANT INFORMATION FOR QUT RESEARCH PROJECT

IF49 QUT Inspire - Incentive spirometry study

QUT Ethics Approval Number 1900000919

RESEARCH TEAM

Principal Researcher:: Mr Clarence Baxter

Supervisors: Dr Julie-Anne Carroll
Dr Brendan Keogh
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DESCRIPTION

This project is being undertaken as part of a QUT PhD Dissertation. The purpose of this project is to investigate a new smartphone application (app) called QUT Inspire for detecting and displaying breathing.

We are seeking opinions from people regarding how well this new smartphone app performs, when compared with a clinical device (a clinical incentive spirometer) commonly used for the same purpose. No excessive breathing is involved, but you will be asked to try both the app and clinical device and give us your impressions.

PARTICIPATION

Your participation will involve completing a short questionnaire and participating in an audio recorded interview on site that will take approximately 15 minutes of your time or less. This interview will be conducted in a screened-off area for privacy by an experienced clinical measurement scientist.

We have developed a smartphone app which displays inhalations graphically to represent breaths in. You will be asked to use your own smartphone to detect at least three (but no more than 6) normal inhalations (breaths in). You will be asked to repeat at least three (but no more than 6) normal inhalations using the clinical incentive spirometer. The order in which you use the devices will be randomly assigned. You will have 1 minute to rest between each inhalation.

The QUT Inspire app screen display and clinical device display will be video recorded, but your image and identity will not be video recorded.

The app uses your phone web browser to operate, but no data is retained or stored outside your phone. Clearing your browser cache (history) deletes the app and data.

We are interested in your impressions as to the usefulness of the timer and attempt counter displayed by the app in motivating your breaths in. We are also interested in your preferences regarding display of instructions for use on-screen.

Examples of questions following use of the new smartphone application include:

Which of the devices do you think is best for displaying breathing effort?
Were the timer and attempt counter useful when using the smartphone app ?
Did you have a preference for on-screen text instructions, a short video or both ?

If you have any medical condition that may affect your breathing, you will be excluded from this study. You will not be asked to inhale or exhale excessively for the purposes of this study.

Examples of medical conditions include any heart or blood pressure problems, breathing conditions (including asthma), any history of dizziness or fainting or other medical conditions that may affect your ability to breathe normally.

Your participation in this research project is entirely voluntary. If you do agree to participate you can withdraw from the research project without comment or penalty. You can withdraw anytime during the interview. If you withdraw with 2 weeks after your interview, on request any identifiable information already obtained from you will be destroyed. Your decision to participate or not participate will in no way impact upon your current or future relationship with QUT (for example your grades).

EXPECTED BENEFITS

It is expected that this project will not benefit you directly. However, it may benefit others by gaining insight into the opinions of people, leading to better and more effective mobile health applications.

Please note that no health information or advice will be provided as part of this project. Please consult with your GP or health practitioner for health information and advice.

RISKS AND ADVERSE EVENTS

There are no risks beyond normal day-to-day living associated with your participation in this project. While your participation in this project is low-risk, if you experience any adverse health effects following participation in this study, please seek immediate medical assistance from your GP or health practitioner if you have any health concerns.

Such adverse events may include, but are not limited to dizziness, nausea, breathlessness, chest pain, jaw or arm pain. For your reference, QUT Medical Clinics are available at the following locations:

Gardens Point Campus	Level 4 X Block	**07 3138 2321**
Kelvin Grove Campus	Level 2 44 Musk Avenue	**07 3138 3161**

PRIVACY AND CONFIDENTIALITY

All comments and responses will be treated confidentially. The names of individual persons are not required in any of the responses. The study will be conducted in a screened-off area for privacy purposes.

As the research project involve audio and video recording:

- You will have the opportunity to verify your comments and responses prior to final inclusion.
- The recording will be destroyed after the contents have been transcribed.
- The recording will not be used for any other purpose.
- Only the interviewer will have access to the recording.
- It is not possible to participate in the project without being recorded.

Any data collected as part of this research project will be stored securely as per QUT's Management of research data policy.

Please note that non-identifiable data from this research project may be used as comparative data in future research projects or stored on an open access database for secondary analysis.

CONSENT TO PARTICIPATE

We would like to ask you to sign a written consent form (enclosed) to confirm your agreement to participate.

QUESTIONS / FURTHER INFORMATION ABOUT THE PROJECT

If have any questions or require any further information please contact one of the listed researchers:

Clarence Baxter c.baxter@hdr.qut.edu.au
Julie-Anne Carroll jm.carroll@qut.edu.au

CONCERNS / COMPLAINTS REGARDING THE CONDUCT OF THE RESEARCH PROJECT

QUT is committed to research integrity and the ethical conduct of research projects. However, if you do have any concerns or complaints about the ethical conduct of the research project you may contact the QUT Research Ethics Advisory Team on 07 3138 5123 or email humanethics@qut.edu.au. The QUT Research Ethics Advisory Team is not connected with the research project and can facilitate a resolution to your concern in an impartial manner.

THANK YOU FOR HELPING WITH THIS PROJECT.
PLEASE KEEP THIS SHEET FOR YOUR INFORMATION.

Appendix B Transcripts of interviews (n=24) - Study 3

A3 Semi-structured Interviews with themes

Interviewer: Clarence Baxter

Legend

Symbol Meaning

... Short pause

[] Non-verbal communication

= Fast reply

[sic] Not grammatically correct but correctly transcribed

Thematic analysis

1. Have you ever seen or used an incentive spirometer before?

2. Which instrument did you like the best for displaying inspiration and why

3. Which instrument do you think provides the most encouragement to maintain effort and why?

4. Did the timer or attempt counter on the app provide additional incentive for your inspirations?

5.Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

6. Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 1

Interview date: Thursday, May 6th, 2021

Interview location: QUT Kelvin Grove Campus - D618

Start time: 12:15 pm

Interviewer: Have you ever seen an incentive spirometer before ? [points at Triflo II device]

Participant 1: … No

Interviewer: Comparing the spirometer with the phone app, which one do you like best to display your inspirations ?

Participant 1:] Easier with the app … [sic] no hose [picks up and holds hose and mouthpiece attached to Triflo device].

Interviewer: Of the two, which one do you reckon gives most encouragement to keep going and maintain effort ?

Participant 1: The app. Its like a game so you feel like going on with it

Interviewer: Now looking at the app, did the timer or counter at the top right give you any extra incentive to breathe in ?

Participant 1: Too busy breathing at first but the clock helped when I tried again … would good to list previous times to beat keeping it going for longer. There's more to look at with the app … I liked that

Interviewer: We have a results page for listing that stuff. Good idea putting it on the display page itself. And what about the counter next to the timer ?

Participant 1: I didn't really look at them. What does the counter count ?.

Interviewer: Its an attempt counter for keeping track of how many inhales you do

Participant 1: OK, that could be handy if you are using it a lot

Interviewer: You watched a short instructional video before running the app. Then you had a practice screen with instructions listed. Do you have a preference for video or on-screen instructions ?

Participant 1: The video looked like the same text as the screen, but animated. The movie is good for showing how its used. I like them both.

Interviewer: Can you think of any improvements we can make to the app encouraging gradual inhalations ?

Participant 1: A few different styles would be good … Something like a windmill spinning when you breathe … [sic] might mix it up a bit and get people using it.

Interviewer: Nice … and your idea about displaying best times is great.

Participant 1: No worries

Interviewer 1: Thank you for time and help with our study

Participant 2

Interview date: Tuesday, May 25th, 2021

Interview location: QUT Kelvin Grove Campus - D618

Start time: 12:05 pm

Interviewer: So, have you ever seen or used an incentive spirometer ? [holds up Triflo device]

Participant 2: No I haven't

Interviewer: Which do you prefer for displaying breathing, the spirometer or the smartphone app ?

Participant 2: I prefer the app … it's better I think. The screen jumps up quicker ... It was harder with plastic one to lift the balls.

Interviewer: In what way ?

Participant 2: I dont know. I had to try harder to make it [Triflo II] move. The app made if easier to elevate them [points at spheres in triflo device]

Interviewer: Which one encourages you the most ?

Participant 2: How do you mean ? They both do.

Interviewer: So do both do the same in terms of motivating you to inhale deeply ?

Participant 2: [Nods] The phone one was easier to use so maybe its better for that. I get the idea to keep the balls in the air Im that used to my phone for other apps … this feels familiar even if its new to me. Does that make sense ?

Interviewer: OK, it does. So is it like you find it easy to use apps on your smartphone and this plays like a new but familiar one ?

Participant 2: Yes

Interviewer: Did you get any additional motivation, any incentive from the timer and counter at the top of the screen using the app ?

Participant 2: I was watching the screen while breathing.

Interviewer: Did you notice a little time and breath counter at the top right of the screen ?

Participant 2: No, not really

Interviewer: No worries

Interviewer: Using the app you read instructions on the screen and then watched a short video. Do you have a preference for text or video instructions ?

Participant 2: The screen instructions were good enough.

Interviewer: Can you think of any way that we can improve the app ?

Participant 2: … maybe make it [the app] harder to use like the plastic one

Interviewer: Good idea. We have a way to do that with a sliding scale to do that with the app. We didn't test that here

Interviewer: So you said it was easier to inhale using the app ? Did changing your mouth shape increase the effort you needed ?

Participant 2: A bit, yes. I spose [sic] I could have puckered up more to make it more work, but I only had a few trys

Participant 2: OK, thanks. Very good suggestion

Interviewer: Many thanks for taking part in our research

Participant 3

Interview date: Tuesday, June 1st, 2021

Interview location: Cooroy

Start time: 9:15 am

Interviewer: Have you ever used or seen one of these incentive spirometers before ? [points at Triflo device]

Participant 3: No, I havent

Interviewer: Which did you like better for displaying inspirations ?

Participant 3: The app doesn't have a fiddly hose [points at Triflo II device]. It would be easy to carry around in your handbag more than the plastic thing.

Interviewer: and what about how the both looked comparing your inhalations ?

Participant 3: I get what it meant about making sound … the lip size [gesturing a lip pucker]. Once I got it, it was much for muchness … the same as the plastic one. I like not having to use a hose.

Interviewer: Of the two devices, which one do you reckon gives you the most encouragement to persist with breathing in ?

Participant 3: Its hard to say … they both encouraged me … [sic] its the same thing with the little balls lifting, like a game. Of the two, the app was better at encouraging me

Interviewer: Looking at the app, did the attempt counter and timer at the top right give you any extra incentive for inspiration .

Participant 3: I looked at the timer … less so with the counter … I was looking at the balls. I was too busy keeping the balls up in the air and making sound to look.

Interviewer: did you have a preference for video instructions about using the app, or the onscreen text instructions ?

Participant 3: The video instructions. The little movie in the video was nice.

Interviewer: Showing the fellow using the spirometer ?

Participant 3: Yes

Interviewer: Can you suggest any improvements to the app or other ways we can motivate people maintain inhalations.

Participant 3: … [shakes head] No

Interviewer: Thanks for participating

Participant 4

Interview date: Saturday, June 5th, 2021

Interview location: Buddina

Start time: 9:05 am

Interviewer: Have you have ever used or seen an incentive spirometer before ? [holds up Triflo device]

Participant 4: … [shakes head] first time

Interviewer: Which device do you like best for displaying your inhalations ?

Participant 4: The phone responded quicker … worked when I breathed in ….

Interviewer: it was easier to inhale with the app ?

Participant 4: yes, it jumped up and stayed up [gestures upwards movement of balls using hand] .

Interviewer: Which instrument encourages you the most to maintain effort and why.

Participant 4: They both make you work to keep things in the air. I reckon they're close to equal but I was most encouraged using the phone … my breathing was more natural without the tube.

Interviewer: Did you get additional incentive to inhale from the timer and attempt counter at the top of the app ?

Participant 4: No. I saw the flashing red button [record icon], but didn't really look at the other things up there … wha was it ? … a counter and timer. Thy may be more help when using it more.

Interviewer: You saw text instructions on screen and a short instruction video. Do you have a preference for text or video instructions.

Participant 4: The on screen help spelled it all out. The video took extra time to watch.

Interviewer: So you reckon text instructions were best ?

Participant 4: [nods] yes

Interviewer: Can you think of any improvements we can make to the app display so we can encourage people to slowly and gradually inhale ?

Participant 4: … [short pause] Maybe like a 'whoosh' sound effect when you breathe …[sic] the phone could vibrate

Interviewer: like an extra sound cue or prompt ?

Participant 4: Yeah, to let you know its listening to your breathing

Interviewer: What a good idea. Thanks for helping with our research

Participant 5

Interview date: Saturday, June 5th, 2021

Interview location: Buddina

Start time: 9:40 am

Interviewer: Have you ever seen or used an incentive spirometer device ? [points at Triflo device]

Participant 5: Dad had one. He had COPD for years. He got new ones for home when he got discharged from hospital … built up a collection.

Interviewer: Which device did you prefer for displaying inspiration ?

Participant 5: The big one [Triflo II] showed air …[sic] flow. The phone thing started and stopped

Interviewer: So the plastic device did a better job at showing your breathing ?

Participant 2: Yes

Interviewer: So comparing the devices, which one provided most motivation to inhale ?

Participant 5: The big one. It looks like a hospital one … makes you work harder and seals your lips to breathe

Interviewer: Considering the app, did the attempt counter and time help motivate you ?

Participant 5: Small writing made it hard to see while huffing on it

Interviewer: So they were both too small to read on the app screen ?

Participant 5: tiny

Interviewer: You read text instructions on screen followed by a video. Do you have a preference for text or video ?

Participant 5: I prefer the text instructions over the video ones. They were simple and easy to follow

Interviewer: Can you suggest any improvements for the app ?

Participant 5: … bigger writing [sic] top of the list

Interviewer: Thanks for helping with our research

Participant 6

Interview date: Saturday, June 5th, 2021

Interview location: Buddina

Start time: 10:20 am

Interviewer: Have you seen or used one of these incentive spirometers before ? [points at Triflo device]

Participant 6: Not really but my wife had one when our daughter was born. She had a caesar.

Interviewer: Did she use it for recovery in hospital or at home ?

Participant 6: In hospital. She complained that breathing hurt with her scar. It looked a bit different, like a plastic jug …I dont remember any balls …[sic] it had a scale to read off.

Interviewer: thats a slightly different syle of the same device. They are both incentive spirometers

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 6: The apps best for displaying how much you are inhaling. It was like there was a lag with the other [points at Triflo II device] one..

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 6: Same the app. The timer lets you see how long each go takes … [short pause] like its a game

Interviewer: So following on from that, did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 6I [sic] didnt need the attempt count but I …[sic] spose it would help you were doing heaps of them. The timer helped. I was keeping track … my times were pretty consistent.

Interviewer: do you have a preference either way for video instructions or on screen text displayed by the app ?

Participant 6: …[sic] crystal clear and all good … happy with either instructions

Interviewer: Can you think of any improvements we could make to the app display, or other ways to motivate slow full inhalations ?

Participant 6: It would be good to be able to use it on a watch … [short pause] nothing else comes to mind at the moment

Interviewer: Thanks for your time and help with our research

Participant 7

Interview date: Saturday, June 5th, 2021

Interview location: Buddina

Start time: 10:55 am

Interviewer: Have you ever seen one of these incentive spirometers? [Holds up the Triflo device]

Participant 7: No

Interviewer: Between the plastic device and the app, which did you like better for displaying inspirations ?

Participant 7: The phone app

Interviewer: Why the app ?

Participant 7: I dont know … [short pause] it was easier to handle and everything was neat on the screen

Interviewer: Which gave you most encouragement to maintain inspirations ?

Participant 7: How do you mean ?

Interviewer: Which do you think would keep you using it for longer, to keep breathing in ?

Participant 7: Definitely the app

Interviewer: Why ?

Participant 7: The Triflo, is it ? [points at Triflo device] just seems clunky … the app would keep me more engaged

Interviewer: With the app, did the timer or attempt counter displayed at the top right of the app give you extra incentive for your inspirations?

Participant 7: Yes, the counter was good for to keeping track of your breathing.

Interviewer: and the timer ?

Participant 7: I used it the last couple of times … culd be useful to see how long each breath takes

Interviewer: Did you prefer detailed on-screen instructions displayed by the app, or the short instructional video or both types of instructions ?

Participant 7: I liked reading the text in the app itself. Better than the annoying video scrolling

Interviewer: So the static text on the phone screen was better and less annoying ?

Participant 7: Yeah [sic] just to get key points across

Interviewer: Can you think of any improvements we could make to the app display, or other ways to encourage slow gradual inhalations?

Participant 7: No

Interviewer: Many thanks for your help with our research

Participant 8

Interview date: Tuesday, June 8th, 2021

Interview location: Cotton Tree

Start time: 12:00 pm

Interviewer: Have you seen an incentive spirometer before ? [points at Triflo device]

Participant 8: I got my hernia fixed years ago. I used one of these [sic] stuck in hospital with stitches …[points to abdomen].

Interviewer: What do you recall about using it ?

Participant 8: Hurt like hell. I called my …[sic] physio a physioterrorist and lots of other names for making me do it. It got easier as I healed

Interviewer: Which of these two devices do you like the best to display inspiration ?

Participant 8: I can hold the phone in my hand and see what's going on. The plastic ball thing [points at Triflo II] is less portable with its size and the tube thing [holds up breathing hose on Triflo devce]. Both show the same thing,

Interviewer: If you had to pick one or other as the best to display inhalation ?

Participant 8: It woud be the app … small and all round better

Interviewer: Which do you think gives the most encouragement to keep up your inhalation effort and why?

Participant 8: App again. The plastic one doesn't have a timer … [sic] no way to keep track of how you are going

Interviewer: So that lead me to the app timer and attempt counter. Did they give additional incentive for your inspirations?

Participant 8: Yep [sic], I kept an eye on the timer.

Interviewer: and the counter ?

Participant 8: Didn't use it … only three breaths … no need.

Interviewer: Considering instructions, do you prefer on-screen instructions for using the app or the short video movie or both?

Participant 8: The vid [sic] didn't do it for me. I liked the phone screen instructions … listed what I needed to know..

Interviewer: Can you suggest any ways to improve the app display, or any other ways to encourage slow gradual inhalations?

Participant 8: A pause button would be good. Hit it so you can stop to cough or take a break. …[short pause]. Maybe add a recorder to see how you are going or to show your doctor ?

Interviewer: Thanks for your time and help with our study

Participant 9

Interview date: Wednesday, June 9th, 2021

Interview location: Cotton Tree

Start time: 2:30 pm

Interviewer: Have you ever seen or used an incentive spirometer before?

Participant 9: Never

Interviewer: Which did you like the best for displaying inspiration, the plastic device or the app and why?

Participant 9: They both show little globe balls …[sic] lifting. I like the phone one.

Interviewer: Is there any reason you favour the app ?

Participant 9: No, I just like it better

Interviewer: Which do you think provides the most encouragement to maintain effort and why?

Participant 9: I think the app. No hose … you can move around.

Interviewer: Did the app timer or attempt counter provide additional incentive for your inspirations?

Participant 9: I guess so. I started looking at both the last couple of times, but it was the main screen thing

Interviewer: Making the spheres float ?

Participant 9: Yes the middle of the main screen … didn't notice much around the edges

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 9: The short quick video wins hands down.

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 9: No

Interviewer: Thanks for taking the time to help with our research

Participant 10

Interview date: Wednesday, June 9th, 2021

Interview location: Cotton Tree

Start time: 3:00 pm

Interviewer: Now, have you ever seen or used an incentive spirometer before? [holds up Triflo device]

Participant 10: First time I've seen one

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 10: The phone app was good to use. I could put it in a …[sic] comfy position and see the screen

Interviewer: Which do you think provides the most encouragement to maintain effort and why?

Participant 10: I think the app kept me trying. It was a bit easier to inhale than the spirometer tool

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 10: I checked the timer to see how long each breath took. Not so much the counter thing.

Interviewer: Do you have a preference for on-screen instructions for using the app, an instructional video or both?

Participant 10: I made use of help from both. The video was easy to read

Interviewer: So both?

Participant 10: Yes

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 10: Can text and image size be bigger, so everything is easier to read ? …[short pause] apart from that I like it

Interviewer: Thanks for your time and participation in our study.

Participant 11

Interview date: Thursday, June 10th, 2021

Interview location: Cooroy

Start time: 3:00 pm

Interviewer: Have you ever seen or used an incentive spirometer before? [holds up Triflo device]

Participant 11: No

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 11: The app one did better. I found harder to lift the balls using the one with the tube

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 11: Definitely this [points at smartphone]. It jumped as soon as I started breathing

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 11:No.

Interviewer: So the timer and counter on the app didn't help

Participant 11: No

Interviewer: Do you have a preference for text instructions on-screen using the app, the video instructions or both?

Participant 11: … [short pause] Either are good to learn how to use it

Interviewer: So no preference for one over the other ?

Participant 11: No

Interviewer: Can you think of any improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 11: I'm not a technical person. [Shakes head indicating No]

Interviewer: Thank you for taking the time to help us with our research

Participant 12

Interview date: Thursday, June 10th, 2021

Interview location: Cooroy

Start time: 3:35 pm

Interviewer: Have you ever seen or used an incentive spirometer before?

Participant 12: My uncle had one. He'd cough after using it …[short pause] said it cleared his chest. I tried it …[sic] it was a real workout

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 12: The phone app was best to use. It picked up my breathing easily

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 12: The app looks like its doing more on the phone.

Interviewer: How do you mean ?

Participant 12: Looks busier than the other one. It keeps my attention more [holds up phone]

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 12: Not the time r. I looked the counter to make sure it counted up … and it did.

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 12: I liked the video and the writing on the app made it easy … two steps … lips and mouth then breathe in.

Interviewer: So you liked both ?

Participant 12: Yes

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 12: No

Interviewer: Many thanks for your time and help with our research

Participant 13

Interview date: Friday, June 11th, 2021

Interview location: Cotton Tree

Start time: 9:50 am

Interviewer: Have you ever seen or used an incentive spirometer before? [points at Triflo device]

Participant 13: All new to me … very interesting

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 13: They showed my breathing. If I had to choose I would pick the phone because it worked better

Interviewer: Is there any thing that stands out that helps you choose one over the other ?

Participant 13: Everything else is on my phone … [short pause] just makes it easier to use and its good to have extra things to stay healthy

Interviewer: So it's the convenience of having it on your phone and that it works better ?

Participant 13: I think so

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 13: The phone gets your attention more than the other one [gestures towards Triflo II spirometer]

Interviewer: In what way ?

Participant 13: It feels more sensitive … picks up the sound better

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 13: No

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 13: Video

Interviewer: What was it about the video that was better than the text on the screen

Participant 13: I think I understand better with pictures … so I can go back and check it again

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 13: No [shakes head indicating no]

Interviewer: Thanks for your help with our study

Participant 14

Interview date: Friday, June 11th, 2021

Interview location: Cotton Tree

Start time: 10:30 am

Interviewer: Have you ever seen or used an incentive spirometer device before? [points at Triflo device]

Participant 14: Mum had one at various times

Interviewer: What did she use it for ?

Participant 14: pneumonia mainly

Interviewer: Did she use it in hospital or at home ?

Participant 14: Both, she was in and out a lot

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 14: The app worked best. It was harder breathing in using the plastic tube … I didn't like it [gestures towards Triflo device]

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 14: The app. I'd be more likely to use it if I needed to … always have my phone with me

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 14: The counter would help people who forget to count. I was too busy breathing and didn't use the timer

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 14: I use whatever is offered. If something is simple I wont bother with a video … so both the on-screen and video work for me

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 14: Different graphics could motivate people, like choosing a character in a video game. You could animate it like a cartoon with moving bits to keep interested

Interviewer: Thanks for your help with our research and your great suggestions

Participant 15

Interview date: Friday, June 15th, 2021

Interview location: Cotton Tree

Start time: 11:05 am

Interviewer: Have you ever seen or used an incentive spirometer before? [holds up Triflo device]

Participant 15: Never needed one. No

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 15: I like the phone system over the plastic device

Interviewer: Why the app ?

Participant 15: I like how to feels to use. Smaller than the plastic one and more manageable

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 15: I could see more happening on the screen with the app compared with the other one

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 15: I saw them tick over but I didn't focus on them. I suppose keeping track of time helps with using it

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 15: I liked the phone on screen written instructions the best.

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 15: …[short pause] No

Interviewer: Thanks for contributing to our research

Participant 16

Interview date: Saturday, June 12th, 2021

Interview location: Buddina

Start time: 9:15 am

Interviewer: Have you ever seen an incentive spirometer before? [points at Triflo device]

Participant 16: No, I havent

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 16: First time Ive seen them. The smartphone was best. Its more user friendly to keep your eye on than the old school one [points at Triflo device].

Interviewer: Which do you think provides the most encouragement to maintain effort and why?

Participant 16: The app definitely … I could see it change as soon as I started breathing in

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 16: No real extra incentive from these numbers

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 16: The text instructions gave me more info

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 16: I can't think of anything else to add

Interviewer: Thanks for helping with our study

Participant 17

Interview date: Saturday, June 12th, 2021

Interview location: Buddina

Start time: 10:30 am

Interviewer: Have you ever seen or used an incentive spirometer before? [holds up Triflo device]

Participant 17: No

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 17: The plastic one was more of a workout

Interviewer: In what way ?

Participant 17: I had to inhale harder to get the plastic balls in the phone to jump

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 17: It took me more effort to get the balls to move with the non-phone one

Interviewer: so the plastic one ?

Participant 17: Yes

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 17: They could be handy to keeping track of personal bests .., but I think it's the floating balls that keeps you using it

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 17: I liked them … they probably suit different people … like [sic] different types of learners. Either would do me

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 17: Would help to make it more of an effort to use, like the plastic one with the hose.

Interviewer: Thanks for your time and help with our research

Participant 18

Interview date: Monday, June 14th, 2021

Interview location: Cotton Tree

Start time: 12:15 pm

Interviewer: Have you ever seen or used an incentive spirometer before? [points at Triflo device]

Participant 18: Ages ago

Interviewer: Were you at home or in hospital when you used one ?

Participant 18: In hospital, after an operation

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 18: I was impressed by the smartphone. It looks like the medical one and shows my breaths on the screen

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 18: The app is more modern. They both do the same job showing breathing. The app would be more accessible.

Interviewer: How do you mean ?

Participant 18: People would use it more if it was convenient on their phones

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 18: I watched both of them for a it. No real preference either way. If I was using it a lot they could help

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 18: No, no preference either way. I would watch or read all of it to get skilled up if needed

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 18: I think you've done a good job with it. Nothing to add

Interviewer: Thanks for taking the time to help with our research

Participant 19

Interview date: Wednesday, June 16th, 2021

Interview location: Cotton Tree

Start time: 12:00 pm

Interviewer: Have you ever seen or used an incentive spirometer before? [Holds up Triflo device]

Participant 19: No, I'd remember if I did

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 19: Im not sure. Ive never used these before … If I had to choose I would go for the phone app because its has a better screen display.

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 19: The phone more engaging than the solid one. Maybe its the colors or how it moved.

Interviewer: How did colors and movement help ?

Participant 19: The phone screen is more lively with the extra colors. Its eyecatching and moves more than … [gestures towards the Triflo device].

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 19: I had to look closely to see the clock. The counter didn't mean much to me. The clock helped, but maybe make it bigger

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 19: The video was a good summary. The screen gave more detail on how to make a noise with your lips like whistling.

Interviewer: Do you have a preference for one or the other ?

Participant 19: No particular preference, they each do their bit

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 19: Bigger writing for old eyes

Interviewer: Fair enough. Thank you for taking part in our research

Participant 20

Interview date: Wednesday, June 16th, 2021

Interview location: Cotton Tree

Start time: 1:25 pm

Interviewer: Have you ever seen or used an incentive spirometer before? [points at Triflo device]

Participant 20: No

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 20: The app responded quicker to my breathing.

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 20:Im more encouraged by using the app It was easier to hold thank the bulky one … like I said it responded faster when I used it.

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 20: No, but maybe if I was doing more breaths they might

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 20: They were helpful but the screen text sizes need to be much bigger to be readable. From what I could make out the content was much the same in video and text

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 20: … [sic] Hard to see text and the timer. Maybe a bigger display or pop up to see large numbers would help.

Interviewer: So overall, the fonts was small and difficult to read ?

Participant 20: Very

Interviewer: That's important to know. Thanks for helping with our research

Participant 21

Interview date: Friday, June 18th, 2021

Interview location: Cotton Tree

Start time: 9:10 am

Interviewer: Have you ever seen or used an incentive spirometer device before? [points to Triflo device]

Participant 21: No

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 21: The app is very cool. I use others to track my sleep. This sort of follows on. I like how it is simple and clean looking

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 21: Im leaning towards the app. The display makes you want to engage with it

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 21: Yes I kept track of the elapsed time with the timer. The counter bounced around a bit … extra noise was making it go off

Interviewer: That's important to know. We have a little slider control to reduce that jumpiness that happens with background noise, but we aren't testing that here.

Participant 21: Good move

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 21: No [shakes head indicating No] … no preference for one or the other … [sic] both tell you with what to do

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 21: No

Interviewer: Thank you for helping with our study

Participant 22

Interview date: Saturday, June 19th, 2021

Interview location: Buddina

Start time: 9:40 am

Interviewer: Have you ever seen or used an incentive spirometer before? [points at Triflo device]

Participant 22: Uh uh ..[shakes head indicating no]

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 22: The Triflo one …The app looked like a bit of a game

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 22: That one [gestures towards Triflo II]. I felt connected to it … chunky sounds from little spheres as they hit the top and dropped down

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 22: No

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 22: On screen. The instructions on the screen clearly spelled out how to do it

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 22: Try and make it more medical and responsive. Make the phone shake when the spheres lift and drop.

Interviewer: Thanks for your time and assistance with our research

Participant 23

Interview date: Saturday, June 19th, 2021

Interview location: Buddina

Start time: 10:35 am

Interviewer: Have you ever seen or used an incentive spirometer before? [points at Triflo device]

Participant 23: Yes, in nursing homes

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 23: I like the smartphone app. I imagine the big one [points at Triflo device] needs washing to keep clean

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 23: The app is more portable I think. We all have smartphones now dont we ? I imagine its cheaper too. Having it on your phone may encourage you to use it

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 23: I only had a few attempts … both worked. Would be helpful if you are doing a lot of attempts or if you had dementia and had counting problems

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 23: Steps on the screen are my preference … clear and concise.

Interviewer: So text instructions on screen over video instructions ?

Participant 23: Yes

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 23: A recorded voice encouraging me like 'breathe more' or 'keep going' … like a fitness instructor yelling at you

Interviewer: That is a great idea. Many thanks for your help with our research

Participant 24

Interview date: Saturday, June 19th, 2021

Interview location: Buddina

Start time: 11:25 am

Interviewer: Have you ever seen or used an incentive spirometer before? [holds up a Triflo device]

Participant 24: No

Interviewer: Which instrument did you like the best for displaying inspiration and why?

Participant 24: If I had this on my phone or watch it would be easy to use anywhere. The app screen looks like the real thing … so go the app

Interviewer: Which instrument do you think provides the most encouragement to maintain effort and why?

Participant 24The phone app would encourage me more. It looks better and I could have it with me on my phone. No hose tube is a bonus

Interviewer: Did the timer or attempt counter on the app provide additional incentive for your inspirations?

Participant 24: They added some incentive, looking at the timer could help improve on my best. I didn't need the [attempt] counter

Interviewer: Do you have a preference for detailed on-screen instructions for using the app, a short instructional video or both?

Participant 24: They were OK.

Interviewer: Did you prefer one over the other, like text or video?

Participant 24: No

Interviewer: Can you suggest improvements to the app display, or other ways to encourage slow gradual inhalations?

Participant 24: No.

Interviewer: Thanks for your help with our study