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Using Digital Health Technology to Optimise Older People's Pain Self-Management Capabilities: A Mixed Methods Study (The DigiTech Pain Project)

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Using <u>Digital</u> health <u>Tech</u>nology to optimise older people's <u>Pain</u> self-management capabilities: a mixed methods study

(The DigiTech Pain Project)

Priyanka Bhattarai

Thesis submitted in fulfilment of the degree of Doctor of Philosophy
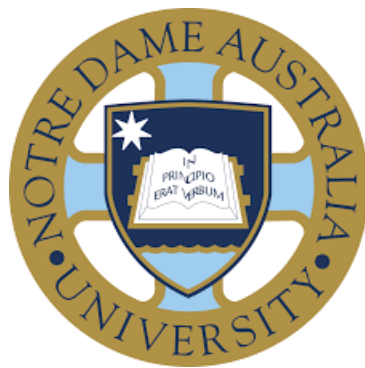
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Abstract

Background

Arthritic pain is a major cause of illness and disability among older people. As the use of smartphones and apps increases in the lives of older people, there is an opportunity to explore the role of these apps in helping older people better manage their arthritic pain.

Aim

To explore the feasibility and acceptability of older people using an arthritic pain self-management app to improve their pain symptoms.

Methods

A parallel convergent, mixed methods design underpinned by Bandura's Self-Efficacy Theory and the Technology Acceptance Model 2; comprising of the following five studies:
(i)   Study 1a: an integrative review;
(ii)   Study 1b: a systematic review;
(iii)   Study 2a: a phase I feasibility study of pre–post-test design;
(iv)   Study 2b: a qualitative sub-study involving participants of study; and
(v)   Study 3: a qualitative interview study with primary care and allied health clinicians.

The data from these studies was integrated to answer the project's research questions.

Results

Study 1a revealed paucity of evidence on use of apps for older people's pain self-management. Study 1b indicated that few publicly available pain self-management apps are based on robust evidence.

Eighteen older people were recruited into Study 2a, 80% via snowballing. Over 59% of participants were provided face-to-face app download and use training, none had used a pain self-management app in the past. Telephone-based survey and interview data collection was found to be acceptable to older people.

Almost 90% of study 2a participants (n=16) took part in study 2b sharing their experiences of using the intervention app. Following four themes emerged: (i) Apps are valuable self-management tool, but they do have the potential for harm; (ii) pain self-management apps need to be strictly relevant to the user; (iii) Clinicians' involvement is crucial; and (iv) pain self-management apps must be designed with the end user in mind.

Study 3 recruited seventeen (n=17) primary care and allied health clinicians who shared their perceptions and attitudes regarding app use by their older patients for pain self-management. Four themes emerged: (i) self-management apps are a potentially useful tool but require careful consideration; (ii) clinicians' involvement is crucial yet potentially onerous; (iii) no single app is right for every older person; and (iv) patient data access is beneficial but caution is needed for real-time data access.

Meta-inference of the data from all five studies indicated that an app intervention involving older people was both feasible and acceptable, with the following caveats: snowballing

recruitment may be required; and access to app download and use training is an important element to implement into the study design. Older people and primary care clinicians were keen to engage with pain self-management apps; however, they wanted these apps to offer high level usefulness, adaptability and information sharing features. Future pain self-management apps need to be underpinned by robust evidence, while providing appropriate support and resources to clinicians.

Conclusion

While older people and their clinicians welcomed the opportunity to use pain self-management apps, their engagement ought to be supported by systems level policies, and high-quality apps. Collaboration among clinicians, older people, researchers and app developers ought to be considered when developing, researching and integrating pain self-management apps.

Statement of Original Authorship

I, Priyanka Bhattarai, affirm that this thesis is my own work and contains no material which has been accepted for the award of any other degree or diploma in any university or other institution. I affirm that, to the best of my knowledge, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

Abbreviations

BPI	Brief Pain Inventory
BPI-sf	Brief Pain Inventory short form
CBT	Cognitive Behavioural Therapy
GP	General Practitioner
HREC	Human Research Ethics Committee
NRS	Numeric Rating Scale
NSW	New South Wales
OTSES	Online Technologies Self-Efficacy Scale
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSEQ-2	Pain Self-Efficacy Questionnaire 2
RAISE	Rheumatoid Arthritis Information Support and Education
RCT	Randomised Controlled Trial
SD	Standard Deviation
TAM	Technology Acceptance Model
TAM 2	Technology Acceptance Model 2
TGA	Therapeutic Goods Administration (Australia)
UK	United Kingdom
USA	United States of America
WHO	World Health Organization

Glossary of terms

App	A self-contained software, developed for use on mobile devices and made available through app stores (Ahmed et al., 2015).
Arthritis	An umbrella term used to refer to more than 100 conditions that affect joints of the body, including hips, knees, wrists and knuckles. Arthritis causes joint inflammation and damage resulting in discomfort and pain (Health Direct, 2018).
Arthritic pain	Pain caused by arthritis.
Cognitive behavioural therapy	A family of interventions that aim to understand and treat health conditions by focusing on the individual's cognitive and behavioural processes (Hofmann & Asmundson, 2017).
Clinician	A healthcare professional who is directly involved in patient care. For the purposes of this thesis, 'clinician' refers to those health professionals who practice under one of the 16 health professions regulated by the Australian Health Practitioner Regulation Agency.
Digital health technology	An umbrella term used to describe the use of emerging communication and information technologies, especially the internet, to improve patient outcomes. It includes eHealth and mHealth (Burke et al., 2015).

- **eHealth**: secure and cost-effective use of computer-based information and communications systems to process, transmit and store data and health related information.
- **mHealth**: a component of eHealth, defined as medical or public health practice supported by mobile devices (World Health Organization, 2015).

Older people	People aged 65 years or over (Age United Kingdom, 2017; American Geriatric Society, 2009; Australian Bureau of Statistics, 2018).
Pain self-management	Set of activities carried out by a person living with chronic pain to enhance their function and mood, while reducing pain (Cameron & Stewart, 2012; Reid, Eccleston, & Pillemer, 2015).
Paradigm	A researcher's philosophical assumptions, shared beliefs and values that can be used to influence and/or guide the research inquiry (Creswell & Clark, 2011).
Self-efficacy	An individual's beliefs about their capacity to carry out behaviours and activities necessary to produce desired outcomes (Bandura, 1977, 1997).

Smartphone	Mobile phones that offer versatile computing features, including diverse internet content, multimedia players and apps (Jung, 2014).
Stanford Program	A well-established and structured pain self-management program that aims to help the person living with chronic pain maintain wellness in the midst of their chronic pain. The ultimate goal is improvement in the quality of life of the person living with chronic pain (Lorig, 2003).
Technology Acceptance Model	A theoretical model which posits that an individual's intention to engage with a technology is determined by two key beliefs, perceived usefulness and ease of use (Davis, 1989), defined as:

- **Perceived usefulness**: the extent to which an individual believes that using a technology will enhance their task performance
- **Perceived ease of use**: the degree to which an individual believes that using a technology will be effortless.

Technology Acceptance Model 2	An extension of the Technology Acceptance Model, which provides additional theoretical constructs influencing perceived usefulness (Venkatesh & Davis, 2000). This model identifies seven factors that influence the perceived usefulness of a technology:

- **Subjective norm**: an individual's perception that people important to him/her think he/she should or should not use the technology
- **Voluntariness**: context of technology use where an individual perceives the technology use decision to be non-mandatory
- **Image**: the degree to which a technology use is perceived to enhance one's status in the social system
- **Job relevance**: the degree to which a technology is applicable to the individual's job
- **Output quality**: the measure of how well technology performs the tasks that are relevant to the individual's job
- **Result demonstrability**: the tangibility of the results of using the technology
- **Perceived ease of use**: the degree to which an individual believes that using a technology will be effortless.

WebMD	An online publisher of human health related news and information based in the United States of America.
WebMD Pain coach	A pain management app developed and offered by WebMD available for public download until September 2017. This app is no longer available.

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Dedication

To my brothers, *Mandy* and *Sanu*.

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Publications Associated with Thesis

1. **Bhattarai, P**., Newton-John, T. R., & Phillips, J. L. (2020). Apps for pain self-management of older people's arthritic pain, one size doesn't fit all: A qualitative study. *Archives of gerontology and geriatrics*, *89*, 104062. https://doi.org/10.1016/j.archger.2020.104062

2. **Bhattarai, P**., Newton-John, T. & Phillips, J. L. (2019). Apps for older people's pain self-Management: Perspectives of primary care and allied health clinicians. *Pain Medicine, pnz218*, https://doi.org/10.1093/pm/pnz1218.

3. **Bhattarai, P**., Newton-John, T.R.O. & Phillips, J. L. (2019). Feasibility evaluation of a pain self-management app-based intervention among older people living with arthritic pain: study protocol. *BMC: Pilot and Feasibility Studies, 5*(1), 57.

4. **Bhattarai, P**., Newton-John, T.R.O. & Phillips, J. L. (2017). Quality and usability of arthritic pain self-management apps for older adults: a systematic review. *Pain Medicine, 19*(3), 471-484.

5. **Bhattarai, P**. & Phillips, J. L. (2017). The role of digital health technologies in management of pain in older people: An integrative review. *Archives of Gerontology and Geriatrics, 68*, 14-24.

Research Outputs Associated with Thesis

Peer reviewed conference oral presentations

1. **Bhattarai, P**., Newton-John, T.R.O. & Phillips. J.L. (2018). mHealth tools in later life pain care. *International Association for Study of Pain (IASP), Boston, USA, 14 September 2018.*

2. **Bhattarai, P**., Newton-John, T.R.O. & Phillips. J.L. (2018). The dynamics of carrying out technology-based research among older people: Lessons learned from a feasibility project. *Palliative Care Nurses Australia Conference, 20 May 2018.*

3. **Bhattarai, P**., Newton-John, T.R.O. & Phillips. J.L. (2018). Quality and usability of arthritic pain self-management apps for older adults: a systematic review. *Palliative Care Nurses Australia Conference, 20 May 2018.*

4. **Bhattarai, P**. & Phillips. J.L. (2016). The role of digital health technologies in management of pain in older people: An integrative review. *Palliative Care Nurses Australia Conference, 11 September 2016.*

5. **Bhattarai, P**., Newton-John, T.R.O. & Phillips. J.L. (2018). Managing older people's pain: The role of pain self-management apps. *Sigma Theta Tau International Nursing Honor Society; Nursing and Midwifery: Transforming Leadership, Education, Practice, and Research, 17 August 2016.*

Peer reviewed conference poster presentations

1. **Bhattarai, P**., Newton-John, T.R.O. & Phillips, J.L. (2018). The dynamics of carrying out technology-based research among older people: Lessons learned from a feasibility project. *International Association for Study of Pain (IASP), Boston, USA, 14 September 2018.*

2. **Bhattarai, P**., Newton-John, T.R.O. & Phillips, J.L. (2018). Quality and usability of arthritic pain self-management apps for older adults: a systematic review. *International Association for Study of Pain (IASP), Boston, USA, 14 September 2018.*

3. **Bhattarai, P**., Newton-John, T.R.O. & Phillips, J.L. (2018). Quality and usability of arthritic pain self-management apps for older adults: a systematic review. *Palliative Care Australia Biennial Conference, Adelaide, Australia, 6–9 September 2017.*

Invited presentations

1. **University of Technology Sydney, Improving Palliative, Aged and Chronic Care through Clinical Research and Translation (IMPACCT), HDR Summer School.** *Challenges of carrying out technology mediated research in older population.* 12 January 2018.
2. **Concord Hospital: Concord Centre for Palliative Care**. *Critical Appraisal for Hospital Clinicians.* 7 February 2017.
3. **University of Technology Sydney, Improving Palliative, Aged and Chronic Care through Clinical Research and Translation (IMPACCT), HDR Summer School.** *Critical Appraisal.* 16 January 2017.
4. **Institute of Health Research (IHR) Health Research Symposium**. *DigiTech Pain Project.* 7 December 2016.

Other publications

CareSearch, palliative care knowledge network. Caresearch Blog: Palliative Perspectives (2019). *Self-management of arthritic pain for older people in the community: Do apps have a role to play?*
https://www.caresearch.com.au/caresearch/TabId/3781/ArtMID/6000/ArticleID/846/Self-management-of-arthritic-pain-for-older-people-in-the-community-Do-Apps-have-a-role-to-play.aspx

Scholarships and awards

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Chapter 1 Introduction to the DigiTech Pain project

1.1 Background

Population aging is a global phenomenon, with estimates suggesting that the world's population aged over 65 years will reach 1.5 billion by 2050 (National Institute of Health, 2014). Although there is no universal criterion to define older people (World Health Organization, 2002), most high income countries around the world use the age cut off of 65 years or above to refer to older people (Age United Kingdom, 2017; American Geriatric Society, 2009; Australian Bureau of Statistics, 2018). Aging is often associated with increased disability and symptom burden (Salive 2013). Chronic unrelieved pain is one of the most distressing and debilitating health issues faced by older people (Blyth et al., 2001; McClean & Higginbotham, 2002).

Older people carry a disproportionate burden of chronic pain. A recent Australian report suggests that over one million older people currently live with chronic pain, which is almost twice as high as the burden of pain experienced by people of working age (Pain Australia, 2019). The burden of unrelieved pain experienced by older people is expected to increase with population aging (Australian Institute of Health and Welfare, 2007; Dionne, Dunn, & Croft, 2006). Despite the advent of new pain treatments, many older people continue to suffer from disability, decreased mobility, depression and impaired quality of life associated with pain (Bryant, Grigsby, Swenson, Scarbro, & Baxter, 2007; Gayman, Turner, & Cui, 2008; Patel, Guralnik, Dansie, & Turk, 2013).

1.1.1 Economic burden of pain

In Australia, unrelieved pain is estimated to cost over $73 billion annually, with a significant proportion of these costs directly attributed to unrelieved pain experienced by older people (Pain Australia, 2019). Pain due to arthritis costs the health system over $5.5 billion annually (Ackerman, Bohensky, Pratt, Gorelik, & Liew, 2016). While health system costs ($12.2 billion) and other financial costs such as aids and modifications and informal care ($12.7 billion) are well known, the more costly outcome of chronic pain is lost productivity, which costs more than $48 billion annually.

1.1.2 Arthritic pain

Arthritis is an umbrella term that refers to more than 100 conditions affecting joints of the body including hips, knees, wrists and knuckles. Arthritis causes joint inflammation and results in discomfort and pain (Health Direct, 2018). Arthritis is one of the most prevalent chronic conditions experienced by older people (Australian Bureau of Statistics, 2015). As arthritis continues to negatively impact older people's mental health and overall quality of life (Australian Institute of Health and Welfare, 2018), the number of Australians living with this condition is expected to increase to almost 5.5 million over the next decade (Ackerman et al., 2016).

While osteoarthritis is the most common joint disease of old age, rheumatoid arthritis affects all ages but is more prevalent among older adults (Australian Institute of Health and Welfare, 2015a, 2015b). Osteoarthritis and rheumatoid arthritis require different pharmacological treatment approaches, however recommended pain self-management strategies for rheumatoid and osteoarthritis tend to be similar (Ersek, Turner, Cain, & Kemp, 2004; National Institute of Health, 2015). Both arthritic conditions require the person living with either condition to assess and interpret their pain (symptom awareness) and to apply adaptive coping strategies (symptom management) such as analgesic adjustment or lifestyle modification (McBain, Shipley, & Newman, 2015). As most older people live in the community, self-management strategies are central to managing their arthritic pain (Nicholas et al., 2012; Schofield et al., 2014).

1.1.3 Pain self-management

Managing pain requires the judicious use of a range of pharmacological and non-pharmacological interventions, with self-management being an essential element of an individualised pain management plan (Schofield et al., 2014). Self-management of chronic pain refers to the set of activities carried out to enhance function, improve mood and reduce pain (Reid et al. 2008). These activities target and challenge the individual's emotional, cognitive and behavioural responses to pain and build capacity to manage pain (Cameron & Stewart, 2012; Reid, Eccleston, & Pillemer, 2015). Active pain self-management strategies such as physical activities are likely to reduce pain and disability, compared to passive treatment methods such as medications or hot packs (Blyth, March, Nicholas, & Cousins, 2005). There is some evidence to indicate that building older people's pain self-management capacity via structured self-management programs may reduce pain,

disability and depressive symptoms and improve pain self-efficacy (Du et al., 2011; Reid et al., 2008). The overall purpose of these structured pain self-management programs is to build the older person's ability to manage their pain and treatment plans, while helping them cope with the physical, psychosocial and lifestyle challenges inherent in living with a chronic painful condition (Barlow, 2001; Barlow, Wright, Sheasby, Turner, & Hainsworth, 2002). Effective self-management strategies are required to help older people maintain their function and quality of life (Nicholas et al., 2012).

A comprehensive pain self-management approach involves: i) medical management (i.e. medication adherence, dietary modification); ii) behaviour modification (i.e. modifying instrumental activities of living, physical and recreational activities) and iii) managing emotion (i.e. dealing with fear, frustration and anger) (Lorig & Holman, 2003). The non-pharmacological approach of pain self-management largely entails the use of Cognitive Behavioural Therapy (CBT)-based approaches.

Cognitive Behavioural Therapy based pain self-management

The CBT approach to pain self-management holds that an individual's beliefs, attitudes and behaviours greatly influence their pain experience (Reid et al., 2015). The approach involves assessment of thoughts associated with pain, helping people understand the influence of their thoughts and beliefs on their pain, and helping them control and manage these thoughts (Reid et al., 2015; Williams, Eccleston, & Morley, 2012). CBT also requires identifying behaviours that are contingent on pain, or upon activities that lead to pain relief or comfort; and then developing behaviours that are instead contingent on attaining goals that are meaningful to the older person living with pain (Williams et al., 2012). The CBT approach to self-management functions within a partnership paradigm of care where the older person living with chronic pain and their clinicians have a collaborative relationship (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Dorflinger, Kerns, & Auerbach, 2012).

Pain self-management and partnership with clinicians

An additional but important element of the self-management approach is the integration of a shared decision-making model where clinicians work closely with people living with chronic conditions to build self-management skills and abilities (Hoving, Visser, Mullen, & van den Borne, 2010; Lovell et al., 2014; Taylor et al., 2014). A collaborative relationship between clinicians and older people living with pain provides an ideal environment for self-management education. It also helps enhance the older person's

motivation and self-efficacy for engaging in a range of relevant self-management activities (Bodenheimer et al., 2002; Dorflinger et al., 2012). Building an individual's capacity to self-manage pain is underpinned by effective instruction, education and support. While most clinicians adopt traditional education methods, such as verbal instructions and pamphlets, there is growing interest and enthusiasm in using digital health technologies in older people's pain self-management plans (Free et al., 2013; Ruland et al., 2013).

The Stanford Arthritis Self-Management Program

The Stanford Arthritis Self-Management Program ('Stanford Program') is a well-established pain self-management program developed by Dr Kate Lorig of Stanford University, United States of America (USA) (Lorig & Holman, 2003; Lorig, Ritter, Laurent, & Plant, 2008; Lorig, Ritter, Moreland, & Laurent, 2015). Led by two trained instructors who have arthritis themselves (Barlow et al., 2008), the Stanford Program consists of two hour-long weekly interactive educational sessions for six weeks covering the following topics: i) overview of arthritis and self-management principles; ii) addressing other symptoms that commonly accompany pain; iii) CBT approaches to pain management; and iv) physical activity regulation (Brady, 2013; Centers for Disease Control and Prevention, 2011; Lorig, Ritter, & Plant, 2005). The Stanford Program is based on self-efficacy theory (Bandura, 1977) and intends to enhance participants' confidence in managing arthritis. The Stanford Program has been consistently effective in improving participants' symptoms, psychosocial outcomes and quality of life (Brady, 2013; Centers for Disease Control and Prevention, 2011). In addition, there is strong evidence to support the Stanford Program's ability to improve participants' pain self-efficacy for up to eight years (Barlow et al., 2008; Lorig et al., 2008).

1.1.4 Self-efficacy in the context of pain self-management

Self-efficacy is defined as an individual's beliefs about their capacity to carry out behaviours and activities necessary to produce desired outcomes (Bandura, 1977, 1997). Self-efficacy as a set of self-beliefs relates to a given activity or behaviour (Turner, Ersek, & Kemp, 2005), and is not applicable across multiple domains of activities or behaviours. For example, an individual may have a high level of self-efficacy in managing their chronic pain, while having low-level efficacy in parenting.

The role of self-efficacy in managing arthritic pain has garnered much interest in the last few decades (Brady, 2013; Lorig et al., 2005). Higher self-efficacy is known to be

associated with lower levels of pain and disability in the person living with chronic pain (Costal, Maherl, McAuleyl, Hancockl, & Smeetsl, 2011; Dohnke, Knäuper, & Müller-Fahrnow, 2005). Older people living with chronic pain who have high pain self-efficacy are also known to more actively engage in pain self-management practices, such as exercising and stretching, making coping self-statements and pacing activity, compared to older people with low self-efficacy levels (Turner et al., 2005).

As pain self-management is an ongoing skills-based endeavour, self-efficacy in this context relates to initiation and continuation of self-management behaviours required to improve pain outcome (Bandura, 1977). As self-efficacy is considered a modifiable attribute, appropriate interventions aimed at enhancing an individual's pain self-efficacy may improve their ability to carry out prescribed and/or recommended pain self-management strategies (Marks & Allegrante, 2005; Turner et al., 2005). The trend of integrating technology into chronic disease self-management calls for exploration of the role of digital health technology interventions in improving older people's efficacy in managing their pain.

1.1.5 Digital health technology

Digital health technology is an umbrella term used to describe the use of emerging communication and information technologies, especially the use of the internet, to improve individuals' health related outcomes (Burke et al., 2015). As shown in Figure 1.1 digital health refers collectively to electronic health (*eHealth)* and mobile health (*mHealth)* technologies, which are defined below:

- *eHealth* refers to the secure and cost-effective use of computer-based information and communications systems to process, transmit and store data and health related information
- *mHealth,* a component of eHealth, refers to the medical or public health practice supported by mobile devices (i.e. mobile phones, patient monitoring devices, personal digital assistants and other wireless devices) (World Health Organization, 2015).
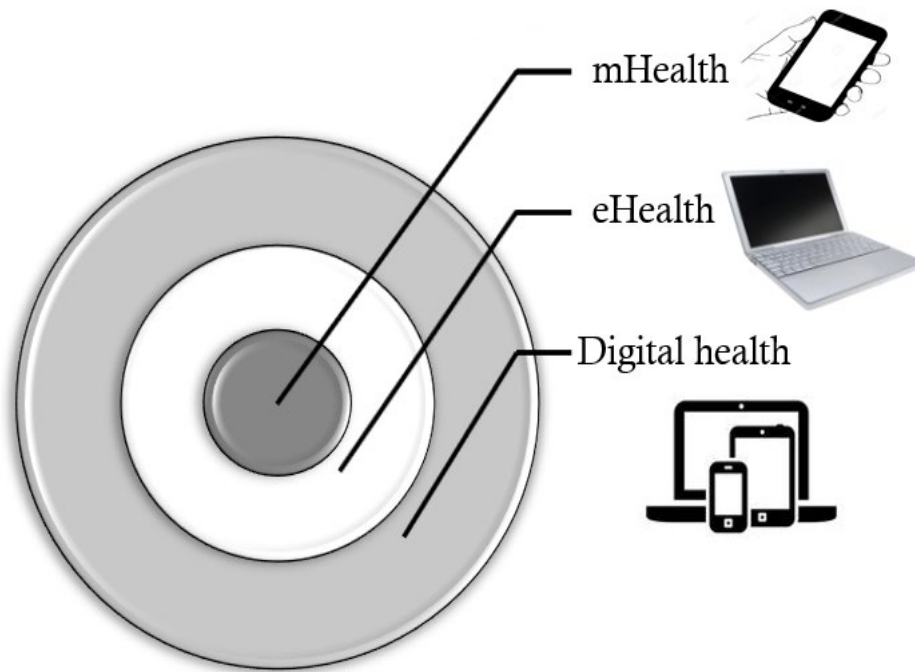
Figure 1.1 Digital health, eHealth and mHealth (based on World Health Organization, 2005, 2015)

The widespread use of digital devices, such as smartphones, provides a range of unique opportunities to develop and implement digital health technology-based interventions to support older people's arthritic pain self-management practices.

1.1.6 Older people and smartphones

Although younger people are more engaged in technology than older people, the uptake of new technologies such as smartphones among older people is rapidly increasing (Pew Research Center, 2017). The number of older Americans using smartphones has more than doubled in the last decade to 40% (Anderson & Andrew, 2017). Similarly, over 50% of older Australians own and use a smartphone (Office of the eSafety Commissioner, 2018). A growing proportion of older people regularly use the internet and source online health information (Office of the eSafety Commissioner, 2018; Pew Research Center, 2017). While little is known about smartphone uptake and use patterns of older people from low or middle income countries, over 70% of the global mobile telephone subscriptions are by people living in the low or middle income countries (International Telecommunications Union, 2015). As such, it is likely that the next generations of older people around the globe who have aged with digital technology will be even bigger users of smartphones. Given this reality, there are increasing opportunities to use technology facilitated approaches to

reach and meet the health and self-management needs of the rapidly growing and aging global population.

1.1.7 Smartphone applications (apps) for pain

Since the introduction of the smartphone in 2007, its widespread adoption has fuelled the development of a range of health-related applications (apps). An app is self-contained software, developed for use on mobile devices and made available through app stores (Ahmed et al., 2015). These apps use software that interacts with users on an individual basis (Ventola, 2014), and can be readily accessed from smartphones (Boulos, Brewer, Karimkhani, Buller, & Dellavalle, 2014). The advanced computing capabilities of smartphone apps present new opportunities to improve health outcomes by empowering people to assume a more active role in monitoring and self-managing their health (Burke et al., 2015). The scalability of apps provides an unprecedented opportunity to reach large numbers of older people regardless of their geographical location.

Health related apps make up a significant proportion of the available apps. Although exercise and wellness apps form the majority of health apps, self-management apps for chronic conditions, including pain, are growing in number (Thurnheer, Gravestock, Pichierri, Steurer, & Burgstaller, 2018; Zhao, Yoo, Lancey, & Varghese, 2019). It is estimated there are more than 350 pain self-management apps offering pain assessment recording, pain information and pain self-management plans available on the internet, and this number is expected to increase (Lalloo, Jibb, Rivera, Agarwal, & Stinson, 2015; Wallace & Dhingra, 2013).

While several recent systematic reviews have evaluated the quality of available pain apps (Lalloo et al., 2015; Reynoldson et al., 2014; Rosser & Eccleston, 2011; Wallace & Dhingra, 2013), little is known about the impact of these apps in the context of older people's pain self-management despite the overwhelming interest from the research community over the last decade in testing apps for assessment and/or self-management of pain (De la Vega et al., 2014; Jibb et al., 2017; Stinson et al., 2013). While older people experience a disproportionate burden of chronic arthritic pain, most pain app studies only include younger participants. Most app interventions tested among older people have focused on areas such as strength training (Van Het Reve, Silveira, Daniel, Casati, & de Bruin, 2014) or falls prevention (Yamada et al., 2011). While pain self-management apps

continue to grow, understanding their role in older people's pain self-management regime is very limited.

1.1.8 Regulatory landscape for apps in Australia

All therapeutic goods and items in Australia are regulated by the Therapeutic Goods Administration (TGA), which is part of the Australian Government Department of Health (Therapeutic Goods Administration, n.d). The TGA only regulates apps that are classed as a 'medical device', defined as any instrument or apparatus that intends to diagnose, monitor, treat or alleviate any disease or disability (Therapeutic Goods Administration, 2018). Similar approach to app regulation is exercised in the USA (Food and Drug Administration, 2015), and the United Kingdom (UK) (Medicines & Healthcare products Regulatory Agency, 2014).

Apps that aim to help the user manage a healthy lifestyle or simply provide health information are not considered a medical device, therefore the majority of health apps are not subject to TGA regulation. Such lack of regulatory oversight has led to a care environment where older people and clinicians are exposed to apps with little evidence of safety and effectiveness (Bates, Landman, & Levine, 2018).

1.2 Rationale for the DigiTech Pain project

Access to pain relief is a human rights issue (Brennan et al., 2007). Despite this, unrelieved pain affects a considerable proportion of older people living in both high income and low-income countries (Australian and New Zealand Society for Geriatric Medicine, 2012; Fine, 2012). Self-management activities are central in achieving optimal pain control among older people. However, as older people are living for longer periods, often alone in the community (Australian Bureau of Statistics, 2006; Dunnell, 2008), there is a need to build their pain self-management capabilities. Helping older people build and maintain their pain self-management capabilities will require a range of responses, including the development of innovative and cost-effective interventions (Hermens & Vollenbroek-Hutten, 2008). As technology continues to integrate in chronic disease self-management, the use of apps in older people's pain self-management warrants further exploration.

The current mismatch between the number of pain self-management apps and the degree to which they have been evaluated points to the need for further research in this area (Reynoldson et al., 2014; Rosser & Eccleston, 2011). Little is known about the relevance,

usefulness or effectiveness of pain self-management apps for community-dwelling older people living with arthritic pain. Similarly, there is limited evidence indicating what features older people and their treating clinicians consider to be most relevant in an arthritic pain self-management app. The *Using **Digi**tal health **Tech**nology to optimise older people's **Pain** self-management capabilities project* ('DigiTech Pain project') set out to address these knowledge gaps.

1.3　Aim and research questions

The aim is to explore the feasibility and acceptability of older people using an arthritic pain self-management app to improve their pain symptoms.

1.4　Research questions

To meet the research aim, the following research questions were used in the DigiTech Pain project:

1. What is the evidence on the use of digital health technologies for older people's arthritic pain management?
2. What is the feasibility and acceptability of undertaking an app intervention study involving community-dwelling older people living with arthritic pain?
3. What are the features that older people and their treating clinicians consider most relevant in a pain self-management app?
4. What are the actions required to build the evidence supporting the integration of an app into older people's arthritic pain self-management plans?

1.5　Thesis outline

To answer the research questions, this doctoral research project used a parallel convergent mixed methods design underpinned by Bandura's self-efficacy theory (Bandura, 1977) and the Technology Acceptance Model 2 (TAM 2) (Venkatesh & Davis, 2000). Informed by the Medical Research Council's Complex Intervention Framework (Campbell et al., 2000; Craig et al., 2008), the DigiTech Pain project has five discrete but inter-related studies (Bhattarai, Newton-John, & Phillips, 2017, 2019a, 2019b; Bhattarai & Phillips, 2017). Studies 1a, 1b and 3 are presented within the thesis as stand-alone chapters. Studies 2a and 2b are reported in a single chapter. The published studies in each chapter have been lightly edited to minimise repetition and provide a logical flow across the thesis. The structure and content of the thesis is presented in Table 1.1.

Table 1.1 Thesis outline

Sequence	Content	Chapter
Preliminary	Introduction to the DigiTech Pain project	One
Stage 1: Identifying the gaps	Study 1a: An integrative review to evaluate digital health technology interventions designed to improve older people's pain across care-settings.	Two
	Study 1b: A systematic review to appraise the quality and usability of currently available pain apps that could be used by older people to self-manage their arthritic pain.	Three
Methods	Research design, conceptual frameworks and study methods	Four
Stage 2: Testing the feasibility of the app	Study 2a (Quant): Phase I feasibility study of pre–post-test design to evaluate the feasibility, acceptability and preliminary outcomes of a pain self-management app among older people living in the community with arthritic pain.	Five
	Study 2b (Qual): A semi-structured interview study with participants of study 2a to explore their experiences of, and attitudes towards, using an app to assist their arthritic pain self-management process.	
	Study 3 (Qual): A semi-structured interview study with primary care clinicians to explore their attitudes and perspectives on integrating a pain app into their older patients' and clients' pain self-management strategy.	Six
Conclusion and recommendations	Data integration and synthesis: Recommendations of actions required to build the evidence supporting the integration of an app into older people's arthritic pain self-management plans.	Seven

1.6 Summary

Despite population aging, the high prevalence of arthritic pain experienced by older people and the rapid adoption of smartphones among older people, little is known about older people's use of pain management apps. The DigiTech Pain project systematically evaluates the feasibility of integrating apps into older people's pain self-management regime. This doctoral project also sought to determine the key components of a pain self-management app designed to assist community-dwelling older people better manage their arthritic pain. This project's findings will inform future work to develop and integrate apps into older people's pain self-management strategy, and to determine if an app can improve this population's arthritic pain.

The following chapter (Chapter 2) reports on the first study undertaken in the DigiTech Pain project, an integrative review. This integrative review evaluated digital health technologies designed to improve older people's pain management practices.

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Chapter 2 Digital health technology interventions designed to improve older people's pain across care-settings: an integrative review

2.1   Chapter preface

Chapter 1 outlined the rationale and motivation for the DigiTech Pain project and presented the project aim and research questions. A brief overview of the content, structure and the concepts of the thesis was also presented.

Chapter 2 reports on an integrative review of digital health technology interventions designed to improve older people's pain management practices across various care-settings.

2.2   Publication reference and citation

This integrative review study was published in 2017 in *Archives of Gerontology and Geriatrics* (Impact Factor: 2.611)*,* a peer reviewed scholarly journal that focuses on research relevant to the fields of experimental gerontology, and clinical and social geriatrics. This chapter contains an edited version of the publication, which is provided in its published form in Appendix 1.

> Bhattarai, P. and Phillips, J.L. (2017). The role of digital health technologies in management of pain in older people: An integrative review. *Archives of Gerontology and Geriatrics*, 68, 14-24.

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1. Amadori, M., Quaggia, D., & Votta, M. (2019). Digital health solutions to fight pain awarded at the European level. *Advances in Health and Behavior, 2*(2), 85-89.

2. Bousquet, J., Pham-Thi, N., Bedbrook, A., Agache, I., Annesi-Maesano, I., Ansotegui, I., ... Bewick, M. (2019). Next-generation care pathways for allergic rhinitis and asthma multimorbidity: a model for multimorbid non-communicable diseases—Meeting Report (Part 2). *Journal of Thoracic Disease, 11*(9), 4072.

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2.3 Introduction

With the global trend of population aging, older people are expected to outnumber children under the age of five by year 2050 (World Health Organization, 2012). Older people experience a disproportionate burden of complex and chronic diseases including various kinds of chronic pain conditions (Australian Bureau of Statistics, 2012). Chronic pain contributes to disability, decreased mobility, depression and impaired quality of life (Patel, Guralnik, Dansie, & Turk, 2013).

The aging population and high pain prevalence require innovative and cost-effective pain self-management strategies targeted at older people, including the use of various digital health technologies (Free et al., 2013; Ruland et al., 2013). As the uptake of technology among older people continues to increase (Office of the eSafety Commissioner, 2018; Pew Research Center, 2017), there is a need to evaluate these novel modalities in the context of older people's pain management. While there has been a proliferation of Randomised Controlled Trials (RCTs) testing various digital health technology-based pain management interventions, most have been largely limited to younger cohorts (Buhrman, Nilsson-Ihrfeldt, Jannert, Ström, & Andersson, 2011; Pombo, Araújo, Viana, & da Costa, 2013). As a consequence, the use of digital health technology for pain management among older people is poorly understood.

This integrative review was undertaken as the first study in the DigiTech Pain project. This integrative review explored the use of digital health technology interventions designed to improve older people's pain management across various care-settings.

2.4 Objectives

The objectives of this integrative review (study 1a) were to identify the:

i) salient features of digital health technology that have been tested as part of a pain management strategy for older people

ii) evidence to support the use of digital health technology in the management of pain in older people

iii) barriers and facilitators to implementation of digital health technology among older people for pain management

iv) gaps in the current evidence base and future research directions.

2.5 Method

Design: Integrative review

An integrative review was considered to be the most appropriate method to systematically analyse currently available research evidence, due to the small number of studies identified in the preliminary search (Whittemore & Knafl, 2005). This approach allowed for inclusion of experimental and non-experimental studies to fully understand the use of digital health technology in managing older people's pain, appraise the strengths of the evidence and identify research gaps (Whittemore & Knafl, 2005).

This integrative review adhered to the following five stages: (i) problem identification; (ii) literature search; (iii) data evaluation; (iv) data analysis; and (v) presentation (Whittemore & Knafl, 2005). The reporting of this integrative review was guided by the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement (Moher et al., 2009).

2.5.1 Eligibility criteria

Studies were included if they were published in a peer-reviewed journal and reported empirical data relating to the use of digital health technology in pain management of older people. The search was limited to studies published since 2000, reflecting the significant advances and increased adoption of digital technologies that have occurred since year 2000 (Oulasvirta, Rattenbury, Ma, & Raita, 2012).

2.5.2 Literature search

A systematic search of the literature was conducted on 2 August 2015 using Academic Search Complete, Cumulative Index of Nursing and Allied Health Literature (CINAHL), Embase, Cochrane Library and MEDLINE databases. The search strategy was developed by the doctoral student in consultation with her primary supervisor, and this was reviewed by a specialist research librarian at the university. The search strategy comprised three sets of terms: Set 1 was designed to capture literature relating to older people, Set 2 aimed to capture literature published in the area of pain, and Set 3 captured studies relating to digital health technologies. A range of search terms relating to each set were used to retrieve relevant papers. Terms within each set were combined using the Boolean 'OR' operator, and the sets were then combined using the 'AND' operator. Potential search terms were trialled on MEDLINE and mapped to indexed medical subject headings (MeSH). MeSH terms and keywords (.mp) identified in MEDLINE were adapted to each database. A full electronic search strategy using the MEDLINE database is included in Table 2.1. Further searches were conducted using Google (Web and Scholar) websites, and Caresearch Palliative Care Knowledge Network. Additional search strategies included hand searching key journals and reference lists of identified articles for eligible papers and searching conference abstracts.

Table 2.1 Medline search strategy: conducted 2 August 2015

Search	Search terms	Hits
Set 1	Concept – Older people	
S1	(MM "Frail Elderly") OR (MH "Aged+")	2429327
S2	(MM "Aged, 80 and Over")	1669
S3	(MM "Geriatrics")	24005
S4	TI ("older people" OR "elderly" OR "senior*" OR "ageing" OR "aging" OR "old age") OR AB ("older people" OR "elderly" OR "senior*" OR "ageing" OR "aging" OR "old age")	425683
S5	S1 OR S2 OR S3 OR S4	2644562
Set 2	Concept – Pain	
S6	(MH "Pain+")	319412
S7	TI pain OR AB pain	440858
S8	S6 OR S7	584,595
Set 3	Concept – Digital health technology	
S9	(MM "Reminder Systems")	1,429
S10	(MM "Information Seeking Behavior")	538
S11	(MM "Cell Phones") OR (MM "Text Messaging") OR (MM "Modems") OR (MM "Answering Services")	4,648
S12	(MM "Electronic Mail") OR (MH "Text Messaging") OR (MH "Cell Phones+") OR (MH "Videoconferencing+")	7,842
S13	(MH "Internet+") OR (MH "Microcomputers+") OR (MM "Minicomputers") OR (MM "Computers, Handheld") OR (MM "Computers")	89,527
S14	(MM "User-Computer Interface") OR (MM "Mobile Applications")	13,946
S15	interactive voice response	531
S16	(MM "Virtual Reality Exposure Therapy")	165
S17	(MM "Attitude to Computers")	1,792
S18	(MM "Computer-Assisted Instruction")	7,429
S19	(MH "Internet+")	54268
S20	(MH "Telemedicine+")	16924
S21	(MM "Text Messaging") OR (MH "Telecommunications+")	65333
S22	(MM "Social Media")	1412
S23	(MM "Brain-Computer Interfaces")	592
S24	S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23	167335
	Concept – Older people + Pain + Digital health technology	
S25	S5 AND S8 AND S24	**564**

2.5.3 Study selection

The pre-specified inclusion criteria were used by two reviewers (PB and JP) to assess the relevance of identified articles independently, with a plan for disagreements to be resolved by discussion and consultation with an academic pain management expert. There were no instances of disagreement requiring a consultation with the pain management expert.

The titles and abstracts of all papers were examined by two reviewers to determine if they met the inclusion criteria. Data extraction was carried out by the doctoral student.

2.5.4 Quality assessment of included studies

The Critical Appraisal Skills Programme (2013) tools and the Quality Appraisal Tool for Case Series Studies (Moga et al., 2012) were used to assess the quality of included studies. Both of these checklists provide an option to indicate if a given quality criteria is present (score of Yes), absent (score of No) or unclear (score of Can't tell for the Critical Appraisal Skills Programme tools and Unclear for the Quality Appraisal Tool for Case Series Studies). The level of evidence generated by each study was determined using the Australian National Health and Medical Research Council's (1999) evidence hierarchy (Coleman et al., 2009).

2.5.5 Data collection

An evidence summary matrix was designed to extract and manage data. Data on methods, setting, level of evidence, intervention detail, findings and strengths and weaknesses was extracted into this matrix. Qualitative data on patient reported pain outcomes, participants' perspectives, and digital health technology barriers and facilitators was also extracted.

2.5.6 Data analysis

The collected data was divided into groups and sub-groups then aligned to specific research questions. After systematic comparison of data across studies, an iterative data examination process allowed for identification of patterns, themes and relationships between and among the groups and sub-groups (Whittemore & Knafl, 2005).

2.6   Results

2.6.1 Study selection

Initial search of the database resulted in 1349 papers. An additional three papers were identified via hand search. After removing duplicates and triplicates, 1003 unique papers were shortlisted for screening. Based on title and abstract review, 883 papers were excluded, leaving 120 papers for full text review. Total of 111 papers were excluded following full-text review as they did not meet the eligibility criteria leaving nine papers for inclusion (Berman et al., 2009; Huang et al., 2003; King & Workman, 2006; Lind et al., 2008; McDonald et al, 2011; McDonald et al., 2009; McDonald et al., 2013; McDonald et al., 2012; Parker et al., 2013) (see Figure 2.1).
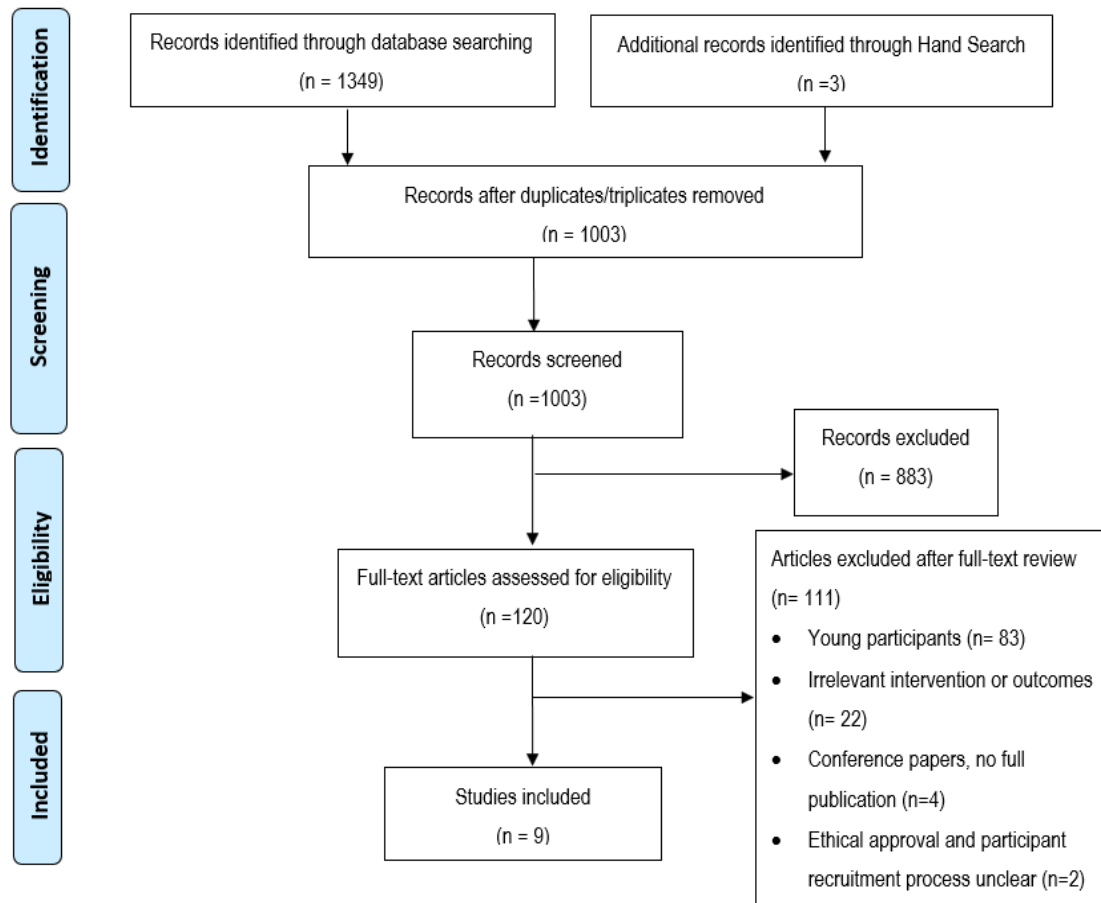
Figure 2.1 PRISMA flow chart of studies through the review process

2.6.2 Study characteristics

All of the studies were undertaken in high income countries using either quantitative (n=7), qualitative (n=1) or mixed method (n=1) designs (see Table 2.2). A total of 549 participants (range 9–312) were included in studies conducted in outpatient clinics (n=6), the participant's home (n=2) or nursing home (n=1). The highest level of evidence was generated by three phase II RCTs (Level II evidence) (Berman et al., 2009; McDonald et al., 2012; McDonald et al., 2013). Two of theses RCTs were pilot studies (McDonald et al., 2012; McDonald et al., 2013), while the other was a feasibility trial (Berman et al., 2009); none provided justification for their sample sizes. Two studies used a comparative design with concurrent controls (Level III-2 evidence) (McDonald et al., 2009; McDonald et al., 2011), while another two used a case-series design (Level IV evidence) (Huang et al., 2003; King and Workman, 2006). The qualitative study used focus group interviews (Parker et al., 2013), while the mixed methods study (QUAL + quan) integrated data from semi-structured interviews and participants' medical records (Lind et al., 2008).

Table 2.2 Summary of included studies

Author_ Year (Country)	Study design- LOE	Participants	Study aims	Intervention	Study outcomes	Strength and weaknesses
(McDonald et al., 2013) (USA)	Phase II RCT Level II	Community-dwelling older adults with arthritic pain. (n= 23); Age (x̄= 68.1 years ± 5.93)	To test the effectiveness of a virtual pain coach and pain communication intervention on older people's pain communication ability	**Control group:** View a 3-minute video of a female practitioner detailing osteoarthritis pain information that is important for patients to share with their care team. **Intervention group:** 3-minute video plus interactive session with a virtual pain coach (video animation of a female practitioner) who asked them to describe their pain, prompting information sharing, and encouraging sharing pain information with their practitioner. The virtual pain coach detected and responded to participants' pauses. Physicians provided with a copy of relevant pain management guidelines	Primary outcome: Not described Participants' consultation with physician immediately after the intervention audiotaped for data extraction. Intervention group participants described significantly more pain source information (p=0.009) and were prescribed significantly more pain treatments (p=0.005) than those in control group. No difference in pain intensity between two groups.	Strength – Intervention guided by a theoretical framework, randomised control design. Weakness – small sample size, no description of power or sample-size calculation. Impact of the intervention on patient's pain outcome on longer term is not reported.
(Parker et al., 2013) (USA)	Focus group interviews (n=6) (QE)	Community-dwelling older adults with chronic pain (n= 41); Age (x̄= 76.2 years ± 9.3)	To examine the willingness of older adults with chronic pain to adopt mHealth technologies to help manage their pain.	An iPhone 4 was introduced during the focus group sessions to prompt conversations about the experience of using mHealth in the healthcare context, willingness, barriers and facilitators, if the technology would make them comfortable etc.	Four major themes: concerns about mHealth use, ways mHealth device might be used, barriers to mHealth use, and facilitators to mHealth use. Barriers include concern of battery dying, cost and lack of familiarity; facilitators include need of training and tailoring device so it meets the functional needs of elderly.	Strength – In-depth exploration of older people's perspective, data saturation achieved. Weakness –Urban-dweller participants only, use of an iPhone 4 during focus groups limits the applicability of the findings to other technologies.

Author_ Year (Country)	Study design-LOE	Participants	Study aims	Intervention	Study outcomes	Strength and weaknesses
(McDonald et al., 2012) (USA)	Phase II RCT Level II	Community-dwelling older adults who only spoke Spanish (n= 18); Age (x̄= 74.3 years ± 7.60)	To test the effects of a virtual pain coach and pain communication intervention on Spanish speaking older people's pain and depressive symptoms.	**Control group**: View a 3-minute video of a Latina practitioner detailing osteoarthritis pain information important to tell their care team. **Intervention group**: 3-minute video plus interactive session with a Spanish speaking virtual pain coach (animated female practitioner) who asked them to describe their pain, prompting information sharing, and encouraging sharing pain information with their practitioner. The virtual pain coach detected and responded to participants' pauses, however visual cues were not detected	Primary outcome: Not described Participants had their physician-consultation immediately after the intervention. BPI done before and one month post-intervention. Significantly more participants from the intervention group compared to control group reported change from non-use to use of opioid one month post-intervention (p=0.023). No improvement in pain intensity and interference detected.	Strength – Intervention guided by a theoretical framework, randomised control design. Weakness – small sample size, no description of power or sample-size calculation, no description of how participants actually reported their pain after taking part in the interventions.
(McDonald et al., 2011) (USA)	Randomised posttest-only double blind pilot test design. Level III-2	Community-dwelling adults with arthritic pain. (n=30); Age (x̄= 71.9 years ± 9.36)	To pilot test the effect of virtual practitioner pain communication coach on older adults' communication of their osteoarthritis pain.	**Control group:** View a 3-minute video of a female practitioner detailing osteoarthritis pain information that is important to tell their care team. **Intervention group (1)**: 3-minute video plus interactive session with a virtual pain coach (animated female practitioner) who asked them to describe their pain, prompting information sharing, and encouraging sharing pain information with their practitioner. The virtual pain coach detected and responded to participants' pauses. **Intervention group (2)**: 3-minute video plus interactive session with a video-taped	Primary outcome: Not described Immediately after watching the videos, participants were asked to talk about their pain by a videotaped practitioner. On average, participants in the intervention group (1) reported one additional important distinctive information about their pain compared to those in the control group and intervention group (2), however this difference was not statistically significant.	Strength – Intervention guided by a theoretical framework. Weakness – patient reported data post-intervention was gathered from an experimental scenario (question asked by a videotaped practitioner), impact of the intervention on patient's pain

Author_ Year (Country)	Study design- LOE	Participants	Study aims	Intervention	Study outcomes	Strength and weaknesses
				practitioner who asked them to describe their pain, prompting information sharing, and encouraging sharing pain information with their practitioner. Participants' pauses were not detected. The total duration of Intervention 1 and 2 is not reported.		outcome on longer term is not reported.
(Berman et al., 2009) (USA)	Phase II RCT Level II	Community-dwelling adults aged 55 years or over (n= 78); Age (x̄ = 65.8 years, range= 55-91)	To assess the feasibility of delivering self-care tools to older adults via internet and to document the changes in pain and ability to manage chronic pain.	**Intervention group** accessed a web-based pain self-care (exercise) modules covering: 1) abdominal breathing, 2) relaxation, 3) writing about positive experiences, 4) writing about difficult experiences 5) creative visual expression, and 6) positive thinking. Intervention included audio, visual and textual components; illustrative examples, and worksheet for reflection and action plan development. Provided suggestion about pain communication. Participants 'use of website monitored, and email prompts sent to encourage completion **Comparison group**: participants not given access to the website until the observation period was over, after which they were given access.	Primary outcomes: Pain intensity, pain interference, self-efficacy, depression and anxiety. Other outcome: awareness of response to pain. Pain intensity and interference improved for both intervention and control group (p< 0.01); Intervention group reported increased confidence in pain management using non-medical self-care techniques (p< 0.01). High satisfaction with the intervention, as measured by author developed satisfaction survey, was reported: intervention helpful (81%), easy to use (88%).	Strengths – Randomised trial design Weaknesses – No description of sample size and power calculation, short intervention duration of six weeks.

Author_ Year (Country)	Study design- LOE	Participants	Study aims	Intervention	Study outcomes	Strength and weaknesses
(McDonald et al., 2009)	Randomised double blind posttest-only experiment. Level III-2	Community-dwelling older adults with arthritic pain. (n= 312); Age (x̄= 75.6 years ± 8.50)	To test how a computer displayed videotaped practitioners' pain question phrasing affects the pain information provided by older adults.	Participants randomly allocated to one of three intervention groups and asked questions about their pain by an animated practitioner. **Intervention group (1)** (open-ended without social desirability) Question "Tell me about your pain, aches, soreness or discomfort". **Intervention group (2)** (closed-ended without social desirability) Question "What would you rate your pain, aches, soreness or discomfort on a 0 to 10 scale with 0, no pain, and 10 the worst pain possible". **Intervention group (3)** (social desirability bias) Question "How are you feeling?"	Older people who were asked an open-ended question without social desirability were likely to describe significantly more pain information than those who were asked a closed-ended question without social desirability ($p<0.009$) or an open-ended question with social desirability ($p<0.001$).	Strength – Intervention guided by a theoretical framework, large sample size. Weakness – unnatural situation (videotaped) of pain assessment.
(Lind et al., 2008) (Sweden)	Case series mixed method study (QUAL + quan) Level IV	Community palliative care patients (n= 12); Age (Median = 65.5 years, range= 58-79)	To describe participants' experience of using pain diary, digital pen and internet technology for pain assessment.	Participants were given pain diary and digital pen technology for self-assessment of pain and analgesic consumption. Pain diary had a unidimensional tool (VAS 100mm) for measurement of pain intensity. It also included a question on consumed extra dose of analgesic. Semi structured interviews were conducted to explore older people's experience of using the technology for pain assessment. Quantitative data collected included ease of used questionnaire, data from the device, and participants' medical records.	Quantitative: Number of days the digital pen was used = 10 (mean), number of pain assessments carried out per patient = 28 (mean). Qualitative themes: Difficult to understand technology, managed to use the technology in spite of poor health, overcame technical problems, increased and improved contact with care givers, increased participation in one's care, and sense of increased security.	Strengths – In-depth exploration of older people's experience of using pain assessment technology. Weakness – Participants had little understanding of the technology, and an inaccurate sense of "connection" with clinicians.

Author_ Year (Country)	Study design- LOE	Participants	Study aims	Intervention	Study outcomes	Strength and weaknesses
(King & Workman, 2006) (Australia)	Case series Level IV	Aged care facility residents (n= 19); Age (Median = 82.4 years, range= 71-95)	To test the feasibility of using information communication technology to improve arthritic pain	**Intervention**: Remote pain assessment via videophone technology. Either a desktop computer or an i2i videophone system was used. Contact established between specialist pain clinician (from a central pain clinic) and participants at the residential aged care facility. Patients' self-reported pain intensity (VAS) recorded before and during video-consultation. Data also collected on patients' QOL and their experience of video consult.	Average reported pain score was 5 on VAS. Video consult was sufficient to assess pain and discuss treatment strategies. 59% of participants preferred video-consultation to face-to-face consultations. 94% satisfied with the consultation and willing to participate again. No result of statistical significance presented.	Strength – user-friendly design of the video-consultation setup, successful video-consult with pain specialist. Weakness – small sample size, no report of the intervention's impact on pain outcomes.
(Huang et al., 2003) (USA)	Test- retest Pilot study Level IV	Patients with bone metastasis related pain attending an outpatient radiation oncology clinic (n=9); Age (x̄= 66 years ±12)	To evaluate the feasibility of using innovative computerised PAINReportIt and manually prepared PAINConsultN in a community radiation oncology setting.	**Intervention**: The PAINReportIt included: a) computerised version of MPQ, and b) a series of questions designed to explore other aspects of participants' pain and analgesic therapies. Administered using a touchscreen computer, with one question per page. Total of 34 screens with 13 screens covering exactly the same questions as the paper version of MPQ and additional 21 measuring further details of participants' pain. Participants were asked 1 week later to complete the PAINReportIt again as the posttest. PAINConsultN: provision of the patient-reported pain related data together with pain management recommendation to the participant's physician.	The computerised PAINReportIt had promising feasibility with reasonable completion time (7–20 min), high acceptability (8–13) (on a 13 item tool), and adequate completeness (100%) in a sample of cancer patients with bone metastasis pain. Impact of PAINConsultN not reported in the study. No result of statistical significance presented.	Strengths – use of validated pain assessment tool, user-friendly design of the device (touchscreen), and the pain assessment program. Weakness – small sample size, report of pain assessment was not transferrable for use by physician.

Legend: BPI=Brief Pain Inventory; LOE=Level of Evidence; MPQ=McGill Pain Questionnaire; n=number of participants; QE=Qualitative Evidence; QOL=Quality of Life; VAS=Visual Analog Scale; x̄=mean age ± standard deviation.

2.6.3 Quality evaluation

Quality evaluation revealed variable quality across the studies (Table 2.3, Table 2.4, Table 2.5). Lack of treatment effects reporting across the experimental studies and inadequate detail of bias minimisation and recruitment in the qualitative studies compromised their quality.

Table 2.3 Quality assessment summary of trials

Quality assessment tool: CASP tool for Trials (Critical Appraisal Skills Programme, 2013)											
Study design: Trials and Experimental studies											
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11
(McDonald et al., 2013) (USA)	Y	Y	Y	Y	CT	Y	CT	CT	Y	CT	Y
(McDonald et al., 2012) (USA)	Y	Y	Y	Y	Y	CT	CT	CT	CT	CT	Y
(McDonald et al., 2011) (USA)	Y	Y	Y	Y	Y	Y	CT	CT	Y	N	Y
(Berman et al., 2009) (USA)	Y	Y	N	Y	Y	Y	CT	CT	Y	CT	Y
(McDonald et al., 2009) (USA)	Y	Y	Y	Y	Y	Y	CT	CT	Y	CT	Y

Legend: Y=Yes, N=No, CT=can't tell

Table 2.4 Quality assessment summary of qualitative studies

Quality assessment tool: CASP tool for Qualitative studies (Critical Appraisal Skills Programme, 2013)									
Study design: Qualitative design									
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
(Parker et al., 2013) (USA)	Y	Y	CT	Y	Y	CT	CT	Y	Y
(Lind et al., 2008) (Sweden) *	Y	Y	Y	CT	CT	CT	CT	Y	Y

Legend: Y=Yes, N=No, CT=can't tell.

*This study included very little quantitative data hence the quality assessment was done using a qualitative study appraisal tool.

Table 2.5 Quality assessment summary of case series studies

Quality assessment tool: Quality Appraisal Checklist for Case Series Studies (Moga et al., 2012)																				
Study design: Case series																				
Question number	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20
(King & Workman, 2006) (Australia)	Y	Y	Y	U	P	Y	U	Y	P	Y	N	Y	U	Y	U	U	NA	NA	Y	Y
(Huang et al., 2003) (USA)	P	Y	N	U	P	N	U	Y	Y	Y	N	Y	Y	Y	U	U	NA	NA	Y	Y

Legend: Y=Yes, P=Partial, U=Unclear, N=No, NA=Not Applicable

2.6.4 Salient features of the tested technological interventions

All of the quantitative studies (n=7) tested a computer-delivered intervention (Berman et al., 2009; Huang et al., 2003; King & Workman, 2006; McDonald et al., 2011; McDonald et al., 2009; McDonald et al., 2012; McDonald et al., 2013), while the role of a digital pen and a smartphone in pain management of older people was explored in the qualitative (Parker et al., 2013) and mixed methods studies (Lind et al., 2008).

Four studies tested a computer-delivered educational and/or interactive video intervention based on the communication accommodation theory among English (McDonald et al., 2009; McDonald et al., 2011; McDonald et al., 2013) or Spanish speaking (McDonald et al., 2012) older people with osteoarthritic pain. Other interventions included an internet-delivered mind–body exercise program for pain management (Berman et al., 2009), remote pain assessment using videoconference (King & Workman, 2006) and patients' self-reported pain assessment using a touchscreen computer (Huang et al., 2003). Participants' experience of using a digital pen for pain assessment in their homes was explored in the mixed methods study (Lind et al., 2008), while the focus group participants' views about the displayed iPhone 4 and its potential to help them manage their pain were explored in the qualitative study (Parker et al., 2013).

2.6.5 Reported pain outcomes

Each of the five studies which measured patients' pain outcomes used the Brief Pain Inventory. Three studies reported on pain intensity and interference (Berman et al., 2009; McDonald et al., 2012; McDonald et al., 2013), while the remaining studies assessed participants' pain description (McDonald et al., 2009; McDonald et al., 2011).

2.6.6 Impact of technology use on patients' pain outcomes

In the feasibility trial (Berman et al., 2009), a web-delivered exercise-based intervention increased older people's confidence in using non-medical pain management strategies ($p<0.01$). In this trial, an improvement in pain intensity and pain interference was reported in both (intervention and control) groups ($p<0.01$) (Berman et al., 2009). Similarly, an interactive video-based pain communication intervention led to no improvement in pain intensity (McDonald et al., 2012; McDonald et al., 2013) and pain interference (McDonald et al., 2012) despite improvement in participants' pain description (pain source) ($p=0.009$) (McDonald et al., 2013). However, the intervention group was either prescribed significantly more pain treatments ($p=0.005$) (McDonald et al., 2013), or they reported a

significant change from non-use to use of an opioid related pain treatment (p=0.023) (McDonald et al., 2012). These changes were not attributed to patients' pain description (McDonald et al., 2012), with authors suggesting the possibility of a *Hawthorne effect* (McDonald et al., 2013).

In a post-test only randomised experiment where older people were asked to describe their pain using various pain questions by an animated practitioner, open-ended pain questions without social desirability elicited significantly more pain information than closed-ended questions without social desirability (p<0.009), or open-ended questions with social desirability (p<0.001) (McDonald et al., 2009). Social desirability is the tendency to answer in a way people deem more socially acceptable than their actual answer (Lavrakas, 2008)

2.6.7 Perspectives, barriers and facilitators to digital health technology

Five studies reported on older people's perspective of using digital health technology for pain management (Berman et al., 2009; Huang et al., 2003; King & Workman, 2006; Lind et al., 2008; Parker et al., 2013). Two studies provided a brief account of the high acceptability and satisfaction of a videoconference (King & Workman, 2006) and a touchscreen computer-based pain assessment intervention (Huang et al., 2003). An internet-delivered pain management intervention was also reported as being highly useful and user friendly (Berman et al., 2009).

Older people's experience of using a digital pen for pain assessment indicated high user acceptance and ease of use despite participants' poor health, limited understanding of the device's functioning and occasional technical malfunction (Lind et al., 2008). The feeling of being more connected with clinicians due to real-time pain assessment data transfer was highlighted (Lind et al., 2008). The barriers and facilitators to use of digital health technology among older people for pain management included concerns regarding the mobile device's battery life, cost, lack of familiarity with the technology, the need for digital technology training, device design friendly for older users, and mHealth facilitated improved communication with clinicians (Parker et al., 2013).

2.7   Discussion

While this integrative review found only a small number of studies exploring the use of digital health technology for pain management of older people, some valuable insights about the state of evidence in this area of research have been generated. This integrative review has helped answer several research questions:

What are the salient features of digital health technology that have been tested as part of a pain management strategy for older people?

Computer-based video interventions in a clinic setting were most commonly tested for pain management of older people (Berman et al., 2009; King & Workman, 2006; McDonald et al., 2009; McDonald et al., 2011; McDonald et al., 2012; McDonald et al., 2013). Although similar findings have been reported by a recent systematic review of internet-based pain management interventions tested across all ages (Heapy et al., 2015), studies using more technologically advanced interventions such as a pain app have largely focused on a younger population (Stinson et al., 2013). Nevertheless, successful use of app-based intervention among older people for purposes such as strength training (Van Het Reve, Silveira, Daniel, Casati, & de Bruin, 2014) shows that apps could have potential applicability for pain management among older people.

The video interventions (live broadcast, videotape or animation) involved a combination of educational, interactive or instructional component. Although video interventions are preferred by older people because they accommodate different learning styles (Hill et al., 2009), the evidence for animations is inconclusive. Animations have been used in gait and mobility assessment of older people (Marsh, Ip, Barnard, Wong, & Rejeski, 2011), however little is known about the use of animation for coaching purposes. Considering the cost effectiveness and ease of technical manipulation of animations, further evidence is necessary to support their use in pain management.

Non-computer-based digital technology interventions including the use of a digital pen for pain assessment showed high acceptability and ease of use among older people (Lind & Karlsson, 2013; Lind et al., 2008). Although digital pens have been used to identify deterioration among older patients with heart failure (Lind & Karlsson, 2013), further investigation of the impact of this technology on older people's pain outcomes is necessary.

While older people report a willingness to use digital health technologies at home for pain management (Currie, Philip, & Roberts, 2015; Parker et al., 2013), very few studies have tested these technologies in the community setting (Berman et al., 2009; Lind et al., 2008). In progressing this work, it is crucial to consider older people's choice and preferences while implementing technology in their lives and homes, and to involve older people in the technological research process so their voices are heard and their needs are met (Borges, et al., 2008).

Is there evidence to support the use of mHealth and eHealth technologies in management of pain in older people?

There is insufficient evidence demonstrating the effectiveness of digital health technologies in reducing older people's pain intensity and pain interference (Berman et al., 2009; McDonald et al., 2012; McDonald et al., 2013). While this finding resonates with a recent systematic review reporting inconclusive evidence of the effectiveness of digital health interventions in improving the outcomes of mental health patients (Naslund, Marsch, McHugo, & Bartels, 2015), it contradicts another review which demonstrated the effectiveness of such an intervention in the general population with somatic diseases (Elbert et al., 2014). This discordance warrants further evaluation of the effectiveness of digital health technology in narrower segments of the population with specific illnesses and needs.

There is some lower level evidence that video-based interactive and instructive interventions may increase a patient's ability to describe their pain and likelihood of using pharmacological pain treatment (McDonald et al., 2012; McDonald et al., 2013). Older people's inability to effectively communicate their pain experiences is a known pain management barrier (Glajchen, 2001). In addition, the causality between improved pain communication and increased likelihood of pain treatment has not been established.

Evidence indicates that watching pain management videos on exercise, pain education and communication could lead to higher confidence in pain self-care, however the improvements in pain intensity observed in both the intervention and comparison groups make these results difficult to interpret (Berman et al., 2009). While the trial was not powered to detect a difference, there is some evidence indicating that the provision of tailored education and guided therapy (exercise or relaxation) could improve patients' pain self-management ability and pain intensity (Marques et al., 2015). Further research on use of tailored video information and instruction on pain management of older people is required to better understand the impact of these interventions.

There is low level evidence that open-ended questions without social desirability could elicit significantly more pain related information from older people, whereas pain questions phrased as social conversation such as "how are you feeling" could encourage a socially desirable answer (McDonald et al., 2009). Although earlier studies have reported the influence of social desirability bias on pain self-reports of chronic pain patients (Deshields, Tait, Gfeller, & Chibnall, 1995), recent evidence in this area is lacking. Nevertheless, recent

studies do suggest that older people are reluctant to acknowledge, report and discuss their pain (Makris et al., 2015). Pain assessment questions on future technological interventions should allow older people to accurately report their pain without causing response distortion.

What are the barriers and facilitators to use of digital technology for older people's pain management?

Older people are willing to learn and use digital technologies for pain management but experience some technological adoption barriers (Currie et al., 2015; Lind et al., 2008; Parker et al., 2013). One of the most highlighted barriers to use of digital technology was concern about battery life (Parker et al., 2013), which resonates with earlier research (Kurniawan, 2008). Future digital health technology interventions aimed at older people should consider implementing cost-effective and power-efficient devices.

Provision of device use training was a key facilitator (Lind et al., 2008). Unlike earlier reports that devices and programs need to be tailored to older people's needs (Al-Razgan, Al-Khalifa, Al-Shahrani, & AlAjmi, 2012), more older people preferred to be device trained rather than having the devices tailored to their needs (Parker et al., 2013). Given the high prevalence of cognitive impairment among older people and the rapidly advancing field of technology, provision of ongoing training and support to older users should be considered when implementing digital technology-based intervention.

An important facilitator supporting the adoption of digital technology was having close contact with clinicians and bidirectional flow of information (Lind et al., 2008; Parker et al., 2013). Future technological interventions need to promote connectedness between patient and clinicians while minimising clinical data overload, especially as clinicians seem unprepared to deal with the large volumes of data generated by such interventions despite welcoming the use for pain management (Levine, Richardson, Granieri, & Reid, 2014).

What are the gaps in the evidence and future research?

There is a lack of high-quality studies investigating the effectiveness of digital health technologies in management of older people's pain, with most limited to pilot or feasibility studies that do not appear to have led to larger adequately powered phase III RCTs. Given the rapid advancement in the field, there is a need to identify older people's needs, preferences, perceptions and attitudes towards the use of digital health technologies as part of a community-based pain self-management strategy and to use these findings to inform

future studies. This review did not identify any studies testing pain related apps, which are increasingly available often with little evidence of having been evaluated.

Strengths and limitations

There are several limitations that should be considered in appraising the results of this integrative review. The exclusion of studies published in languages other than English, non-empirical research and un-published reports may have led to selection bias. With its focus on digital health technology this integrative review has limited ability to identify the role of other technologies such as fixed line telephone for improving the management of older people's pain. However, this integrative review has provided valuable insight into the efficacy of such novel technologies and identified barriers and facilitators that need to be considered before developing and implementing interventions for older people.

2.8 Conclusion

This chapter has reported an integrative review that evaluated the current state of evidence in the field of digital health technology interventions designed to improve older people's pain management across care-settings. Despite the growing interest over the past decade in the use of various digital health technologies, there is limited evidence of the efficacy of such interventions among older people for pain management. Optimising the integration of digital health technology pain self-management strategies for older people requires inter-professional collaboration. The provision of high-quality technological interventions informed by a thorough understanding of older people's digital technology pain management needs and underpinned by systematic frameworks is required to ensure greater integration of this technology in clinical practice. Further, as adoption of mHealth devices such as smartphones and tablet computers continues to increase, the role of pain related apps should also be explored when planning for a digital health technology intervention for older people's pain management.

The following chapter (Chapter 3) reports on the second study (study 1b), a systematic review of pain self-management apps. This systematic review evaluated the evidence-based quality and the specific usability for older people of publicly available pain self-management apps in Australia.

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Chapter 3   Quality and usability of arthritic pain self-management apps for older people: a systematic review

3.1   Chapter preface

As detailed in Chapter 2, despite the growing interest in the use of various digital health technologies over the past decade, there is inadequate evidence of the efficacy of such interventions among older people for pain management. Further, despite the growing trend of smartphone uptake among older people and the significant increase in the number of smartphone-based pain self-management apps over the last decade, little remains known about the role of smartphone apps in older people's pain management (Bhattarai, Newton-John, & Phillips, 2017). Given this reality, a detailed and systematic evaluation of the evidence-based quality and older people specific usability of available pain apps is essential to better understand current apps, and to evaluate their scope and capabilities.

This chapter reports on a systematic review of the quality and usability of available pain apps that could be used by community-dwelling older adults to better self-manage their arthritic pain.

3.2   Publication reference and citation

This systematic review was published in 2017 in *Pain Medicine* (Impact Factor: 2.64)*,* a peer reviewed scholarly journal focusing on the area of pain management. This chapter contains an edited version of the publication, which is provided in its published form in Appendix 2.

> Bhattarai, P., Newton-John, T.R.O. & Phillips, J.L. (2017). Quality and usability of arthritic pain self-management apps for older adults: a systematic review. *Pain Medicine, 19*(3), 471-484.

This systematic review has been cited in the following publications:

1. Devan, H., Farmery, D., Peebles, L., & Grainger, R. (2019). Evaluation of self-management support functions in apps for people with persistent pain: systematic review. *JMIR mHealth and uHealth*, 2019. **7**(2): p. e13080.

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3.3 Introduction

It is estimated that by year 2050, 1.5 billion of the world's population will be older than 65 years, with most living in the community (Australian Bureau of Statistics, 2013; Office for National Statistics, 2011; United States Department of Health and Human Services, 2014). Between 20% and 46% of all community-dwelling older adults live with comorbid conditions that cause varying levels of disability and symptoms, including unrelieved pain (Abdulla et al., 2013). For 70% of older adults, arthritis is a major cause of chronic,

unrelieved pain (Australian Bureau of Statistics, 2012). Across high income countries arthritic conditions cost between 1% and 2.5% of the gross national product (March & Bachmeier, 1997).

As described in Chapter 1, the Stanford Program has been found to be effective in improvement and longer-term maintenance of self-efficacy, psychological well-being and self-management techniques in older people (Barlow et al., 2008). For the purpose of this review, the Stanford Program was chosen as the 'gold standard' self-management model as it has been widely used among community-dwelling older people living with arthritic pain (Brady, 2013; Centers for Disease Control and Prevention, 2011), and has also been empirically validated in a number of studies across a variety of formats (face-to-face, internet delivery, expert patient delivery) (Lorig, Ritter, Laurent, & Plant, 2008; Lorig, Ritter, Moreland, & Laurent, 2015).

3.3.1 Mobile technology and pain self-management

Significant advances in smartphone technology and app development have occurred since the release of the first Apple iPhone in 2007 (BinDhim & Trevena, 2015). There are over 350 pain self-management apps providing functions such as pain assessment recording, pain related information and pain self-management plans (Lalloo, Jibb, Rivera, Agarwal, & Stinson, 2015; Wallace & Dhingra, 2013). As many of the available pain apps have been developed with minimal input from clinicians or consumers, and very few are based on a scientific, theoretical or conceptual foundation (Lalloo et al., 2015; Reynoldson et al., 2014; Rosser & Eccleston, 2011; Wallace & Dhingra, 2013), it is difficult to know whether any meet the specific self-management needs and expectations of older people with arthritic pain.

Several systematic reviews of pain apps have been undertaken, but none have focused specifically on the needs of older people with arthritic pain (Lalloo et al., 2015; Rosser & Eccleston, 2011; Wallace & Dhingra, 2013). The evaluation and reporting approaches used in these systematic reviews varied widely, with some only providing a descriptive account of the pain app features (Rosser & Eccleston, 2011; Wallace & Dhingra, 2013), while others provide details of an evidence-based quality appraisal (Lalloo et al., 2015; Portelli & Eldred, 2016; Reynoldson et al., 2014). However, these quality appraisals were limited because the systematic reviews either excluded arthritis pain apps (Reynoldson et al., 2014), focused on non-arthritic literature (Lalloo et al., 2015), and/or were based only on CBT pain

management literature (Portelli & Eldred, 2016). Most systematic reviews have not considered the needs of older users and/or used a quality assessment criteria based on the extensive arthritic pain self-management literature.

3.3.2 Usability of pain self-management apps

Usability of an app can be defined as the extent to which it can be used for a specific goal, in a specific situation, while providing an efficient, effective and satisfying experience (Bevan, 2001). Although usability evaluations of healthcare applications have become increasingly prevalent in recent years (Arnhold, Quade, & Kirch, 2014; Kalz et al., 2014; Nayebi, Desharnais, & Abran, 2012; Tsai et al., 2007), there has been little research addressing usability evaluations of pain apps (Reynoldson et al., 2014). While the usability of pain apps has been evaluated in a recent systematic review, it was limited to evaluation of only two pain apps, and was based on ratings of middle-aged raters (aged between 19 and 59 years) in an author developed rating tool (Reynoldson et al., 2014). No systematic evaluation of older adult specific usability of pain apps has been undertaken. As the vast proportion of the arthritic pain population is older adults, an evidence-based usability evaluation of pain apps considering older adults' technology specific needs is necessary to help users make informed choices.

3.4 Aim

The aim is to appraise the quality and usability of currently available pain applications that could be used by community-dwelling older adults to self-manage their arthritic pain.

3.5 Method

Design: A systematic review.

This systematic review was underpinned by three frameworks adopted to appraise the quality and usability of pain apps (see Figure 3.1): (i) the World Health Organization (2002) Innovative Care for Chronic Conditions (macro level); (ii) the domains of chronic disease self-management (meso level) (Lorig & Holman, 2003); and (iii) the elements of the Stanford Program (micro level) (Lorig et al., 2008; Lorig et al., 2015). The reporting of this systematic review was guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher et al., 2009).
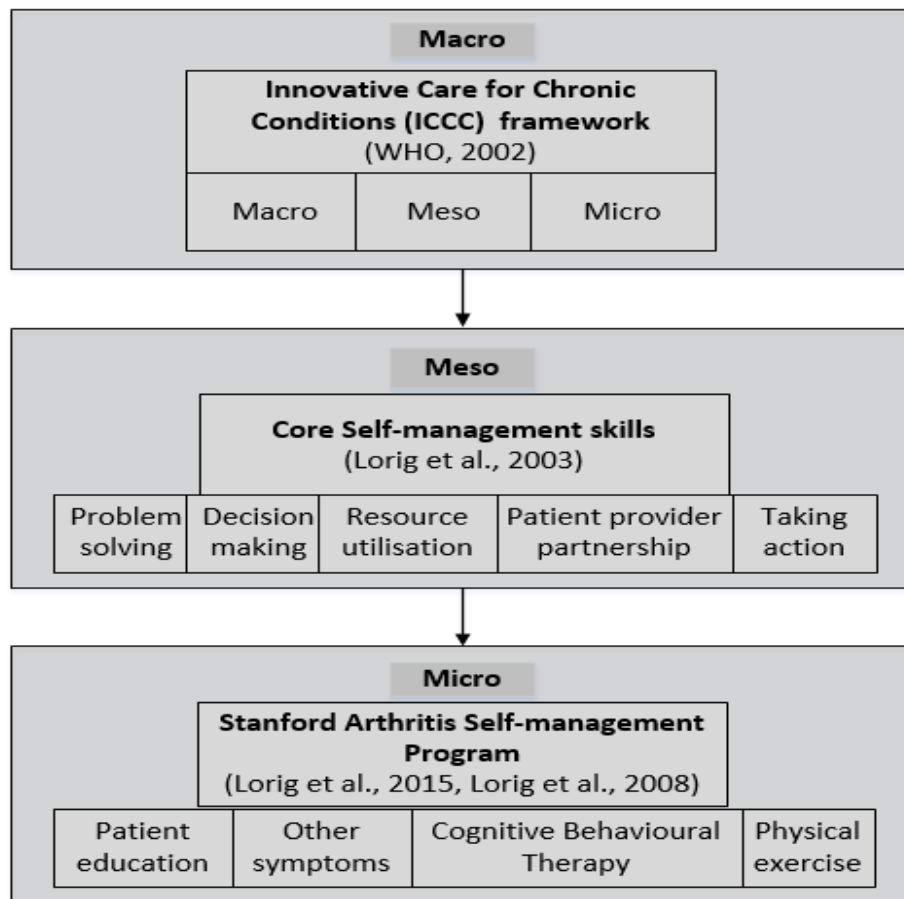
Figure 3.1 Guiding framework for the systematic review

3.5.1 Eligibility criteria

English language pain self-management apps developed from 2007 onwards and including at least one symptom awareness function (i.e. pain assessment, pain recording, pain management recording and/or recording other complaints) *and* one symptom management function (i.e. patient education, other symptoms, CBT approach and/or physical exercise) were eligible for inclusion. An app with only one function (either symptom awareness or symptom management) was deemed unlikely to comprehensively assist with pain self-management activities and was therefore excluded. Apps focusing on migraine, dental or gynaecological pain were excluded as the management approaches of these conditions tend to be different from the self-management of arthritic pain.

3.5.2 Search process

Searches were conducted between 1 and 30 May 2016 on two leading mobile operating systems which make up 99% of the global smartphone market (International Data Corporation, 2016) (App store for Apple and Google Play for Android) using the keywords

pain, arthritis, osteoarthritis, back pain and iPain. A Google web search using the phrase "pain app" was also conducted to ensure adequate coverage. Resultant apps were screened based on their name and description. As the resultant list of apps was potentially endless (similar to a Google search), an approach used in a previous systematic review (Luckett et al., 2015) was adopted. The screening process was conducted until twenty consecutive apps yielded no new potentially relevant apps. These apps were downloaded to an iOS (Apple iPhone 5S) or an Android device (Samsung Galaxy S5) for assessment against the inclusion criteria. Multi-platform apps were downloaded to the Apple device.

3.5.3 App selection

The pre-specified inclusion criteria were used by three reviewers (PB, TNJ and JP) to assess the relevance of identified apps independently, with a plan for disagreements to be resolved by discussion. Inter-rater reliability of included/excluded apps was determined by calculating Cohen's kappa statistic for the primary author's independent ratings (PB) against the two other authors (JP, TNJ). There was moderate to excellent agreement among raters (k=0.595–1.00; p<0.001) in the initial rating, and with subsequent discussion, full agreement was reached on all included/excluded apps. Apps meeting the inclusion criteria were saved for data extraction.

3.5.4 Data collection tools

App evaluation audit tool

An app quality evaluation audit tool (Appendix 3) was developed *a priori* to evaluate app content quality. This audit tool was informed by the Stanford Program (Lorig et al., 2015; Lorig, Ritter, & Plant, 2005), Cochrane Reviews of pain management (Henschke et al., 2010; Williams, Eccleston, & Morley, 2012), established arthritic pain management guidelines (American Geriatric Society, 2002; Katz et al., 2001) and an RCT that found electronic pain diaries to be a feasible method of pain assessment and documentation (Gaertner, Elsner, Pollmann-Dahmen, Radbruch, & Sabatowski, 2004) (see Table 3.1). Two key aspects of pain self-management, symptom monitoring (pain assessment and ability to document assessment findings) and symptom management (pain management concepts and strategies: promoted via education/instruction) were the focus of the quality evaluation. Each item in the quality evaluation tool was allocated one point if it was present ('Yes') and zero if not present ('No'). An aggregate score for each symptom monitoring and

management sub-section was calculated. Three reviewers (PB, JLP and TNJ) independently rated each of the included apps using this quality evaluation audit tool.

Table 3.1 Evidence summary for app quality and usability evaluation

Symptom awareness (Pain assessment and awareness function)
Pain Diary   This section assessed if the app in question provided key functionalities expected in a pain diary   • Pain assessment recording   • Pain management recording   • Recording of other symptoms and complaints.   These key components were derived from an earlier randomised trial study that developed and tested an electronic pain diary (Gaertner et al., 2004).
Symptom management (Pain management function)
Patient education   This section assessed if the app in question included the following key components of the Stanford Program: • Education on important pain related topics   • Management of symptoms that commonly accompany pain   • CBT approach   • Physical activity.   These key components were then developed as sections with corresponding sub-sections designed to collect information on how each app delivers the component to the user. The items in the sub-sections were compiled based on recommendations from Cochrane reviews (Henschke et al., 2010; Williams et al., 2012), established guidelines (American Geriatric Society, 2002; Katz et al., 2001) or from best practice evidence such as the Stanford Program itself (Lorig et al., 2005). However not all of the items included within the sub-sections of each key component have established evidence to support their efficacy in pain self-management.
Usability evaluation
This section assessed how usable the app is from the perspective of older users. The following components were assessed (Arnhold et al., 2014):   • Comprehensibility   • Presentation (image and text)   • Usability   • General characteristics.

Usability evaluation tool

The older adult specific usability of the included apps was assessed using the tool developed by Arnhold et al. (2014) (Appendix 4). Used in a number of studies evaluating the usability of diabetes apps (Arnhold et al., 2014; Gao, Zhou, Liu, Wang, & Bowers, 2017), this tool ranks four functionality criteria using a 5-point Likert-scale: comprehensibility,

presentation, usability and general characteristics (Arnhold et al., 2014). An overall usability score is calculated by averaging the scores of each of the functionality criteria (ranges 1–5), with a score of ≥3.0 reflecting acceptable usability (Arnhold et al., 2014).

3.5.5 Data collection process

An evidence summary matrix was designed to extract and manage data. General details (name, developer, cost) and functionality as per the headings of the app quality evaluation audit tool and the mean of each rater's score for quality and usability for each app were extracted and entered into this matrix.

3.6 Results

3.6.1 Study selection

Initial search of the Android and Apple (iOS) platform resulted in identification of 433 apps. After removal of duplicates and triplicates, 373 unique apps were shortlisted for screening (see Figure 3.2). After reviewing the name and developer provided description, 293 apps were excluded leaving 80 apps for detailed eligibility assessment. All of the apps were available in the Apple (iOS) platform, however one app (WebMD Pain Coach) (WebMD, 2016) was downloaded to the Android device due to it repeatedly crashing on an Apple device. An in-depth assessment of all of the features of these 80 apps was conducted by the doctoral student. The reason for proposed inclusion or exclusion of each app was noted in an Excel spreadsheet and shared with two supervisors (TNJ and JP) for their appraisal. This was followed by an agreement that 76 out of the 80 shortlisted app did not meet the eligibility criteria, leaving four apps for inclusion in this systematic review: Arthritis Foundation United States (2016); Pain Sense (2016); St James's Hospital & Arthritis Ireland (2015) and WebMD (2016). The Google web search yielded no additional apps.
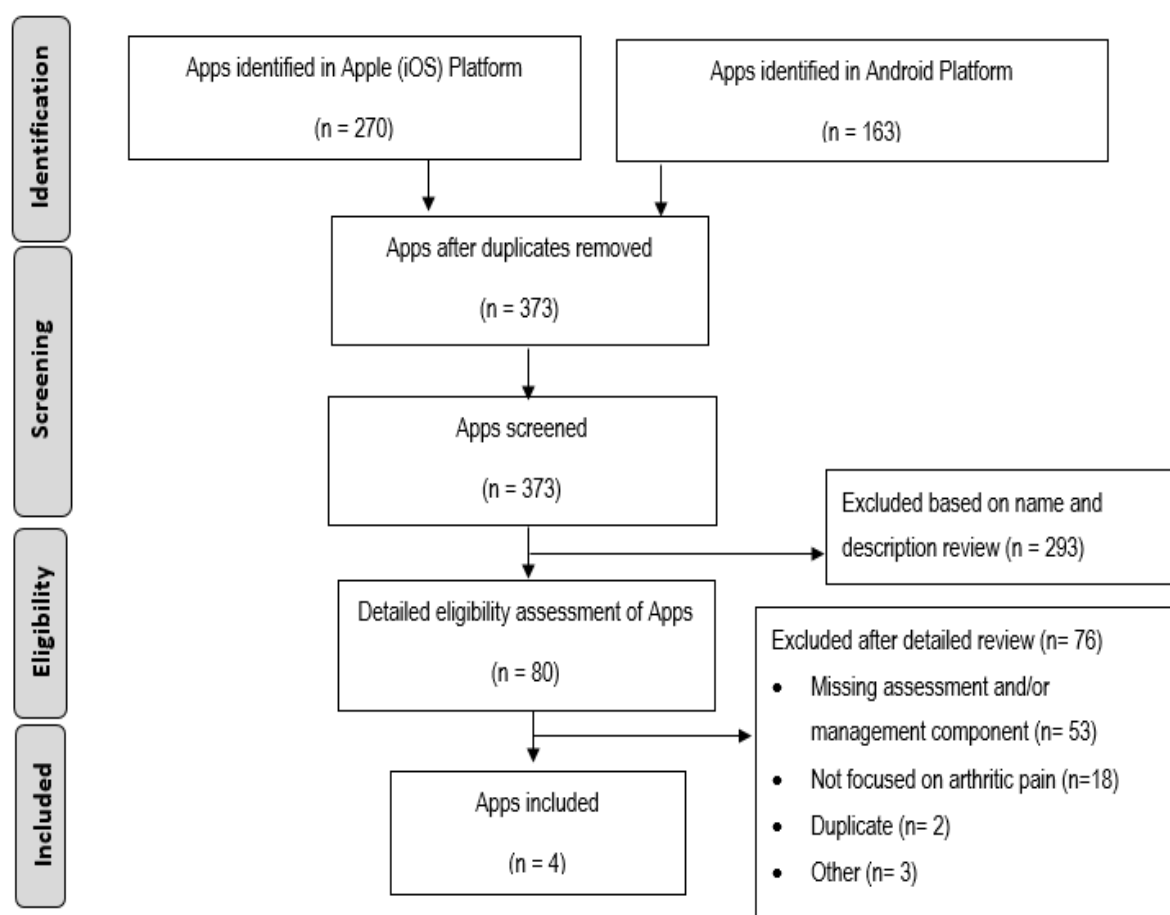
Figure 3.2 Flow chart of app from search to inclusion

3.6.2 App characteristics

Table 3.2 summarises the included apps. All of the apps were developed in high income countries in the northern hemisphere: two in the USA (Track + React, WebMD Pain Coach) (Arthritis Foundation United States, 2016; WebMD, 2016), one in the UK (Pain Toolkit) (Pain Sense, 2016), and one in Ireland [Rheumatoid Arthritis, Information, Support and Education (RAISE)] (St James's Hospital & Arthritis Ireland, 2015). All of the apps were developed in consultation with a healthcare authority or clinicians. None of the apps required payment for download, however one app (Pain Toolkit) (Pain Sense, 2016) required either a UK-based General Practitioner (GP) provided token number or a payment of $7.99 (AUD) for access to all functions of the app.

Table 3.2 Summary and ranking of included apps

App Name	Developer	Cost/ Pain type	Assessment and documentation function	Management function	Usability	Total Score [a]	Rank
WebMD Pain Coach (WebMD, 2016)	WebMD	Free/ All type	At least daily assessment and recording of pain using 11 point NRS. Option to record the name of analgesic taken (time stamped). Option to record other symptoms and complaints as desired.	Education on pain/ self-management, medication, communication with clinicians and pain related problem solving. Information on sleep, nutrition and psychological issues management. CBT pain management instruction on relaxation, mindfulness, meditation, distraction, imagery and goal setting. Customisable exercise plan, with information on stretching, isotonic, aerobic and aqua exercises.	Average general features (1.9/5) and presentation (2.9/5), moderate usability (3.4) and high comprehensibility (4/5).	Quality = 27.7/39 Overall usability = 3.2//5	1
			*Score 4.7/7	*Score 23/32	*Score=3.2/5		
RAISE (St James's Hospital & Arthritis Ireland, 2015)	St James's Hospital + Arthritis Ireland	Free/ Rheumatoid Arthritis	At least daily assessment and recording of pain and activity level using 6-point (0–5) NRS. Pain management approach documentation not included.	Education on pain self-management, medication use, communication with clinicians and pain related problem solving. Information on fatigue, sleep, psychological issues, CBT pain management instruction on relaxation, goal setting and activity pacing. Videos of stretching, isotonic and aerobic exercise with warm-up and cool-down. Duration and frequency indicated.	Poor general features (1.2/5), average presentation (2.8/5), moderate usability (3/5) and comprehensibility (3.6/5)	Quality = 22.7/39 Overall usability = 2.9/5	2
			*Score=1.2/7	*Score=21.5/32	*Score=2.9/5		

Track + React (Arthritis Foundation United States, 2016)	Arthritis Foundation USA	Free/ Arthritis	At least daily assessment and recording of pain using 11 point NRS. Option to record the name of analgesic taken, nutrition, fitness, sleep, medication, overall feeling, fatigue, mood, stiffness and joint function.	Education on pain self-management process, medication use, communication with clinicians and pain related problem solving. Information on management of fatigue, sleep, nutrition and affect. Inclusion of goal-setting function, information on activity pacing. Customisable stretching, isotonic, aerobic and aqua exercise; warm-up, cool-down included.	Poor general features (1.1/5), average presentation (2.3/5), moderate usability (3.2/5) and comprehensibility (3.6/5)	Quality = 22.5/39 ___ Overall usability = 2.7/5	3
			*Score=4.5/7	*Score=18/32	*Score=2.7/5		
Pain Toolkit (Pain Sense, 2016)	Pain Sense	$7.99/ Chronic pain	One off assessment of pain type and location, no intensity reporting. Health needs and pain impact measuring option. Option to record medication on the diary function. Assessment and recording of other complaints not prompted.	Education on pain and pain self-management, medication use, communication with clinicians, and sleep management. CBT approach to pain management recommended via use of general relaxation, activity pacing and goal setting. Personalised approach recommended for stretching and aqua exercise	Poor general features (1.2/5), average presentation (2.5) and usability (2.7/5), and high comprehensibility (4.2/5)	Quality = 16.7/39 ___ Overall usability = 2.8/5	4
			*Score=2.7/7	*Score=14/32	*Score=2.8/5		

Legend: * = mean scores of three raters

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3.6.3 Quality evaluation

Table 3.3 summarises the app quality evaluation (see Appendix 5 for each rater's scores). All of the apps included a pain assessment function (Arthritis Foundation United States, 2016; Pain Sense, 2016; St James's Hospital & Arthritis Ireland, 2015; WebMD, 2016); three featured a Numeric Rating Scale (NRS) for pain intensity assessment that could be used as frequently as the user wished (Arthritis Foundation United States, 2016; St James's Hospital & Arthritis Ireland, 2015; WebMD, 2016), whereas the fourth (Pain Sense, 2016) included a body chart based assessment of pain location, pain impact assessment, and questions on pain type that was only completed as part of the initial assessment. Two apps also included an option for recording analgesic(s) taken and other accompanying symptoms and/or complaints (Arthritis Foundation United States, 2016; WebMD, 2016). The Pain Toolkit (Pain Sense, 2016) provided a free text option for users to enter information relating to their pain medication and the effect of non-pharmacological interventions employed.

All of the apps provided education on topics such as pain self-management principles and medication use (Arthritis Foundation United States, 2016; Pain Sense, 2016; St James's Hospital & Arthritis Ireland, 2015; WebMD, 2016). However, this content was generic with no capacity to be tailored to individual need(s) or preferences. In addition, all four apps encouraged users to regularly communicate their pain concerns with their treating clinicians, and seek advice when contemplating a new pain management approach. Disease related problem solving was covered by three apps (Arthritis Foundation United States, 2016; Pain Sense, 2016; St James's Hospital & Arthritis Ireland, 2015; WebMD, 2016). None of the apps highlighted strategies to minimise or address pain related fear avoidance.

Information relating to the management of nutrition, general mood, depression and anxiety was included in two apps (St James's Hospital & Arthritis Ireland, 2015; WebMD, 2016). The RAISE app (St James's Hospital & Arthritis Ireland, 2015) also included information on fatigue management and the WebMD Pain Coach (WebMD, 2016) included comprehensive information on sleep management. The Track + React app (Arthritis Foundation United States, 2016) included information on management of sleep, fatigue, general mood and nutrition, whereas the Pain Toolkit (Pain Sense, 2016) only included information on sleep management.

Table 3.3 Quality evaluation summary of included apps as rated by three reviewers

Broad elements of quality	Quality components	WebMD Pain Coach	Track + React	RAISE	Pain Toolkit
Recording/ diary function (Gaertner et al., 2004)	Daily NRS	✓	✓	✓	×
	Pharmacological pain management	✓	✓	×	✓
	Non-pharmacological pain management	×	×	×	✓
Patient education (Lorig et al., 2005)	Pain/pain self-management	✓	✓	✓	✓
	Fear avoidance	×	×	×	×
	Medication use	✓	✓	✓	✓
	Communication with HP	✓	✓	✓	✓
	Problem solving	✓	✓	✓	×
Education on Other symptoms (Lorig et al., 2005)	Fatigue	×	✓	✓	×
	Sleep	✓	✓	×	✓
	Nutrition	✓	✓	✓	×
	Affect	✓	✓	✓	×
	Depression	✓	×	✓	×
	Anxiety	✓	×	✓	×
CBT pain management techniques (Henschke et al., 2010; Lorig et al., 2005 Williams et al., 2012)	Relaxation	✓	×	✓	✓
	Mindfulness meditation	✓	×	×	✓
	Diversion distraction	✓	×	×	×
	Imagery	✓	×	×	×
	Goal setting	✓	✓	✓	✓
	Biofeedback	×	×	×	×
	Activity pacing	×	✓	✓	✓
	Operant treatment	×	×	×	×
Physical exercise (American Geriatric Society, 2002; Katz et al., 2001; Lorig et al.2005)	Personalised	✓	✓	×	✓
	Warm-up cool down	×	×	✓	×
	Stretching	✓	✓	✓	✓
	Isotonic	✓	✓	✓	×
	Isometric	×	×	×	×
	Aerobic	✓	✓	✓	×
	Aqua exercise	✓	✓	×	✓
	Duration	×	×	✓	×
	Frequency	×	×	✓	×

The WebMD Pain Coach (WebMD, 2016) integrated a number of CBT-based pain management approaches (5/8), including information on general relaxation, mindfulness meditation, distraction, imagery and goal setting. The RAISE (St James's Hospital & Arthritis Ireland, 2015) and Pain Toolkit (Pain Sense, 2016) apps both included information on general relaxation, goal setting and activity pacing. The Pain Toolkit (Pain

Sense, 2016) also included information on mindfulness meditation. The Track + React app (Arthritis Foundation United States, 2016) only covered goal setting and activity pacing.

While varying levels of physical exercise information were included in all of the apps, the WebMD Pain Coach (WebMD, 2016) and RAISE (St James's Hospital & Arthritis Ireland, 2015) apps provided users with an option to create a personalised exercise program from a list of recommended stretching, isotonic, aerobic and aqua exercises. The RAISE app (St James's Hospital & Arthritis Ireland, 2015), in addition to detailing the World Health Organization (WHO)'s recommendation for duration and frequency of exercise for adults (American Geriatric Society, 2002), also included a series of warm-up and cool-down exercises. The Pain Toolkit (Pain Sense, 2016) provided information on stretching and aqua exercises and highlighted the need for an exercise program to be personalised for individualised needs and capabilities. Several elements of the quality evaluation were not found in any of the included apps such as education on fear avoidance principles, biofeedback treatment and operant conditioning.

3.6.4 Usability evaluation

WebMD Pain Coach (WebMD, 2016) was the only app to obtain a moderate usability score of ≥3, while Track + React (Arthritis Foundation United States, 2016), RAISE (St James's Hospital & Arthritis Ireland, 2015), and Pain Toolkit (Pain Sense, 2016) all fell just below the acceptable moderate usability score of ≤3 (Table 3.1).

3.7   Discussion

This systematic review demonstrated that only a very small number of pain apps offer pain self-management strategies based on the evidence-based arthritic pain self-management program. Additionally, there seems to be very little consideration of older adult specific usability in currently available pain apps. Although there were only four apps, some valuable insights have been generated about the quality and usability of pain self-management apps, particularly on the elements of the Stanford Program as detailed below.

3.7.1 Elements of Stanford Program

Recording diary function

Despite the abundance of pain apps, very few promoted pain self-management practices in accordance with the elements of the Stanford Program (Lorig & Holman, 2003; Lorig et al., 2008). At a minimum, all of the four included apps provided options to assess pain

(pain intensity or pain type and location). While pain intensity assessment is noted to be one of the most common features of pain apps (Reynoldson et al., 2014; Rosser & Eccleston, 2011), this measure is less relevant than pain impact in the context of chronic arthritic pain (Fraenkel et al., 2012; Krebs, Carey, & Weinberger, 2007). Pain intensity scores are known to be a poor indicator of clinically important pain (Krebs et al., 2007), with little evidence of accuracy and effectiveness in improving delivery of care and outcome. Instead, pain impact assessment, which evaluates the impact of pain on the individual's function and overall quality of life, could be a better indicator of the individual's treatment preferences. Inclusion of a pain impact assessment feature could be a valuable addition to future pain apps with potential to guide appropriate self-management strategies (Fraenkel et al., 2012).

Although international guidelines recommend arthritic pain management plans to include both pharmacological and non-pharmacological approaches (Fernandes et al., 2013; Zhang et al., 2010), the latter is rarely integrated in pain self-management apps. While the recording of analgesic use was a prominent feature, the recording of non-pharmacological treatments as part of an active self-management plan is a noticeable gap in the majority of pain apps. By focusing disproportionately on analgesics, pain apps may inadvertently under promote non-pharmacological strategies. In addition, poor access and limited availability of non-pharmacological pain self-management strategies such as mindfulness and tai-chi, together with limited promotion of such approaches by primary care clinicians (Woolf et al., 2004), could further contribute to the underutilisation of these strategies among older people living in the community with arthritic pain (Henderson, Harrison, Britt, Bayram, & Miller, 2013; Porcheret, Jordan, & Jinks, 2007).

Patient education

Pain education and self-management instructions were featured in all of the included apps. This approach is consistent with the conceptual definition of the persistent pain self-management process where older adults are expected to acquire knowledge and skills necessary to respond to and control their pain (Stewart, Schofield, Elliott, Torrance, & Leveille, 2014). Furthermore, the provision of information and skills necessary to attain mastery over the care of one's health condition is the foundation of the patient empowerment process (Funnell & Anderson, 2003) and is recommended in the self-management of chronic diseases such as diabetes (Funnell et al., 2009).

Of note, three of the four included pain apps also provided information on nutrition management (Arthritis Foundation United States, 2016; St James's Hospital & Arthritis Ireland, 2015; WebMD, 2016). Although appropriate nutritional intake is an important component of healthy living among older adults (Ahmed & Haboubi, 2010), there is little evidence supporting a specific diet for pain self-management purposes. While nutritional interventions for older adults with reduced functionality may improve energy levels, they fail to translate into improved functional outcomes (Beck, Dent, & Baldwin, 2016).

Written learning content embedded within the majority of apps was the prime medium used to educate consumers. Only one of the apps integrated a different learning format in the form of providing supplemental audio-visual material (Pain Sense, 2016). Although written communication is a widely used passive health information dissemination strategy, the addition of audio-visual modes leads to relatively greater information recall (Bol, van Weert, de Haes, Loos, & Smets, 2015). Recall of health information is crucial if consumers are to effectively implement the recommended self-management instructions (Watson & McKinstry, 2009). Optimising learning opportunities in apps is crucial given many older adults have low health literacy levels (Zamora & Clingerman, 2011). Health literacy is defined as an individual's ability to access, process and understand health information and services necessary to make appropriate health decisions (Chesser, Keene Woods, Smothers, & Rogers, 2016). People with poor health literacy not only lack the necessary skills to understand and use health related information (Australian Bureau of Statistics, 2009), but also have poorer recall (McCarthy et al., 2012).

3.7.2 CBT approach to pain management

Although a CBT-based pain management approach is recommended for older adults as an adjunct (Abdulla et al., 2013), most of the included apps only alluded to CBT approaches in very basic form such as written instruction on relaxation or activity pacing. This finding is consistent with a recent review of adult pain apps where features consistent with evidence-based CBT principles were present in very few apps (Portelli & Eldred, 2016).

As behavioural goal setting is an effective strategy supporting self-management behaviours (Funnell et al., 2009), it was pleasing that CBT goal-setting approaches were incorporated in all of the apps included in this systematic review. This finding differs from earlier research which found that goal setting was rarely included in pain apps (Lalloo et al., 2015; Portelli & Eldred, 2016). It is unclear if CBT features have been under-reported in previous

app reviews or if this finding reflects recent advances in technology that have increased the inclusion of goal-setting features. Goal setting is prominently featured in apps on physical activity (Direito et al., 2014) and weight loss (Carter, Burley, Nykjaer, & Cade, 2013), with a corresponding indication from consumers of its desirability (Rabin & Bock, 2011). However, the role of goal setting in pain apps and the views of consumers of this feature ought to be explored. There is also a need to explore the effectiveness of integrating CBT into pain apps as a recent RCT of a CBT-based app for depression demonstrated clinically significant improvements (Watts et al., 2013).

3.7.3 Physical exercise

The inclusion of some form of physical exercise component in all of the four apps reflects the established recommendation to incorporate physical exercise in pain management plans of older adults (Abdulla et al., 2013; American Geriatric Society, 2002). The importance of regular exercise in older adults with chronic pain and arthritis is supported by high level evidence (American Geriatric Society, 2002; Katz et al., 2001), yet few if any pain self-management apps have included comprehensive physical exercise plans.

The exclusion of tailored physical exercise prescription, including duration and frequency of movements, by the majority of apps is a notable gap that needs to be addressed in future pain self-management apps. A tailored physical exercise prescription which can be adapted according to the comorbidities, functionality and safety profile of an individual user may assist older users to better self-manage their pain, and also help prevent falls and injury (Chang et al., 2004; Nelson et al., 2007). Additionally, providing information on the beneficial role of physical exercise in preventing falls may also encourage older users to engage effectively with their physical exercise prescription.

3.7.4 Usability

Overall, the older adult specific usability of pain self-management apps could be classified as moderate at best. Functions important to older users, such as enlarging the app screen size or font, was not provided in any of the apps, indicating that these apps were developed without consideration of the visual and motor impairment prevalent among older adults, the group that forms the significant proportion of the pain population (Darroch, Goodman, Brewster, & Gray, 2005). Consideration of the usability requirement of older adults is necessary in future pain app development endeavours, as providing high quality

information in an app may have no benefit if the usability needs of the target users are not met (Boulos, Brewer, Karimkhani, Buller, & Dellavalle, 2014).

3.7.5 Future technological advances

Given that smartphones have high quality on-board sensors that can capture advanced movement and sound-based assessment data (Behar, Roebuck, Domingos, Gederi, & Clifford, 2013), there are opportunities to integrate these features into future pain self-management apps. Apps capable of assessing and interpreting sensor-based data in the future may assist cognitively impaired older adults and/or carers to better manage their pain. While sensor-based features have been used in screening and monitoring apps for depression (BinDhim et al., 2015), and sleep disorders (Behar et al., 2013), none have the capacity for exchange of electronic health information between users and their treating clinicians. Given the importance of the patient–clinician partnership as technology advances, building electronic health information exchange capacity into future pain apps will strengthen their utility.

Patient recorded pain management data, if shared with clinicians, could not only assist with the development and/or refinement of an individualised pain management plan, but also facilitate technology use among older users (Lind, Karlsson, & Fridlund, 2008). However, as primary care clinicians will often be unable to deal with the large volumes of data generated by these technological interventions, caution should be exercised in data sharing with clinicians to minimise data overload (Levine, Richardson, Granieri, & Reid, 2014). While future pain apps should prioritise electronic health information exchange, clinicians should be involved in setting up this process to ensure useful and practical presentation of the data (Levine et al., 2014).

3.7.6 Implications for practice

The lack of clinician involvement in the development of pain related apps and other healthcare apps has been noted previously, indicating concerns about the accountability, accuracy and reliability of the app contents and calling for increased regulatory oversight to safeguard the welfare of end users of these apps (O'Neill & Brady, 2013; Reynoldson et al., 2014; Rosser & Eccleston, 2011; Visvanathan, Hamilton, & Brady, 2012). It is worth noting that all four apps included in this review that had some merit based on the pain self-management literature had some input from a healthcare authority or professionals. Although there is not enough evidence to suggest that apps developed with clinician

involvement are superior to those developed without such input, such collaboration has the potential to ensure the self-management and patient education inclusions are appropriately well-integrated and evidence-based (Wallace & Dhingra, 2013). Involvement of pain experts should be considered in future pain app development endeavours.

Despite being considered an important inclusion in a pain self-management plan (Henschke et al., 2010; Leeuw et al., 2007; Wertli et al., 2014), operant treatment, biofeedback and fear avoidance education were not features of the included apps and were probably beyond the scope of an app to deliver. This suggests that while apps may be helpful adjuncts in the pain self-management process, the creation of the expert patient occurs when the patient is supported and empowered by their clinicians throughout the pain self-management journey (Lorig & Holman, 2003). Clinicians providing care to patients who use apps to facilitate their pain self-management process should be aware of the capabilities and limitations of the apps and provide appropriate support and education to these patients.

In addition, the inclusion of a non-evidence-based component such as nutrition management in the apps indicates that clinicians should exercise caution in recommending or 'prescribing' apps to their patients. There is a need for a health app rating system so that clinicians and consumers are able to easily appraise which app promotes the best available evidence for the purpose of pain self-management. A valid and reliable tool designed for quality and usability evaluation of pain self-management apps is necessary to enhance this area of research.

3.7.7 Strengths and limitations

Some limitations should be considered in interpreting the results of this systematic review. Firstly, as the app searches were conducted in Australia, apps exclusively available in App stores of other countries could have been missed by our search. In addition, although searches were conducted in the two most popular app platforms (Apple store and Google Play), some apps hosted exclusively in websites may have been missed in this review. Secondly, although the tools used to evaluate the quality and usability of the apps were evidence-based, they are not validity and reliability tested; future work in testing the validity and reliability of these tools is warranted. Thirdly, this review did not involve any older adults in the quality appraisal and evaluation process thereby limiting the review's potential to provide the views of older adults who are the end users of the apps. Finally,

although care was taken to rate the apps as objectively as possible, we acknowledge that some level of subjectivity or bias may have existed in rating the apps. Involving three raters and reporting the mean scores of the quality criteria were used to minimise this issue.

Nevertheless, this review also has notable strengths. The development and use of an evidence-based app quality evaluation tool to appraise the merit of currently available pain apps (paid and free) has allowed this study to offer an evidence-based comparison of the capabilities of these apps. The quality evaluation tool can serve as a basic guide for future app development or existing app refinement process. To our knowledge this is the first review to investigate the older adult specific usability of pain apps.

3.8 Conclusion

This chapter has reported a systematic review of pain self-management apps that could be used by community-dwelling older adults to self-manage their arthritic pain. Despite the availability of a large number of pain apps, this systematic review has revealed that few offer a comprehensive pain self-management approach aligned with established evidence. Although a very small number of apps did provide a pain self-management function, the range of included strategies was not comprehensive. The poor older people specific usability of the included apps also indicates a need to consider the usability requirements of the older population in future pain self-management app development work. Given the paucity of robust studies evaluating the role of apps in older people's pain self-management process (as reported in Chapter 2), and the current state of publicly available pain apps (as reported in this chapter), there is a need to further explore the area of pain self-management apps in the context of older people's arthritic pain self-management.

The following chapter (Chapter 4) presents the details of the DigiTech Pain project's design, methodology, theoretical framework, study procedures and ethical considerations. An overview of the research design and methods of each of the three distinct but interlinked primary studies that comprise this doctoral research project is also presented in Chapter 4.

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Chapter 4   Methods

4.1 Introduction

The integrative review (study 1a) and systematic review (study 1b) reported in Chapters 2 and 3 found a paucity of digital health technology evidence supporting older people's pain self-management practices. The integrative review confirmed the feasibility and acceptability of computer-based pain self-management interventions for older people, but highlighted the limited evidence of the efficacy of this type of intervention (Bhattarai & Phillips, 2017). Older people who engaged with these digital health technology interventions reported barriers to their widespread adoption, and highlighted the need for continued training to facilitate longer term use. None of the studies in the integrative review (Bhattarai & Phillips, 2017) tested an app-based digital health intervention. The systematic review reported in Chapter 3 identified a very small number of pain apps offering an evidence-based pain self-management approach (Bhattarai, Newton-John, & Phillips, 2017). The usability of the identified pain apps for older people was poor, with little consideration given by the developers to this population's visual and digital motor impairments (Bhattarai, Newton-John, & Phillips, 2017). This systematic review concluded there was little evidence that the use of apps assisted older people to self-manage their pain. The relevance, usefulness or effectiveness of pain self-management apps for older people living with arthritic pain is not well understood. Further, little is known about the features that older people and their treating clinicians consider to be relevant in an arthritic pain self-management app.

The DigiTech Pain project was designed to address these gaps and explore the feasibility and acceptability of older people using an arthritic pain self-management app to improve their pain symptoms. This chapter details the DigiTech Pain project's design, study procedures, theoretical framework and ethical considerations. The justification for a mixed methods research design is also described. An overview of the research design and methods of each of the three distinct but interlinked primary studies that comprise this doctoral research project is also presented in this chapter. The design and methods of the integrative review and the systematic review conducted within the DigiTech Pain project have been previously presented in Chapters 2 and 3.

4.2   The DigiTech Pain project objectives

The objectives of the DigiTech Pain project were to:

1. Identify the evidence on the use of digital health technologies for older people's arthritic pain management.

2. Evaluate the feasibility and acceptability of undertaking an app intervention study involving community-dwelling older people living with arthritic pain.

3. Identify the features that older people and their treating clinicians consider most relevant in a pain self-management app.

4. Describe the actions required to build the evidence supporting the integration of an app into older people's arthritic pain self-management plans.

4.3   Research design

The DigiTech Pain project adopted a pragmatic, parallel convergent mixed methods design. This project had three stages: i) defining the gaps in the evidence; ii) testing the feasibility of the app; and iii) generating the recommendations. Five discrete but inter-related studies were conducted, as summarised below:

- Study 1a: An integrative review of the literature to evaluate digital health technology interventions designed to improve older people's pain across care-settings (Bhattarai & Phillips, 2017), as reported in Chapter 2

- Study 1b: A systematic review to appraise the quality and usability of currently available pain apps that could be used by older people to self-manage arthritic pain (Bhattarai et al., 2017), as reported in Chapter 3

- Study 2a: A phase I (Campbell et al., 2000) feasibility study of pre–post-test design to evaluate the feasibility, acceptability and preliminary outcomes of a pain self-management app among older people living in the community with arthritic pain

- Study 2b: A semi-structured interview study with participants of study 2a to explore their attitudes and experiences of using an app to help them better manage their arthritic pain

- Study 3: A semi-structured interview study with primary care clinicians to explore their attitudes and perspectives on integrating a pain app into older patients' and clients' pain self-management strategy (Bhattarai, Newton-John, & Phillips, 2019a).

The alignment of this project's research questions, study stages and research methods is presented in Table 4.1.

Table 4.1 Overview of the DigiTech Pain project's research questions, study stages and methods

Study stage	Associated research questions	Method	Output
Stage 1: Identifying the gaps	• What is the evidence on the use of digital health technologies for older people's arthritic pain management?	Study 1a: Integrative review	(Bhattarai & Phillips, 2017)
		Study 1b: Systematic review	(Bhattarai et al., 2017)
Stage 2: Testing the feasibility of the app	• What is the feasibility and acceptability of undertaking an app intervention study involving community-dwelling older people living with arthritic pain?	Study 2a: phase I feasibility study	Protocol paper: (Bhattarai et al., 2019b):
			Results paper: (Bhattarai, Newton-John, & Phillips, n.d.); *In preparation*
		Study 2b: Qualitative sub-study (Older people)	Bhattarai, Newton-John, & Phillips, n.d.) Submitted to *Archives of Gerontology and Geriatrics* on 2-12-2019
	• What are the features that older people and their treating clinicians consider most relevant in a pain self-management app?	Study 2b: Qualitative sub-study (Older people)	Bhattarai, Newton-John, & Phillips, n.d.) Submitted to *Archives of Gerontology and Geriatrics* on 2-12-2019
		Study 3: Qualitative study (Clinicians)	(Bhattarai et al., 2019a)
Stage 3: Generating recommendations	• What are the actions required to build the evidence supporting the integration of an app into older people's arthritic pain self-management plans?	Data integration and meta inference	

4.4 Theoretical foundations informing the DigiTech Pain project

The project's pain self-management aspect was underpinned by Bandura's self-efficacy theory (Bandura, 1977), and the evaluation of a novel technology was underpinned by the TAM 2 (Venkatesh & Davis, 2000). The design and development of this project's phase I feasibility study was informed by the Medical Research Council's Complex Intervention Framework (Campbell et al., 2000; Craig et al., 2008a). The following sections describe these theoretical frameworks and elaborate on how they informed the DigiTech Pain project.

4.4.1 Bandura's self-efficacy theory

Bandura's self-efficacy theory provides a theoretically based predictive model to identify an individual's ability to engage in health promoting behaviours (Hoffman, 2013). In Bandura's self-efficacy model (see Figure 4.1) initiation and continuation of a behaviour required to achieve a given outcome rests on the individual's efficacy expectation, and their estimation that the conducted behaviour will lead to the anticipated outcome (Bandura, 1977).
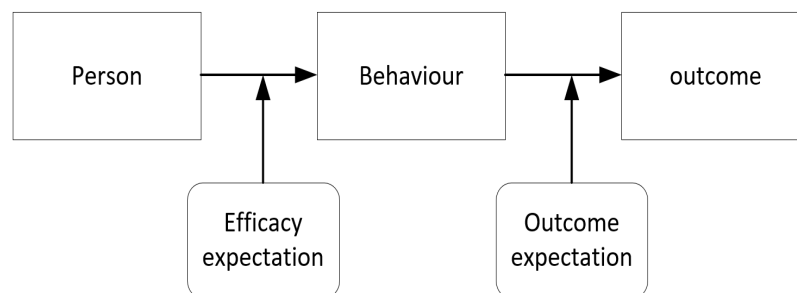
Figure 4.1 Efficacy expectation and outcome expectation (adapted from Bandura, 1977)
Permission to use of this diagram (Appendix 6)

In accordance with Bandura's self-efficacy theory (see Figure 4.2), efficacy expectations are developed and influenced through four main sources: (i) performance accomplishments (performing an activity); (ii) vicarious experiences (observing others similar to oneself successfully perform an activity); (iv) social/verbal persuasion (being influenced to believe in the capabilities to achieve a goal); and (iv) interpreting inferences from physiological and psychological states indicative of personal strengths and vulnerabilities to reach goals (Bandura, 1997b). These four sources are the indicators of efficacy expectations for symptom self-management and form the foundation of self-efficacy enhancing interventions (Bandura, 1997b).

Source

Mode of Induction

Performance accomplishments
- Participant modeling
- Participant desensitization
- Performance exposure
- Self-instructed performance

Vicarious experience
- Live modeling
- Symbolic modeling

Verbal persuasion
- Suggestion
- Exhortation
- Self-instruction
- Interpretive treatments

Emotional arousal
- Attribution
- Relaxation, biofeedback
- Symbolic desensitisation
- Symbolic exposure

Figure 4.2 Factors influencing efficacy expectations (adapted from Bandura, 1977)

Permission to use this diagram (Appendix 7)

Self-efficacy in the context of pain self-management

Self-management includes a range of active undertakings that people living with chronic conditions carry out to maintain wellness within their illness. Appropriately carried out self-management strategies are central to improving the management of painful symptoms and reducing disability in community-dwelling older people (Nicholas et al., 2012; Nicholas et al., 2013). Pain self-management requires the person living with pain to regularly carry out a range of active strategies, including pain assessment and interpretation, followed by application of adaptive coping strategies such as analgesic adjustment, or lifestyle modification on a continuous basis (Lorig & Holman, 2003; McBain et al., 2015). However, not all people living with pain provided with self-management education and skills carry out similarly effective self-management behaviour.

This discrepancy is best described by Bandura's self-efficacy theory which posits that efficacy expectations (or perceived self-efficacy) greatly influence a range of behavioural outcomes including choice of action, degree of effort provided and perseverance despite unpleasant experiences (Bandura, O'Leary, Taylor, Gauthier, & Gossard, 1987). Efficacy expectations are defined as beliefs in one's capabilities to organise and execute the courses of action required to manage prospective situations (Bandura, 1997a).

High self-efficacy is a statistically significant predictor of better arthritis related outcomes including greater ability to manage pain (Arnstein, Caudill, Mandle, Norris, & Beasley, 1999; Keefe et al., 1997; Somers et al., 2010) and enhanced psychological functioning (Schiaffino & Revenson, 1995; Skidmore et al., 2015). As self-efficacy is a modifiable attribute, appropriate interventions aimed at enhancing pain self-efficacy of the person living with pain could improve their ability to integrate effective pain self-management strategies into daily practices (Marks & Allegrante, 2005).

Defining self-efficacy within the DigiTech Pain project

The DigiTech Pain project adopted the definition of self-efficacy as proposed by Albert Bandura (Bandura, 1977, 1997b), as people's beliefs about their capacity to carry out behaviours and activities necessary to produce desired outcomes (Bandura, 1977, 1997b). Based on Bandura's self-efficacy model, the DigiTech Pain project upholds that initiation and continuation of pain self-management behaviour required to achieve improved pain outcome rests on the individual's perceived self-efficacy, and their estimation that the conducted behaviour will lead to the anticipated outcome (Bandura, 1977). For the purpose of the DigiTech Pain project, perceived self-efficacy relates to older people's personal judgements of their capabilities in performing pain self-management activities facilitated by or aided by the use of a pain self-management app.

4.4.2 Technology Acceptance Model 2

While Bandura's self-efficacy theory explains an individual's belief in their ability to perform a given act, the technology acceptance model (TAM) explains the factors influencing an individual's technology engagement decisions (Davis, 1989; Venkatesh & Davis, 1996). The original TAM was developed in the late 1980s to predict the adoption and use of new information technologies (Davis, 1989). Adapted from the theory of reasoned action proposed by Fishbein and Ajzen (1975), this model posits that an

individual's intention to engage with a technology is determined by two key beliefs: perceived usefulness and ease of use (see Figure 4.3).

Within the context of the TAM, 'perceived usefulness' is defined as the extent to which a person believes that using the technology in question will enhance their task performance and 'perceived ease of use' is defined as the degree to which a person believes that using the technology will be effortless (Davis, 1989). Since its original publication (Davis, 1989), the TAM has received extensive empirical support through validations, applications and replications in the context of integrating emerging technologies (Adams, Nelson, & Todd, 1992; Venkatesh & Davis, 1996; Venkatesh & Morris, 2000).

The TAM is consistent with the concept of self-efficacy in the context of technology adoption where self-efficacy is considered an important influencer of the technology adoption decision (Al-Haderi, 2013). An individual's self-efficacy in using a given technology is known to mediate the ease of use and the usefulness of that technology (He, Chen, & Kitkuakul, 2018).
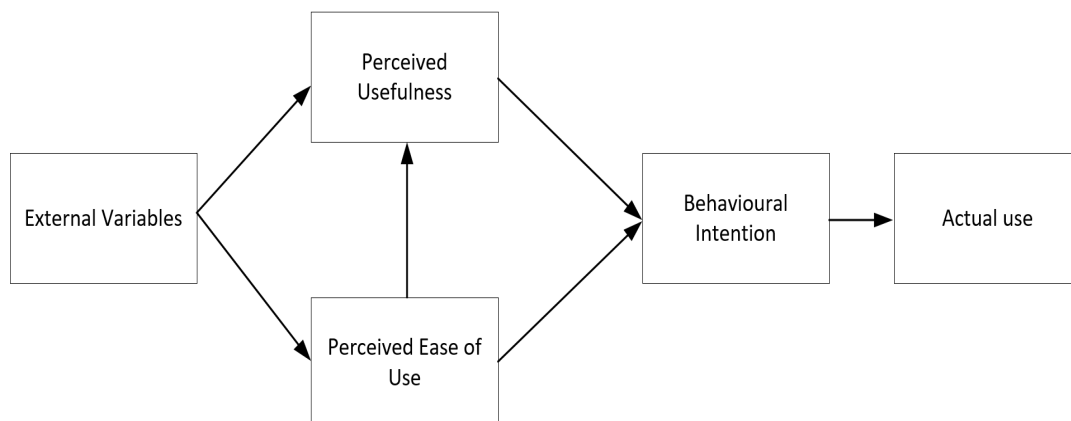
Figure 4.3 Technology Acceptance Model (Davis & Venkatesh, 1996)
Used with permission from Elsevier (Appendix 8)

As the TAM continued to be adopted in research and industry throughout the 1990s, the need to further understand the determinants of perceived usefulness became apparent. Subsequently, Venkatesh and Davis (2000) proposed an extension to the TAM by devising and validating the TAM2 which builds on the original TAM, providing additional theoretical constructs that determine perceived usefulness (see Figure 4.4).
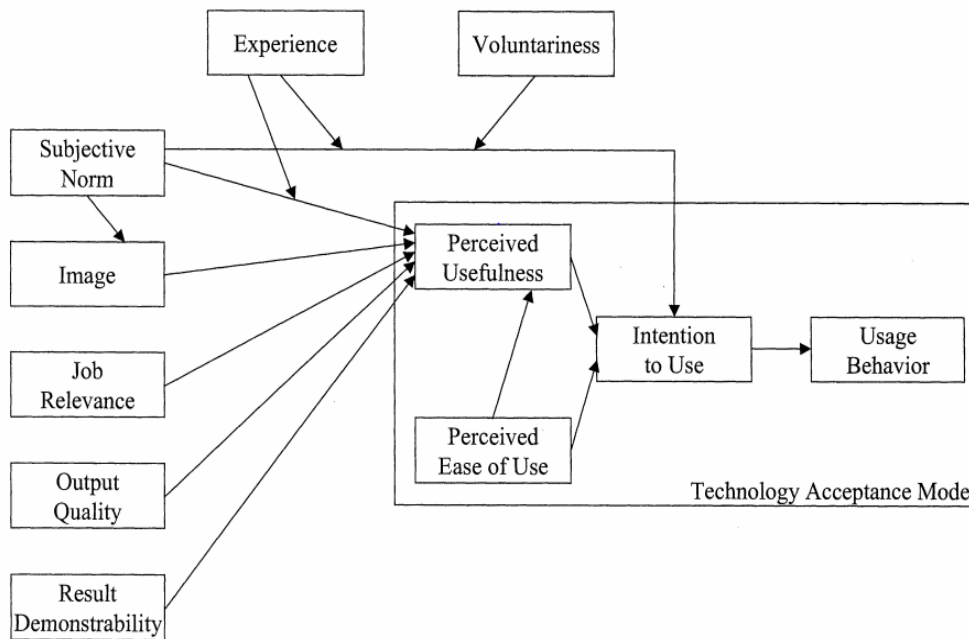
Figure 4.4 Technology Acceptance Model 2 (adapted from Venkatesh and Davis, 2000)

The determinants of perceived usefulness

The determinants of perceived usefulness of a technology can be categorised as social influence processes (subjective norm, voluntariness and image), and cognitive instrumental processes (job relevance, output quality, result demonstrability and perceived ease of use) (Venkatesh & Davis, 2000). Any individual facing the opportunity to adopt (or not adopt) a new technology is influenced by the following social forces: (i) what people important to them think about their engagement with the said technology (subjective norm); (ii) freedom of use (voluntariness); and (iii) the degree to which the new technology is perceived as status enhancing (image) (Venkatesh & Davis, 2000). Additionally, four key cognitive processes also impact on the potential user's decision to engage (or disengage): effortlessness of engagement (ease of use); relevance of the technology (job relevance); quality of the output the new technology would produce (output quality); and discernibility of positive outcomes resulting from the technology use (result demonstrability) (Venkatesh & Davis, 2000). A description of each of the processes is presented in Figure 4.4.

Table 4.2 Summary of the determinants of perceived usefulness of TAM2

Processes	Determinant	Description
Social Influence	Subjective norm	An individual's perception that people important to him/her think he/she should or should not use the technology.
	Voluntariness	Usage context where a technology use is mandated, as opposed to being non-mandatory.
	Image	The degree to which a technology use is perceived to enhance one's status in the social system.
Cognitive Instrumental	Job relevance	The degree to which a technology is applicable to one's job. Consideration of compatibility.
	Output quality	How well does the technology perform the tasks that are relevant to one's job (job relevance)? Consideration of profitability.
	Result demonstrability	Tangibility of the results of using the technology. Consideration of discernibility.
	Perceived ease of use	The degree to which an individual believes that using a technology will be effortless.

Rationale for using TAM2 in DigiTech Pain project

Using an app for pain self-management requires an older person with arthritic pain (user) to interact with the app. Since the appropriate use of a pain self-management app entails technology use (i.e. of an app and a mobile device), the variables of TAM are used to inform the DigiTech Pain project's technology (app) use aspect. The theoretical constructs of TAM2 provide the foundations of this project's enquiry on the acceptability of older people using a pain self-management app as part of their daily routine.

4.4.3 Medical Research Council Complex Intervention Framework

The design and development of this project, especially the feasibility study, was informed by the Medical Research Council (UK)'s Complex Intervention Framework (Campbell et al., 2000; Craig et al., 2008a).
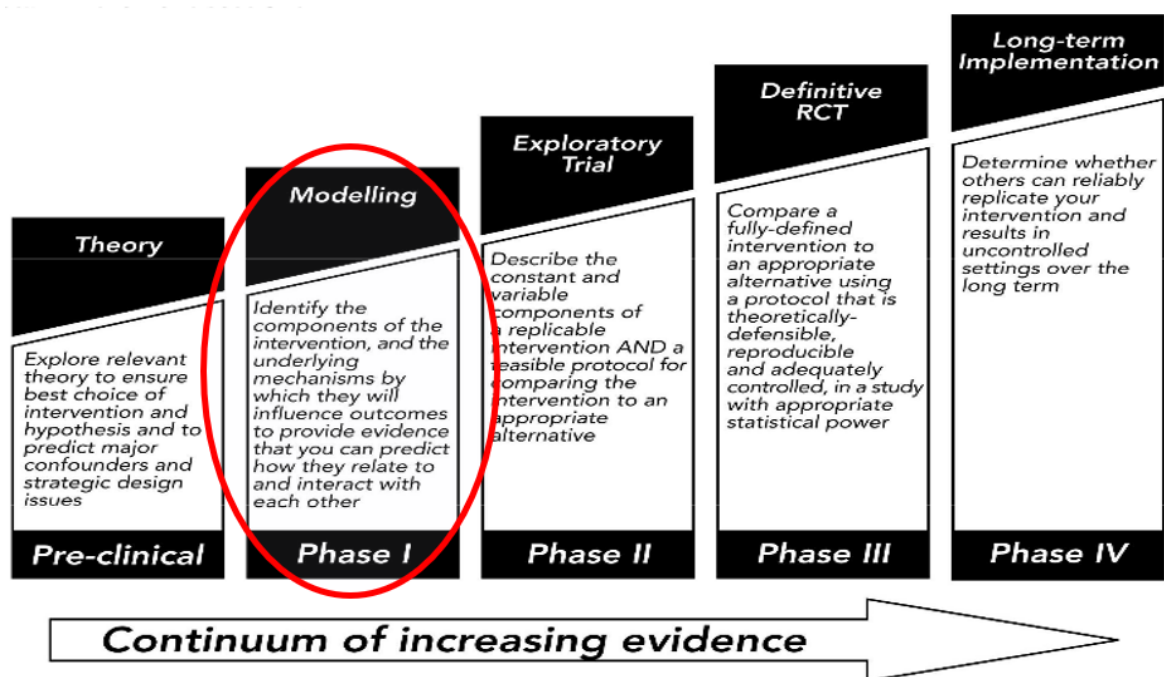
Figure 4.5 Medical Research Council framework for developing and testing complex interventions (adapted from Campbell et al., 2000)

Position in the evidence continuum

Based on the Medical Research Council's continuum of evidence structure (see Figure 4.5), this DigiTech Pain project is classed as a feasibility study (Campbell et al., 2000; Craig et al., 2008b). It is important to note that the DigiTech Pain project is not a pilot study (Eldridge et al., 2016). Feasibility studies differ from pilot studies as they are carried out to estimate important parameters required to design a larger investigative study in future, whereas a pilot study is a smaller version of a larger trial carried out to evaluate if all of the components of the larger trial can work together (Tickle-Degnen, 2013).

In the DigiTech Pain project, a phase I pre–post-test study (study 2a) was carried out followed by two qualitative studies (studies 2b and 3). Phase I studies are designed to improve the understanding of the components of an intervention and their interrelationships. Qualitative testing is recommended for use in these studies to facilitate understanding how the intervention might work (Campbell et al., 2000; Craig et al., 2008b). The Medical Research Council's framework was considered suitable for use in the DigiTech Pain project because few studies have explored app-based interventions among older people. Early stage investigations relating to the implementation and/or integration of an intervention as complex and novel as an app require a detailed understanding of its

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scope, interacting components and the complexities involved in trialling a pain self-management app with older people who are likely to have lower levels of digital literacy than a younger population. It was therefore necessary to evaluate this intervention's feasibility (appropriateness for further evaluation) and its acceptability (extent of, suitability, satisfaction and appropriateness) to the end users (older people) and implementers (primary care clinicians) before proceeding to designing a phase II trial (Bowen et al., 2009).

Summary

Having described the theoretical and conceptual frameworks informing the DigiTech pain project, the following section will detail the DigiTech Pain project's research design, the rationale for using mixed methods, and the adoption of the convergent parallel design in this project.

4.5   Mixed methods design in the DigiTech Pain project

Mixed methods research designs involve the collection, analysis and integration of data using both quantitative and qualitative approaches in a single study or a program of inquiry (see Figure 4.6) (Creswell & Tashakkori, 2007). The mixing can be used across many phases of the research process, including its philosophical assumptions to drawing conclusions (Creswell & Clark, 2007). The collection of both quantitative and qualitative data in mixed methods research allows for the generation of comprehensive evidence for the research problem of interest, while offsetting the weaknesses inherent in the separate application of these approaches (Creswell & Clark, 2007; Creswell & Tashakkori, 2007).
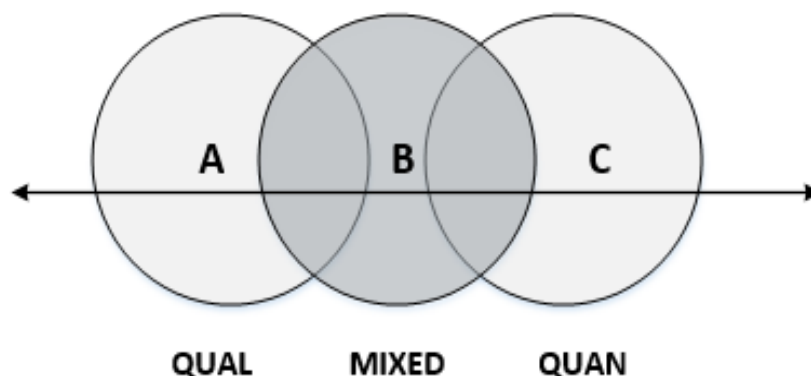
Figure 4.6 The qualitative, mixed methods and quantitative continuum (adapted from Teddlie and Tashakkori, 2009)

4.5.1 History and evolution of mixed methods research

The use and integration of qualitative and quantitative strategies in the natural sciences predates this approach in the social sciences arena (Maxwell, 2016). For instance, Galileo in his study of solar observation used a combination of visual observations and numerical calculation (Stanford University, 2008). However, the use of qualitative strategies was limited to descriptive observations and lacked the most prominent feature of modern-day qualitative research: focus on meaning (Maxwell, 2016). By the late 1950s, mixed methods research entered its formative period where a number of scholars started advocating for the collection of multiple forms of data for validation purposes (Campbell & Fiske, 1959). Such advocacy paved the way for the collection and interpretation of meaning-based qualitative data together with quantitative data in research (see Figure 4.7) (Creswell & Clark, 2007).

Seven year after Campbell and Fiske's publication advocating multimethod research, Webb, Campbell, Schwartz and Sechrest (1966) coined the term *triangulation,* which has become synonymous with mixed methods research. Triangulation is defined as the application of different data analysis methods, datasets or researchers' perspectives to examine a research question or a theme (Bergin, 2018). By the 1970s, mixed methods research entered the paradigm debate period. In this period, the concept of triangulation was elaborated further by use of survey and fieldwork in sociology (Sieber, 1973), and use of the qualitative and quantitative data triangulation method by Jick (1979). In the 1980s as the mixed methods research entered its procedural development period*,* discussions occurred on whether qualitative and quantitative data could be combined. While the mutual exclusiveness of qualitative and quantitative approaches was being advocated by some authors (Smith, 1983), social science researchers proposed connections within the two dominant research traditions (quantitative and qualitative) and suggested a reciprocal and mutually respectful use of both paradigms in mixed methods research (Greene & Caracelli, 1997).
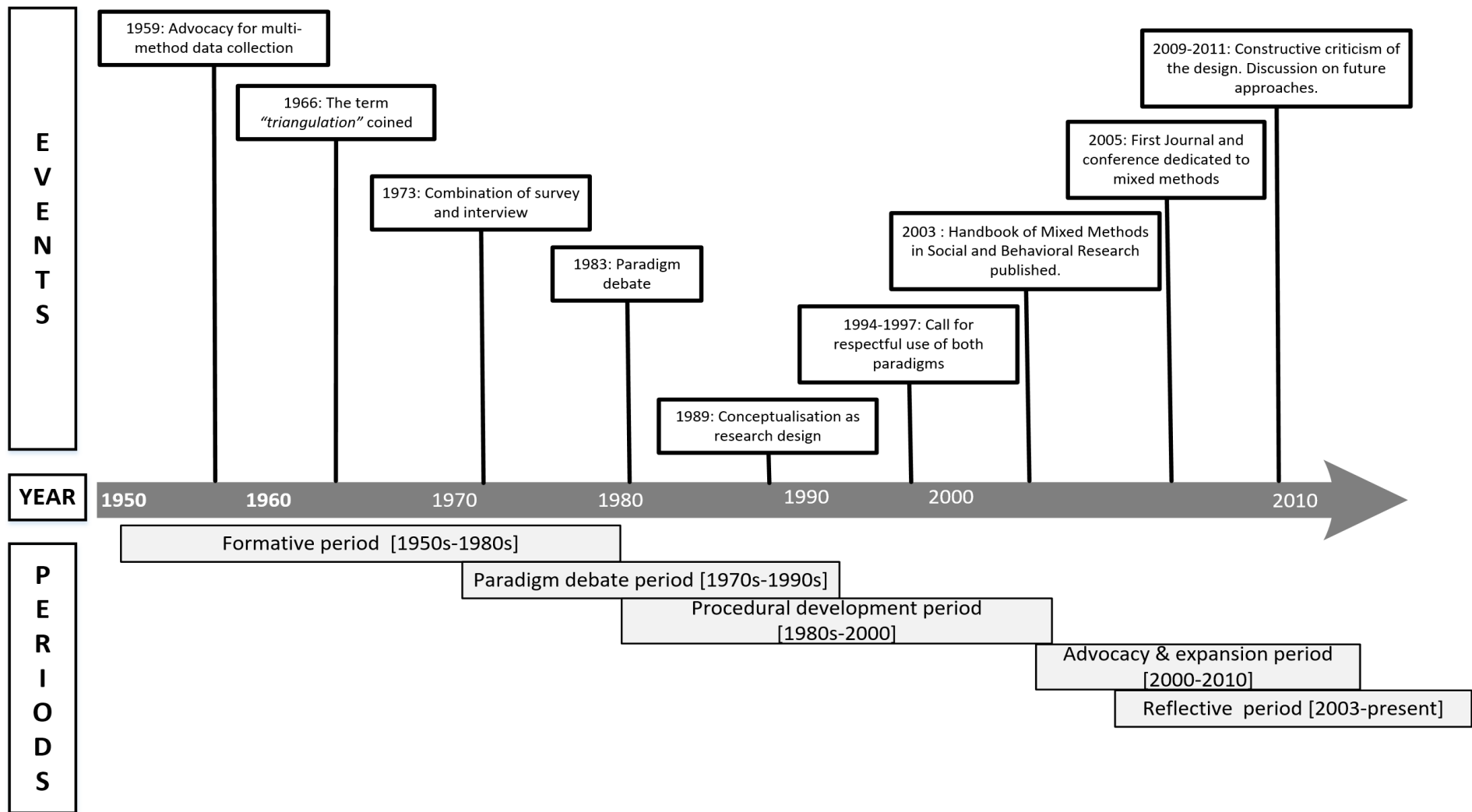
Figure 4.7 Evolution of mixed methods research (developed from Creswell & Clark, 2011)

A paradigm is defined as a researcher's philosophical assumptions, shared beliefs and values that can be used to influence and/or guide the research inquiry (Creswell & Clark, 2011). The choice of research questions, methods and approach to interpretation of research findings reflects the researcher's adopted paradigm (Feilzer, 2010), necessitating explicit articulation and justification of the chosen paradigmatic stance (Creswell & Clark, 2007).

Although the paradigm debate was ongoing in the 1990s, methodological advancement in mixed methods research was also occurring, with mixed methods conceptualised as a research design (Greene, Caracelli, & Graham, 1989). Scholars began to report on mixed methods with defined procedure and typology (Morgan, 1998; Newman & Benz, 1998). Since the start of the new millennium, mixed methods research entered the period of advocacy and expansion, receiving considerable interest from the research community. A new textbook offering in-depth accounts of the various methodologies, procedures and historical context of mixed methods research was published in the early 2000s (Tashakkori & Teddlie, 2003). The development in the field resulted in the first journal and an international conference dedicated to mixed methods research in 2005 (Creswell & Clark, 2007). Since then, greater awareness and application of mixed methods research design across different disciplines has occurred (Creswell & Clark, 2011). Mixed methods research has now entered the reflective period, garnering constructive criticism and discussions on future approaches (Creswell & Clark, 2007).

4.5.2 Mixed methods research paradigms

Mixed methods researchers use one or more paradigms in their process of inquiry (Campbell & Fiske, 1959). Paradigms can be broadly classed into four categories: post-positivism, constructivism, advocacy and participatory, and pragmatism (Creswell & Clark, 2011).

Post-positivism

The post-positivistic paradigm dictates that reality or knowledge can only be understood imperfectly and probabilistically. This paradigm holds that reality exists, however our human faculties are unable to totally comprehend it (Howell, 2012). Post-positivism is associated with traditional research approaches such as experimental designs with a causal comparative and correlational focus (Tashakkori & Teddlie, 2003). Research governed by this paradigm aims to acquire knowledge via quantitative and qualitative methods while trying to explain, predict or control events (Howell, 2012). In a sequential–explanatory

mixed methods design with a strong focus on quantitative data, post-positivism may be considered as a paradigm of choice (Creswell & Clark, 2011).

Constructivism

The constructivist paradigm maintains that reality or knowledge is not objectively 'out there' awaiting discovery; rather it is constructed by people, often influenced by a range of social and cultural factors (Guba, Lincoln, Lincoln, & Sage, 1989). This paradigm is closely associated with qualitative research approaches with significance placed on the participant's self-understanding of the phenomena in question (Creswell & Clark, 2011). Inclusion of quantitative data in a primarily qualitative study is allowed, making this paradigm a suitable choice for sequential–exploratory mixed methods design studies (Tashakkori & Teddlie, 2003).

Advocacy and participatory

A participatory research paradigm holds that knowledge is organic and strongly based on the critical subjectivity and practical understanding of the researcher and the researched (Howell, 2012). This paradigm calls for community involvement from inception and throughout the research process (Hesse-Biber & Johnson, 2015). Research relating to socio-political issues such as marginalisation and empowerment are influenced by this paradigm (Creswell & Clark, 2007). Participation of and collaboration with the stakeholders is the key in this paradigm (Hesse-Biber & Johnson, 2015).

Pragmatism

Pragmatism is one of the most widely used and recommended mixed methods paradigm (Creswell & Clark, 2011). Although pragmatism agrees with the post-positivist stance of the existence of reality, it maintains that *truth* regarding reality cannot be determined (Teddlie & Tashakkori, 2009). Reality is considered open for empirical inquiry employing approaches *that work* using both objective and subjective knowledge (Creswell & Tashakkori, 2007; Feilzer, 2010). Pragmatism supports the assumption that no one set of methods is appropriate or perfect, instead the choice of methods is guided by what fits best with the research question (Hesse-Biber & Johnson, 2015).

A mixed methods study can be informed by one or more paradigms (Campbell & Fiske, 1959). However, a non-paradigmatic approach that rejects the relevance of any paradigm could also be used (Hall, 2012; Teddlie & Tashakkori, 2009). Researchers could select the

paradigm considered to be the best fit for their mixed methods study or multiple paradigms to fit the qualitative and quantitative components separately (Creswell & Clark, 2007). A research program's underpinning paradigm(s) should inform its design, data collection and analysis (Creswell & Clark, 2011). However, studies carried out in the complex healthcare environment should also consider factors such as ethics, feasibility and resource constraints. It is for this reason studies grounded in a pragmatist paradigm offer a comprehensive approach to answer the complex research questions inherent in modern healthcare (Shaw, Connelly, & Zecevic, 2010).

Paradigmatic orientation of DigiTech Pain project

The DigiTech Pain project was guided by a pragmatic world view where the researcher considered that the research questions were more important than either the method used to answer the questions or the paradigm that underlies the method (Teddlie & Tashakkori, 2009). Adhering to the pragmatic stance of approaching the DigiTech Pain project research objectives from more than one (*pluralistic*) perspective, this project uses both inductive and deductive procedures to provide a comprehensive answer to the broad research questions posed by this project (Richards & Hallberg, 2015).

4.5.3 Rationale for using mixed methods design

The DigiTech Pain project comprised a series of discrete but interlinked studies. Distinct research questions associated with each of the studies required consideration of both quantitative (study 2a) and qualitative (studies 2b and 3) approaches to appropriately answer the research question. The choice of a mixed methods design for the DigiTech Pain project was based on a pragmatic stance, in order to conduct a successful trial needed to build the evidence supporting the use of pain self-management apps for older people.

While carrying out a feasibility study of a novel digital health intervention, it is crucial to explore the perspectives of different stakeholders and potential users about the intervention in question (Bowen et al., 2009). Consequently, both quantitative and qualitative data is often required to answer feasibility questions relevant to evaluation of novel and complex health interventions in a dynamic health services research context. It is important to note that while each of the DigiTech Pain project's five studies all stand alone, the project's questions are adequately answered only via integration of data created across all five studies (see Figure 4.8).
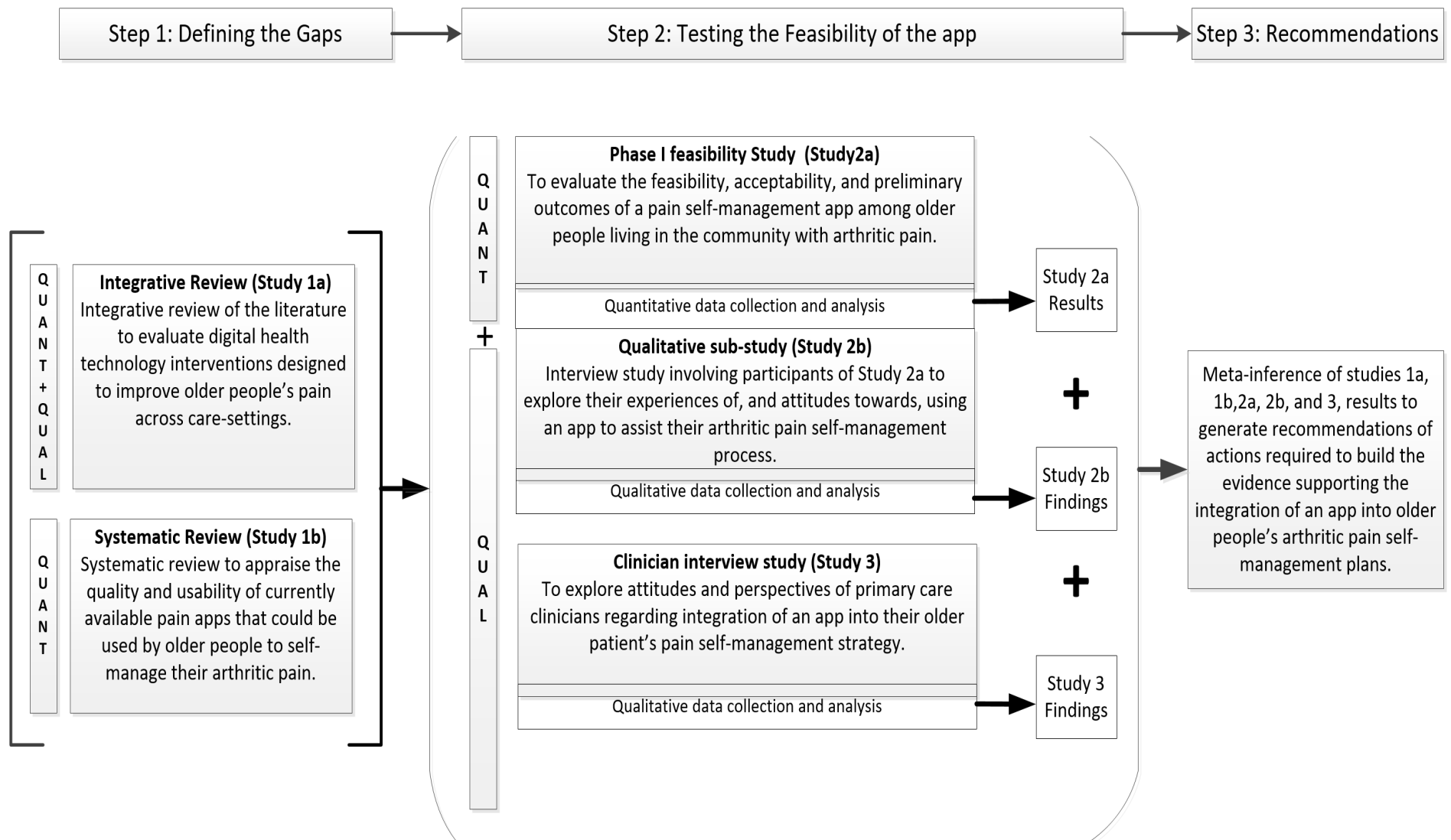
Figure 4.8 Schematic overview of the DigiTech Pain project's mixed methods design

4.5.4 Contextualising the need for a mixed methods design

Given that pain self-management apps are relatively novel and few have been evaluated robustly, it was important to capture the perceptions and experiences of older people's app use. While there is some evidence of older people's perspectives of using mobile technology for pain self-management (Parker et al., 2013), this evidence is based on just 5% of the study participants with any prior exposure to smartphones. This indicates the need to explore the acceptability of pain apps in a methodologically robust study where older people are asked to use an app and then to share their perspective, rather than base their report on hypothetical use perception. Thus, a qualitative study (study 2b) that aimed to explore the perceptions and attitudes of the participants of study 2a was planned.

When considering the pain self-management strategies of community-dwelling older people, the diverse range of primary and allied health clinicians likely to be involved in this process also needs to be taken into consideration. Older people's pain self-management process ought to be a collaborative multi-disciplinary team effort, involving clinicians who provide input to optimise the person's relevant care. Primary care and allied health clinicians play an important role in helping older people develop, maintain and adapt their self-management strategies. Given this reality, the question of feasibility and acceptability of using apps for older people's pain self-management calls for exploration of the views of primary and allied health clinicians. Thus, study 3 was formulated to be a qualitative study exploring the attitudes and perspectives of various primary and allied health clinicians on integrating an app into their older patients' pain self-management treatment plans. The DigiTech Pain project required a combination of qualitative and quantitative approaches to comprehensively evaluate the feasibility and acceptability of older people using an arthritic pain self-management app to improve their pain symptoms.

4.5.5 Mixed methods procedure in DigiTech Pain project

A pragmatic parallel convergent design was considered the ideal methodology for the DigiTech Pain project given the nature of the research questions. Figure 4.9 illustrates the three primary studies included in the DigiTech Pain project and the convergent parallel mixed methods design procedures. In accordance with a convergent parallel mixed methods design, the research questions and the objectives of the DigiTech Pain project did not require the data collection and analysis of studies 2a, 2b and 3 to be carried out in any sequential order, allowing for the data to be collected separately before being integrated.

A mixed methods study requires a 'weighting' decision to be made at the outset to determine the relative priority of the qualitative and/or quantitative data required to answer the research question(s). In a mixed methods study, one approach (quantitative or qualitative) may have higher weight than the other (quantitative or qualitative); alternatively, both approaches (quantitative and qualitative) may be given equal weight (Creswell & Clark, 2007). In the DigiTech Pain project, the quantitative (study 2a) and the qualitative data (studies 2b and 3) were given equal priority for addressing the project's research questions (QUAN + QUAL+ QUAL).

Providing equal priority to the QUAN and QUAL data in the DigiTech Pain project was expected to enhance *expansion* (Creswell & Clark, 2011). *Expansion* occurs when research methods are mixed to extend the scope and breadth of the inquiry (Tashakkori & Teddlie, 2003). The quantitative and qualitative studies in the DigiTech Pain project focused on different aspects of the app intervention. The quantitative study (study 2a) evaluated the feasibility of undertaking an app intervention study involving older people living with arthritic pain. The qualitative studies focused on exploring the views of older users (study 2b) and their treating clinicians (study 3) on the use of a pain app. Incorporating qualitative and quantitative approaches led to extension of the scope of this project, leading to a comprehensive understanding of the use of a pain self-management app (Azorín & Cameron, 2010).

Collectively, studies 2a, 2b and 3 sought to explore different aspects of feasibility and acceptability of an app in helping community-dwelling older people better manage their pain. The research questions of this project did not necessitate analysis of any one study's data to inform the recruitment or data collection of another study, lending itself to a convergent parallel mixed method design (Creswell & Clark, 2011).

Concurrent data collection and analysis	Procedure	Product

QUANT data collection — Pre-post test data collection using a collection of pain validated assessment tools with older people (n=18) [Study 2a]
- Clinical and demographic data
- Data on pain and self-efficacy outcomes

QUANT data analysis — Descriptive and inferential statistics; SPSS
- Joint display table and quantitative data inferences

QUAL data collection — Semi-structured interviews with participants of Study 2a (n=16) [Study 2b]
- Interview transcripts
- Field notes
- Qualitative dataset

QUAL data analysis — Data coding followed by thematic analysis; NVivo V12
- Codes, themes, and subthemes
- supporting quotes

QUAL data collection — Semi-structured interviews with Primary care clinicians (n=17) [Study 3]
- Demographic information collection
- Interview transcripts
- Field notes
- Qualitative dataset

QUAL data analysis — Data coding followed by thematic analysis; NVivo V12
- Codes, themes, and subthemes
- supporting quotes

Integration of QUANT and QUAL data — Interpretation and explanation of qualitative and quantitative data using joint displays and meta-inference
Development of :
(ii) conclusion;
(iii) implications for practice; and
(iv) recommendations for future research.
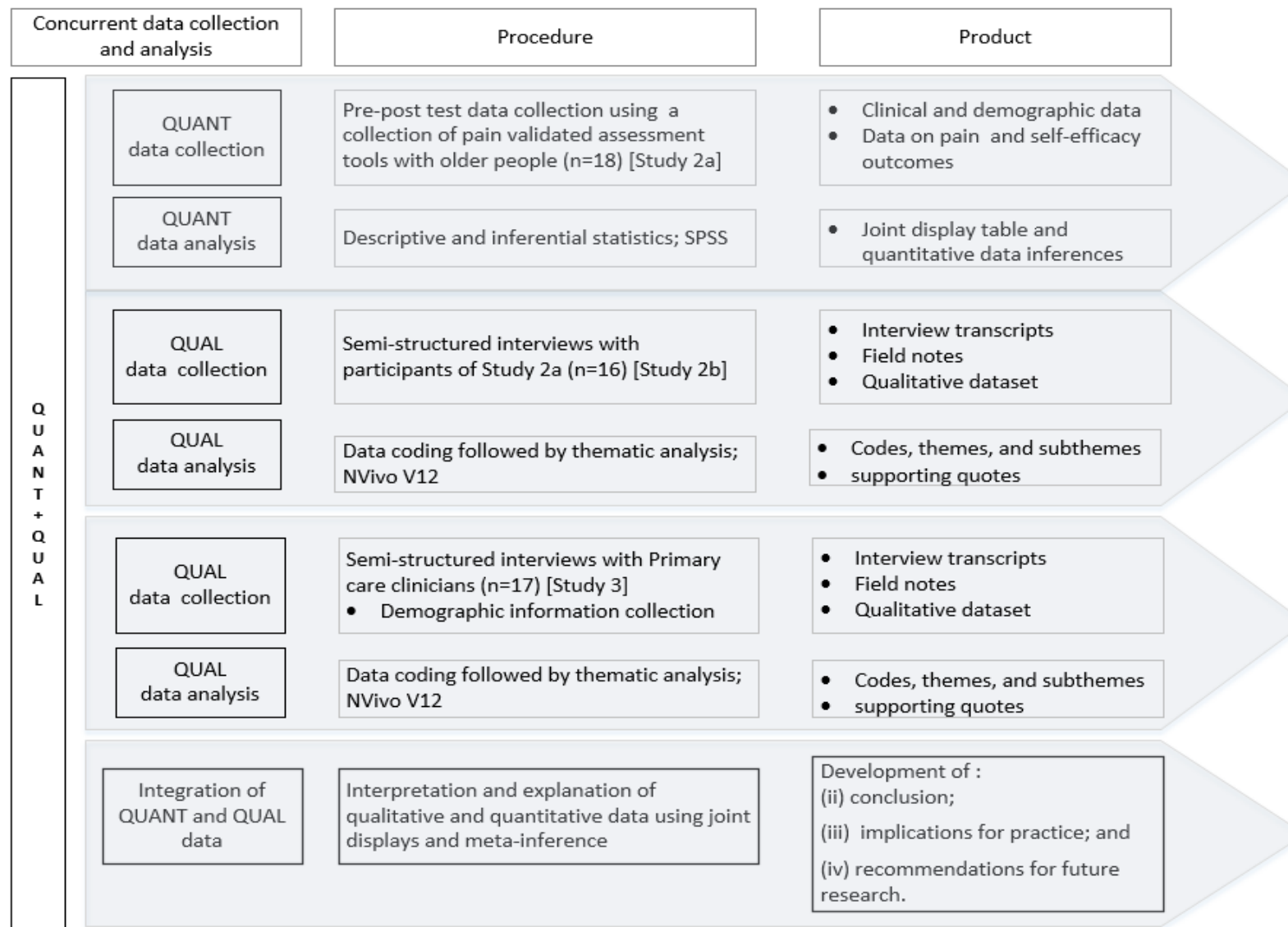
Left column label (vertical): QUANT+QUAL

Figure 4.9 Visual model of the convergent parallel design procedures of the DigiTech Pain project

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4.5.6 Data integration in mixed methods research design

Data integration refers to the point in the research process where the researcher mixes or integrates the quantitative and qualitative data collection and analysis (Tashakkori & Teddlie, 2003) and is a very crucial part of all mixed methods studies (Creswell & Clark, 2011). The purposeful and deliberate integration of qualitative and quantitative data can enhance the value of a project finding by providing new insights that are not limited by what is separately identified by the individual qualitative and quantitative studies (Fetters, Curry, & Creswell, 2013).

Four key steps were considered in planning and implementing the integrative data analysis of this parallel convergent mixed methods project (Creswell & Plano Clark, 2018):

(i)   the intent of data integration

(ii)   primary data analysis procedure

(iii)   representation of the integrated results

(iv)   interpretation of the integration results.

The *intent of integrating* the studies in the DigiTech Pain project was to consolidate the quantitative (study 2a), qualitative (studies 2b and 3) and the review (studies 1a and 1b) data, to comprehensively report on all relevant feasibility and acceptability aspects of the app intervention. The *primary data analysis* phase unfolded with separate data analyses carried out for each study: the two reviews (study 1a and study 1b), and the three studies [QUANT (study 2a) + QUAL (studies 2b and 3)]. This was followed by data integration of the quantitative results and the qualitative findings to answer the research questions.

The data integration process was *represented* using joint display tables (Creswell & Plano Clark, 2018). These joint display tables allowed the quantitative and qualitative data to be presented side-by-side, allowing researchers to visually display the process of drawing inferences from the integrated data (Guetterman, Fetters, & Creswell, 2015). For the purposes of the DigiTech Pain project, each joint display had five to six columns representing the research question domain, data from each study (quantitative, and/or qualitative, and/or review data) relevant to each domain, the degree of data convergence, and the mixed methods inference for each domain. The joint displays visually represented the connection between the quantitative and qualitative data across all study question domains, and the degree of data convergence in each domain, and whether the data

confirmed ('confirm'), contradicted ('contradict') or enhanced ('enhance') each other (Fitzpatrick, 2016). In addition, the joint display tables also presented the inferences generated through data integration to answer each of the DigiTech Pain project research questions (Creswell & Plano Clark, 2018; Guetterman et al., 2015).

Interpretation of the integrated data was achieved via data consolidation followed by development of meta-inferences (Caracelli & Greene, 1993; Teddlie & Tashakkori, 2009). The inferences created during the process of data integration were coded to create a new qualitative dataset. This dataset was analysed in iterative cycles to gain a deeper understanding with each cycle of analysis (Caracelli & Greene, 1993). This process of meta-inference enabled the elicitation of new understandings and explanations of key components necessary to support the integration of apps into community-dwelling older people's arthritic pain self-management strategy. Meta-inference enabled the development of a coherent conceptual framework to answer the project aim (Caracelli & Greene, 1993; Teddlie & Tashakkori, 2009), which is reported in Chapter 7.

4.5.7 Benefits and challenges of using a mixed methods design

The advantage of using a mixed methods design in the DigiTech Pain project was the expansion of the scope of inquiry. By using a mixed methods design, this project was able to include multiple inquiry components of the pain app intervention, such as impact on pain and self-efficacy; participant experiences; perceived barriers and facilitators to app usage; and primary care providers' perspective. This detailed analysis offers a comprehensive understanding of app use for pain self-management in older people (Azorín & Cameron, 2010).

The notable challenge to successful completion of a mixed methods study is that it requires the researcher to acquire a thorough understanding of quantitative, qualitative and mixed methods designs (Creswell & Clark, 2007). As doctoral research projects often encounter time and resource constraints, the necessity to learn about conducting and mixing multiple research designs could significantly challenge a novice researcher.

To address these challenges, the doctoral student engaged in an ongoing process of knowledge acquisition regarding various research designs, through self-directed learning and formal education at workshops and seminars. Writing peer-reviewed manuscripts for publication and taking a peer-reviewer role allowed the doctoral student to increase her understanding of various research methods and methodologies. Further, ongoing guidance

was provided to the doctoral student throughout the project by the supervisory panel that included clinical experts in the field of nursing and allied health with extensive mixed methods and clinical trials research expertise.

Summary

Having described the rationale for using mixed methods, and the adoption of the convergent parallel design in the DigiTech Pain project in this section, the following section outlines the study procedures of the three discrete primary studies of the DigiTech Pain project: phase I feasibility study (quantitative, study 2a) and the two qualitative studies (study 2b and study 3). The methods of study 1a and study 1b were presented in Chapters 2 and 3.

4.6 DigiTech Pain project recruitment, consenting and sample size considerations

The following section provides a detailed description of the procedures involved in DigiTech Pain project's recruitment and consenting, and sample size determination.

4.6.1 Settings and participants

The DigiTech Pain project focused on the community setting. Two distinct groups of participants were recruited to the three primary studies of the DigiTech Pain project:

- community-dwelling older people living with arthritic pain (studies 2a and 2b)

- primary care and allied health clinicians (study 3).

4.6.2 Screening and recruitment of older people (studies 2a and 2b)

The DigiTech Pain project was grounded in promoting a self-management approach, with the focus on maintaining wellness within the context of living with a chronic illness (Lorig & Holman, 2003). In accordance with a wellness-based approach, the recruitment strategy focused exclusively on identifying and enrolling community-dwelling older people living with and managing their arthritic pain, as opposed to an illness model focused on older people actively seeking treatment for their arthritis in a hospital or clinic. In Australia, there are very few, if any, clinics that focus exclusively on treating older people with osteoarthritis, making it difficult to recruit the population of interest under an illness model. Given these considerations, a community focused recruitment strategy was selected.

Inclusion/exclusion criteria for older people

Older people were eligible to participate if they met all the following criteria:

- Aged 65 years or over.

- Have any form of arthritis (self-reported)

- Live in the community setting

- Own a smartphone or a tablet

- Be able to read and write in English

Older people were ineligible to participate if they met any of the following criteria:

- Aged under 65 years

- Living in an institutional home

- Experiencing cancer pain

- Unable to read and write in English

Prospective participants were sought from various older people's clubs and organisations, including Facebook groups across metropolitan and regional New South Wales (NSW), Australia. Many older Australians use their free time keeping active and participating in leisure activities by engaging in social clubs (Patford & Breen, 2009). This recruitment approach was initially chosen because over 77% of community-dwelling older Australians are involved in a social or support group (Australian Institute of Health and Welfare, 2018). It was anticipated that members of social clubs and organisations specific to older people would represent the target population for this program of research.

The Office for Ageing unit within the Department of Family and Community Services NSW has a list of services and information, including recommended social clubs and organisations for older people living in NSW (Seniors Information Service, 2006). Fourteen older people specific non-profit social clubs from this list were approached (Appendix 9).

The invitation approach to each club or organisation comprised either emailing or telephoning their publicly listed contact details to provide a brief overview of the project and inviting them to circulate the DigiTech Pain project's recruitment poster among their members. Interested clubs and organisations were offered an on-site presentation, and

provided with a recruitment poster (Appendix 10) for dissemination: electronic and/or display in the club's notice board. The recruitment poster contained brief information about the study, inclusion criteria and the doctoral student's contact number.

The clubs and organisations-based approach to recruitment had very little success (details presented in Chapter 5), requiring the DigiTech Pain project team to broaden the recruitment method. Subsequently, two additional recruitment strategies were incorporated as outlined below.

Revised recruitment strategy

Two new approaches were added to share the study invite to older people: (i) snowballing; and (ii) social media based. The revised recruitment approaches are described in detail in the following section.

Snowballing sampling approach: Snowballing sampling is a non-probability sampling approach widely used in qualitative and sociological research where the study sample results through referrals made among people who know of others possessing some characteristics that are of research interest (Biernacki & Waldorf, 1981). This approach assumes that knowledge is differentially distributed and some people (or social groups) have greater accessibility and knowledge about a specific area of life than others due to their past or present situation (Biernacki & Waldorf, 1981). The snowballing approach was used at the organisational (older people specific clubs), and individual (participant) level to enrich the sample cluster and access new social groups when the randomly selected sample ceased to provide new recruits.

Social media based recruitment approach: With the unprecedented growth of social media use over the last decade, there is an increasing interest among researchers in using social media platforms to recruit study participants (Topolovec-Vranic & Natarajan, 2016). As older people are one of the highest user groups of social media (Pew Research Center, 2017), use of this platform to share the study invitation was deemed appropriate. A designated study Facebook page was created (Pain Apps for Older people–DigiTech study, 2018) (Appendix 11). Facebook groups and communities likely to have a significant number of older members were sent an introductory message, seeking their interest in sharing the DigiTech Pain project's recruitment poster in their Facebook page. Administrators of interested Facebook-based groups were asked to upload the study's poster on the group's Facebook page on behalf of the investigator team. The researchers

did not initiate direct contact with any potential participants via Facebook directly. Instead, any interested older person was asked to get in touch with the research team via the Facebook page or via the contact details provided in the study recruitment poster.

4.6.3 Screening and recruitment of clinicians (study 3)

A different recruitment approach was used to identify and recruit clinicians caring for older people with arthritic pain. A purposive sampling method (Patton, 2002) was used to recruit primary care clinicians registered with the Australian Health Practitioner Regulation Agency (AHPRA) as 'health professionals'. The initial clinician recruitment plan was to seek contact details of primary care clinicians of study 2a participants. Older people participating in study 2a were asked if they were willing to share the name and contact details of three primary care clinicians who help them with their pain management. It was clearly explained to the participants that details of their health professionals would only be used for the purpose of sending out an invitation to participate. Approval was sought to send all nominated clinicians an invitation letter with an indication to contact the study team if they wish to participate in this qualitative study.

Inclusion/exclusion criteria for clinicians

Clinicians were eligible to participate if they met all of the following criteria:

- Primary care provider registered as health professional under AHPRA
- Involved in providing pain related care and consultation to older people

Clinicians were ineligible if they met any of the following criteria:

- Not a primary care provider
- Not registered with AHPRA
- Not involved in providing care to older people (such as paediatric pain specialists)

Unfortunately, none of the older people participants of study 2a were comfortable in sharing the contact details of their treating clinician, necessitating broadening of the clinician recruitment approach. This led to the addition to two other recruitment strategies as outlined below.

Revised recruitment strategy

Two new approaches were added to share the study invitation among primary care and allied health clinicians: (i) national peak bodies of various health professions; and (ii) professional networks. The details of these two approaches are described below.

Electronically via national peak bodies of various health professions

Peak bodies of the health professions listed below were approached with a request to circulate the clinician interview study's recruitment invitation among their network:

- General practitioners (Royal Australian College of General Practitioners)

- Practice nurses (Australian Primary Health Care Nurses Association)

- Physiotherapists (Australian Physiotherapy Association)

- Chiropractors (Australian Chiropractors Association)

- Psychologists (Australian Psychological Society)

- Exercise physiologists (Exercise and Sports Science Australia).

The four professional organisations that agreed to assist were provided with a small written invitation for electronic circulation. The invitation clearly noted that anyone interested should directly contact the project team.

Professional network of the project team

As the DigiTech Pain project team were all experienced clinicians and had working relationships with various primary care and allied health professionals, a decision was made to use the team's network to ask them to share the study 3 invite with others.

A strict "arm's length approach" was used where the referring contact was asked to share the invite within their network and advise anyone interested to contact the project team if they had any questions prior to consenting to the study or wished to participate in the study. The approach of asking participants to contact the study team (instead of the study team approaching the potential participants directly) was adopted to minimise the risk of persuasion or influence on potential participants, and to keep the referrer away from the active recruitment and consenting process.

4.6.4 Informed consent process of older people (studies 2a and 2b)

Eligible older people wishing to participate in the phase I feasibility study (study 2a) were provided with a verbal introduction to the research. This was followed by provision of the written Participant Information and Consent Form (PICF) designed for older participants (Appendix 12). Participants were also requested to indicate (in a tick box) if they would

also like to contribute to a one-on-one semi-structured telephone interview (study 2b) to share their experience of using the app after completing the 14-day intervention period.

4.6.5 Informed consent process of clinicians (study 3)

Primary care and allied health clinicians who wished to participate in study 3 and contacted the research team were asked to nominate a preferred time for the doctoral student to contact them about the study. The aim of this conversation was to provide a verbal explanation of the study and its purpose; confirm their eligibility; and provide the written PICF (Appendix 13) via email. Participants were asked to read the PICF and to ask the researcher any questions before signing and returning the consent form. Once the signed written consent form was obtained from participants an interview time was determined.

4.6.6 Sample size

Each of the three studies in the DigiTech Pain project had different sample size requirements, as outlined below:

Phase I feasibility study [participants – older people living with arthritic pain]

As study 2a was a phase I feasibility study using a pre–post-test design, a formal sample size calculation was not indicated (Billingham, Whitehead, & Julious, 2013; Thabane et al., 2010). However, a recent pilot (Paul et al., 2017) and a phase II (Silveira et al., 2013) trial of an app intervention involving older people have reported sample sizes of 16–44 participants. Based on this data, and a discussion with a biostatistician, a sample size of 30 participants was considered appropriate for a phase I evaluation study.

Qualitative sub-study [participants – older people of study 2a]

As study 2b was a qualitative study, the sample size was directed by the research question and analytical requirements of achieving data saturation (Pope, Ziebland, & Mays, 2000) which is the point where the new data stops generating new insight (Saunders et al., 2018). A total of 15–20 participants were sought for study 2b, considering likely data saturation would occur with this sample size (Marshall, 1996). Previous studies exploring older people's view on use of technology for pain management have reported including 6–11 participants (Currie, Philip, & Roberts, 2015; Lind, Karlsson, & Fridlund, 2008).

Clinician interview study [participants – primary care and allied health clinicians]

Study 3 was also a qualitative study, therefore the sample size for this study was also directed by the research question and analytical requirements such as data saturation (Pope et al., 2000). A total of 15–20 clinicians were sought for this qualitative study as this size was considered likely to result in data saturation (Marshall, 1996). A recent study exploring the views of clinicians regarding their patients' use of telemedicine technologies for pain management involved 25 primary care clinicians over the course of six focus groups (Levine, Richardson, Granieri, & Reid, 2014).

Summary

The above section presented the recruitment, consenting and sampling approaches adopted in studies 2a, 2b and 3. The following section presents the design and procedures of each of these studies.

4.7   Study procedures

The details of the study procedures of the phase I feasibility study (study 2a) are presented in the following section, followed by the details of the qualitative sub-study (study 2b) and the clinician interview study (study 3).

4.7.1 Phase I feasibility study (study 2a)

Study design

Study 2a was a phase I feasibility study using a pre–post-test design. This study evaluated the feasibility, acceptability and preliminary outcomes of a pain self-management app among a cohort of older people. The main focus of pre–post-test research designs is measuring change resulting from experimental treatment (Dimitrov & Rumrill, 2003). In this study design, measurements were conducted on two separate occasions: before the intervention (pre-test) and after the intervention (post-test) with an aim to identify any difference between the first and the second measurements.

The intervention [pain self-management app]

Apps are individually running software that interact with users for different purposes (Ventola, 2014). Although some apps can be downloaded and used on desktop or laptop computers, the majority of apps are smartphone based. Health related smartphone apps form a significant proportion of the applications available on the internet (Boulos, Brewer,

Karimkhani, Buller, & Dellavalle, 2014). Exercise and wellness apps form the major proportion of health related applications, however disease specific apps, such as pain management apps, are also widely available for download. The app systematic review reported in Chapter 2 details the procedure of quality and usability evaluation of currently available pain self-management apps. Briefly, out of 373 unique apps identified in the search process, only four met the inclusion criteria. The results of this systematic review demonstrated that none of the apps offer a comprehensive pain self-management plan as outlined in the evidence, and the apps overall had low level *older people specific usability score*. The WebMD Pain Coach app scored the highest in terms of its quality and older people specific usability score, followed by the Rheumatoid Arthritis, Information, Support and Education (RAISE) app (St James's Hospital & Arthritis Ireland, 2015).

It is important to note that, although the RAISE app is branded as a rheumatoid arthritis app, its contents were applicable to self-management of all arthritis-based chronic pain conditions. Literature suggests that despite different pharmacological treatment approaches, the recommended rheumatoid and osteoarthritis pain self-management strategies tend to be similar (Ersek, Turner, Cain, & Kemp, 2004; National Institute of Health, 2015). Both arthritic conditions require the person living with these conditions to assess and interpret their pain (symptom awareness) and to apply adaptive coping strategies (symptom management) such as analgesic adjustment or lifestyle modification on a regular basis (McBain, Shipley, & Newman, 2015). For this reason, the systematic review reported in Chapter 3 included apps developed for any type of arthritic pain self-management, and the contents of the RAISE app were considered relevant for the context of studies 2a and 2b.

Initial intervention: Based on the quality and usability scoring achieved in the systematic review (Bhattarai et al., 2017), the WebMD Pain Coach app (WebMD, 2016) was selected as the intervention for study 2a, however this app was removed from the public domain soon after the commencement of recruitment in September 2017. Unfortunately, the WebMD Pain Coach app developing team declined to make any comments regarding if and when this app would be reinstated in the public domain. Given this uncertainty, the research team moved to revise the study 2a protocol and adopted the second highest scoring app as the intervention.

Refined intervention: As the RAISE app (St James's Hospital & Arthritis Ireland, 2015) ranked second in the pain app systematic review (Bhattarai et al., 2017), it was selected as the intervention for study 2a. Written permission was obtained from the developers of the RAISE app for its use in study 2a, and an ethics amendment was sought (Appendix 14).

Intervention details

The RAISE app was collaboratively designed by the Rheumatology Department of St James's Hospital in Ireland and Arthritis Ireland. The RAISE app focuses on self-management management of arthritic pain. The features of the RAISE app could be broadly classed as encompassing the following functions:

- *Assessment and documentation*: The RAISE app offers an option to assess pain in a 0–5 NRS and keeps a time-stamped record of each NRS score. This pain intensity scale can be used as frequently as the user desires. The RAISE app also allows users to record their activity level on a 0–5 NRS.

- *Pain self-management education*: The RAISE app provides information on pain and pain self-management processes, medication use and communication with health professionals and pain related problem solving. Information on fatigue, sleep and the management of distress along with CBT pain management instructions on relaxation, goal setting and activity pacing (20–30 minutes session) are provided. Finally, there are videos of stretching, isotonic and aerobic exercise with warm-up and cool-down stages with the duration and frequency of exercise also indicated. As previously stated, these strategies are not rheumatoid arthritis-specific, but can be applied to any musculoskeletal chronic pain condition.

Intervention delivery

Following recruitment, participants from a variety of locations in Australia including Adelaide, Sydney, Brisbane, and Melbourne were enrolled in studies 2a and 2b. A face-to-face or telephone meeting was offered to all participants in order to: (i) download and set up the RAISE app on their smartphone; (ii) provide participants with app training and brief them to use the app for 14 days; and (iii) collect the pre-test data [Time.1]. Participants from Sydney and Adelaide metropolitan areas were offered a face-to-face meeting at a mutually convenient location, while those living elsewhere were offered a telephone meeting, as resource and logistical limitations prevented a face-to-face meeting.

During the first meeting, participants were guided through the features of the app until they were comfortable using it. A wireless enabled device (wireless internet dongle) was purchased and used for downloading the app to the face-to-face participant's device so they did not have to use their mobile phone's data allowance to download the app.

Telephone participants were informed that they would have to use their own internet (mobile data or wi-fi) to download the app. All telephone participants were guided through each section of the app by the doctoral student who also had the app downloaded to her own phone. A detailed verbal explanation was provided to the participants on the functions and features of the app. Participants were also advised to contact the doctoral student if they required any assistance in using the app throughout the 14-day period. Participants were advised to use the RAISE app as desired for the next 14 days. This study was not prescriptive in terms of how often participants were to use the app. The frequency and pattern of app use was completely dependent on participant preference.

Study registration

This phase I feasibility study is registered with the Australian and New Zealand Clinical Trials Registry, registration number: ACTRN1261700092138.

Outcomes measurement

Congruent with a phase I feasibility study, three preliminary outcomes were measured before and after the intervention period: (i) pain severity and interference; (ii) pain self-efficacy; and (iii) online technology self-efficacy. The outcome evaluation of this phase I study is guided by the 'limited-efficacy testing' focus of the feasibility study design, where the focus is to evaluate an intervention in a limited way. An example of this approach includes use of a convenience sample, with intermediate outcomes rather than final outcomes, and with a shorter follow-up period (Bowen et al., 2009). Similarly, the comparison of preliminary data in this phase I study was expected to indicate if there is any evidence of a likely effect of the intervention on the outcomes of interest rather than provide a definitive answer of the app intervention's efficacy or effectiveness (Bowen et al., 2009; Kazak et al., 2005). Several feasibility outcomes including (i) recruitment, retention, refusal and attrition rates; (ii) proportion and patterns of missing data; and (iii) ability to recruit 30 participants within six months were also measured as part of this phase I study.

Data collection

Study 2a data collection overview

Data collection in study 2a was carried out using a collection of questionnaires (see Table 4.3 and Appendix 15). The 'Pain outcomes measurement Case Report form' was designed including three valid and reliable outcomes measurement questionnaires: Brief Pain Inventory short form (BPI-sf) (Mendoza, Mayne, Rublee, & Cleeland, 2006), short form Pain Self-Efficacy Questionnaire (Miles, Pincus, Carnes, Taylor, & Underwood, 2011; Tonkin, 2008), and the Online Technology Self-efficacy Scale (Miltiadou & Yu, 2000). In addition, an investigator designed demographic and clinical survey was also developed to collect relevant demographic and clinical information from participants. The detail of the data collection tools is reported in the following sections.

Table 4.3 Data collection tool and time points for study 2a

Tool	Time 1 Day 0	Time 2 Day 14
Demographic and clinical survey. Includes: • Participant's demographic information • Comorbidity profile: Charlson comorbidity Index • Medication use details • Mobility: Life Space Assessment Questionnaire • Performance status: Australian-modified Karnofsky Performance Scale • Question on technology use pattern • Social support, and • Clinician details	✓	✗
Pain outcomes measurement Case Report Form. Includes: • Brief Pain Inventory Short Form (Mendoza et al., 2006) • Pain Self-Efficacy Questionnaire – Short Form (Nicholas et al., 2015). • Online Technology Self-Efficacy Scale (Miltiadou & Yu, 2000)	✓	✓

Study 2a data collection tools

Demographic and clinical survey

The demographic and clinical survey was designed to collect basic demographic information such as age, gender and living arrangements. Sections of this survey also included various validated data collection instruments to collect relevant health and comorbidity information such as the Charlson Comorbidity Index (Charlson, Pompei, Ales, & MacKenzie, 1987) to collect comorbidity data; the Life Space Assessment questionnaire (Stalvey, Owsley, Sloane, & Ball, 1999) to collect mobility information; and the

Australian-modified Karnofsky Performance Scale (Abernethy, Shelby-James, Fazekas, Woods, & Currow, 2005) to collect participants' physical performance data. This survey also included sections designed to collect information on participants' technology use pattern, level of family support in pain self-management, and a section to provide the details of participant-nominated pain clinicians (for those consenting to do so).

Pain outcomes measurement case report form

The Brief Pain Inventory–short form (BPI-sf) (Mendoza et al., 2006): The BPI-sf is a validated, widely used, self-administered questionnaire developed to assess the severity of pain and the impact of pain on daily functions (Mendoza et al., 2006). This tool measures pain severity by asking the respondent to rate their "worst" pain, "least" pain, "average" pain and "present" pain on a 0–10 NRS with 0 indicating "no pain" and 10 representing "pain as bad as you could imagine". The four pain severity scores are averaged to generate a Pain Severity Scale. The BP-sf also consists of seven questions exploring pain interference. The seven aspects are general activity; mood; walking ability; normal work; relations with other people; sleep; and enjoyment of life. Pain interference is measured on a 10-point scale with 0 representing "does not interfere" and 10 representing "interferes completely". These seven scores are averaged to generate a Pain Interference Score.

Short Form Pain Self-Efficacy Questionnaire (PSEQ-2) (Nicholas, McGuire, & Asghari, 2015): The Pain Self-Efficacy Questionnaire is a valid and reliable 10-item tool designed to assess the confidence people with ongoing pain have in performing activities while experiencing unrelieved pain (Miles et al., 2011; Tonkin, 2008). A shorter form of this tool (PSEQ-2) has been recently developed to reduce user burden and save time. The PSEQ-2 has been demonstrated to possess sound reliability and validity, and is deemed to be a robust measure of pain self-efficacy (Nicholas et al., 2015).

Online Technologies Self-Efficacy Scale (OTSES) (Miltiadou & Yu, 2000): The OTSES is a valid tool designed to measure an individual's self-efficacy in using online technologies (Miltiadou & Yu, 2000). The OTSES comprises 29 items clustered into four subscales: (i) internet competencies, (ii) synchronous interaction, (iii) asynchronous interaction, and (iv) asynchronous interaction.

Data analysis

The data generated by study 2a was analysed using the IBM Statistical Package for Social Science (SPSS) software. Descriptive statistics were used to analyse demographic, health and technology-use related data. Participants' pre-test self-reported pain data (intensity and interference), pain self-efficacy and online technology self-efficacy were compared with their post-test reports. The small sample size of this study limited the kinds of inferential statistics that could be carried out. A simple non-parametric hypothesis testing procedure was conducted using the Wilcoxon signed-rank test. The Wilcoxon signed-rank test is a nonparametric test used to investigate any change in scores of a single group of participants from one time point to another (Weaver et al., 2017).

Reporting of the results

Reporting of the results of this phase I feasibility study adheres to the mHealth Evidence Reporting and Assessment methodology checklist (Agarwal, Lefevre, & Labrique, 2017).

4.7.2 Qualitative sub-study (study 2b)

Study design

Study 2b was a qualitative interview study. Qualitative studies allow exploration of the views and perspectives of participants within the contextual conditions in which their lives take place. Not only does this provide a rich account of the intervention or phenomenon in question, but it also allows the researcher to explain these processes via existing and emerging concepts from the rich qualitative data (Yin, 2011). Study 2b was essential to understand older people's experiences and perspectives in relation to the two weeks use of a pain self-management app (intervention of study 2a). This exploration was important to inform the acceptability components of app use, and to better understand older people's experiences of, and attitudes towards, using an app to assist their arthritic pain self-management process. The semi-structured interview design was chosen to collect in-depth data on the topic while allowing participants the freedom to express their views in their own terms.

Data collection

The chosen data collection method for this study was a series of semi-structured telephone interviews. Semi-structured interviews are well suited for exploration of perceptions, attitudes and experiences of participants regarding complex and sensitive issues while

enabling probing for clarification and depth of information (Barriball, Christian, While, & Bergen, 1996). Semi-structured interviews carried out via telephone are considered a legitimate method of data collection that produces data of comparable quality to face-to-face interviews (Barriball et al., 1996; Carr & Worth, 2001). Telephone interviews have been used by previous studies to elicit older people's views on their chronic pain self-management practices (Carnes, Anwer, Underwood, Harding, & Parsons, 2008; Kralik, Koch, Price, & Howard, 2004; Richardson, Lee, Nirenberg, & Reid, 2017).

Informed by current evidence in the area of pain self-management apps (Lalloo, Jibb, Rivera, Agarwal, & Stinson, 2015), and barriers and facilitators to digital technology use for pain management among older people (Parker, Jessel, Richardson, & Reid, 2013; Richardson et al., 2017) an interview guide was developed to guide the interview process (Appendix 16). The interview guide included a mixture of open-ended and theoretically driven questions allowing for responses that truly reflect each participant's experiences, while also being relevant to the context and purpose of the research (Galletta & Cross, 2013).

The doctoral student conducted all the interviews. The interview data was recorded via use of a voice recorder (Samsung Galaxy S5) supplemented by handwritten field notes. Audio recordings of qualitative interviews are noted to be superior to handwritten interview notes only as they offer a highly reliable record of naturally occurring interactions during the interview process (Seale & Silverman, 1997). Field notes offer the interviewer an opportunity to observe and record the participant's verbal and non-verbal behaviours and their own immediate personal reflections of the interview (Guion, Diehl, & McDonald, 2001). A professional transcribing service (www.rev.com) was used to create transcripts of audio recordings of the interviews. These transcripts were cross checked with the interview audios to ensure accuracy of transcription. The refined interview transcripts and the handwritten field notes were considered for data analysis.

Evaluation of data saturation

The doctoral student noted summaries of each interview session as soon as they were concluded. These notes together with the field notes written up during the interview were consulted to evaluate the emerging themes from the interviews in an ongoing manner. Evaluation of emerging themes was carried out concurrently with the interviews.

Additionally, member checking was undertaken within and across interviews to ensure data collection was undertaken until data saturation was reached (Lincoln et al., 1985).

Data analysis

The NVivo 12 software package was used to manage the qualitative data. An integrative approach to qualitative data analysis designed for informing the development of health interventions was used (Bradley, Curry, & Devers, 2007). The TAM2 (Venkatesh & Davis, 2000) was used as the framework for data analysis and to guide data classification. The data analysis was carried out using thematic analysis. Thematic analysis allows for identification, analysis and reporting of patterns or themes within the data enabling the researcher to carry out data interpretation (Braun & Clarke, 2006). A stepwise process of thematic data analysis was adopted. Firstly, the interview transcripts and interview notes were read and re-read to achieve data familiarisation, followed by identification of common and recurring themes and open coding of the content. A hierarchical coding structure was developed where branching arrangements of sub-codes (child code) were created under each code (parent code). The code and sub-code development process was constantly cross validated with the supervisory team (JLP and TNJ) to ensure coding validity. Recurring data patterns and themes were identified using the constant comparison method.

Reporting of the results

Reporting of the findings of study 2b was guided by the consolidated criteria for reporting qualitative research (Tong, et al., 2007).

4.7.3 Clinician interview study (study 3)

Study design

Study 3 was also a qualitative interview study. Study 3 was essential to explore primary care and allied health clinicians' perspective and attitudes on integration of apps into their older patients' pain self-management strategy. This exploration was important because primary care and allied health clinicians play a significant role in helping community-dwelling older people to develop or facilitate their pain self-management plans. The role of these clinicians cannot be overlooked when considering technology-mediated interventions such as apps to facilitate community-dwelling older people's pain self-management strategy. Therefore, a semi-structured interview design was adopted to gain

an in-depth understanding of primary care and allied health clinicians' views on use of apps for pain self-management by older people.

Data collection

The chosen data collection approach for this study was a series of semi-structured telephone interviews. As noted in section 4.7.2, telephone-based semi-structured interviews are a legitimate method of data collection (Barriball et al., 1996; Carr & Worth, 2001), commonly used in studies with busy participants (Heneka et al., 2019; Stirman et al., 2013).

An interview guide was developed to provide structure to the interview process (Appendix 17). Similar to the procedure of study 2b noted above, the clinician interviews were audio recorded supplemented with handwritten interview notes. The interview audios were professionally transcribed using a professional transcription service (www.rev.com) and cross checked for accuracy. The refined interview transcripts and the handwritten field notes were considered for data analysis. Data saturation was determined in the similar approach as noted above for study 2b.

Data analysis

The NVivo 12 software package was used to manage the qualitative data. An inductive thematic analysis approach was used for data analysis. Study 3 used similar data analytic procedures as study 2b.

Reporting of the results

Similar to study 2b, the reporting of the findings of study 3 was also guided by the consolidated criteria for reporting qualitative research (Tong, et al., 2007).

4.7.4 Integration of DigiTech Pain project data

The findings of the two reviews, the integrative review in study 1a and the systematic review in study 1b, were integrated to draw meta-inferences that would help answer research question 1: *What is the evidence on the use of digital health technologies for older people's arthritic pain management?*. The quantitative data from study 2a and the qualitative data from study 2b were integrated to answer research question 2: *What is the feasibility and acceptability of undertaking an app intervention study involving community-dwelling older people living with arthritic pain?*. The guiding questions for feasibility

studies developed by Orsmond and Cohn (2015) were adopted to guide this data integration and appropriately answer research question 2. Orsmond and Cohn (2015) note that a feasibility study ought to answer questions relating to: (i) recruitment; (ii) data collection; (iii) acceptability of the intervention; (iv) resources needed for intervention implementation; and (v) response to the intervention. Research question 2 of the DigiTech Pain project addressed recruitment, data collection and response to the intervention aspect of feasibility.

The findings of the two qualitative studies (study 2b and study 3) were integrated to answer research question 3: *What are the features that older people and their treating clinicians consider most relevant in a pain self-management app?*. The TAM2 was used to guide the data integration work required to appropriately answer research question 3. All five studies included in the DigiTech Pain project (studies 1a, 1b, 2a, 2b and 3) were integrated to answer research question 4: *What are the actions required to build the evidence supporting the integration of an app into older people's arthritic pain self-management plans?*. The Innovative Care for Chronic Conditions Framework (World Health Organization, 2002) was used to guide the data integration work carried out to appropriately answer research question 4.

Summary

The above section outlined the study procedures of the three discrete primary studies of the DigiTech Pain project. The details of how the data from each of the study was integrated to answer the research questions was also provided. The following section outlines the ethical considerations of the DigiTech Pain project.

4.8   Ethical considerations

4.8.1 Values

The DigiTech Pain project was undertaken in accordance with the National Statement on Ethical Conduct in Human Research ('National Statement') (National Health and Medical Research Council Australia, 2007) and the Australian Code for Responsible Conduct of Research (National Health and Medical Research Council, 2018). Accordingly, the DigiTech Pain project addresses and reflects on each of the following values.

Research merit

The DigiTech Pain project sought to make a substantial contribution to the body of knowledge on the use of digital health technologies for pain self-management of older people living with arthritis. Prior to submission for ethical review, the project's proposal was presented at the University of Notre Dame Australia (Sydney Campus) to seek critical feedback from university academics and peers. The project proposal was also sent out for examination (peer review) to ensure the research merit of the project and the appropriateness of the research design. Collectively, the DigiTech Pain project team (PB, TNJ, JP) had appropriate qualification and extensive experience in chronic pain management research, digital technology research and mixed methods research methodology.

Research integrity

The DigiTech Pain project was undertaken following the principles of research integrity: seeking new knowledge; following recognised principles of research conduct; and conducting research with honesty and transparency (National Health and Medical Research Council, 2018; National Health and Medical Research Council Australia, 2007). The study results were communicated through peer reviewed oral and poster presentations at various conferences (see Research Outputs Associated with Thesis in the front matter).

Justice

The participant inclusion criteria for the DigiTech Pain project were broad. Older people from four Australian states with varying degrees of arthritic pain were included in this project. Similarly, clinicians across three Australian states belonging to various primary and allied health professions were included in the DigiTech Pain project. Participation was voluntary and participants were informed of the time burden and what the research activities would entail, prior to consenting to the study.

Beneficence

The likely benefit of DigiTech Pain project extended to older people, who had an opportunity to consider if a pain self-management app would be useful to them, and clinicians, who had an opportunity to reflect on their clinical practice and consider the role of pain self-management apps in assisting their patients/clients. Participants' right to freedom from harm and discomfort and protection from exploitation was upheld by

informing them they can withdraw from the study at any time without the need for any explanation or any repercussion. All participants were provided with the contact details of the Ethics Committee overseeing the DigiTech Pain project (University of Notre Dame Australia Ethics Committee), in case participants had any concern or complaint.

Respect

To ensure the DigiTech Pain project was conducted in a respectful manner, due regard was given to the preferences and welfare of the participants (older people and clinicians). The dates, locations and times for consent, app download and training, and data collection were guided by the participants' preference. Face-to-face meetings were offered to all older participants from Sydney and Adelaide regions to facilitate the app download and use training. When a face-to-face meeting was not possible, participants were guided over the phone to download and install the app, followed by provision of app training. Participants were assured they did not need to answer any questions they were not comfortable with and were made aware of support options if the semi-structured interviews raised any issues for them.

4.8.2 Ethical approval

Ethical approval for the DigiTech Pain project was obtained from the University of Notre Dame Australia's Human Research Ethics Committee (HREC). The full ethics approval for this study was received on 6 June 2017, approval number 017049S (Appendix 18). As the participants of this project were recruited from the community setting, there was no need to obtain any other institutional level ethics approval.

4.8.3 Ethical amendments

Subsequent to the initial full ethics approval granted in June 2017, the DigiTech Pain project sought several ethical amendments to accommodate the evolving needs of the project. An amendment was obtained to accommodate the change of the intervention app from WebMD Pain Coach to RAISE. Difficulty in recruiting participants to studies 2a and 3 necessitated an amendment of the recruitment strategy for these studies. An amendment was obtained to include additional recruitment strategies for study 2a (use of snowballing and a social media based approach), and for study 3 (use of professional networking and health professionals peak body referral based recruitment approach). The evidence of all amendment approvals is attached as Appendix 14.

4.8.4 Consideration for study participants

Older people

The DigiTech Pain project's ethical considerations relating to older participants (studies 2a and 2b) focused on minimising the burden of participation. Firstly, eligible participants were advised that study participation was voluntary, and that they were free to decline participation, or withdraw from the study at any time without any consequences. Written informed consent was collected from all participants prior to their enrolment to the study.

Secondly, all participants were provided detailed information on what they would be asked to do as part of each study. To minimise the burden of app download and familiarisation, the doctoral student offered support and guidance (face-to-face or over the phone) to each participant. Finally, participants were also advised that intervention app use during the 14-day trial period was not prescriptive which meant they could use and/or engage with the app as much or as little as they desired. These strategies were designed to minimise participant burden.

Primary care clinicians

Ethical consideration relating to clinician participants (study 3) focused on consenting and data collection procedures. As outlined in section 4.6.3, potential clinician participants were accessed via referral from peak bodies and the DigiTech Pain project team's network. To minimise the risk of influence of the referrer on the potential participants, the following steps were taken:

- No direct contact was made by the study team to any potential participants.

- Referring contacts were asked to inform anyone interested to contact the study team directly without informing the referrer.

When the potential participants got in touch with the project team to ask any questions about participation or to express their wish to participate, they were clearly informed that taking part in the study was voluntary, and that they were free to decline participation without any consequences. Written informed consent was collected from all participants prior to study enrolment. As clinicians are known to have busy work schedules, participants were offered the option of interview times within or outside office hours (9am–5pm). This flexibility was provided to accommodate the variable work hours of clinicians and to minimise participant burden.

4.8.5 Positioning of the researcher

Having worked as a palliative care clinical trials nurse, and a research officer, the doctoral student has extensive experience in the area of chronic and palliative care research. A combination of her palliative care nursing expertise, clinical trials experience and previous research experience in aged care was expected to help her detect, respond appropriately and monitor any pertinent ethical concerns.

Considering the need to uphold reflexivity in qualitative research (Palaganas, Sanchez, Molintas, Visitacion, & Caricativo, 2017), analytical attention was given to the role of the doctoral student in this project. While conducting the qualitative interviews, the doctoral student kept a reflective journal, and made entries following each interview to exercise critical self-reflection and to minimise any bias that the interviewer's position may pose. Items noted in the reflective journal include interpretation of the participant's behaviours, personal insight to the interview data, and the urge to switch to the clinician (Registered Nurse) role. Pertinent items relating to reflexivity were discussed in the monthly supervision meetings. The supervisory team encouraged the doctoral student to reflect upon her assumptions and helped her think about the implications of such assumptions on the research process.

To ensure openness and transparency during the recruitment, consenting and data collection process, the doctoral student openly presented herself as a PhD candidate with a background in nursing (Registered Nurse). This positioning was important to establish an open and transparent interaction with any leads for recruitment (peak bodies of various health professions, clubs specific for older people) and/or any potential participants; especially given the area of chronic disease management apps is vastly commercialised. The recruitment contacts and participants welcomed the researcher's open disclosure and were delighted that the research arena (university/academia) was keen to explore app use for pain management of the elderly.

4.8.6 Data management and storage

The collected data was used only for the purposes of answering the DigiTech Pain Project's research questions. The collected data was not (and will not be) be disclosed or shared with any external organisation or authority, unless required by law. All data arising from the DigiTech Pain project were stored on a secured, password protected and encrypted research drive, or in a locked filing cabinet in a secure office at the Centre for Improving Palliative,

Aged and Chronic Care through Clinical Research and Translation (IMPACCT), University of Technology Sydney, where the doctoral student's primary supervisor is based. A copy of the de-identified project data is also stored on a secure, password protected research drive at the University of Notre Dame School of Nursing as per the University requirement. While the study was in progress, de-identified electronic data were also stored on an encrypted repository accessible via the doctoral student's password protected computer. This institutional repository was deemed secure due to its encrypted nature and its in-built mechanism for *Multi-factor Authentication* for access.

Study data items were collected in electronic and hard copy form.

Electronic recording

An Excel spreadsheet was created to store each participant's confidential contact information together with their allocated study ID. This was the only link between the participant and their study ID. This linkage of information was necessary to carry out follow-up data collection (study 2a) and to organise the semi-structured interviews (study 2b) and also where a participant wished to withdraw from the study and wanted their data removed. Participant confidentiality, privacy and anonymity were ensured via the use of de-identified participant code used throughout data analysis

The audio recordings of the semi-structured interviews (studies 2b and 3) were also transcribed in electronic form (Microsoft Word file). Each interviewee was provided with a study ID and any identifiable information that was present in the audio recording was de-identified in the transcription process before transferring the data to NVivo software. As noted above all the electronic data arising from the DigiTech Pain project were stored in a secure and encrypted institutional repository that required *Multi-Factor Authentication* for access. The study data was only accessible to the doctoral student. All data collection and entry work were carried out by the doctoral student. Access to the study data folder was limited to the doctoral student.

Hard copy recording

The consent forms of each participant were obtained in hard copy or electronic form. In addition, participant data for study 2a was also collected in hard copy form. The hard copies of the signed consent forms were stored in a locked cabinet securely and separately from participants' study data. The hard copy data collected in study 2a in the form of surveys

and questionnaires for each participant was kept in a participant file (identified by study ID) in a different locked cabinet from the consent forms.

As noted above, hard copy data was stored in a locked filing cabinet in the office at the IMPACCT University of Technology Sydney. All study data will be stored for a period of five years from the date of any associated publications in accordance with national requirements (National Health and Medical Research Council, 2018; National Health and Medical Research Council et al., 2007). At the completion of the study, all study material (electronic and hard copy) will be reconciled and archived as per the relevant state regulation regarding research data retention and disposal of that time.

4.9 Conclusion

This chapter has outlined the rationale for a mixed methods design, study procedures, theoretical underpinnings and ethical considerations of the DigiTech Pain project. The following chapters report, in detail, the individual studies that comprise the DigiTech Pain project, the project conclusions and recommendations.

The following chapter (Chapter 5) reports the results of the phase I feasibility study (study 2a) and the qualitative sub-study (study 2b). Study 2a aimed to evaluate the feasibility, acceptability and preliminary outcomes of a pain self-management app among older people living in the community with arthritic pain. The qualitative sub-study explored older people's (study 2a participants) attitudes and experiences of using the intervention app.

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Chapter 5 The feasibility and acceptability of conducting a pain self-management app trial among older people

5.1 Introduction

There has been extensive promotion of digital health technologies to assist older people with their pain self-management practices. However, the integrative review (study 1a) and systematic review (study 1b) reported in Chapters 2 and 3 found limited evidence supporting the use of digital health technologies for older people's pain self-management plans. Given these gaps in the literature, studies 2a and 2b sought to evaluate the feasibility and acceptability of a freely available pain self-management app among community-dwelling older people living with arthritic pain. This chapter reports the individual results of the feasibility study (study 2a) and the qualitative sub-study (study 2b).

5.2 Publication reference for phase I feasibility study

The protocol of study 2a was published in 2019 in *BioMed Central Pilot and Feasibility Studies,* a peer reviewed, open access journal that publishes research papers relating to future clinical trials or large-scale observational studies, as well as protocols, commentaries and methodology articles (Appendix 19).

> Bhattarai, P., Newton-John, T. R. O. & Phillips, J. L. (2019). Feasibility evaluation of a pain self-management app-based intervention among older people living with arthritic pain: study protocol. *BMC: Pilot and Feasibility Studies, 5*(1), 57.

A manuscript covering the results of study 2a is currently in preparation for submission to the *Journal of Telemedicine and Telecare.*

5.3 Context for the phase I feasibility study

In Australia almost 60% of females and 40% of males aged over 65 years live with some form of arthritis (Australian Bureau of Statistics, 2019). Arthritis is the second most common cause of disability in Australia (Australian Bureau of Statistics, 2015) and costs the healthcare system over $5.5 billion annually (Ackerman, Bohensky, Pratt, Gorelik, & Liew, 2016). For most older people living in the community, self-management strategies

are central to managing their arthritic pain and maintaining a good quality of life (Nicholas et al., 2012; Schofield et al., 2014).

While formalised pain self-management programs generally involve face-to-face coaching approaches, there is growing interest in using technology mediated approaches, such as smartphone apps, to facilitate pain self-management among people of all ages (Chiew, 2019; Thurnheer, Gravestock, Pichierri, Steurer, & Burgstaller, 2018). Given this interest the number of pain self-management apps are rapidly growing, with over 350 pain apps currently available across various app stores. Despite the majority of older Australians using smartphones (Office of the eSafety Commissioner, 2018), little is known about the role apps play in helping older people better manage their pain. Therefore, a phase I study was undertaken to better understand the feasibility and acceptability of trialling an app intervention among a cohort of community-dwelling older people living with arthritic pain.

5.4 Objectives

The objectives of the phase I feasibility study were to evaluate the:

(i)   feasibility of carrying out an app intervention study involving older people as measured by: (a) recruitment, refusal and attrition rates; (b) proportion and patterns of missing data; and (c) ability to recruit 30 participants within six months; and

(ii)   preliminary impact of an app intervention on older people's pain and self-efficacy outcomes.

5.5 Methods

A phase I feasibility study using a pre–post-test design, as described in Chapter 4.

5.6 Results

The results are reported as per the mHealth Evidence Reporting and Assessment (mERA) methodology checklist (Agarwal, Lefevre, & Labrique, 2017).

5.6.1 Recruitment, refusal and attrition rate

As reported in Chapter 4, the recruitment efforts firstly focused on older people specific clubs and organisations (n=14). Out of 14 clubs and organisations approached, 10 (70%) declined due to lack of interest, 3 (22%) offered a face-to-face presentation opportunity, and one (7%) offered to share the study invite via their social media page. The DigiTech Pain project was presented at the club meetings of three different clubs. The three separate

face-to-face presentation sessions were attended by a total of 66 older people, four of whom (6%) met the eligibility criteria. None of the four eligible older people were interested in participating in the DigiTech Pain project. This poor recruitment outcome resulted in revision of the recruitment approach and focus on social media and snowballing methods, which proved to be more successful. The details of overall referral, recruitment and refusal are presented in Figure 5.1.
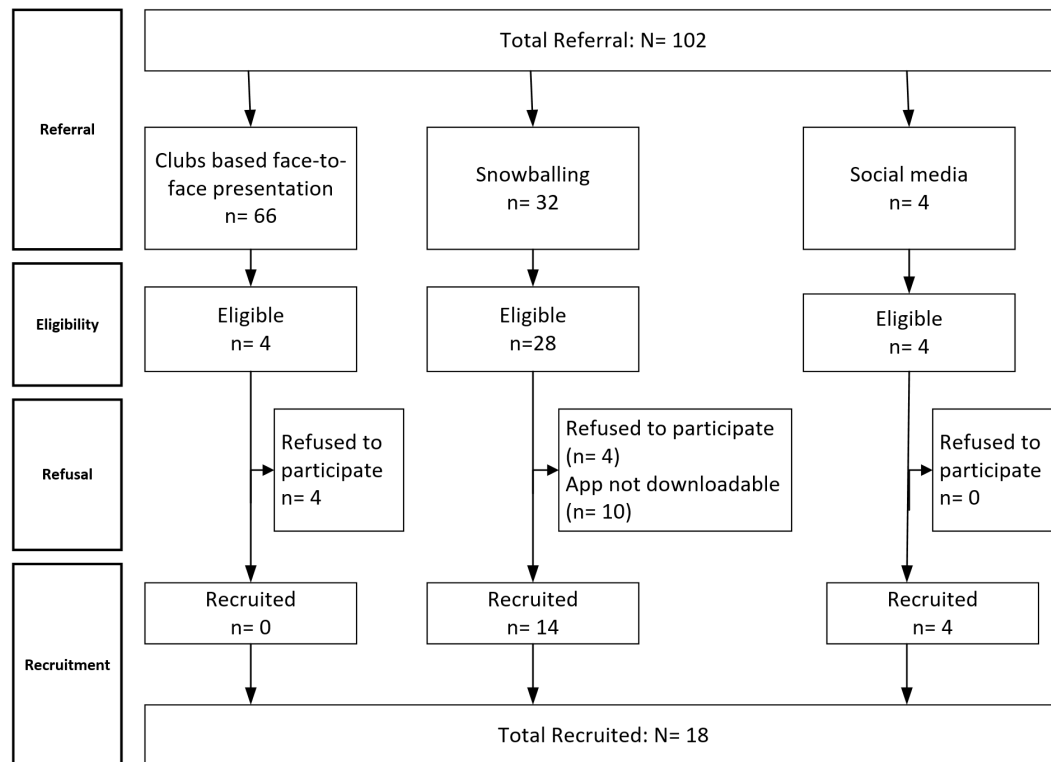

Figure 5.1 Consort diagram of the referral, refusal and recruitment rates

5.6.2 Demographics and sample characteristics

Eighteen participants were recruited during the six-month recruitment period. The majority (80%) were recruited via snowballing, with 59% recruited via a face-to-face meeting. The screening to recruitment ratio was 6:1. The mean age of participants was 73.1 (±5) years, and the majority (89%) were female (see Table 5.1). Participants were based in four Australian states with the majority based in NSW (n=8), and 50% lived with their spouse. Almost 90% of participants reported moderate level comorbidity as per the Charlson Comorbidity Index (Charlson, Pompei, Ales, & MacKenzie, 1987). Just over 80% had no self-reported psychological condition. Almost 70% of participants experienced some level of pain but required no assistance from others, as assessed by the Australian-modified Karnofsky Performance Scale (Abernethy, Shelby-James, Fazekas, Woods, & Currow,

2005). Almost 90% of participants reported low level loneliness as per the University of California Los Angeles Loneliness Scale (Hughes, Waite, Hawkley, & Cacioppo, 2004). A significant majority (95%) reported moderate level mobility as per their Life Space Assessment score (Stalvey, Owsley, Sloane, & Ball, 1999). Half of the participants used less than three prescribed medications, and almost three quarters (72%) used over the counter supplements.

Table 5.1 Sample characteristics

Baseline characteristics	Breakdown	Total Sample N= 18 (100%)	
Socio-demographic profile			
Age	Mean (SD)	73.1	(±5)
Gender	Male	2	(11)
	Female	16	(89)
Living arrangements	With spouse	9	(50)
	Alone	5	(28)
Health history profile			
Charlson Comorbidity score	< 3 (Low comorbidity)	1	(5)
	4-5 (Moderate comorbidity)	16	(89)
	> 5 (High comorbidity)	1	(6)
Presence of psychological condition	Depression	2	(11)
	Anxiety	1	(6)
	None	15	(83)
Australian-modified Karnofsky Performance Scale	100 (no assistance needed, no symptoms)	2	(11)
	90-80 (no assistance needed, some symptoms)	12	(67)
	70-60 (occasional assistance needed, considerable symptoms)	4	(22)
UCLA Loneliness Scale score	3-4 (low level loneliness)	16	(89)
	5-6	2	(11)
	7-9 (high level loneliness)	0	(0)
	> 100 (High mobility)	1	(5)
Prescribed medications	< 3	9	(50)
	3-5	7	(39)
	> 5	2	(11)
Over the counter medications	< 3	13	(72)
	3-5	3	(17)
	> 5	2	(11)

Legend: UCLA=University of California Los Angeles; SD=Standard Deviation

5.6.3 Technology use pattern

Participants used various technologies in their daily lives. All used a smartphone (eligibility criteria), 72% owned a desktop computer, and over two-thirds (67%) owned a tablet computer (see Table 5.2). The majority (56%) reported using their smartphones for between 60 and 120 minutes every day for communications, information seeking and entertainment. None of the participants had previously used a pain self-management app.

Table 5.2 Technology use profile of the sample

Technology engagement type	Detail	Total Sample	
		N (18)	(100%)
Technological device ownership	Smartphone	18	(100)
	Desktop	13	(72)
	Tablet	12	(67)
	Laptop	8	(44)
	Activity tracker	4	(22)
Smartphone use pattern	< 60 minutes	4	(22)
	60-120 minutes	10	(56)
	> 120 minutes	4	(22)
Activities carried out using smartphone	Electronic communication	13	(72)
	Internet browsing	11	(61)
	Cellular calls and text	10	(56)
	Social media	9	(50)
	Gaming	7	(39)
	Banking	5	(28)

5.6.4 Attrition and missing data

Of the 18 participants, 17 (96%) completed the study. One participant missed the post-test assessment due to personal reasons. None of the participants withdrew or expressed the interest to withdraw from the study. Of the 17 participants who completed the study, two (11%) had missing responses to some assessment questions (missing data).

5.6.5 Descriptive comparison of the preliminary outcomes

The majority of participants had low level (≤ 3 NRS) pain severity (56% at pre-test, and 71% at post-test) and pain interference (67% at pre-test and 71% at post-test) (see Figure 5.2). Over three quarters of the participants (83% at pre-test and 78% at post-test) had high pain self-efficacy (aggregate score ≥ 8 out of 12). Similarly, the online technology self-efficacy of the majority of participants (67% at pre-test and 81% at post-test) was also high (score ≤ 57 out of 116). Participants' pain intensity score decreased from pre-test to post-

test (increase in the proportion of participants with nil-mild pain: 56% pre-test to 71% post-test; and decrease in the proportion of participants with moderate to severe pain: 44% pre-test to 29% post-test). However, these changes were not statistically significant, or observed for the scores of pain interference and self-efficacy.
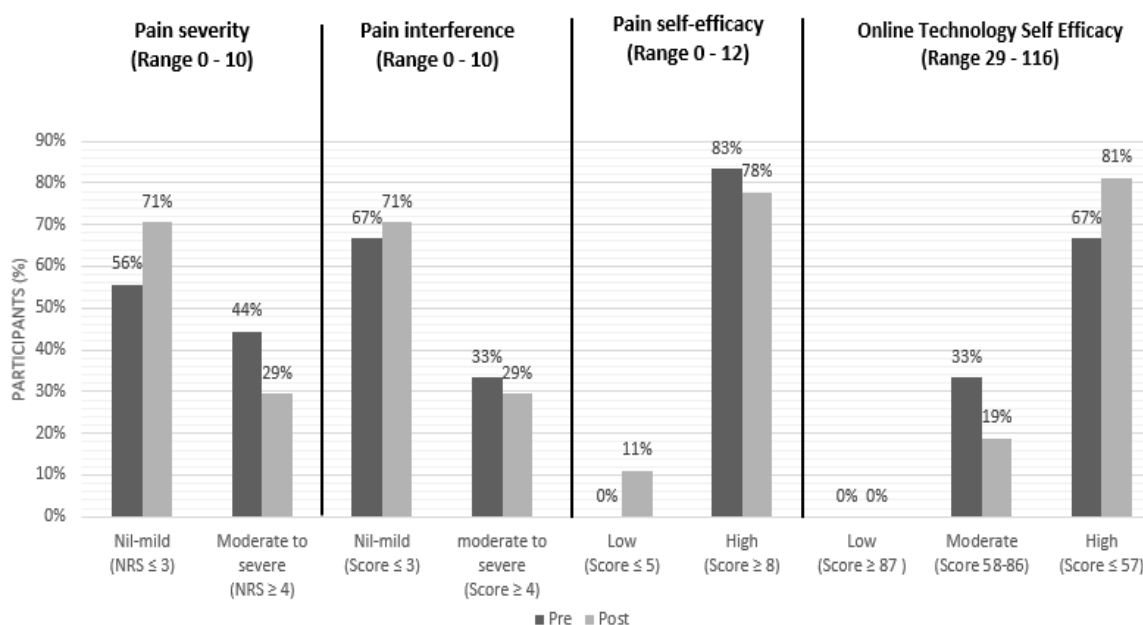

Figure 5.2 Preliminary outcomes scores classification of the sample

5.6.6 Impact on pain and self-efficacy scores

While this study was not powered to detect a difference, the results of the Wilcoxon signed-rank test revealed no significant differences in the pain and self-efficacy scores from the pre to post time point (see Table 5.3).

Table 5.3 Comparison of pre and post test scores of the sample's pain and self-efficacy outcomes

Outcomes	Instrument used	Pre Mean (±SD)	Post Mean (±SD)	Z	p value
Pain					
Pain Severity	Brief Pain Inventory (short form)	3.08 (±2.1)	2.3 (±2.1)	-1.4	0.16
Pain interference		2.9 (±2.2)	2.3 (±2.3)	-1.5	0.14
Pain self-efficacy					
Pain Efficacy score	Pain Self-Efficacy Questionnaire- 2	9.6 (±1.8)	9.6 (±2.1)	0.00	1.0
Technology self-efficacy					
Technology self-efficacy score	Online Technology Self-Efficacy Questionnaire	50.7 (±15)	47.9 (±15)	-0.84	0.4

Legend: SD: Standard Deviation

5.7 Discussion

This phase I feasibility study has revealed several valuable insights relating to an app-based intervention among older people with arthritic pain. Although conducting this study involving older people living with arthritic pain was feasible, various recruitment challenges were experienced. The evidence generated by this study showed no impact of the two-week use of the intervention app on older people's pain or self-efficacy outcomes.

5.7.1 Feasibility of conducting an app study involving older people

The recruitment challenges experienced in this study are similar to those reported in previously published literature (Dibartolo & McCrone, 2003; Harris & Dyson, 2001). Issues relating to physiological and cognitive changes associated with aging, multi-morbidity, lower literacy levels and general distrust of research are known barriers to recruiting older people to research studies (Dibartolo & McCrone, 2003). Similar challenges were faced in recruiting older people to the DigiTech Pain project where a general disinterest in research participation was found among the attendees of the face-to-face presentation about this study. Furthermore, as outlined in a recent systematic review, recruitment to digital health intervention-based studies requires additional careful considerations such as use of peer-based recommendation and clinical endorsement (O'Connor et al., 2016). A similar phenomenon was observed in the recruitment process of the DigiTech Pain project where the majority of the participants were recruited via snowballing, compared to cold calling at clubs or organisations specific to older people or Facebook-based open invitation. This finding indicates that, despite the increasing trend of smartphone uptake among older Australians (Office of the eSafety Commissioner, 2018), those that have deeper understanding of this technology and incorporate it into their daily lives still make up a small proportion of older people. It is quite likely that technologically savvy older people living with chronic arthritic pain are a small and unique group. Given this reality, it is plausible that the snowballing approach of recruitment was the most successful recruitment approach for the DigiTech Pain project (Atkinson & Flint, 2001).

The older people in the DigiTech Pain project were relatively old and mostly female. This finding reflects the Australian national data which indicates that 30% of people between the ages of 65–79 live with arthritis, which affects twice as many women as men in this age group (Australian Institute of Health and Welfare, 2018). While there is emerging data about the smartphone uptake rate among older Australians (Office of the eSafety

Commissioner, 2018), this study provides a valuable snapshot of smartphone usage patterns among a small sample of older Australians. In addition to their smartphones, a significant proportion of older people in this study also owned a tablet computer. This finding is reflective of other published reports which indicate that over a third of older Americans (Pew Research Center, 2017) and over half of older Australians (Office of the eSafety Commissioner, 2018) own a tablet device. The high level of tablet computer adoption could be partly attributed to its unique features including a large touchscreen interface (Kobayashi et al., 2011); and high level portability and usability such as adjustable font or icon size (Chan, Haber, Drew, & Park, 2014); all of which are advantageous to older people who tend to experience age related motor and visual limitations. While older people of the DigiTech Pain project used their smartphones to download and use the intervention app, there is a need to explore the potential benefits of tablet computer-based app interventions among older people.

Older people of the DigiTech Pain project were found to be relatively light users of their smartphones with the majority reporting engagement times of 1–2 hours/day. While little is known about the smartphone usage patterns of older Australians, data from the UK (Fisher, 2019) and the USA (Wurmser, 2019) indicates that an average smartphone user spends over 3.5 hours/day on these devices. Furthermore, the DigiTech Pain project finding that older people primarily use their smartphones for basic communication, internet browsing and social media with no prior history of pain self-management app use is congruent with the literature which reports that users of health apps are generally younger with higher level e-health literacy skills (Bol, Helberger, & Weert, 2018). Prior experience of using smartphones and tablet computers is known to increase the likelihood of an individual's intention to use apps (Scheibe, Reichelt, Bellmann, & Kirch, 2015). With the currently increasing rate of smartphone use among older people, it is likely that the next generation of older people will be much more familiar users of smartphones who are keen to engage with a variety of apps, including health apps (Scheibe et al., 2015).

5.7.2 Preliminary impact of the app intervention on pain and self-efficacy outcomes

Although establishing the effectiveness or efficacy of the intervention app on older people's pain and self-efficacy levels was beyond the scope of this study, descriptive comparison of pre and post outcomes suggests slight, but statistically insignificant decrease in older people's pain severity scores. However, the low level of pain severity and

interference observed at the pre-test timepoint could indicate minimal opportunity for reduction in these scores. This observation, together with the lack of statistical significance and small sample size of the DigiTech Pain project calls for caution when interpreting these results. Further, no differences were observed in pain self-efficacy and the online technology self-efficacy of older people. Although the reason for this occurrence was not apparent in the results, the considerably high baseline self-efficacy levels (pain and online technology) observed among the participants might point to the possibility of limited applicability of these modalities among highly self-efficient individuals. Future work should explore this phenomenon further.

Strengths and limitations

There are a number of limitations of this study. Firstly, the sample size of this study was relatively small, non-random and limited to interested community-dwelling older people living with arthritic pain within Australia, therefore these results are not generalisable to the wider community. Secondly, as the participants were not instructed to use the app in any specific frequency or pattern (i.e. no dose prescription), it is difficult to ascertain if any changes in outcomes could be attributed to their app usage. Thirdly, it is possible that there was some participant bias in that older people with lower symptom burden and higher self-efficacy (pain and technology) may have chosen to participate in the study more than those with higher symptom burden and lower self-efficacy. And finally, while this study has provided initial feasibility insights into carrying out a pain app trial among older Australians, further research is necessary to confirm or refute the study findings. Despite these limitations, this study has provided valuable insights into the feasibility of conducting an app intervention-based study among community-dwelling older Australians living with arthritic pain, which, to our knowledge, has not been previously reported. The findings of this study could inform recruitment approaches for adequately powered future trials involving older people.

5.8 Summary

While conducting an app intervention study involving community-dwelling older people is feasible, future studies should prioritise snowballing approach for successful recruitment. Older people were also found to be light users of smartphones with device engagement primarily carried out for communication. App use of two weeks did not impact on older users' pain and self-efficacy outcomes. While these findings provided some

helpful insights regarding the feasibility of carrying out an app intervention study among older people, there was a need to qualitatively explore older people's experiences and attitudes regarding the use of an app in their everyday pain self-management practices.

5.9   Context for the qualitative sub-study

The qualitative sub-study (study 2b) sought to further explore the acceptability of a pain self-management app among older people by conducting semi-structured interviews with interested participants of the feasibility study.

5.10 Publication reference (qualitative sub-study)

The manuscript of this qualitative sub-study is currently submitted to the journal *Archives of Gerontology and Geriatrics* (Impact Factor: 2.611), a peer reviewed scholarly journal disseminating research and reviews concerning the fields of experimental gerontology and clinical and social geriatrics. The following section contains an edited version of the submitted manuscript.

5.11 Objective

To explore the attitudes and experiences of older people with chronic arthritic pain towards using an app for their pain management.

5.12 Study design

Study 2b is a qualitative semi-structured interview study. The details of the study methods have been described in Chapter 4.

5.13 Findings

Out of all study 2a participants (n=18) approached with an invitation to participate in this qualitative sub-study (study 2b), two (n=2) declined due to lack of time. Qualitative interview data was collected from 16 participants with a mean age of 73.2 (±5) years. The majority (89%) were female. The mean duration of the interview was 27 (±9) minutes, the majority (88%) of the participants were interviewed individually via telephone, while the remaining (n=2), who were a married couple, requested a combined interview. Data saturation was reached after 13 interviews.

Four themes emerged from the thematic analysis: (1) apps are valuable self-management tools, but they do have the potential for harm; (2) a pain self-management app needs to be

strictly relevant to the user; (3) clinician involvement is crucial when integrating an app into older people's pain self-management regime; and (4) pain self-management apps must be designed with the end user in mind.

5.13.1 Apps are valuable self-management tools, but they do have the potential for harm

Participants perceived that the app was a valuable platform to access pain self-management resources, information and instructions. Participants appreciated the accessibility of an app that contained a range of helpful pain self-management instructions to simplify everyday living with arthritis.

I have quite a lot of arthritis in my fingers... and gripping things is quite difficult for me. So there was a lot of information on that part of the app about putting a rubber band around a lid. (Participant 01, Female, aged 74)

The app was considered a helpful tool to diarise various aspects of the participant's pain self-management plan and assisted with monitoring progress and management planning. This recording and monitoring of progress helped participants to accurately gauge their pain thresholds and activity capacities and plan their management strategies accordingly.

I was able to think about the pain level and try and associate the pain level with the activities that I've used up during the day. That was a really good link, the fact to see if there is any correlation... I thought that was good, because if I could find that the pain was caused by certain activities that repeated themselves over time, then I could minimise those activities or do things differently. (Participant 19, Male, aged 72)

Participants' positivity for this novel application was balanced by some level of apprehension when considering the ongoing use of the app to manage their pain. Although participants perceived the progress monitoring feature of an app as useful, many expressed concerns that this could lead to an over-focus on pain and catastrophising behaviours.

It made me think more about the pain, that's really all. Which I normally don't do. (Participant 14, Female, aged 75)

If you are regulated by your pain then you can easily get obsessed with the monitoring of your pain. (Participant 17, Female, aged 75)

5.13.2 A pain self-management app needs to be strictly relevant to the user

Relevant to the user's self-management style and preferences

Participants suggested that a pain self-management app must be individualised to the specific type of arthritic pain so that the management strategies are tailored accordingly.

> *...whether it's going to be rheumatoid arthritis, or whether it's going to be something else... you need to be able to have a button that says, "select your relevant (sic, arthritis)," ...is yours osteo? Is it rheumatoid? (Participant 07, Male, aged 66)*

This suggestion extended beyond the overall orientation of the app, with participants perceiving that an app should have personalisation features to suit the user's preferences.

> *... it can't just be, like you said, a generic thing. Because people aren't generic. (Participant 11, Female, aged 71)*

Participants indicated that the ideal arthritic pain app ought to include interactive video(s) of their personalised exercise regime, which they believed would act as a reminder, and ensure better compliance with the exercise instructions provided by their clinicians.

> *Well, so the three things that would interest me more are about some exercise and some videos that I could actually watch and do so that it would prompt me to do a particular exercise... The physio verbally gives me a list of exercises I should do. By the time I get home, of the five (sic exercises), I've only remembered two. So, having the video of an exercise which would remind me to do the five rather than just the two that I can remember, would be helpful. (Participant 01, Female, aged 74)*

Participants indicated that these apps need to be personalised so that they took account of how long the user had experienced chronic pain, their baseline knowledge and skills level, and then tailored the information and instructions accordingly.

> *I really felt that I had all of those skills under my belt at this stage. I believe that that app would be a brilliant tool for someone in the early stages of their pain management. (Participant 09, Female, aged 76)*

Some participants mentioned that they felt no need to engage with an app for their pain management needs, however they were open to trying this approach.

I wouldn't see any need to have an app like that. I went to the app because I wanted to try something new. (Participant 02, Female, aged 76)

<u>Relevant to the user's context and environment</u>

Participants suggested that the app would be more relevant if it included research and resources that provided local context.

Most of the websites that they referred you to were overseas ones. I don't think that's much use to us. I'd prefer to have something from Australian research. (Participant 10, Female, aged 76)

Participants also suggested that a helpful app would signpost locally available services that could be used by older people for their ongoing arthritic pain self-management. This was essential as people often are unaware of where and how to seek assistance.

I often talk to people and they say – "I had a fall the other day and I should go and do some exercise" and they don't, because they don't know where to go... And if they talk to me, I can tell them this particular organisation in Adelaide runs these kind of strengthening exercises for people of our age. Join up, it's very good for you. (Participant 01, Female, aged 74)

Participants also considered it beneficial for an app to include information on novel and contemporary discoveries in the area of arthritic pain self-management delivered by a reputable source.

It could be quite good to have a doctor or somebody, who could talk to recent research. A rheumatologist who's doing this little video that tells you, there might have been a breakthrough somewhere in Argentina, where they have discovered that agave plant cures arthritis. (Participant 10, Female, aged 76)

5.13.3 Clinicians' involvement is crucial

Participants felt that their clinicians had a role to play when considering app integration into their routine pain self-management strategy.

I think if it would come from your own GP that he would entice the clients to do something different and to try out a few things until they feel comfortable with what they are doing. It would improve, especially when you get older and suffer from arthritis, your balance isn't there, your security in walking isn't there, and I think

little things that would need to be taken into consideration by your GP. (Participant 17, Female, aged 75)

The need for clinician involvement was expected beyond the time of first recommendation. Using an app's ability to store the user's assessment data and activity record, participants were open to sharing this data with their clinicians to receive timely and appropriate care, support and guidance.

Yeah, and my doctor's quite open to that kind of thing ... If I took it along and said, "Look, this is what it reads", I am sure he would find that helpful. (Participant 04, Female, aged 85)

I had never quantified my pain before. But now, when I go see a surgeon, I'll be able to say how it's changed over (sic, time). (Participant 13, Female, aged 68)

5.13.4 Pain self-management apps must be designed with the end user in mind

While participants found the trial app to be relatively easy to use, they offered a range of suggestions on how an app could be more user friendly and helpful to them.

Participants noted the challenges relating to vision and reading they faced when engaging with the app on a small screen.

Yeah and if the graphs were such that you could actually see how you were going, that then that would perhaps help. I might be more likely to use it. (Participant 12, Female, aged 66)

I found the reading was beyond my capabilities. Too much writing and too small writing. (Participant 19, Male, aged 72)

It was apparent that a pain self-management app ought to include a peer to peer engagement feature that would enable users to share their pain self-management experiences to better support one another.

If you could check with other people because it's not always necessarily a lot of people placed around you who've got it (arthritis). You need to be talking to other people from here, there or other places. You might be talking to someone who lives in a different climate who can say, "Do this or that," so I think that would be a helpful part of it. (Participant 04, Female, aged 85)

Furthermore, participants were also keen that the pain app ought to have an interactive push-notification feature to remind or prompt them to input their various assessment data.

A little email reminder or a text reminder would be good. "Do your exercise" or "Do your breathing" or "Assess your pain and activity" ... those kinds of things. (Participant 04, Female, aged 85)

5.14 Discussion

This study adds to the emerging empirical literature on the role of apps in assisting pain self-management process of older people. While older people found pain self-management apps to be a potentially valuable tool, they highlighted the need to ensure the app's content and usability features are relevant and value adding to the user. Various suggestions useful for future app development and integration were offered by older people.

In line with the growing evidence base on pain apps (Irvine et al., 2015; Jamison, Mei, & Ross, 2018), the older people in this study considered apps to add value to their everyday self-management practices. These older people appreciated being able to electronically diarise their symptoms and activity level, and being provided with relevant exercise instructions was also highly valued. While there is paucity of evidence in the area of pain self-management apps involving older people, trials conducted with younger populations have reported similar preferences and improved pain outcomes when using apps that offer pain education (Huber et al., 2017), symptom diarising (Huber et al., 2017; Jamison et al., 2018) and exercise and relaxation instructions (Huber et al., 2017). However, older people did express some concerns about the frequency of the assessment and recording of their chronic pain and feared that the app could inadvertently lead to them over-focusing on their pain. While there is evidence suggesting that regular self-assessment of symptoms of chronic conditions can provoke negative emotions (Ancker et al., 2015; Gucciardi et al., 2013), literature on regular assessment and diarising of pain symptoms among younger adults indicates no such apprehensions (Milton et al., 2013; Ranney, Duarte, Baird, Patry, & Green, 2016). Hence, while assessment and progress tracking of pain and activity may be a helpful feature for younger adult users, there is a need to acknowledge that producing such self-assessment data might evoke negative emotions among older users (Ancker et al., 2015).

Studies evaluating the use of apps among younger people for smoking cessation (Smith, Ploderer, Wadley, Webber, & Borland, 2017), weight loss (Tang, Abraham, Stamp, &

Greaves, 2015) and harmful drinking reduction (Milward et al., 2016) indicate that users value features such as ease of use, a well-designed interface, personal tailoring, contextualised advice and user networking capability. These preferences were echoed by the older people of the DigiTech Pain project, with suggestions that a pain self-management app ought to include personalisation features that match the user's pain type, preferences, and knowledge and skills level. The idea of personalisation is crucial if an app is to be adapted into a tool to facilitate pain self-management. Much different to the traditional method of information provision to people living with pain, the concept of self-management is based on the idea that an individual can learn to manage their health using their skills and resources, and become less reliant upon external agents (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Lorig et al., 1999). In this context, personalised learning is essential to meet the unique needs, interests and capacities of an individual user, while allowing them to exercise ownership and control over their experiences of engagement with the app (Green, Facer, Rudd, Dillon, & Humphreys, 2005; McLoughlin & Lee, 2010).

Furthermore, there was a strong desire among participants for access to information on evidence-based developments in the area of arthritis remedies and management. This suggestion seems particularly helpful as older people can be exposed to many different opinions and views on how they should be managing their pain, and conflicting general views on the efficacy of infinite possible remedies. Unfortunately, despite a lack of empirical support and even some reports of harm, there is a risk that older people will seek out such approaches if they do not find adequate symptom relief from conventional treatment approaches (Li, Forbes, & Byrne, 2018). The inclusion of evidence-based information on arthritis management could not only provide older people with reliable information on new scientific discoveries, but also minimise the risk of harm from engaging in potentially harmful remedies.

Although studies indicating older people's willingness to engage with smartphones for chronic pain management are emerging (Parker, Jessel, Richardson, & Reid, 2013; Richardson, Lee, Nirenberg, & Reid, 2018), older people in the DigiTech Pain project had mixed views regarding this approach. Our results indicated that some older people may have reservations about engaging with an app. Similar findings have been reported by some studies where older people expressed no interest in using a novel technology and struggled to think of a need for such an application in their own lives (Ancker et al., 2015; Grindrod,

Li, & Gates, 2014). This indicates that when considering app integration into an older person's pain self-management regime, clinician involvement is crucial. Clinicians have an important role in establishing the effectiveness of their patients' or clients' existing self-management strategies, and to assist their patients/clients in making an informed decision as to whether it would be useful for them to adopt an app-based self-management approach.

Older people noted that the recommendation or prescription of a pain self-management app use from their clinicians could serve as a validation for adoption of this modality. While clinicians' recommendations of a given therapy could have a key role in its adoption and use (Fyfe, Quinn, Kiraly, & Kernerman, 2016), the potential influence of the inherent power differential in the patient–provider relationship needs to be acknowledged (Alexander, Hearld, Mittler, & Harvey, 2012; Thom & Campbell, 1997). Promisingly, the chronic disease management approach continues to move away from the paternalistic model of providers as the experts and people living with chronic conditions as passive recipients of care and information, to a partnership-based model where people living with chronic conditions are considered active agents in managing their condition (Zangi et al., 2015). Nevertheless, caution should be exercised by clinicians in recommending apps to their older patients/clients, ensuring the principles of shared-decision making are adopted and due consideration is given to the older person's values and preferences (Chewning et al., 2012).

There was a level of openness observed among the participants when considering clinician involvement, with a desire to share their assessment data with their treating clinicians. While there are apps offering clinicians the ability to remotely monitor their patients/clients (Mosa, Yoo, & Sheets, 2012), and a corresponding willingness among patients/clients to share health assessment data with clinicians (Bietz et al., 2015), literature reveals that clinicians are not as interested in having such access (Bietz et al., 2015). This disinterest could partially be attributed to concerns relating to data overload, security and privacy challenges, liability issues and cost (Adhikari, Richards, & Scott; Levine, Richardson, Granieri, & Reid, 2014). While apps have the potential to be much more than mere data-gathering devices and can offer an integrated self-management data-sharing portal, health systems-level policies and support are required to outline how clinicians should manage and use such data.

Literature (Petrovčič, Taipale, Rogelj, & Dolničar, 2018) indicates that the unique challenges faced by older people such as poor hearing, vision and motor and cognitive skills may impact their mobile phone use. The participants of this study alluded to similar challenges and offered suggestions regarding improvement in the design aspects of the app to best suit their needs. While there is an established evidence base outlining the considerations to be made while developing devices for human–computer interaction for older people (Gao, Ebert, Chen, & Ding, 2015; Kobayashi et al., 2011; Leitão & Silva, 2012; Zhou, Rau, & Salvendy, 2012), it is important for developers of apps targeted at older people to adopt a participatory design process where the end users (older people) are involved throughout all stages of the app development. This is especially important as recent systematic reviews of pain apps report no evidence of older people's involvement in the design process of currently available apps (Bhattarai, Newton-John, & Phillips, 2017; Chiew, 2019).

Being aware of the versatility and adaptability of a smartphone, participants suggested the inclusion of features such as push notifications as reminders for data logging, and social networking features within the app. Despite older people's willingness to engage with such advanced features, the current state of pain self-management apps only extends to basic manual assessment data collection, and inclusion of some pain self-management related content (Bhattarai et al., 2017; Chiew, 2019; Zhao, Yoo, Lancey, & Varghese, 2019). As older people continue to engage with technologies such as apps, the next generations of older people (the "baby boomers") who have grown old with digital technology are likely to be even more familiar users. This reality should be considered as an opportunity to capitalise on advanced computing features of contemporary smartphone technologies, to broaden the capacity of future pain self-management apps while meeting the expectations of the next generation of older users.

Strengths and limitations

Several limitations of this study should be considered. Firstly, the study sample was relatively small, non-random, and limited to community-dwelling older people living with chronic arthritic pain within Australia. Therefore, the findings of this study may not be transferable to other settings (such as acute care), or older people from other geo-political or socio-economic regions. Secondly, there is a possibility of sampling bias as all participants of this study were predisposed to be supportive of and interested in app

technology for pain management. Finally, while this study has provided initial insights into the views of Australian older people on the integration of apps into their pain self-management strategies, further research is necessary to confirm or refute the study findings.

5.15   Conclusion

The increasing integration of smartphones and apps into the sphere of chronic disease self-management, coupled with increasing willingness among older people to engage with these technologies, offers opportunities to harness the ability of these modern-day approaches to help older people better manage their pain. A range of factors that should be considered when deciding on the integration of a pain self-management app into an older person's pain self-management strategy have been identified and discussed. It is hoped that the findings of this study will inform the development and integration of future pain self-management apps, where due consideration is given to the unique needs and preferences of older people.

This chapter has reported the results of the phase I feasibility study (study 2a) and the findings of the qualitative sub-study (study 2b), involving community-dwelling older people living in the community with arthritic pain. The following chapter reports the final study (clinician interview study) of the DigiTech Pain project, which explored the attitudes and perspectives of primary care and allied health clinicians on integrating a pain app into their older arthritic patients' pain self-management strategy.

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Chapter 6 Exploring primary care and allied health clinicians' views on integrating apps into older people's pain self-management strategy

6.1   Chapter preface

Chapter 5 reported the results of the phase I feasibility study (study 2a) and the qualitative sub-study (study 2b). The phase I feasibility study (study 2a) sought to better understand the feasibility and acceptability of trialling an app intervention among a cohort of community-dwelling older people living with arthritic pain. The qualitative sub-study (study 2b) explored the attitudes and experiences of study 2a participants on the use of a pain self-management app.

This chapter reports the findings of the second qualitative study of the DigiTech Pain project which was undertaken with primary care and allied health clinicians to explore their perspectives on the use of pain self-management apps to help their older patients/clients better manage arthritic pain.

6.2   Publication reference

This qualitative study was published in 2019 in *Pain Medicine* (Impact Factor: 2.782), a peer reviewed scholarly journal focusing on the area of pain management. This chapter contains an edited version of the published study exploring the perspectives of Australian primary care and allied health clinicians on the use of pain self-management apps to help their older patients/clients better manage their arthritic pain (Appendix 20).

Bhattarai, P., Newton-John, T. & Phillips, J. L. (2019). Apps for older people's pain self-management: Perspectives of primary care and allied health clinicians. *Pain Medicine, pnz218*, https://doi.org/10.1093/pm/pnz1218.

This qualitative study was featured in an article by the 'Australian Doctor Plus', an online platform sharing news summaries, opinion pieces and expert guidance (Appendix 21).

6.3 Background

As noted in Chapter 5, the interviews with older people living with arthritic pain who trialled a pain self-management app for two weeks suggested an openness towards this approach, and consideration of their clinicians' involvement crucial. While primary care and allied health clinicians have an important role in facilitating community-dwelling older people's pain self-management process, little remains known about their views and perspectives regarding integration of apps in this process. To fully understand the factors essential to consider in integrating apps into older people's pain self-management strategy, it is important to explore the perspectives of primary and allied health clinicians.

6.4 Objective

To explore the attitudes and perspectives of primary care and allied health clinicians regarding the integration of pain apps into their older arthritic patients' pain self-management strategies.

6.5 Methods

Study methods have been described in Chapter 4.

Participants are reported using the following key (Participant ID, Gender [M=Male, F=Female], age, Clinician type), for example, HP01, female, aged 56, GP. Clinician classification key: GP=General practitioner, Physio=Physiotherapist.

6.6 Findings

Data was collected from 17 primary care and allied health clinicians including GPs (n=4), physiotherapists (n=8), clinical psychologists (n=2), an osteopath (n=1), an emergency department physician (n=1) and a specialist pain physician (n=1) (Table 6.1). Participants were from across Australia with the majority based in NSW (n=10). Most participants were female (n=10; 59%), with a mean age 45.8 years (±10). Over half of the participants worked fulltime (n=11), and the mean years of practice was 20 years (±10). The mean duration of the interview was 23.4 minutes.

Table 6.1 Participant demographics

Characteristic	Classification	*N=17*
Gender		
	Female	10
	Male	7
Age		
	Mean (SD)	46 (±10)
	Median (IQR)	47 (21)
Discipline		
	Medicine	6
	Physiotherapy	8
	Clinical psychology	2
	Osteopathy	1
Years of practice		
	≤10 year	3
	10–20 years	6
	20–30 years	5
	>30 years	3
Highest level of education		
	Graduate Diploma	2
	Undergraduate	5
	Postgraduate	10
Employment status		
	Full-time	11
	Part-time	6
Practice setting		
	Public	6
	Private	9
	Community	2
Percentage of older patients/clients with arthritis		
	≤ 25%	5
	26%–50%	8
	> 50%	4

The overarching theme underlying participants' views on integration of apps into older people's pain self-management strategy was that this approach is an idealistic, but uniquely challenging endeavour. Four sub-themes emerged: (1) self-management apps are a potentially useful tool but require careful consideration; (2) clinicians' involvement is crucial yet potentially onerous; (3) no single app is right for every older person with arthritic pain; and (4) patient data access is beneficial, but caution is needed for real-time data access.

6.6.1 Self-management apps are a potentially useful tool but require careful consideration

With the increasing uptake of smartphones and adoption of app-based approaches in chronic disease self-management, most participants were positive about the integration of apps into older people's pain self-management strategies.

> *I think generally the concept of tools like apps being useful in self-management of chronic disease is definitely one that would seem to have traction. ... I can really see the potential in that. (HP01, male, aged 57, GP)*

Participants were open towards recommending a pain self-management app to their older patients.

> *I think I would (sic, recommend a pain self-management app), I guess I would have to know how aware they (sic, patients) are with technology and if they are using smartphones or not. I think if they were and they seemed like they are the right kind of person and they are interested to learn, I think I would definitely recommend it. (HP06, female, aged 30, GP)*

However, this positivity was accompanied by concerns about the challenges inherent in app use by an older population.

> *There are a lot of barriers to using apps... apps can be quite intimidating and overwhelming to the older person. A lot of my clients won't even let me assist them to set up an alarm on their phone for their medications, because it all sounds too difficult. So, I think there are a lot of barriers to successful use of an app. (HP11, female, aged 31, physio)*

App as an empowerment tool

The integration of apps into the pain self-management process was considered to empower older people by fostering a sense of responsibility and engagement.

> *Most people want something to do, they want to feel as though they are doing something actively towards helping their pain. And that (sic, using an app) is a way of engaging them in an activity that can help them get mastery, or at least help them feel like they are doing something towards their self-management. (HP02, female, aged 54, clinical psychologist)*

Participants considered apps to be a helpful educational tool that could facilitate digital delivery of point-of-care information and instructions to older people, instead of using paper-based action plans.

> *I guess in the past we've always relied on paper plans to sort of help guide people in what they do when things like say the Action Plan or the COPD Action Plan so I guess that sort of stuff could be incorporated into an app for arthritis in terms of like 'What symptom are you having' and 'What could you do about it?' It sort of could guide people in the same sort of way. (HP06, female, aged 30, GP)*

An app's ability to share data with clinicians was perceived as a potential motivator, which could improve patients' adherence to the self-management instructions.

> *If we could look at their (sic, patients') practices and they knew we could look at their practices, I think they might be more keen to engage (sic, in self-management). (HP10, male, aged 41, physio)*

Encompassed in this perspective was the understanding that apps could serve as a progress monitoring tool that could be used by clinicians to monitor their patients' progress.

> *It (app) can really record whether they've actually kept up with the exercise and the second thing might be if they did need stronger analgesia like opiates, it could help record whether they were actually becoming more functional from that because that's a marker of whether an opioid is useful and then opioid shouldn't be used if someone isn't more functional. So potentially I think an app could be very useful in monitoring progress. (HP01, male, aged 57, GP)*

Digital familiarity is still unmapped territory for older people

While participants seemed enthusiastic about the use of the app, they expressed some uncertainty about the suitability of an app-based pain self-management approach for older users. Participants acknowledged the increasing uptake of smart devices among older people; however they were unsure if this has yet translated into increased user engagement with apps.

> *A lot of older clients are getting mobile phones and smartphones, but of my clients who have a mobile phone, probably 60% of them only use it for calling or texting. Not many use it for its other features, and it can be quite overwhelming and intimidating to them to think about using an app. (HP11, female, aged 31, physio)*

However, there was an acknowledgement that this situation is continually changing, and that clinicians should be open to such engagements.

> *I think technology is underutilised (sic, among older people) … I am seeing more and more of my clients with mobile phones and smartphones… the proportion of my clients with mobiles that are over the age of even 70, over the age of 70, they have the phones there and I think, yeah, really we could be utilising it more. And we are an evolving kind of digital race so I think, yeah, we should be using it to our advantage. (HP11, female, aged 31, physio)*

The complexity involved in downloading and purchasing apps was raised as an important element in the context of user burden when considering app use by the older group.

> *It's not just about usability of it, it's the actual process: "Do I know my Apple ID and password or my Google ID and password? Ah. No, I don't know it. Now I need to reset it. I don't know how to reset it. Ooh, ooh, ooh. I'm getting scared. Wait, I don't have a credit card saved on my device. I haven't set up a credit card. I'm not putting my credit card details in, there's no way." You know. "Oh, I'm worried about a virus." All this stuff that comes with the mandatory download of something from an app store. (HP16, female, aged 33, physio)*

6.6.2 Clinicians' involvement is crucial yet potentially onerous

Participants perceived that integration of apps into older people's pain self-management regime will be taxing on clinicians' time. Involvement of clinicians was considered crucial in various stages of app integration.

Participants considered it crucial to assess their patients for suitability of app use.

> *Yeah, I think some people just shouldn't go down that rabbit hole because they are already there. They already over-focus on the negative: the pain. It is a very negative experience for them and if you give them an outlet to complain more about the pain, they will take it… I think you just have to be really careful with who accesses the app. (HP11, female, aged 31, physio)*

Participants also noted a range of factors they would consider if they had to identify and recommend a pain self-management app for their patient.

> *I think I would want to see a level of evidence-based endorsement, in the literature. So, I would be looking for… a clear endorsement of a particular app, from a recognised authority and some evidence base for it. (HP01, female, aged 52, GP)*

This meant that participants had to download the app and familiarise themselves with it before recommending it to their patients.

> *The problem with recommending an app for patients is you have to be familiar (sic, with the app). Making sure myself or other clinicians using an app will have adequate training to know all the functions. Because, if recommending things you don't necessarily agree with, then we probably shouldn't be recommending the app. (HP06, female, aged 30, GP)*

Consequently, time constraints in relation to app use were noted by participants.

> *Most of the work that I do with these apps is outside of the consultation time. I am finding myself needing more and more time at the end of the day. I'll finish meeting patients at 7 pm or 7.30 pm, and then I'll need another half an hour to an hour to put together the exercise prescription, then utilise the app. (HP09, male, aged 59, osteopath)*

In addition, clinicians were also cautious about the possibility of over scrutiny that could be posed by patient data access.

I guess for me, I don't want to become a parent in this, and I feel less likely to use that kind of function because I am moving them to take ownership. (HP02, female, aged 54, F, clinical psychologist)

6.6.3 No single app is right for every older person with arthritic pain

Participants reinforced the importance of personalising care and that no single pain management approach is right for everyone.

The ability of an app to offer personalisation in relation to self-management skills building was considered important.

Exercise should be tailored to the individual and if they're not there's a risk that (sic, they) could be doing something that's inappropriate. Probably around the types of exercise. The trouble with administering exercise for pain management is tailoring it to the right exercise and giving the right advice and seeing how to modify things if things aren't going well, or even if they are going well, how you progress. So, how activities are progressed and how they're tailored to the individual. (HP10, male, aged 41, physio)

This suggestion of personalisation extended to types of self-management strategies that are suitable and preferred by each user, suggesting that an app had the potential to be a companion tool that assisted older people to build their CBT and physical exercise-based skills. Integration of various elements of a CBT-based pain management approach such as goal setting, mindfulness meditation, thought management and physical activity and exercise into an app was considered useful to help older people better manage their pain.

Maybe some kind of goal setting with that. I would suggest physical activity of course, and then some way to track their progress toward that goal and maybe some reward system when they achieve that goal. Gold stars, or a medal, not an actual medal obviously, like an image of a medal, or a different level. Maybe they could have it like a platform computer game where you graduate to the next level if you achieve your goal. You guide them towards making a goal, and then they set a timeframe and maybe the app could take those two things. (HP05, female, aged 35, physio)

...things like meditation, mindfulness, relaxation, that side of it. Something like that in an app would be really great. (HP11, female, aged 31, physio)

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Instructional videos on how to, for example, recall and identify and challenge an unhelpful thought. A sort of video instruction on how to use the strategy. That would be helpful. (HP15, 56, M, clinical psychologist)

Apps were considered capable of offering prompts and motivation to exercise, provide accurate instructions on exercise, and be an exercise support and progress-monitoring tool for older people.

I think videos of the exercises are very useful because I do often go back to clients and as much as we write it out and draw it out for them, you do often go back and they have been doing it wrong or they have been a bit confused about it. So I think videos are a really useful tool. I think videos of the clients doing it themselves is even more useful. (HP11, female, aged 31, physio)

In addition, successful integration of apps was perceived to be very much dependent on the apps' user-friendliness, ease of use and intuitiveness.

I guess user-friendliness is probably the main thing. If it's not user-friendly then it is probably not going to be something that they (sic, patients) are going to engage with or continue using. (HP10, male, aged 41, physio)

Age related limitations and challenges such as poor vision and dexterity were also considered important when thinking of suggesting an app to an older person.

Some patients in this demographic you are addressing have limited ability to manipulate a handheld device to work some of these things, so that's a bit of a catch 22. (HP09, male, aged 59, osteopath)

You need to make sure that you make your text really large. (HP16, female, aged 33, physio)

6.6.4 Patient data access is beneficial, but caution is needed for real-time data access

The capability of apps to collect (manual entry and automatic) and share various patient assessment data was perceived to be beneficial. Participants were interested in a range of different data points.

…quite accurate measure of activities and also the pain relief and a quite accurate picture of how much pain relief and when they are taking it… It's also quite useful to know what's happening to people's activity levels and what they do with their pain.

So, for example – you can see that people's movements going up, and mood decreasing, and at the same time the pain is increasing. That leads you down the set of ideas that what happens if the pain was going up and down? Then that leads you down a certain set of ideas. That would be really useful. (HP03, male, aged 47, GP)

However, participants were mindful of the possibility of data overload that might be brought on by this level of data sharing from the app, especially with the real-time data sharing feature.

You wouldn't want to be in the position where you were having lots of data sent your way that you are meant to be looking at outside consultations. If you weren't being appropriately reimbursed. GPs are not going to go for that. (HP13, female, aged 57, GP)

This concern was quite prominent when participants considered the prospect of real-time data sharing.

It's probably something that sounds like a good idea but realistically I don't know if you would really have time to make use of it. I think the real-time, I don't know, I just can't imagine, I don't know if I would be able to look at it outside of my allocated clinic time. I don't know if there would be any particular advantage to real-time data. (HP05, female, aged 35, physio)

Consequently, most participants wished to access (and review) aggregated patient data, preferably during the consultation.

I find summaries of recent data much more useful, so what I mean is – I don't know what people are doing on a day to day basis, but that doesn't really tend to give me anything that I need to know. But having a summary of what happened is useful. (HP03, male, aged 47, GP)

Because it's only relevant to me when I'm seeing the patient. It's good enough for them to bring it with them to the consult. (HP15, male, aged 56, clinical psychologist)

6.7   Discussion

This study adds to the growing empirical literature on the use of pain self-management apps. Various factors that should be considered before and during the integration of apps into older people's pain self-management strategy from the perspectives of primary care

and allied health clinicians have been identified, many of which have not been previously reported.

In line with the growing evidence on the role of apps in self-management of various chronic illnesses (Miller, Cafazzo, & Seto, 2016; Whitehead & Seaton, 2016), participants of this study perceived apps to be useful in facilitating the pain self-management process of older people. Patient empowerment is considered one of the critical elements of any self-management intervention (Aujoulat et al., 2008). Apps were considered able to empower older users by helping them assume responsibility of care and become more knowledgeable, and subsequently committed to their treatment regimens (Aujoulat et al., 2008). However, this optimism was accompanied by a feeling of ambivalence when considering the digital familiarity of older people. These concerns on the low-level proficiency in app download and use among older people reflect the published literature with studies conducted in the USA (Pew Research Center, 2012), Hong Kong (Shen et al., 2017) and Germany (Rasche et al., 2018) attributing this to the low level technical readiness and computer literacy prevalent among the elderly (Rasche et al., 2018; Shen et al., 2017).

Growing concerns about the quality of health related apps is known to cause uncertainty among clinicians in recommending these apps to their patients (Wyatt, 2018). An app's ability to be a good vehicle of electronic information and instruction relay makes it useful, but at the same time it highlights the concern among clinicians about the quality of the app's content (McMillan, Hickey, Mitchell, & Patel, 2015). Participants of this study similarly felt a need to personally evaluate the evidence base and the credibility of the developer and endorser of the app. Consequently, the pressure this puts on clinicians' existing workload was a reasonable concern. This concern resonates with reports in the literature (Karduck & Chapman-Novakofski, 2018; Lieffers, Vance, & Hanning, 2014) indicating that making apps mainstream demands a considerable time commitment from clinicians. The literature also points towards the potential risks of this modality (Wyatt, 2018), indicating a need for individualised suitability assessment before an app is recommended to patients and confirming the perception of the clinicians of this study. However, when considering older people with a possibility of cognitive decline, a preliminary assessment on commencement of app use may not suffice, requiring ongoing technical support and regular assessment of patients' ability to engage.

Ease of use requiring minimal effort is a preferred design feature of disease self-management apps (Boulos, et al., 2014; Hilliard, Hahn, Ridge, Eakin, & Riekert, 2014), including pain apps (Ledel Solem et al., 2019). However, when considering older users, this concept extends beyond intuitive and user-friendly design to considerations of unique needs related to aging (Boulos et al., 2014; Zhou, Rau, & Salvendy, 2012). This view was confirmed by the participants of this study with recommendations regarding the inclusion of exercise personalisation features. While the recent guideline on arthritis management stipulates the value of personalised regular physical exercise (Osthoff et al., 2018), lack of access to a personal coach or ability to develop one's own personalised training regime remains a well-known barrier to exercise engagement (Joseph, Ainsworth, Keller, & Dodgson, 2015; Thorpe, Johnston, & Kumar, 2012). Given this reality, apps with advanced personalised exercise prescription features may be able to offer an acceptable way of facilitating evidence-based physical exercise therapy to older people. Furthermore, the clinicians' suggestion of integrating various CBT-based approaches into apps is largely aligned with the published evidence on elements of a comprehensive pain self-management plan (Lorig, Ritter, Laurent, & Plant, 2008; Lorig, Ritter, Moreland, & Laurent, 2015).

An app's potential to share patient data with clinicians has been widely lauded in the context of chronic disease self-management (Boulos, et al., 2011; Heron & Smyth, 2010), where regular communication with and support from clinicians is considered beneficial. Previous studies exploring the views of people with chronic conditions (Boulos et al., 2014; Peng, Yuan, & Holtz, 2016) and primary care providers (Levine, et al., 2014) on the data sharing features of apps have similarly valued this capability. In line with this evidence, the participants of this study also perceived access to patients' data to be beneficial in their care planning and provisioning process. The data points of interest to the clinicians were mostly related to the assessment and documentation of pain and analgesia intake, and physical activity tracking, which also confirms the reports of the literature (Levine et al., 2014). As clinicians play a pivotal role in helping patients accept and adhere to pain self-management treatments and plans (Jensen, Nielson, & Kerns, 2003), their interest in patients' self-management activity related data is understandable.

However, this openness towards data access was correspondingly balanced by some level of caution. In line with previously published literature (Levine et al., 2014), clinicians were cognisant of the challenges of potentially unlimited access to patient data, including the need to consider its value and systems for its management (Vedel, et al., 2013). In addition,

there was some uncertainty regarding how this level of data access by clinicians could impact patients and their behaviours. Although patients in general are open to sharing their self-assessment data with clinicians via an app (Boulos et al., 2014; Peng et al., 2016), some researchers consider clinicians' ability to scrutinise their patients' actions and communications on a very fine-grained level to be unnecessarily intrusive (Di Matteo, et al., 2018). Pain app studies involving older people who use the data sharing features of apps are needed to better understand this area.

Strengths and limitations

Several limitations of this study should be considered. Firstly, the sample was small, non-random, and limited to primary care and allied health clinicians within Australia. Therefore, the findings may not be transferable to other settings, or areas with different data accessibility patterns and laws. Secondly, the profession-specific breakdown of the sample is uneven with small numbers of participants from some disciplines and higher numbers from others. Therefore, these findings reflect the collective perspective of primary care and allied health clinicians, rather than the perspective of a single discipline. Finally, although there was nothing in the data to suggest a selection bias, we cannot discount the possibility that providers who chose to take part may have differed in some important ways from those who did not participate. For example, recruited clinicians may have had a greater affinity with technology, or view the implementation of mHealth strategies more positively, than those who did not take part.

6.8 Conclusion

This chapter has reported the findings of the qualitative interview study conducted to understand primary care and allied health clinicians' perspectives on use of a pain self-management app by their older patients and clients for arthritic pain self-management. The findings of this study indicate that a range of factors should be considered before and during implementation of a pain self-management app in older people's pain self-management regime. There is a possibility that apps could offer a cost-effective and time-efficient method to assist primary care and allied health clinicians in planning and provisioning pain self-management processes for their older patients, while also improving patient outcomes.

The following chapter (Chapter 7) reports the integration of the mixed methods data generated by the DigiTech Pain project's five discrete studies (studies 1a, 1b, 2a, 2b and 3) to answer the research questions posed in Chapter 1.

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Chapter 7   Conclusion and recommendations

7.1   Introduction

As described in Chapter 1, the catalyst for the DigiTech Pain project was the interest in exploring the opportunities to use digital health technologies as part of older people's arthritic pain self-management process. A detailed account of the evidence for the use of digital health technology by older people living with pain was presented in Chapter 2. The integrative review reported in Chapter 2 found that few studies had evaluated the role of apps in assisting older people to better manage their arthritic pain at home (Bhattarai & Phillips, 2017). Similarly, the systematic review reported in Chapter 3 found that pain apps are rarely informed by self-management theories or evidence, and do not adopt a comprehensive self-management approach (Bhattarai, Newton-John, & Phillips, 2017). Given this reality, a thorough exploration of the feasibility and acceptability of a pain self-management app to assist community-dwelling older people better manage their arthritic pain was warranted. Chapters 5 and 6 presented the results of the three discrete studies undertaken to explore the relevance, usefulness or effectiveness of pain self-management apps for older people living with arthritic pain.

This final chapter integrates the mixed methods data generated by the DigiTech Pain project's five studies to answer the research questions posed in Chapter 1. The technology acceptance model 2 (Venkatesh & Davis, 2000) was used to guide the data integration and meta-analysis of the DigiTech Pain project. The joint display tables produced for each research question are included to clearly demonstrate the data integration process.

7.2   Research question 1: What is the evidence on the use of digital health technologies for older people's arthritic pain management?

The data from the integrative review (study 1a) (Bhattarai & Phillips, 2017) and the app systematic review (study 1b) (Bhattarai et al., 2017) was integrated to answer the research question: *What is the evidence on the use of digital health technologies for older people's arthritic pain management?* The data integration summary is presented in the joint display table (see Table 7.1).

Table 7.1 Joint display table of data integration for research question 1

Research question 1: What is the evidence on the use of digital health technologies for older people's arthritic pain management?				
Domain	**Integrative review (study 1a)**	**Systematic review (study 1b)**	**Data convergence**	**Meta-inference (Review inference)**
Types of pain management digital health technologies that have been evaluated	The most common pain management interventions identified for older people were computer-based videos (n=7). One study evaluated the role of a digital pen for pain assessment (n=1). Another study (n=1) explored older people's view on using a smartphone to help them manage their chronic pain.	Out of 433 identified pain self-management apps, very few (n=4) included the features considered essential to assist older people better manage their arthritic pain. None of the identified apps had undergone any form of empirical evaluation.	Enhance	There is a paucity of studies evaluating the role of pain self-management apps for older people. Little is known about which self-management features in an app are helpful to older people.
Evidence base of the digital health technologies	The computer-based video interventions were delivered as live broadcast, videotape and/or animation. They involved a combination of educational, interactive or instructional components. The only non-computer intervention evaluated the use of a digital pen for ongoing pain assessment.	Of the 433 chronic pain apps identified, only four apps included some features that align with the empirically validated Stanford Program (Lorig, Ritter, Laurent, & Plant, 2008; Lorig, Ritter, Moreland, & Laurent, 2015). Included features were (i) symptom awareness (pain assessment and documentation) and (ii) symptom management (pain management). The included apps provided education on pain self-management and medication use, and information on physical exercise and Cognitive Behaviour Therapies. The content of these apps could not be personalised, with no opportunity for the older person to share assessment data with, or seek real-time input from, their treating clinicians.	Enhance	While empirically tested digital health interventions included various elements of pain self-management, no single intervention addressed all of the elements of the Stanford Program (Lorig et al., 2008; Lorig et al., 2015). The currently available pain self-management apps are not based on self-management theories and/or have been robustly evaluated. The app content and functionality is basic, with no opportunity for bidirectional flow of information between the older person and their treating clinicians.

Research question 1: What is the evidence on the use of digital health technologies for older people's arthritic pain management?

Domain	Integrative review (study 1a)	Systematic review (study 1b)	Data convergence	Meta-inference (Review inference)
Impact of digital health technologies on pain outcomes	There is insufficient evidence demonstrating the effectiveness of digital health technologies in reducing older people's pain intensity and/or pain interference ratings.	None of the apps identified in the systematic review reported being trialled among older people living with arthritic pain.	Enhance	There is limited evidence of efficacy of digital health technology interventions, including apps, to assist older people better manage their arthritic pain at home.
Adoption of digital health technologies	There is emerging evidence that older people are willing to use digital health technologies for pain management, but they have concerns about battery life, cost, lack of familiarity and poor user-friendliness of the devices.	The currently available pain self-management apps have given very little consideration to older people's age related challenges such as poor vision and dexterity. Three of the four included apps had below moderate level usability score (≤ 3). None of the apps reported having engaged older people in the app development process.	Enhance	Older people are open to engaging with digital health technologies for pain management. However, current pain self-management apps have not included older people in the design and development process or attempted to address their unique usability needs.
Facilitators of digital health technologies adoption	Close contact with treating clinicians via sharing of pain assessment data is an important facilitator of adoption of digital health technology by older people.	None of the current pain self-management apps had the capacity for electronic health information exchange between older people and their clinicians.	Enhance	While digital health technology's data sharing ability facilitates its adoption among older people, none of the current pain self-management apps offer a unidirectional or bidirectional data sharing feature.

The integrative review (study 1a) and the systematic review (study 1b) undertaken as part of the DigiTech Pain project confirm the paucity of evidence in the area of digital technology adoption for pain management of older people. No studies evaluating the use of apps to help older people better manage their arthritic pain were identified.

The number of older people living with chronic persistent pain is increasing globally (Fayaz, Croft, Langford, Donaldson, & Jones, 2016; Zimmer & Zajacova, 2018). The consistent rise in healthcare costs has led to a growing interest among clinical and academic experts in integrating mobile technologies to assist in the care and management of chronic pain (Bacon et al., 2018; Wethington et al., 2018). Despite this interest, the DigiTech Pain project did not identify any study evaluating an app for pain self-management of older people. Studies involving digital health technology for pain management of older people were primarily computer-based video information and/or instruction (Bhattarai & Phillips, 2017).

However, overall research interest in pain self-management apps is growing (Chiew, 2019; Lalloo, Jibb, Rivera, Agarwal, & Stinson, 2015; Zhao, Yoo, Lancey, & Varghese, 2019). A number of studies have evaluated the role of apps in helping younger people (people under the age of 65 years) self-manage their pain (Grasaas et al., 2019; Irvine et al., 2015; Jibb et al., 2017). Few studies have focused exclusively on the needs of older people who are less digitally literate. A recent systematic review (Thurnheer, Gravestock, Pichierri, Steurer, & Burgstaller, 2018) evaluated the efficacy of apps in the management of any type of pain across all ages. While this review included 15 studies, only one study had a mean participant age over 65 years (Thurnheer et al., 2018). Currently, there is disproportionately more research in the area of pain self-management app use among younger people (Thurnheer et al., 2018). Interest in investigating the use of apps by older people to manage their pain is growing, as evidenced by a recently published study protocol (Fanning, Brooks, Ip, Nicklas, & Rejeski, 2018).

Despite this interest, the DigiTech Pain project identified that the currently available pain self-management apps are limited in their functionality, features and older people specific usability (Bhattarai et al., 2017). Other more recent systematic reviews have also identified the limitations of many pain self-management apps to share basic pain assessment data between older people and their treating clinicians (Zhao et al., 2019) and minimal involvement of older people and clinicians in the app design and development process (Chiew, 2019). Both of these gaps are noted barriers to the adoption and usefulness of health

apps (Jamison, Jurcik, Edwards, Huang, & Ross, 2017). As the ownership rates of smartphones continue to grow among older people (Office of the eSafety Commissioner, 2018; Pew Research Center, 2017b), older people are becoming increasingly keen to engage with smartphones and apps for pain self-management (Parker, Jessel, Richardson, & Reid, 2013; Richardson, Lee, Nirenberg, & Reid, 2018). Given this reality, the lack of involvement of older people in the design and development of pain self-management apps, and the current low-level functionality and usability of these apps, indicates a missed opportunity. As the recent mHealth research agenda (Wethington et al., 2018) notes the need to explore, understand and harness the adaptability and versatility of mHealth devices (including apps) to assist pain self-management processes, there is a need for inter-sectorial collaboration in future pain self-management app research and development work.

Summary

- Older people living with arthritic pain ought to be involved in the design and development of future pain self-management apps to ensure the content quality and usability of apps meet end user requirements.
- Collaboration among app developers, researchers, clinicians and older people is necessary to develop a robust, evidence-based and person-centred pain self-management app.

7.3 Research question 2: What is the feasibility and acceptability of undertaking an app intervention study involving community-dwelling older people living with arthritic pain?

Data from studies 2a and 2b was integrated to answer research question 2: *What is the feasibility and acceptability of undertaking an app intervention study involving community-dwelling older people living with arthritic pain?* Study 2a (quantitative data) evaluated the feasibility of a two-week trial use of a pain self-management app among older people living with arthritic pain. Study 2b (qualitative data) explored the attitudes and experiences of older people with arthritic pain who trialled the pain self-management app in study 2a. Research question 2 of the DigiTech Pain project addressed recruitment, data collection and response to the intervention aspect of feasibility. An overview of the data integration is presented in the joint display table (see Table 7.2).

Table 7.2 Joint display table of data integration for research question 2

Research question 2: What is the feasibility and acceptability of undertaking an app intervention study involving community-dwelling older people living with arthritic pain?				

Domain	Quantitative data (study 2a) (QUAN)	Qualitative data (study 2b) (QUAL)	Data convergence	Meta-inference
Recruitment				
Approach methods	Reaching community-dwelling older people with arthritis via social clubs and organisations for digital technology research participation is challenging. The majority (70%) of approached clubs declined involvement in the DigiTech Pain project. The most successful recruitment strategy was 'snowballing', with the majority (87%) of older people approached keen to participate.	Not applicable.	Not applicable	Pain app studies aiming to recruit community-dwelling older people with arthritic pain should prioritise snowballing recruitment approaches for higher recruitment success.
Screening to recruitment	Of the 102 older people who were invited to participate, only a third (n=36) met the study inclusion criteria. Over three-quarters of those eligible to participate agreed to participate (n=28), however only half (n=18) could be recruited due to device/software mismatch issues such as incompatible handset or older version software. The screening to recruitment ratio was 6:1.	Nearly all (94%) of study 2a participants contributed to the qualitative interview study (study 2b).	Enhance	It is challenging to identify community-dwelling older people living with arthritic pain who own and use a smartphone. However, once these individuals are identified they seem keen to participate in an app intervention study.
Obstacles to recruitment	Smartphone and app incompatibility prevented recruitment of 30% of interested and eligible older people into the study. Many older people were using older version hardware and/or	Nearly all (94%) of study 2a participants contributed to the qualitative interview study (study 2b).	Enhance	A sub-section of older people are keen to participate in arthritic pain app studies. However, rapid smartphone (hardware and software) evolution coupled with

Research question 2: What is the feasibility and acceptability of undertaking an app intervention study involving community-dwelling older people living with arthritic pain?

Domain	Quantitative data (study 2a) (QUAN)	Qualitative data (study 2b) (QUAL)	Data convergence	Meta-inference
	software, which prevented them from participating in the study.			apps needing to keep up with these changes to remain functional, resulted in frequent device/software and app mismatch. This mismatch needs to be addressed in future app studies involving older people, especially if the researchers are not the intervention app developers or owners.
Telephone and email facilitated recruitment	All participants were offered a face-to-face or telephone meeting to facilitate consent, app download/training, and pre-test data collection. Participants from Sydney and Adelaide metropolitan areas were offered a face-to-face visit. Participants outside these areas were offered a telephone meeting due to logistics. Most participants were recruited via a face-to-face meeting (59%). The remainder (41%) were recruited via telephone and email.	As per study 2	Confirm	Recruitment of older people to studies using tele and electronic communication is feasible, but a face-to-face approach is preferred.
Data collection				
Telephone based data collection	The majority of participants provided the pre-test data during the face-to-face meeting. None of the participants who lived outside the recruitment area declined to participate and/or	All participants were interviewed via telephone. None of the interviews were impacted by common aging related	Confirm	Telephone based data collection is acceptable to older people, who consent to be involved in a community-based app study.

Domain	Quantitative data (study 2a) (QUAN)	Qualitative data (study 2b) (QUAL)	Data convergence	Meta-inference
	withdrew from the study due to lack of a face-to-face meeting option. Pre-test data: 59% via face-to-face survey and 41% telephone survey. Post-test data: 100% via telephone. Data collection procedures were not impacted by common aging related limitations such as hearing impairment or cognitive changes.	limitations such as hearing impairment or cognitive changes.		
Missing data	There was no missing data in the pre-test survey, with 59% of the data collected during a face-to-face meeting and the remainder (41%) collected via phone. In the post-test assessments, two participants (11%) had missing responses to some post-test assessment questions. All post-test data was collected via phone.	All participants completed the qualitative telephone interview.	Confirm	Data collection via a short survey and a telephone interview is acceptable to older people living with arthritic pain who consent to participate in a community-based app study.
Appropriateness of intervention				
Telephone-based app download and training.	85% (n=11) of participants preferred a face-to-face meeting over a telephone meeting for the intervention app download and training. Less than half (41%, n=7) of the participants were happy to receive app download training and guidance over the phone.	Participants found the app easy to navigate and use following brief training. *Nobody helped me ... It (app) was very simple to use. (Participant 14, female, aged 75).*	Enhance	Older people prefer to receive face-to-face guidance on app download and use, rather than via telephone. However, a telephone-based approach was acceptable and adequate in enabling older people's

Domain	Quantitative data (study 2a) (QUAN)	Qualitative data (study 2b) (QUAL)	Data convergence	Meta-inference
				successful engagement with a pain self-management app.
Attrition	Only one participant withdrew from the study due to unexpected overseas travel.	One participant did not take part in the interview, due to lack of time.	Confirm	An easy to use simple pain self-management app is well accepted by older people living with arthritic pain.
Engagement	All participants reported using the app during the trial period .	Participants found the intervention app was simple and easy to use. *I found it (app) quite simple. I think it's good that the (app) icons are big enough. And it's easy to define, it was easy to say, I know what that one does and what that one does (Participant 07, male, aged 66).*	Confirm Enhance	Older people living with arthritic pain are willing and able to use a simple pain self-management app.
Appeal of the intervention	None of the participants had ever previously used a pain self-management app. Despite this lack of experience, all the participants were open to trialling an app that assists them to better manage their arthritic pain.	Some participants found the app helpful in their pain self-management process. *I found it quite useful to go in (to the app) and put the pain level, activity level, and make the little graph. I can look back (in the app) and see when the pain was up and down… (Participant 04, female, aged 85).* However, other participants found little use for an app. *… I have already done so much research (on pain self-management). So, for me to*	Enhance	Older people living with arthritic pain welcomed the opportunity to trial a self-management app. However, wider and longer-term adoption may depend on the perceived usefulness and ease-of-use of the pain self-management app.

Research question 2: What is the feasibility and acceptability of undertaking an app intervention study involving community-dwelling older people living with arthritic pain?				
Domain	Quantitative data (study 2a) (QUAN)	Qualitative data (study 2b) (QUAL)	Data convergence	Meta-inference
		use that in the app, it's most probably just providing the same information to me that I have found elsewhere before (Participant 07, male, aged 66).		
Response to the intervention				
Changes in outcome variables	No significant differences were observed between participants' pre and post-test: pain severity (p=0.16), pain interference (p=0.14), pain self-efficacy (p=1.0), and online technology self-efficacy (p=0.4) scores. In terms of directionality, pain severity scores decreased from pre to post-test time point with increase in the proportion of participants with nil-mild pain from pre-test (56%) to post-test (71%) time point; and a corresponding decrease in the proportion of participants with moderate-severe pain from pre-test (44%) to post-test (29%) time point.	Not applicable	Not applicable	There is inconclusive evidence that use of a pain self-management app leads to improvement in older people's pain and self-efficacy outcomes. However, these findings are based on a small sample size which may have limited the ability to detect a difference.

7.3.1 Recruitment

As detailed in Chapter 5, it was challenging to recruit older people with arthritic pain through community-based clubs and organisations into the DigiTech Pain project. The approached community clubs and organisations' disinterest in sharing information about the app trial prevented older, potentially eligible, members from being informed about the study, limiting their opportunity to participate (Ford et al., 2008). A conceptual model for clinical trial recruitment developed by Ford et al. (2008) notes that for an individual to accept or refuse participation in a clinical trial, they must first be aware that the study is being conducted and must have an opportunity to participate. The numerous challenges associated with recruiting older people into clinical studies are well documented (Ridda, MacIntyre, Lindley, & Tan, 2010; Witham & McMurdo, 2007). These challenges include older people's cognitive difficulties, self-imposed ageism, fear of harm and multi-morbidities. While these challenges remain, the DigiTech Pain project found snowballing to be a much more successful recruitment approach, even when the recruitment was conducted via telephone or electronic communication.

The success of a snowballing recruitment approach in the DigiTech Pain project compared to cold calling older people through specific clubs and organisations, or Facebook-based open invitations, was understandable given the wellness focused approach of this project. As noted in Chapter 4 the DigiTech Pain project adopted a self-management based viewpoint where the older person maintains wellness within their illness symptoms (Lorig & Holman, 2003; Lorig, Ritter, & Plant, 2005). The target population for the DigiTech Pain project were community-dwelling older people who (quite likely) were managing their pain relatively well, and not clinic or hospital-based patients who were treatment seeking. There is a possibility that, despite increasing smartphone uptake among older Australians (Office of the eSafety Commissioner, 2018), community-dwelling older people living with arthritic pain who are also technologically savvy are a small but unique group. Given this context, the success of a snowballing recruitment approach in the DigiTech Pain project is understandable. Snowballing is known to help access "hard to reach" populations primarily because the knowledge of insiders is helpful for locating potentially eligible participants (Atkinson & Flint, 2001; Waters, 2015).

Summary

- Future pain self-management app studies involving community-dwelling older people ought to consider prioritising a snowballing recruitment strategy over other recruitment approaches to reach the target population.

7.3.2 Data collection

The DigiTech Pain project has confirmed that conducting telephone-based surveys and/or telephone interviews is an acceptable way of collecting data from older people who consent to be involved in a community-based app study. Telephone-based surveys and semi-structured interviews are considered to be a valid and cost-effective data collection method (Block & Erskine, 2012; Musselwhite, Cuff, McGregor, & King, 2007; Worth & Tierney, 1993). These data collection methods have been widely adopted by other studies involving older people (Gill, Gahbauer, Han, & Allore, 2015; Rantakokko et al., 2016). Telephone surveys and telephone interviews also have cost and time saving advantages compared to a face-to-face approach. However, caution should be applied when considering telephone-based data collection involving older people who are known to have high prevalence of hearing impairment and cognitive changes (Worth & Tierney, 1993).

Summary

- Data collection using telephone-based surveys and/or interviews in app studies involving older people is feasible and a low-cost methodology worthy of consideration.

7.3.3 Response to the intervention

The DigiTech Pain project confirms that while a simple, user friendly pain self-management app is acceptable to older people, longer-term app use may depend on its perceived usefulness. This finding is in line with the growing body of evidence which indicates that older people are willing and able to engage with smartphones and apps if the app can assist them better self-manage their pain (Currie, Philip, & Roberts, 2015; Levine, Richardson, Granieri, & Reid, 2014; Parker et al., 2013). However, a recent literature review reporting older people's mHealth adoption behaviours identified four different kinds of barriers: cognitive, physical, perception and motivational (Wildenbos, Peute, & Jaspers, 2018). While these barriers were not apparent in the DigiTech Pain project, future pain self-management

app studies ought to consider strategies to address these four adoption barriers to achieve seamless integration of the app.

Furthermore, older people's successful engagement with the app used in the DigiTech Pain project was dependent on the app download, installation and use guidance provided by a digital native ('expert'). While telephone guidance is acceptable to older people, their preference was for this guidance to be provided face-to-face. This preference reflects digital inequalities which occur as a result of a person or population's digital literacy and skills, and patterns of engagement with technology (Scheerder, van Deursen, & van Dijk, 2017; Van Deursen & Helsper, 2015). While the DigiTech Pain project did not compare the digital literacy and skills of older people with their younger counterparts, evidence indicates that older people are slow adopters of new technology (Pew Research Center, 2017a). Older people have low levels of digital literacy and skills and often only lightly engage with mobile technologies (Bol, Helberger, & Weert, 2018). Therefore, the inclusion of initial support for the download and set-up of the app, and app use training, is an essential enabler for any future app-based intervention studies involving older people.

Evaluating these findings within the context of Bandura's self-efficacy theory (Bandura, 1977, 1997b), the above noted findings reflect low level self-efficacy among older people when it comes to downloading, installing, and using a new app. Literature indicates that low level self-efficacy in using a technology indicates poor engagement (He et al., 2018). As the adoption of Bandura's elf-efficacy theory (Bandura, 1977, 1997b) in DigiTech Pain project relates to older people's personal judgements of their capabilities in performing pain self-management activities facilitated by or aided by the pain self-management app, the low level efficacy in engaging with pain self-management app itself indicates the need to strengthen and support older people's confidence in using apps, before these apps could facilitate or enhance older people's pain self-management behaviours.

Summary

- Face-to-face training on app use, app download and installation support provided by a digital native is a *must* for future app studies involving older people

7.4 Research question 3: What are the features that older people and their treating clinicians consider most relevant in a pain self-management app?

Data from studies 2b and 3 was integrated to answer research question 4: *What are the features that older people and their treating clinicians consider most relevant in a pain self-management app?* Study 2b (qualitative data) explored attitudes and experiences of older people with chronic arthritic pain towards using a pain self-management app, while study 3 (qualitative data) explored the attitudes and perspectives of primary care and allied health clinicians on the integration of pain apps into their older arthritic patients' pain self-management strategies. The detail of data integration is presented in the joint display table (see Table 7.3).

Table 7.3 Joint display table of data integration for research question 3

Research question 3: What are the features that older people and their treating clinicians consider most relevant in a pain self-management app?

Domain [Alignment with TAM 2] (Venkatesh & Davis, 2000)	Qualitative data (study 2b) Participants=Older people	Qualitative data theme and sample quote (study 3) Participants=Clinicians	Data convergence	Mixed methods inference
Prompt motivation [Ease of use]	In order to facilitate ease of use, older people wanted pain self-management apps to provide them with notifications and reminders at set intervals to use the app. [Facilitate ease of use] *A little email reminder, or a text reminder (from the app) would be good. "Do your exercise" or "Do your breathing" or "Assess your pain and activity" ... those kinds of things (Participant 04, female, aged 85).*	Clinicians felt that a pain self-management app ought to include reminders for self-management activities and app engagement [Facilitate ease of use] *So, you just get a pop-up window every morning (from the app) that says, do these exercises, the window stays up until you click on it, and it goes away. And by just clicking on it, that automatically gets registered so it's simple for the patient" (HP 14, male, aged 36, GP)*	Confirm	Both older people and clinicians wanted a pain self-management app to include features that encourage self-management behaviours while making it easy to engage with the app.
Older people specific needs [Ease of use]	Older people noted that aging related challenges such as poor vision limited the extent of their engagement with the app. App features that mitigate such limitations were preferred by older people. [Facilitate ease of use] *Yeah and if the graphs were such that you could actually see how you were going, that then that would perhaps help. I might be more likely to use it. (Participant 12, female, aged 66).*	Clinicians suggested that a pain self-management app should consider aging related limitations prevalent among older people living with arthritic pain. [Facilitate ease of use] *Some patients in this demographic you are addressing have limited ability to manipulate a handheld device to work some of these things, so that's a bit of a catch 22 (HP09, male, aged 59, osteopath).*	Confirm	The design and functionality of a pain self-management app should accommodate the aging specific needs of older people.
Support pain self-management activities	Older people wanted pain self-management apps to be supportive of the self-management	Clinicians felt that pain self-management apps ought to support older people's self-management activities.	Confirm	Features and inclusions of a pain self-management app should support self-management

Research question 3: What are the features that older people and their treating clinicians consider most relevant in a pain self-management app?

Domain [Alignment with TAM 2] (Venkatesh & Davis, 2000)	Qualitative data (study 2b) Participants=Older people	Qualitative data theme and sample quote (study 3) Participants=Clinicians	Data convergence	Mixed methods inference
[Output quality]	activities they carry out. [Improved pain self-management activities (outcomes)] *I go to Pilates, so my knees maybe going to be a little bit sorer for a few days. Being prepared for it and planning. That was helpful …. I hadn't done that before, but I find that really helpful. Knowing I am going to walk a couple of kilometres, but I might need to rest afterwards. (Participant 13, female, aged 68)*	[Improved pain self-management activities (outcomes)] *It can record whether they have kept up with the exercise, if they did need stronger analgesia like opiates? It could record whether they were becoming more functional. Because that's a marker of whether an opioid is useful, and then opioid shouldn't be used if someone isn't more functional. (HP01, female, aged 52, GP)*		activities in a way that leads to actionable outputs, and subsequently improved pain self-management practices.
Personalisation [Job relevance]	Older people wanted pain self-management apps to be customisable as per their unique needs. [Job relevance] *I reckon there's so many possibilities that it could be done. It can't just be, like you said, a generic thing. Because people aren't generic (Participant 11, female, aged 71).*	Clinicians suggested that a pain self-management app ought to offer personalisation features, especially in relation to exercise plans. [Job relevance] *Exercise should be tailored to the individual and if they are not, there is a risk that they (patients) could be doing something that's inappropriate (HP10, male, aged 41, physio).*	Confirm	A pain self-management app should be adaptable to meet the learning needs and skill-sets of the older person.
Interactive features [Job relevance]	Older people desired pain self-management apps to offer interactive video exercise features that are tailored and recommended by their treating clinician. [Facilitate ease of use] *The physio verbally gives me a list of exercises I should do. By the time I get home, of the five*	Clinicians considered the inclusion of interactive exercise video instructions within a pain self-management app to be a helpful feature to support older people's pain self-management plans. [Facilitate ease of use]	Confirm	A pain self-management app ought to provide electronic instruction thereby promoting better recall and understanding of clinician instructions.

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Domain [Alignment with TAM 2] (Venkatesh & Davis, 2000)	Qualitative data (study 2b) Participants=Older people	Qualitative data theme and sample quote (study 3) Participants=Clinicians	Data convergence	Mixed methods inference
	(sic exercises), I've only remembered two. So, having the video of an exercise which would remind me to do the five rather than just the two that I can remember, would be helpful (Participant 01, female, aged 74).	*I think an app would make it easier for a patient to see how an exercise is performed, rather than following a stick figure or a photograph, you can have videos on apps. I think that would be more engaging and probably reduce the risk of exercise being done incorrectly and probably increase compliance (HP10, male, aged 41, physio).*		
Data sharing with clinicians [Result demonstrability]	Older people wanted pain self-management apps to help them quantify and demonstrate their pain related assessment data with their clinicians. [Result demonstrability] *I had never quantified my pain before. But now, when I go see a surgeon, I'll be able to say how it's changed over (sic, time) (Participant 13, female, aged 68).*	Clinicians felt that a pain self-management app ought to allow the older person to capture their assessment data, and offer the ability to share it with their treating clinicians. [Result demonstrability] *I think what would be quite useful is sort of monitoring the progress. If he (the client) had some sort of an app, maybe I could monitor his progress, and maybe he could monitor his own progress (HP12, female, aged 56, physio).*	Confirm	A pain self-management app should enable discernible assessment data output, and bidirectional data sharing mechanisms between older people and their clinicians.
Clinician involvement [Perceived usefulness: Subjective norm, Job relevance, Output quality	Older people were open to having their treating clinicians involved in recommending or prescribing them a pain self-management app. [Influence of Subjective norm] *I am thinking more that if doctors could use it almost as a prescription, rather than have it in thought. "Here, download this app, and start*	Acknowledging the complex and dynamic self-management needs of older people living with arthritic pain, clinicians wanted to be involved in the process of app recommendation, and integration into their older patients' and clients' pain self-management regime. [Ensure app's job relevance, and output quality]	Enhance	Involvement of clinicians is necessary when considering the use of apps by older people for their arthritic pain self-management. Yet, none of the current pain self-management apps offer unidirectional or

Domain [Alignment with TAM 2] (Venkatesh & Davis, 2000)	Qualitative data (study 2b) Participants=Older people	Qualitative data theme and sample quote (study 3) Participants=Clinicians	Data convergence	Mixed methods inference
	working with it" (Participant 09, female, aged 76).	*We need to be careful that clinicians aren't removed from this process and that patients don't think that apps can provide all the information and be the one tool that they need. Because I struggle to see how an app can take into account all their medical history, tailor an exercise program to their specific needs, their specific goals, educate or advise them on how to modify the exercise program and progress it over time (HP10, male, aged 41, physio).*		bidirectional exchange of information between older people and their treating clinicians.
What others think [Subjective norm]	Older people wanted pain self-management apps to offer social interaction for the purposes of peer support and to maintain their own self-management skills. [Interaction and support from peers] *Some kind of like… chatroom or something that goes along with this that people share things that work for them. (Participant 10, female, aged 76)*	Clinicians suggested that a pain self-management app ought to offer the older person an opportunity for social interaction [Subjective norm to support motivation] *The other potential that a lot of people build into apps is social interactivity. If there was some sort of social interaction, which would encourage and motivate people to maintain their skills, I think that could be potentially useful. (HP17, male, aged 62, Male, GP)*	Enhance	A pain self-management app should offer socialisation features to enable vicarious reinforcement and peer-support among users.

TAM2: Technology Acceptance Model 2 (Venkatesh & Davis, 2000); HP: Health Professional

Community-dwelling older people; and primary care and allied health clinicians have similar requirements for the desired features of a pain self-management app. Both populations perceive that an effective pain self-management app should provide interactive and personalisable content to support the older person's pain self-management process. They also wanted pain self-management apps that provide ongoing prompts and motivations to encourage healthy behaviours. The design features should consider older people's capabilities and limitations, offer a peer-to-peer support feature, and enable older users to build and share their assessment data with their treating clinicians.

Describing the above findings within the TAM2 framework (Venkatesh & Davis, 2000), the features considered essential to a good pain self-management app according to community-dwelling older people living with arthritic pain and their primary care and allied health clinicians are perceived ease of use (effortlessness of app use); job relevance (app's relevance to the user); output quality (desirable outcome from app engagement); result demonstrability (tangibility of the desired outcome results from app use); and social influence (subjective norm) (see Figure 7.1). All these factors determine the app's overall *perceived usefulness* (app's ability to enhance the user's self-management activity performance).
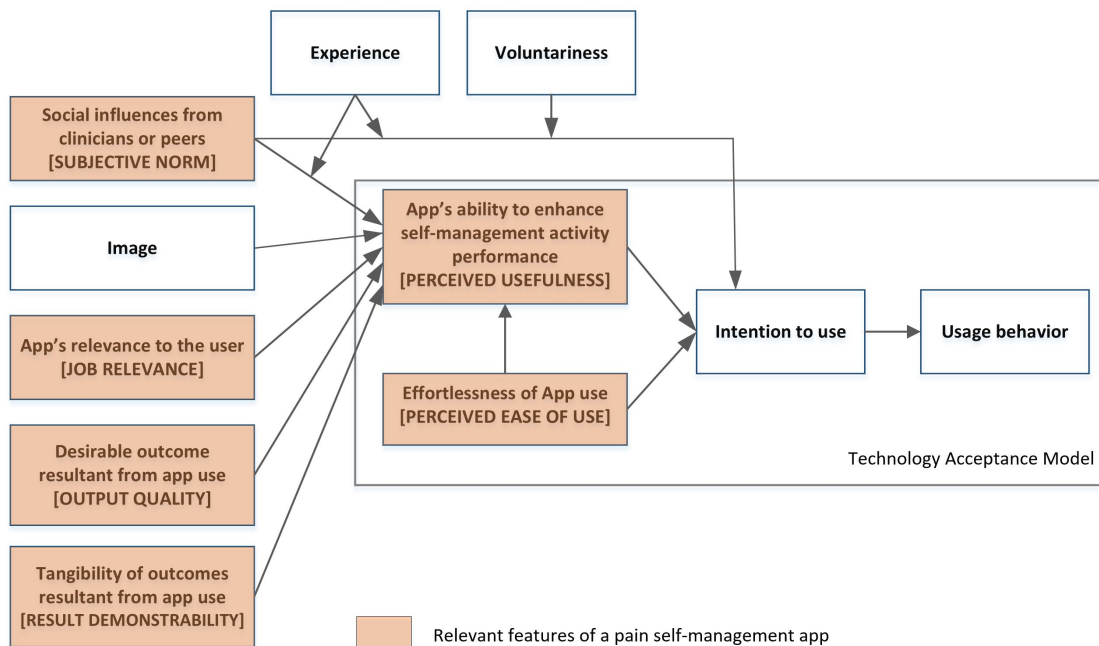
Figure 7.1 Desired features of a pain self-management app, based on Technology Acceptance Model 2

7.4.1 Perceived usefulness

The established evidence indicates that appropriate self-management of chronic persistent pain is more dependent on "what an individual does for themselves" than on "what is done to and/or for them" (Jensen, Nielson, & Kerns, 2003). Effective self-management of chronic pain is an ongoing task, requiring the person living with pain to initiate and successfully carry out a range of self-management activities (Cameron & Stewart, 2012; Jensen et al., 2003). Within this context, usefulness relates to the app's ability to enhance the self-management task performance of an older person living with arthritic pain. Perception of usefulness is also known to influence older people's engagement with a diverse range of technologies, including online government information platforms (Phang, Li, Sutanto, & Kankanhalli, 2005), virtual reality for leisure activities (Roberts, De Schutter, Franks, & Radina, 2019) and remote monitoring programs for chronic conditions (Cook et al., 2018). The lack of involvement of older people in the design and development of apps, and the lack of comprehensive pain self-management evidence underpinning these apps could also negatively impact the app's usefulness. Improving the factors that influence a pain self-management app's usefulness as identified by the DigiTech Pain project could help enhance the overall usefulness of future arthritic pain self-management apps. The following section describes the features that older people and primary care and allied health clinicians consider most relevant in a pain self-management app as per the TAM2 (Venkatesh & Davis, 2000).

Perceived ease of use

The DigiTech Pain project found that community-dwelling older people and their clinicians wanted a pain self-management app that considers the unique limitations of this older population, such as poor vision and dexterity. This finding is in line with previous studies that indicate ease of use as one of the key factors for acceptance of a chronic disease self-management app (Scheibe, Reichelt, Bellmann, & Kirch, 2015; Watkins, Kules, Yuan, & Xie, 2014). *Perceived ease of use* is the most important determinant of the *perceived usefulness* (McCloskey, 2006; Phang et al., 2005). Indeed, a technology such as an app must be easy enough for the intended target population to use, and to be able to realise the app's usefulness. The interrelationship of *perceived ease of use* and *perceived usefulness* is strongly supported by prior research (Gefen, 2003; Gefen, Karahanna, & Straub, 2003; Gillenson & Sherrell, 2002).

Similarly, there is a growing body of literature that points to the unique usability needs of older people in engagement with health apps (Scheibe et al., 2015; Urdaibay-Villaseca, 2010; Watkins et al., 2014). When considering older users, the concept of ease of use extends beyond intuitive and user-friendly design to considerations of unique usability needs related to aging and/or physical and cognitive impairment (Boulos, Brewer, Karimkhani, Buller, & Dellavalle, 2014). Older people require more time to complete a given task on a smartphone compared to younger people. Their app engagement is influenced by factors such as small text size, interface of data entry (keyboard), menu size and structure (Urdaibay-Villaseca, 2010), and unfamiliar symbols and icons (Watkins et al., 2014). The DigiTech Pain project similarly revealed that older people find it challenging to engage with small sized text and diagrams. If the abilities and limitations of older people are not considered at the design and development stage of pain self-management apps, it can result in poor adoption and engagement and ineffective use, thus negating all possibilities of improved self-management outcomes (Isaković, Sedlar, Volk, & Bešter, 2016).

Further it was considered beneficial for a pain self-management app to include reminder functions (via push notification) to provide older people ongoing prompts and motivation to keep up their pain self-management activities. Previous studies in the field have also reported that reminders for symptom tracking (Scheibe et al., 2015) and activity reminders (Harrington, Wilcox, Connelly, Rogers, & Sanford, 2018) are preferred by older users in a self-management app. The reminder feature is important to older people considering the high prevalence of memory and cognitive impairment in this demographic (Salthouse, 2003; Verhaeghen & Salthouse, 1997).

Summary

- Future pain self-management apps ought to be built using a co-design approach ensuring the apps are easy to use and cater for the age related limitations that older people often experience.
- Future pain self-management apps should offer versatile reminder functions that allow older users and their treating clinicians to create a relevant set of reminders based on the user's needs and preferences.

Job relevance

Job relevance relates to how *applicable* older people feel the given app is in supporting their pain self-management activities (Venkatesh & Davis, 2000). The DigiTech Pain project

indicates that community-dwelling older people and their clinicians considered it important for an app to offer personalisation features so that an app could be relevant to older people with varying self-management needs. Customisable apps that could provide information and instructions to match the skill-set and education level of the older person were preferred. The international literature indicates that lack of relevance is a highly salient reason behind non-adoption and use of a technology (Olphert, Damodaran, & May, 2005; Selwyn, 2004). There is a need to ensure that future pain self-management apps, in addition to being co-designed with the end users, are highly relevant and are developed in consultation with primary care and allied health clinicians.

The ability of an app to be an electronic platform for delivery of personalised video instructions, from clinicians to their older patients/clients, was also preferred. This finding is in line with the published literature which indicates that older users of a disease self-management app prefer the app to be customised as per their needs and preferences (Parker et al., 2013; Scheibe et al., 2015). While apps with high level job relevance are likely to be perceived as beneficial for adoption, literature also indicates the need to clearly communicate the concrete benefit of app adoption while addressing the end users' concerns about technology use (Peek et al., 2014). There is a need for apps that offer customisation features for optimal relevance and clear articulation of benefit of app use to older users.

Summary

- Future pain self-management apps ought to be developed with a strict focus on keeping the content relevant while incorporating the ability of tailoring information, instructions and resources.
- Future pain self-management apps ought to include adaptable features that enable optimal relevance of the app for each individual user while explicitly stating the clear benefits of using the app.

Output quality

The output quality of a pain self-management app refers to the desirable and successful outcomes achieved as a result of using the app (Venkatesh & Davis, 2000). The DigiTech Pain project found that older people and their clinicians want a pain self-management app that supports their self-management activities in a way that leads to actionable outputs. These features primarily relate to the symptom and activity tracking function of pain self-management apps, such as assessment and recording of pain and other symptoms, physical

activities and exercise. Studies exploring older people's views on diabetes self-management apps have similarly reported older users valued the assessment data recording function (Rasche et al., 2018; Scheibe et al., 2015). As assessment, documentation and monitoring of pain, other symptoms and self-management activities are hallmarks of an evidence-based pain self-management plan (Henschke et al., 2010; Lorig et al., 2015; Lorig et al., 2005; Williams, Eccleston, & Morley, 2012), it is understandable that these features were desired by both older users and clinicians.

Summary

- Future pain self-management apps developed for older people ought to offer practical and actionable functions that can assist users carry out desired and meaningful self-management activities.

Result demonstrability

Community-dwelling older people and their clinicians considered it important for an app to serve as a platform for relevant pain, symptom and activity assessment data sharing. Previous studies involving older diabetic patients using a diabetes self-management app have shown similar results where patients were keen to share their assessment data with their clinicians (Rasche et al., 2018). A comprehensive pain self-management plan is dependent on a strong therapeutic alliance between the older person and their clinicians. This alliance is necessary to establish treatment goals and expectations, and to develop and implement appropriate pharmacologic, non-pharmacologic and rehabilitative pain management approaches (Makris, Abrams, Gurland, & Reid, 2014). Inclusion of features such as bidirectional exchange of information in a pain self-management app can act as a facilitator of the therapeutic alliance between the older person living with arthritic pain and their treating clinicians. None of the currently available pain self-management apps offer the information sharing (unidirectional or bidirectional) feature or are founded on a robust self-management theory (Bhattarai et al., 2017), which indicates a missed opportunity. Versatile and evidence-based pain self-management apps that are useful to older people across various stages of their arthritic condition while offering a bidirectional information sharing feature may be highly relevant and translate into longer term use.

While bidirectional flow of information between older users and their treating clinicians could be a valuable reinforcer of pain self-management activities, clinicians seem apprehensive of such data access (Bhattarai, Newton-John, & Phillips, 2019). This

apprehension could be partly attributed to the increasingly digitalised health environment in which primary care and allied health clinicians operate with little formal education, guidance and support on mHealth practices (Lapão & Dussault, 2017; Lewis & Wyatt, 2014). Providing relevant guidance and support to clinicians on appropriate management and use of app-based data is necessary when considering data sharing functions within a pain self-management app. There is a need for an enabling policy environment where clinicians have access to appropriate mHealth resources, practice guidelines and support (Lapão et al., 2017).

Summary

- Future pain self-management apps ought to offer assessment data capture and sharing features between older users and their treating clinicians.
- While access to patient data generated via apps could improve monitoring and management of older people, clinicians may benefit from health systems level policies and procedures outlining appropriate management and use of such data.

Subjective norm

Subjective norm relates to the role of clinicians' and peers' influence on the app engagement decisions of the end users (Venkatesh & Davis, 2000). The DigiTech Pain project found that inclusion of social features such as peer interactions and information sharing within a pain self-management app is considered important by older people and their clinicians. These features help facilitate social influence on app engagement, while also enabling vicarious reinforcement and peer support among users. In addition, the peer support component of a chronic disease self-management program could be an effective intervention in its own right as it offers the combined benefits of both receiving and providing support (Heisler, 2007).

A number of studies have indicated that older people are sensitive to the influences of their clinicians, family members and peers who already engage with new health technology (Mallenius, Rossi, & Tuunainen, 2007; Peek et al., 2014). Indeed, if an individual perceives that people important to them endorse (or disapprove of) a given behaviour, they are more (or less) likely to perform it (Ajzen, 1991; Armitage & Conner, 2001). The impact of social influence on an individual's intention to use mobile apps is well documented (Hsu & Lin, 2016; Wang, Liao, & Yang, 2013). While there is evidence to suggest that health app adoption and use among younger people is influenced by subjective norms (Cho, Quinlan, Park, & Noh, 2014), little is known about the impact of subjective norms on health app use

among older people. Integration of social features within a pain self-management app might promote app use, while allowing older users to build on each other's strengths, knowledge and experience.

Summary

- Future pain self-management apps ought to incorporate social networking and support features that allow older people to interact with, influence and support each other.

7.5 Research question 4: What are the actions required to build the evidence supporting the integration of an app into older people's arthritic pain self-management plans?

This final research question is answered through meta-inference of the collective DigiTech Pain project data. The meta-inference process is reported in detail in Chapter 4.

7.5.1 Understanding app integration as a multi-level operation

The integration of novel technology such as an app into older people's pain self-management plan is yet to be fully realised. While there is growing evidence to show the approach has some promise, it is important to consider the complex social and healthcare context in which older people use these apps. The challenge of integrating a pain app into an older person's pain self-management plan is further complicated by unregulated app development and rapidly proliferating self-management apps. Successful adoption and longer-term use of pain self-management apps by older people requires considering the factors at the micro (individual) level, wider context (meso) level and a broader systems level (macro) (World Health Organization, 2002). The factors at each level interact and dynamically influence the other two (Gjestsen, Wiig, & Testad, 2017). Therefore, developing a multi-level strategy to guide pain self-management app development, research and integration is a critical starting point. Such concerted effort can facilitate a sustainable and meaningful use of apps in supporting older people to better manage their arthritic pain. Meta-inferences from the DigiTech Pain project data revealed that arriving at this requires three steps:

i)   Develop highly useful pain self-management apps

ii)   Conduct research activities involving pain self-management apps

iii)   Integrate pain self-management apps.

The conceptual framework illustrating the relationships between the elements is depicted in Figure 7.2.
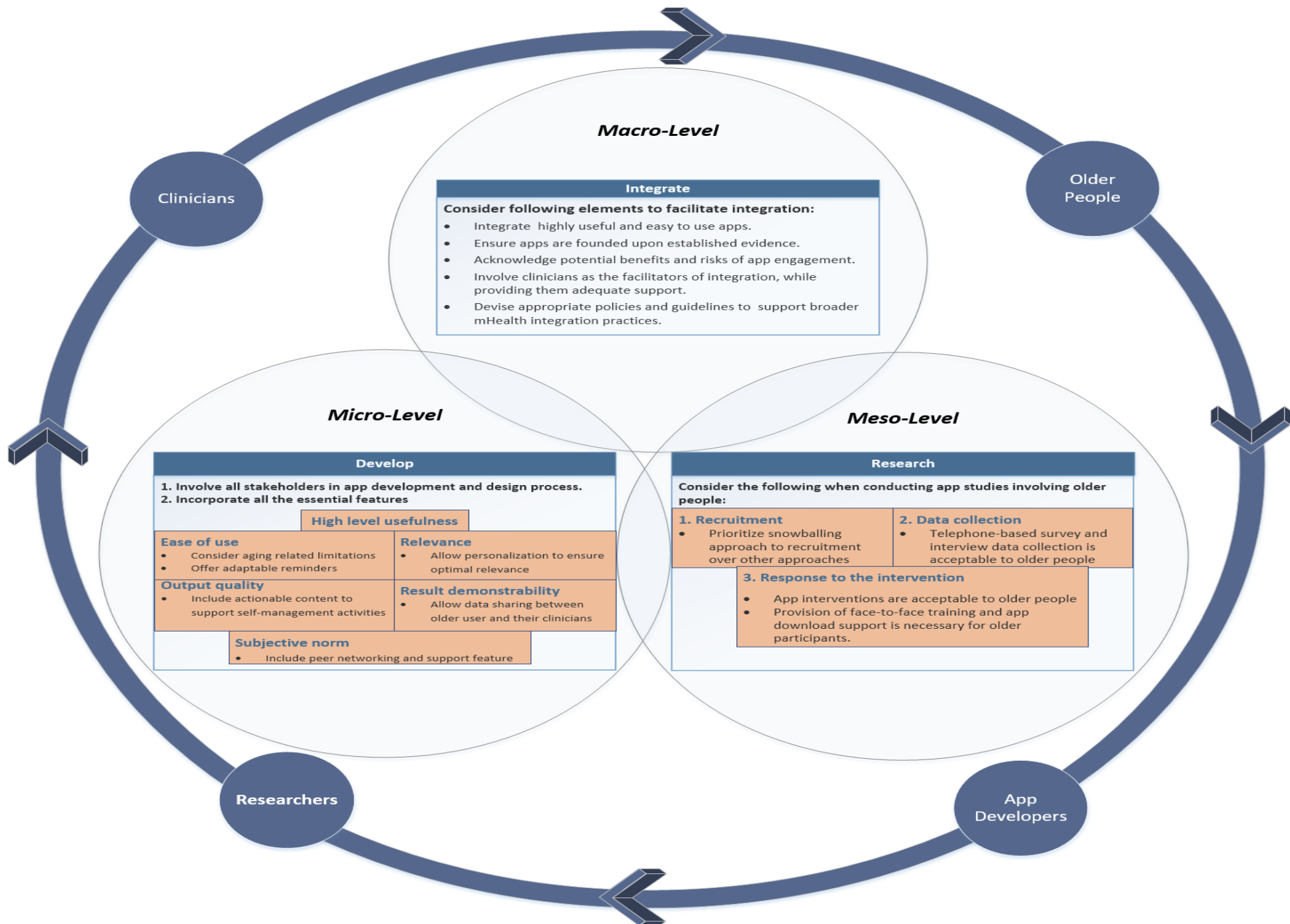
Figure 7.2 Conceptual framework of factors necessary to support the integration of apps into older people's arthritic pain self-management plan

Develop highly useful pain self-management apps (micro level)

A micro-level engagement with older people living with arthritic pain, and their clinicians, in the app development process is necessary to ensure apps are highly engaging, enhance self-management support and promote a patient–provider partnership (Nundy et al., 2012). A collaborative approach involving researchers, developers, health professionals and end users (older people) in the co-design and development of mHealth interventions is supported by strong evidence (Matthew-Maich et al., 2016; McCullagh et al., 2012). Such collaboration facilitates iterative app design processes and enables identification of features that are helpful and desirable to the end users, yet are technically feasible and informed by a robust evidence base and self-management theories (Matthew-Maich et al., 2016).

Involving clinicians and older people in the design and development of a pain self-management app also recognises the patient–provider partnership and the complex and dynamic nature of self-management needs of older people living with arthritic pain (Lorig & Holman, 2003; Novak, Costantini, Schneider, & Beanlands, 2013). A collaborative relationship between clinicians and older people living with pain is known to provide an ideal environment for self-management education and engagement in self-management activities (Bodenheimer, Lorig, Holman, & Grumbach, 2002; Dorflinger, Kerns, & Auerbach, 2012). Such collaboration is very relevant in the context of arthritic pain, as people living with arthritic pain have complex, changing and continuing needs (Osborne, Spinks, & Wicks, 2004). Pain self-management apps that facilitate the patient–provider partnership and offer dynamic and customisable features that cater for the complex self-management needs of older people living with arthritis pain are likely to garner sustained and meaningful engagement.

Conduct research activities involving pain self-management apps (meso level)

Another relevant component to adoption and longer-term use of pain self-management apps is the need for high quality studies evaluating and refining the ways in which rigorously built pain self-management apps can contribute to older people's pain self-management practices (Wethington et al., 2018). This responsibility falls primarily to the academic research community (the meso level) which is appropriately skilled in conducting studies grounded in robust theoretical frameworks. Researchers should be open to adopting a participatory approach where older people, clinicians and app developers are offered the opportunity to provide their input to research activities (Matthew-Maich et al., 2016).

While the numerous challenges associated with engaging older people in research are well known (Dibartolo & McCrone, 2003; Harris & Dyson, 2001), findings of the DigiTech Pain project suggest that it is feasible to conduct app evaluation studies with older people. Considerations when conducting pain self-management app research among older people include prioritising a snowballing approach to recruitment, collecting data via telephone, and providing support for app download and training. The rapid evolution of mHealth technology presents additional challenge where rigorous yet timely evaluation of new apps is required to ensure resources are not wasted on ineffective app interventions, while successful app interventions are quickly recognised and disseminated (Heerden, Tomlinson, & Swartz, 2012). As such, the research feasibility findings of the DigiTech Pain project provide helpful practical tips for future pain app studies on recruitment, data collection and implementation of interventions. The DigiTech Pain project's feasibility findings include the need to prioritise a snowballing recruitment approach; indication of acceptability of telephone-based data collection methods; and the need to provide guidance to older people in relation to the intervention app download and training.

Integrate pain self-management apps (macro level)

Broader contextual (macro level) factors such as laws and regulations, external policies, and funding structures can significantly influence the uptake and integration of a health intervention (Ree, Johannessen, & Wiig, 2019). When considering integration of mHealth technologies such as pain self-management apps, it is important to adopt a coordinated and strategic approach where the complexity of mHealth development, uptake and evaluation is recognised (Matthew-Maich et al., 2016; Wethington et al., 2018). Systems level initiatives that focus on improving research and care practices involving pain self-management apps for older people living with arthritis could be the starting point (Wethington et al., 2018).

App integration efforts directed at research should ensure that pain self-management apps are developed and underpinned by robust evidence and self-management theories, while also being highly relevant and useful to the older person (Thurnheer et al., 2018; Wethington et al., 2018). In addition, policy makers and funders may need to promote and fund programs that aim to evaluate the evidence for, and the impact and cost-effectiveness of, pain self-management apps (Heerden et al., 2012). These research activities should be

conducted with collaboration among researchers, developers, older people living with arthritic pain and their clinicians.

App integration efforts aimed at care practices should equally incorporate an inclusive approach where the older person living with arthritic pain and their clinicians work together as partners. There is potential for primary care and allied health clinicians to become facilitators to the implementation of pain self-management apps. However, these clinicians need to be well supported by adequate education, resources and practice frameworks on use of apps (Wethington et al., 2018) before they are asked to take on such responsibility. Further, there is a need for a balanced view point that using apps for older people's pain self-management has potential benefits but there are also some risks of engagement.

Summary

Integrating apps into the pain self-management regime of older people living with arthritic pain calls for a comprehensive plan that addresses the micro, meso and macro level requirements. Meaningful and sustainable use of apps by older people for their arthritic pain self-management requires involvement of all stakeholders (older people, clinicians, researchers and app developers) in the design, development and integration process. Ongoing research activities are necessary to continually evaluate and refine these apps, while also assessing their impact and cost effectiveness. Synchronised and strategic approaches are necessary from the systems level to promote, legislate and guide practices on the use of pain self-management apps for arthritic pain self-management of older people.

7.6 Significance of the DigiTech Pain project

The DigiTech Pain project is one of the few programs of research to have comprehensively explored the feasibility and acceptability of a pain self-management app among older people living in the community with arthritic pain. Better understanding of older people and their clinicians' attitudes and perspectives on the use of pain self-management apps has identified the need to develop strategies to support app development, research and integration efforts. The DigiTech Pain project has revealed the actions necessary for meaningful and longer-term use of apps in older people's pain self-management strategies. The DigiTech Pain project aligns with the research priorities outlined in a recently published mHealth research agenda for later life pain care (Wethington et al., 2018):

- expanding research on ways to enhance the accessibility of mHealth tools for diverse audiences

- promoting the integration of users and other relevant stakeholders into the mHealth research process

- evaluating ways to personalise and tailor mHealth tools for individual users

- promoting research on ways to initiate and sustain patient behaviour change using mHealth tools

- researching how mHealth tools can improve patient–provider communication.

7.7 Limitations

While the limitations of each study undertaken in the DigiTech Pain project have been described in the relevant chapters, there are several limitations that need to be highlighted. The DigiTech Pain project focused on older people living in the community with arthritic pain and not those who were actively seeking treatment. Therefore, the findings from this project may not be generalisable to older people who are actively seeking treatment for their arthritic pain. In addition, while this project recruited a diverse cohort of older people, and primary care and allied health clinicians, voluntary participation means that the characteristics of participants versus non-participants may have biased the study findings. Another limitation is that the DigiTech pain project findings may not be transferrable to other settings, as the study involved English speaking older Australians in four Australian states. The findings of this project may not be applicable to other geographical locations, healthcare systems with different data accessibility patterns and laws, and culturally diverse populations. Finally, research into pain self-management apps for older people is still an emerging area of research, with multiple gaps in the published literature. Thus, one of the overarching challenges faced by the DigiTech Pain project was the paucity of comparable literature, which limited the conclusions that could be drawn.

7.8 Conclusion

The aging global population, high prevalence of chronic pain and increasing smartphone adoption among older people require a better understanding of the role of pain self-management apps in assisting older people to better manage their arthritic pain. The DigiTech Pain project identified that it is feasible to conduct an app-based intervention study involving older people living in the community with arthritic pain, however the recruitment strategy needs to consider a snowballing approach. While engagement with

apps is welcomed by older people and their clinicians, these engagements should be supported by broader systems level policies and high quality apps, and underpinned by ongoing research. Collaborative approaches involving clinicians, older people, researchers and app developers should be considered in developing, researching and integrating pain self-management apps.

7.8.1 Implications for practice

Based on the findings of the DigiTech Pain project, the following recommendations are made:

- Build collaborative ventures between app developers, researchers, clinicians and older people to develop pain self-management apps that are based on principles of self-management theories and best practice evidence.

- Develop customisable pain self-management apps that meet the unique needs and preferences of older people with different pain types and self-management demands.

- Evaluate individual user's preferences before app recommendation or prescription as some older people do not find pain self-management apps to be interesting or relevant.

- Involve older people's usual primary care and/or allied health clinicians throughout the app integration process.

- Develop relevant policies, guidelines and reimbursement processes to guide and support mHealth practices of primary care and allied health clinicians.

7.8.2 Implications for future research and development

Further exploration of the role and impact of pain self-management apps involving older people with a range of different pain types across various settings is warranted to build on the evidence base. In anticipation of the digitally native next generation of older people, future research should focus on evaluating the value-added nature of smartphone apps, by evaluating their unique and advanced features that can potentially help enhance the pain self-management process of older people.

Future pain app development work should consider a co-design approach involving academic experts in pain self-management, experts in technology implementation, primary care and allied health clinicians, and older people to ensure apps are rigorous and based on pain self-management theories, while also being relevant, effective and user friendly. These recommendations agree with the newly published report (Wethington et al., 2018) outlining a research agenda on mHealth technology for chronic pain management in older adults.

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Appendix 1

Publication: The role of digital health technologies in management of pain in older people: An integrative review

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BACK   CLOSE WINDOW

Review

The role of digital health technologies in management of pain in older people: An integrative review

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ABSTRACT

Pain is one of the most distressing and debilitating health issues faced by older people. The burden of unrelieved pain experienced by older people and its associated high symptom and economic costs demands consideration of new strategies to better this condition. As the global uptake of digital technology increases, exploring its potential to impact positively on older peoples' pain self-management practices warrants investigation. This integrative review aimed to evaluate the use of digital health technology for management of older people's pain across care-settings. Searches were conducted to identify relevant English language studies published in CINHAL, Medline, Academic Search Complete, EMBASE, Cochrane library databases, and Google and Google Scholar websites. A total of 1003 papers were identified, 9 met the inclusion criteria. The highest level of evidence (Level II) was generated by three Phase II randomized controlled trials. These trials demonstrated the feasibility of computer based interactive or instructive video interventions however there was limited evidence to support their use for reduction of pain intensity and interference. Qualitative evidence demonstrated older people's willingness to use mobile technologies (iPhone or digital pen) to help manage their pain, however, the need of device-use training and connectedness with clinicians were highlighted.

In conclusion, there is some evidence that integrating digital health technology into older peoples' pain self-management plan is feasible and acceptable. However, the provision of high-quality technological interventions informed by a thorough understanding of older people's digital technology pain management needs is required to ensure greater integration of this technology in clinical practice.

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1. Introduction

The global population is ageing rapidly and older people (people over 65 years of age) will shortly outnumber children under the age of five (World Health Organisation, 2012), with a fifth (13–17%) of older people living in high-income countries (Age UK, 2014; United States Department of Health and Human Services, 2011; Australian Institute of Health And Welfare, 2007). Older people often live with arthritic conditions, osteoporosis, back and/or cancer pain (Australian Bureau of Statistics, 2012). Chronic pain contributes to disability, decreased mobility, depression, and impaired quality of life (Patel, Guralnik, Dansie, & Turk, 2013), which is estimated to costs the Australian economy $34 billion annually in health care expenses and lost productivity (Conway & Higgins, 2011).

Population ageing and high pain prevalence demands innovative and cost-effective pain self-management strategies targeted at older people, including the use of various digital health technologies (Free et al., 2013; Ruland et al., 2013). Digital health technologies are categorized into either: eHealth, which involves secure and cost effective use of computer-based information and communications systems to process, transmit and store data and information for health related matters (WHO, 2005, 2015); or mHealth, which is a component of eHealth and is defined as medical or public health practice supported by mobile devices (i.e. mobile phones, personal digital assistants, and other wireless devices) (WHO, 2015).

While digital health technology uptake among older people has been slow, this trend is being averted with the development of more user friendly devices (Pew Research Center, 2015; Smith, 2014). It is estimated that 60% of older adults now regularly use the internet, 18% own a smartphone and 18% own a tablet computer (Smith, 2014), and 30% regularly seeking health information online (Pew Research Center, 2015). Routine integration of digital technology into older people's health management strategies will increase as people have more digital experience (Currie, Philip, & Roberts, 2015).

While there has been a proliferation of randomized controlled trials (RCTs) testing various digital health technology based pain management interventions, most have been largely limited to younger cohorts (Buhrman, Nilsson-Ihrfeldt, Jannert, Ström, & Andersson, 2011; Pombo, Araújo, Viana, & DA Costa, 2013). As a consequence the use of digital health technology for pain management among older people is poorly understood.

1.1. Aim

To evaluate digital health technology interventions designed to improve older people's pain management across care-settings.

This integrative review set out to answer the following research questions:

1. What are the salient features of digital health technology that have been tested as part of a pain management strategy for older people?
2. Is there evidence to support the use of digital health technology in the management of pain in older people?
3. What are the barriers and facilitators to implementation of digital health technology among older people for pain management?

4. What are the gaps in the current evidence base and future research direction?

An integrative review was considered to be the most appropriate method to systematically analyze currently available research evidence, due to the small number of studies identified in the preliminary search (Whittemore & Knafl, 2005). This approach allowed for inclusion of experimental and non-experimental studies to fully understand the use of digital health technology in managing older peoples' pain, appraise the strengths of the evidence and identify research gaps (Whittemore & Knafl, 2005).

2. Methods

This integrative review adhered to the following five stages: (1) problem identification, (2) literature search, (3) data evaluation, (4) data analysis, and (5) presentation (Whittemore & Knafl, 2005). The reporting of this integrative review adheres to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) statement (Moher, Liberati, Tetzlaff, & Altman, 2009).

2.1. Eligibility criteria

Studies reporting empirical data related to the use of digital health technology in pain management of older people that were published in peer reviewed English language journals from 2000 to August 2015 were included (Table 1). This date range was selected because significant advances; and increased adoption of digital technologies have all occurred since 2000 (Oulasvirta, Rattenbury, Ma, & Raita, 2012).

2.2. Literature search

A search strategy was developed by two reviewers (PB and JLP) and checked by a librarian. One reviewer (PB) conducted the search on 02 August 2015 using the following databases: Academic Search Complete, Medline, CINAHL, EMBASE, and Cochrane Library using a combination of free-texts (as keywords) and MeSH terms

Table 1
Inclusion criteria.

	Inclusion criteria
Population	Studies focusing on older people
Intervention	Use of digital health technology such as computer or mobile device for pain management purpose.
Comparator	Any
Outcomes	Any pain related outcomes.

including: Older people (elderly; senior; geriatric; aged over 65) AND Pain AND technology (computer; mobile phone; internet; robotics; mHealth; mobile application) (Appendix A). Further searches were conducted using Google Web and Google Scholar websites. Reference lists of relevant articles were hand searched. Identified citations were exported to Endnote reference management program.

2.3. Study selection

The pre-specified inclusion criteria were used by two reviewers (PB and JP) to assess the relevance of identified articles independently, with a plan for disagreements to be resolved by discussion and consultation with an academic pain management expert. There were no instance of disagreement necessitating a consultation with the pain management expert.

2.4. Quality assessment of included studies

The Critical Appraisal Skills Programme (2013) tools plus the Quality Appraisal Tool for Case Series Studies (Moga, Guo, Schopflocher, & Harstall, 2012) were used to assess the included studies' quality. Both of these checklists provide an option to indicate if a given quality criteria is present (score of *Yes*), absent (score of *No*) or unclear (score of *Cant tell* for the CASP tools and *Unclear* for the Quality Appraisal Tool for Case Series Studies). The level of evidence generated by the studies adheres to the National Health And Medical Research Council, 1999 guideline.

2.5. Data collection

Methods, setting, level of evidence, intervention detail, findings, and strengths and weaknesses data was extracted into an evidence summary matrix (PB and JP). Qualitative data on patient reported pain outcomes, participant's perspectives, and digital health technology barriers and facilitators was also extracted into this matrix.

2.6. Data analysis

The collected data was divided into groups and sub-groups then aligned to specific research questions. After systematic comparison of data across studies, iterative data examination process allowed for identification of patterns, themes and relationships between and among the groups and sub-groups (Whittemore & Knafl, 2005).
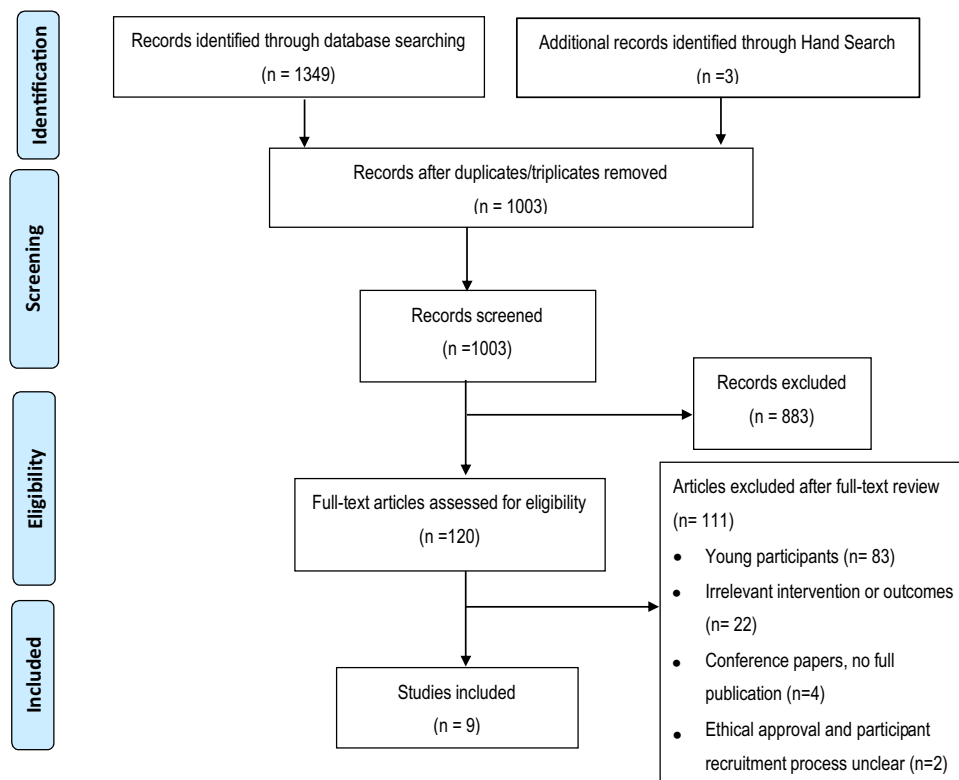
Fig. 1. Flowchart of studies from search to inclusion.

Table 2
Summary of included studies.

Author_Year (Country)	Study design-LOE	Participants	Study aims	Intervention	Study outcomes	Strength and weaknesses
McDonald et al. (2013) (USA)	Phase II RCT Level II	Community dwelling older adults with arthritic pain. (n = 23); Age (X = 68.1 years ± 5.93)	To test the effectiveness of a virtual pain coach and pain communication intervention on older people's pain communication ability	**Control group**: View a 3-min video of a female practitioner detailing osteoarthritis pain information that is important for patients to share with their care team. **Intervention group**: 3-min video plus interactive session with a virtual pain coach (animated female practitioner) who asked them to describe their pain, prompting information sharing, and encouraging sharing pain information with their practitioner. The virtual pain coach detected and responded to participant's pauses. Physicians provided with a copy of relevant pain management guidelines	Primary outcome: Not described Participant's consultation with physician immediately after the intervention audiotaped for data extraction. Intervention group participants described significantly more pain source information (p = 0.009) and were prescribed significantly more pain treatments (p = 0.005) than those in control group. No difference in pain intensity between two groups.	Strength- Intervention guided by a theoretical framework, Randomized control design. Weakness- small sample size, no description of power or sample-size calculation. Impact of the intervention on patient's pain outcome on longer term is not reported.
Parker et al. (2013) (USA)	Focus group interviews (n = 6) (QE)	Community dwelling older adults with chronic pain (n = 41); Age (X = 76.2 years ± 9.3)	To examine the willingness of older adults with chronic pain to adopt mHealth technologies to help manage their pain.	An iPhone 4 was introduced during the focus group sessions to prompt conversations about the: experience of using mHealth in healthcare context, willingness, barriers and facilitators, if the technology would make them comfortable etc.	Four major themes: concerns about mHealth use, ways mHealth device might be used, barriers to mHealth use, and facilitators to mHealth use. Barriers include concern of battery dying, cost, and lack of familiarity; facilitators include- need of training and tailoring device so it meets the functional needs of elderly.	Strength- In-depth exploration of older people's perspective, data saturation achieved. Weakness- Urban-dweller participants only, use of an iPhone 4 during focus groups limits the applicability of the findings to other technologies.
McDonald et al. (2012) (USA)	Phase II RCT Level II	Community dwelling older adults who only spoke Spanish (n = 18); Age (X = 74.3 years ± 7.60)	To test the effects of a virtual pain coach and pain communication intervention on Spanish speaking older people's pain and depressive symptoms.	**Control group**: View a 3-min video of a Latina practitioner detailing osteoarthritis pain information important to tell their care team. **Intervention group**: 3-min video plus interactive session with a Spanish speaking virtual pain coach (animated female practitioner) who asked them to describe their pain, prompting information sharing, and encouraging sharing pain information with their practitioner. The virtual pain coach detected and responded to participant's pauses, however visual cues were not detected	Primary outcome: Not described Participants had their physician-consultation immediately after the intervention. BPI done before and one month post-intervention. Significantly more participants from the intervention group compared to control group reported change from non-use to use of opioid one month post-intervention (p = 0.023). No improvement in pain intensity and interference detected.	Strength- Intervention guided by a theoretical framework, Randomized control design. Weakness- small sample size, no description of power or sample-size calculation, no description of how participants actually reported their pain after taking part in the interventions.
McDonald et al. (2011) (USA)	Randomized posttest-only double blind pilot test design. Level III-2	Community dwelling adults with arthritic pain. (n = 30); Age (X = 71.9 years ± 9.36)	To pilot test the effect of virtual practitioner pain communication coach on older adult's communication of their osteoarthritis pain.	**Control group**: View a 3-min video of a female practitioner detailing osteoarthritis pain information that is important to tell their care team. **Intervention group (1)**: 3-min video plus interactive session with a virtual pain coach (animated female practitioner) who asked them to describe their pain, prompting information sharing, and encouraging sharing pain	Primary outcome: Not described Immediately after watching the videos, participants were asked to talk about their pain by a videotaped practitioner. On average, participants in the intervention group (1) reported one additional important distinctive information about their pain compared to those in the control group and Intervention group (2). However this difference	Strength- Intervention guided by a theoretical framework. Weakness- patient reported data post-intervention was gathered from an experimental scenario (question asked by a video-taped practitioner), impact of the intervention on patient's pain outcome on longer term is not reported.

Table 2 (Continued)

Author_Year (Country)	Study design-LOE	Participants	Study aims	Intervention	Study outcomes	Strength and weaknesses
				information with their practitioner. The virtual pain coach detected and responded to participant's pauses. **Intervention group (2)**: 3-min video plus interactive session with a Video-taped practitioner who asked them to describe their pain, prompting information sharing, and encouraging sharing pain information with their practitioner. Participant's pauses were not detected. The total duration of Intervention 1 and 2 is not reported.	was not statistically significant.	
Berman et al. (2009) (USA)	Phase II RCT Level II	Community dwelling adults aged 55 years or over (n = 78); Age (X = 65.8 years, range = 55–91)	To assess the feasibility of delivering self-care tools to older adults via internet and to document the changes in pain and ability to manage chronic pain.	**Intervention group**: accessed a Web-based pain self-care (exercise) modules covering: (1) abdominal breathing, (2) relaxation, (3) writing about positive experiences, (4) writing about difficult experiences (5) creative visual expression, and (6) positive thinking. Intervention included audio, visual and textual components; illustrative examples, and worksheet for reflection and action plan development. Provided suggestion about pain communication. Participant's usage of website monitored, and email prompts sent to encourage completion **Comparison group**: participants not given access to the website until the observation period was over, after which they were given access.	Primary outcomes: Pain intensity, pain interference, self-efficacy, depression, and anxiety. Other outcome: awareness of response to pain. Pain intensity and interference improved for both intervention and control group (p < 0.01); Intervention group reported increased confidence in pain management using non-medical self-care techniques (p < 0.01). High satisfaction with the intervention, as measured by authors developed satisfaction survey, was reported. Intervention helpful (81%,) easy to use (88%).	Strengths- Randomized trial design Weaknesses- No description of sample size and power calculation, short intervention duration of six weeks.
McDonald et al. (2009)	Randomized double blind posttest-only experiment. Level III-2	Community dwelling older adults with arthritic pain. (n = 312); Age (X = 75.6 years ± 8.50)	To test how a computer displayed videotaped practitioners' pain question phrasing affects the pain information provided by older adults.	Participants randomly allocated to one of three intervention groups, and asked question about their pain by an animated practitioner. **Intervention group (1)** (open-ended and without social, desirability) – Question "Tell me about your pain, aches, soreness, or discomfort". **Intervention group (2)** (closed-ended and without social desirability- Question "What would you rate your pain, aches, soreness, or discomfort on a 0 to 10 scale with 0, no pain, and 10 the worst pain possible". **Intervention group (3)** (social desirability bias)- Question = "How are you feeling?"	Older people who were asked an open-ended question without social desirability were likely to describe significantly more pain information that those who were asked a closed-ended question without social desirability (p < 0.009), or an open-ended question with social desirability (p < 0.001).	Strength- Intervention guided by a theoretical framework, large sample size. Weakness- unnatural situation (videotaped) of pain assessment.

Table 2 (*Continued*)

Author_Year (Country)	Study design-LOE	Participants	Study aims	Intervention	Study outcomes	Strength and weaknesses
Lind et al. (2008) (Sweden)	Case series mixed method study (QUAL + quan) Level IV	Community palliative care patients (n = 12); Age (Median = 65.5 years, range = 58–79)	To describe participant's experience of using pain diary, digital pen and internet technology for pain assessment.	Participants were given pain diary and digital pen technology for self-assessment of pain and analgesic consumption. Pain diary had a unidimensional tool (VAS 100 mm) for measurement of pain intensity. It also included a question on consumed extra dose of analgesic. Semi structured interviews were conducted to explore older people's experience of using the technology for pain assessment. Quantitative data collected include- ease of used questionnaire, data from the device, and participant's medical records.	Quantitative: Number of days the digital pen was used = 10 (mean), number of pain assessment carried out per patient = 28 (mean). Qualitative: Main themes include: • Difficult to understand the technology • Managed to use the technology in spite of one's health • Overcome technical problems • Increased and improved contact with care giver • Increased participation in one's care • Sense of increased security	Strengths- In-depth exploration of older people's experience of using pain assessment technology. Weakness- Participants had little understanding of the technology, and an inaccurate sense of "connection" with clinicians.
King and Workman (2006) (Australia)	Case series Level IV	Aged care facility residents (n = 19); Age (Median = 82.4 years, range = 71–95)	To test the feasibility of using information communication technology to improve arthritic pain	**Intervention**: Remote pain assessment via use of a videophone technology. Either a desktop computer or an i2i videophone system was used. Contact established between specialist pain clinician (from a central pain clinic) and participants at the residential aged care facility. Patient's self-reported pain intensity (VAS) recorded before and during video-consultation. Data also collected on patient's QOL and their experience of video consult.	Average reported pain score was 5 on VAS. Video consult was sufficient to assess pain and discuss treatment strategies. 59% of participants preferred video-consultation to face-to-face consultations. 94% satisfied with the consultation and willing to participate again. No result of statistical significance presented.	Strength- user-friendly design of the video-consultation setup, successful video-consult with pain specialist. Weakness- Small sample size, no report of the intervention's impact on patient's pain related outcomes.
Huang et al. (2003) (USA)	Test- retest Pilot study Level IV	Patients with bone metastasis related pain attending an outpatient radiation oncology clinic (n = 9); Age (X = 66 years ±12)	To evaluate the feasibility of using innovative computerized PAINReportIt and manually prepared PAINConsultN in a community radiation oncology setting.	**Intervention**: The PAINReportIt included: (a) computerized version of MPQ, and (b) a series of questions designed to explore other aspects of participant's pain and analgesic therapies. Administered using a touchscreen computer, with one question per page. Total of 34 screens with 13 screens covering exactly same questions as the paper version of MPQ and additional 21 measuring further details of participant's pain. Particpants were asked 1 week later to complete the PAINReportIt again as the posttest. PAINConsultN: provision of the patient-reported pain related data together with pain management recommendation to the participant's physician.	The computerized PAINReportIt had promising feasibility with reasonable completion time (7–20 min), high acceptability (8–13) (on a 13 item tool), and adequate completeness (100%) in a sample of cancer patients with bone metastasis pain. Impact of PAINConsultN not reported in the study. No result of statistical significance presented.	Strengths- Use of validated pain assessment tool, user-friendly design of the device (touchscreen), and the pain assessment program. Weakness- small sample size, report of pain assessment was not transferrable for use by physician.

Key: BPI: Brief Pain Inventory; LOE: Level of Evidence; n: number of participants; A: mean age of participants; QOL: Quality of Life; X = mean age ± standard deviation.

3. Results

3.1. Study selection

Of the 1352 articles 9 met the inclusion criteria (Fig. 1). The reference list of included articles yielded no additional papers.

3.2. Study characteristics

All of the studies were undertaken in high-income countries utilising either: quantitative (n = 7), qualitative (n = 1), or mixed-method (n = 1) designs (Table 2). A total of 549 participants (range 9–312) were included in studies conducted in: outpatient clinics (n = 6), participant's home (n = 2) or nursing home (n = 1).

The highest level of evidence was generated by three phase II RCTs (Level II evidence) (Berman, Iris, Bode, & Drengenberg, 2009; McDonald, Walsh, Vergara, Gifford, & Weiner, 2012; McDonald, Walsh, Vergara, & Gifford, 2013) however no justification for the feasibility sample sizes were provided. Two studies used a comparative design with concurrent controls (Level III-2 evidence) (McDonald, Shea, Rose, & Fedo, 2009; McDonald, Gifford, & Walsh, 2011), while another two used a case-series design (Level IV evidence) (Huang et al., 2003; King & Workman, 2006). The qualitative study used focus group interviews (Parker, Jessel, Richardson, & Reid, 2013), while the mixed methods study (QUAL + quan) integrated data from semi-structured interviews and participant's medical records (Lind, Karlsson, & Fridlund, 2008).

3.3. Quality

Quality evaluation revealed variable quality across the studies (Tables 3–5). Lack of treatment effects reporting across the experimental studies, and inadequate detail of bias minimization and recruitment in the qualitative studies compromised their quality.

3.4. Salient features of the tested technological interventions

All of the quantitative studies (n = 7) tested a computer-delivered intervention (Berman et al., 2009; Huang et al., 2003; King & Workman, 2006; McDonald et al., 2009, 2011, 2012, 2013), while the role of a digital pen and a smartphone in pain management of older people were explored in the qualitative (Parker et al., 2013) and mixed methods studies (Lind et al., 2008).

Four studies tested a computer-delivered educational and/or interactive video intervention based on the communication accommodation theory among English (McDonald et al., 2009, 2011, 2013) or Spanish speaking (McDonald et al., 2012) older people with osteoarthritic pain. Other interventions included internet-delivered mind-body exercise program for pain

management (Berman et al., 2009), remote pain assessment using videoconference (King & Workman, 2006), and patient's self-reported pain assessment using a touchscreen computer (Huang et al., 2003). Participants' experience of using a digital pen for pain assessment in their homes was explored in the mixed methods study (Lind et al., 2008), while the focus group participants' views about the displayed iPhone 4 and its potential to assist them manage their pain were explored in the qualitative study (Parker et al., 2013).

3.5. Reported pain outcomes

Five studies measured patient's pain outcomes; all used Brief Pain Inventory (BPI). Three reported on pain intensity and interference (Berman et al., 2009; McDonald et al., 2012, 2013), the rest assessed participants' pain description (McDonald et al., 2009, 2011).

3.6. Impact of technology use on patient's pain outcomes

In the feasibility trail, web-delivered exercise based intervention led to increase in older people's confidence in using non-medical pain management strategies (p < 0.01) (Berman et al., 2009). Improvement in pain intensity and pain interference was reported in both (intervention and control) groups (p < 0.01) (Berman et al., 2009). Similarly, an interactive video-based pain communication intervention led to no improvement in pain intensity (McDonald et al., 2012, 2013) and pain interference (McDonald et al., 2012) despite improvement in participant's pain description (pain source) (p = 0.009) (McDonald et al., 2013). However, the intervention group was either prescribed significantly more pain treatments (p = 0.005) (McDonald et al., 2013), or they reported a significant change from non-use to use of an opioid related pain treatment (p = 0.023) (McDonald et al., 2012). These changes were not attributed to patient's pain description (McDonald et al., 2012), with authors suggesting the possibility of a *Hawthorne effect* (McDonald et al., 2013).

In a post-test only randomized experiment where older people were asked to describe their pain using various pain questions by an animated practitioner, open-ended pain questions without social desirability elicited significantly more pain information than closed-ended question without social desirability (p < 0.009), or open-ended question with social desirability (p < 0.001) (McDonald et al., 2009).

3.7. Perspectives/barriers/facilitators towards digital health technology

Five studies reported on older peoples' perspective of using digital health technology for pain management (Berman et al., 2009; Huang et al., 2003; King & Workman, 2006; Lind et al., 2008;

Table 3
Quality assessment summary of Trials (CASP).

Quality assessment tool: CASP tool for Trials (Critical Appraisal Skills Programme, 2013)											
Study design: Trials and Experimental studies.											
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11
McDonald et al. (2013) (USA)	Y	Y	Y	Y	CT	Y	CT	CT	Y	CT	Y
McDonald et al. (2012) (USA)	Y	Y	Y	Y	Y	CT	CT	CT	CT	CT	Y
McDonald et al. (2011) (USA)	Y	Y	Y	Y	Y	Y	CT	CT	Y	N	Y
Berman et al. (2009) (USA)	Y	Y	N	Y	Y	Y	CT	CT	Y	CT	Y
McDonald et al. (2009) (USA)	Y	Y	Y	Y	Y	Y	CT	CT	Y	CT	Y

Table 4
Quality assessment summary of Qualitative studies (CASP).

Quality assessment tool: CASP tool for Qualitative studies (Critical Appraisal Skills Programme, 2013)								
Study design: Qualitative design								
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
Parker et al. (2013) (USA)	Y	Y	CT	Y	Y	CT	CT	Y	Y
Lind et al. (2008) (Sweden)[a]	Y	Y	Y	CT	CT	CT	CT	Y	Y

Key: Y = Yes, N = No, CT = Can't tell.

[a] This study included very little quantitative data hence the quality assessment was done using a qualitative study appraisal tool.

Table 5
Quality assessment summary of Case Series Studies.

Quality assessment tool: Quality Appraisal Checklist for Case Series Studies (Moga et al., 2012)																			
Study design: Case series																			
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20
King and Workman (2006) (Australia)	Y	Y	Y	U	P	Y	U	Y	P	Y	N	Y	U	Y	U	U	NA	NA	Y	Y
Huang et al. (2003) (USA)	P	Y	N	U	P	N	U	Y	Y	Y	N	Y	Y	Y	U	U	NA	NA	Y	Y

Key: Y = Yes, P = Partial, U = Unclear, N = No, NA = Not applicable.

Parker et al., 2013). Two studies provided brief account of high acceptability and satisfaction of a videoconference (King & Workman, 2006) and a touchscreen computer-based pain assessment intervention (Huang et al., 2003). An internet delivered pain management intervention was also reported as being highly useful and user friendly (Berman et al., 2009).

Older people's experience of using a digital pen for pain assessment indicated high user-acceptance and ease of use despite participants' poor health, limited understanding of device's functioning, and occasional technical malfunction (Lind et al., 2008). The feeling of being more connected with clinicians due to real-time pain data-transfer was highlighted (Lind et al., 2008). The barriers and facilitators to use of digital health technology among older people for pain management included: concerns regarding mobile device's battery life, cost, lack of familiarity with the technology, need for digital technology training, older user friendly device design, and mHealth facilitated improved communication with clinicians (Parker et al., 2013).

4. Discussion

Although this integrative review found only a small number of studies exploring the use of digital health technology for pain management of older people, some valuable insights about the state of evidence in this area of research have been generated and helped answer the following search questions.

4.1. What are the salient features of digital health technology that have been tested as part of a pain management strategy for older people?

Computer-based video interventions in clinic setting were most commonly tested for pain management of older people (Berman et al., 2009; King & Workman, 2006; McDonald et al., 2009, 2011, 2012, 2013). Although, similar finding has been reported by a recent systematic review of internet based pain management interventions tested across all ages (Heapy et al., 2015), technologically more advanced intervention such as a pain app have largely focused on younger population (Stinson et al., 2013). Nevertheless, successful use of app based intervention among older people for purposes such as strength training (Van Het Reve,

Silveira, Daniel, Casati, & Bruin, 2014) shows that these technologies could have potential applicability for pain management among older people.

The video interventions (live broadcast, videotape, or animation) involved a combination of educational, interactive, or instructional component. Although video interventions are preferred among older people because they accommodate different learning styles (Hill et al., 2009), the evidence for animations is inconclusive. Animations have been used in gait and mobility assessment of older people (Marsh, Ip, Barnard, Wong, & Rejeski, 2011), however little is known about its use for coaching purposes. Considering the cost effectiveness and ease of technical manipulation of animations, further evidence is necessary to support their use in pain management.

Non-computer based digital technology interventions included the use of a digital pen for pain assessment showing high acceptability and ease of use among older people (Lind & Karlsson, 2013; Lind et al., 2008). Although digital pens have been used for identification of symptom deterioration among older heart failure patients (Lind & Karlsson, 2013), further research investigating the impact of this technology on older people's pain outcomes is necessary.

While older people report a willingness to use digital health technologies at home for pain management (Currie et al., 2015; Parker et al., 2013), very few studies have tested these technologies in this setting (Berman et al., 2009; Lind et al., 2008). In progressing this work, it is crucial to consider older people's choice and preferences while implementing technology in their lives/homes; and to involve older people in technological research process so that their voices are heard and their needs are met (Borges, Sinclair, Mollenkopf, & Rayner, 2008).

4.2. Is there evidence to support the use of mHealth and eHealth technologies in management of pain in older people?

There is insufficient evidence demonstrating the effectiveness of digital health technologies in reducing older people's pain intensity and pain interference (Berman et al., 2009; McDonald et al., 2012, 2013). While this finding resonates with a recent systematic review reporting inconclusive evidence of effectiveness

of digital health intervention in improving outcomes of mental health patients (Naslund, Marsch, Mchugo, & Bartels, 2015) it contradicts with another review which demonstrated effectiveness of such intervention in general population with somatic diseases (Elbert et al., 2014). This discordance warrants further research testing the effectiveness of digital health technology in narrower segment of population with specific illness and unique needs.

There is some lower level evidence that video based interactive/instructive interventions may increase patient's ability to describe their pain and higher likelihood of using pharmacological pain treatment (McDonald et al., 2012, 2013). Older people's inability to effectively communicate their pain experiences is a known pain management barrier which may limit its applicability (Glajchen, 2001). In addition, the causality between improved pain communication and increased likelihood of pain treatment has not been established.

Evidence indicates that watching pain management videos on exercise, pain education and communication could lead to higher confidence in pain self-care, however the improvements in pain intensity observed in both the intervention and comparison groups make these results difficult to interpret (Berman et al., 2009). Whilst this trial was not powered to detect a difference further work in this area is required, because there is some evidence that the provision of tailored education and guided therapy (exercise or relaxation) could improve patient's pain self-management ability and pain intensity (Marques, Gonçalves, Meira, Pereira, & Sousa, 2015),

There is low level evidence that open-ended questions without social desirability could elicit significantly more pain related information from older people, whereas pain questions phrased as social conversation such as "how are you feeling" could encourage a socially desirable answer (McDonald et al., 2009). Although earlier studies have reported the influence of social desirability bias on pain self-reports of chronic pain patients (Deshields, Tait, Gfeller, & Chibnall, 1995), recent evidence in this area is lacking. Nevertheless, recent studies do suggest that older people are reluctant to acknowledge, report and discuss their pain (Makris et al., 2015). Pain assessment questions of future technological interventions should allow older people to accurately report their pain without causing response distortion.

4.3. Barriers and facilitators to digital technology use

Older people are willing to learn and use digital technologies for pain management but experience some technological adoption barriers (Currie et al., 2015; Lind et al., 2008; Parker et al., 2013). One of the most highlighted barriers to use of digital technology was the concern relating to battery life (Parker et al., 2013), which resonates with earlier research (Kurniawan, 2008). Future digital health technology interventions aimed at older people should consider implementation of cost-effective and power-efficient devices.

Provision of device use training was a key facilitator (Lind et al., 2008). Unlike earlier reports that devices and programs need to be tailored as per older people's need (Al-Razgan, Al-Khalifa, Al-Shahrani, & Alajmi, 2012), more older people preferred to be device trained than having the devices tailored to their need (Parker et al., 2013). Given the high prevalence of cognitive impairment among older people and rapidly advancing field of technology, provision of ongoing training and support to older users should be considered when implementing digital technology based intervention.

An important facilitator supporting the adoption of digital technology is having close contact with clinicians and bi-directional flow of information (Lind et al., 2008; Parker et al., 2013). Future technological interventions need to promote connectedness between patient and clinicians while minimizing clinical data overload. Especially, as clinicians seem unprepared to deal with the large volumes of data generated by such interventions despite welcoming its use for pain management (Levine, Richardson, Granieri, & Reid, 2014).

4.4. What are the gaps in the evidence and future research?

There is lack of high-quality studies investigating the effectiveness of digital health technologies in management of older people's pain, with most limited to pilot or feasibility studies that do not appear to have led to larger adequately powered phase III RCTs. Given the rapid advancement in the field, there is a need to identify older people's needs, preferences, perceptions and attitudes towards the use of digital health technologies as part of a community based pain self-management strategy and to use these findings to inform future studies. This review did not identify any studies testing pain related apps, which are increasing exponentially often with little evidence of having been evaluated.

4.5. Limitations

There are several limitations that should be considered in appraising the results of this review. The exclusion of studies published in languages other than English, non-empirical research and un-published reports may have led to selection bias. With its focus on digital health technology this integrative review has limited ability to identify the role of other technologies such as fixed line telephone for improving older people's pain. However this integrative review has provide valuable insight into the efficacy of such novel technologies and identified barriers and facilitators that needs considering prior to developing and implementing such intervention in older population.

5. Conclusion

Despite the growing interest in use of various digital health technologies over the past decade, there is limited evidence of efficacy of such interventions among older people for pain management. Optimizing the integration of digital health technology pain self-management strategies for older people requires inter-professional collaboration. The provision of high-quality technological interventions informed by a thorough understanding of older people's digital technology pain management needs and underpinned by systematic frameworks is required to ensure greater integration of this technology in clinical practice. This is an abundant area for future research considering the increasing uptake of technology among older people globally.

Conflict of interest

The authors have no conflicts of interest to report. The employing organization of both authors did not play any role in this research work.

Author contributions

Both authors (PB and JP) contributed to the concept and design of this review, and in the manuscript preparation process.

Sponsor's role

There were no sponsors for this manuscript.

Appendix A.

Medline Search Strategy (Date: 2/08/2015).

Search Number	Search Terms	Hits
	Concept- Older people	
S1	(MM "Frail Elderly") OR (MH "Aged+")	2,429,327
S2	(MM "Aged, 80 and Over")	1669
S3	(MM "Geriatrics")	24,005
S4	TI ("older people" OR "elderly" OR "senior*" OR 'ageing' OR "aging" OR "old age") OR AB ("older people" OR "elderly" OR "senior*" OR 'ageing' OR "aging" OR "old age")	425,683
S5	S1 OR S2 OR S3 OR S4	2,644,562
	Concept-Pain	
S6	(MH "Pain+")	319,412
S7	TI pain OR AB pain	440,858
S8	S6 OR S7	584,595
	Concept- Digital health technology	
S9	(MM "Reminder Systems")	1429
S10	(MM "Information Seeking Behavior")	538
S11	(MM "Cell Phones") OR (MM "Text Messaging") OR (MM "Modems") OR (MM "Answering Services")	4648
S12	(MM "Electronic Mail") OR (MH "Text Messaging") OR (MH "Cell Phones+") OR (MH "Videoconferencing+")	7842
S13	(MH "Internet+") OR (MH "Microcomputers+") OR (MM "Minicomputers') OR (MM 'Computers, Handheld') OR (MM "Computers")	89,527
S14	(MM "User-Computer Interface") OR (MM "Mobile Applications")	13,946
S15	interactive voice response	531
S16	(MM "Virtual Reality Exposure Therapy")	165
S17	(MM "Attitude to Computers")	1792
S18	(MM "Computer-Assisted Instruction")	7429
S19	(MH "Internet+")	54,268
S20	(MH "Telemedicine+")	16,924
S21	(MM "Text Messaging") OR (MH "Telecommunications+")	65,333
S22	(MM "Social Media")	1412
S23	(MM "Brain-Computer Interfaces")	592
S24	S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23	167,335
	Concept- Older people + Pain + Digital health technology	
S25	S5 AND S8 AND S24	**564**

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Appendix 2

Publication: Quality and Usability of Arthritic Pain Self-Management Apps for Older Adults: A Systematic Review

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Review Article

Quality and Usability of Arthritic Pain Self-Management Apps for Older Adults: A Systematic Review

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Abstract

Objective. To appraise the quality and usability of currently available pain applications that could be used by community-dwelling older adults to self-manage their arthritic pain.

Methods. A systematic review. Searches were conducted in App Store and Google Play to identify pain self-management apps relevant to arthritic pain management. English language pain management apps providing pain assessment and documentation function and pain management education were considered for inclusion. A quality evaluation audit tool based on the Stanford Arthritis Self-Management Program was developed a priori to evaluate app content quality. The usability of included apps was assessed using an established usability evaluation tool.

Results. Out of the 373 apps that were identified, four met the inclusion criteria. The included apps all included a pain assessment and documentation function and instructions on medication use, communication with health professionals, cognitive behavioral therapy–based pain management, and physical exercise. Management of mood, depression, anxiety, and sleep were featured in most apps (N = 3). Three-quarters (N = 3) of the apps fell below the acceptable moderate usability score (≥3), while one app obtained a moderate score (3.2).

Conclusions. Few of the currently available pain apps offer a comprehensive pain self-management approach incorporating evidence-based strategies in accordance with the Stanford Arthritis Self-Management Program. The moderate-level usability across the included apps indicates a need to consider the usability needs of the older population in future pain self-management app development endeavors.

Key Words. Older Adults; Pain Management; Arthritis; Smartphone; App; Usability; Technology

Introduction

Population aging is a global phenomenon. By 2050, 1.5 billion of the world's population will be older than 65 years ("older adults") [1], with most living in the community [2–4]. Between 20% and 46% of all community-dwelling older adults live with comorbid conditions that cause varying levels of disability and symptoms, including unrelieved pain [5]. For 70% of older adults, arthritis [6] is a major cause of chronic, unrelieved pain [7]. Across the developed world, arthritic conditions cost between 1% and 2.5% of the gross national product [8].

While osteoarthritis is the most common joint disease of old age, rheumatoid arthritis affects all ages but is more prevalent among older adults [9,10]. Despite different pharmacological treatment approaches, the recommended rheumatoid and osteoarthritis pain self-management strategies tend to be similar [11,12]. Both arthritic conditions require the patient to assess and interpret their pain (symptom awareness) and to apply adaptive coping strategies (symptom management)

such as analgesic adjustment or lifestyle modification on a regular basis [13]. An additional but important element of the self-management approach is the integration of a shared decision-making model where clinicians work closely with patients to build their self-management capabilities by provisioning appropriate instruction, education, and support [14–16]. All of these elements are integral to the Stanford Arthritis Self-Management Program ("Stanford Program").

The Stanford Program is a well-established pain self-management program [17,18], found to be consistently effective in improving patients' self-efficacy by increasing physical exercise, adoption of healthier eating and pain-coping strategies, and better medication adherence [19,20]. Delivered either face to face or via the Internet [18], the Stanford Program focuses on; 1) patient education; 2) addressing other symptoms that commonly accompany pain; 3) cognitive behavioral therapy (CBT) approaches to pain management; and 4) physical exercise regulation [19,20]. For the purpose of this review, the Stanford Model was chosen as the "gold standard" self-management model as it has been empirically validated in a number of studies across a variety of formats (face to face, Internet delivery, expert patient delivery) and successfully applied to arthritic pain management with community-dwelling older adults, the focus of the current review [17–20].

Mobile Technology and Pain Self-Management

Significant advances in smartphone technology and a proliferation of app development has occurred since the release of the first Apple iPhone in 2007 [21]. There are currently over 300 pain self-management apps providing functions such as pain assessment recording, pain-related information, and pain self-management plans [22,23]. These pain self-management apps could potentially be utilized by older adults to facilitate their pain self-management, especially as increasing numbers of older adults are now using the Internet (60%), smartphones (18%), and tablet computers (18%) in their daily lives [24]. There is also emerging evidence that a growing number of older adults are willing to use smartphones to better manage their pain [25–27] and that simpler designs, clearer instructions, and features help compensate for older people's reduced sensory and motor skills [28,29]. As many of the currently available pain apps have been developed with minimal input from clinicians or consumers and very few are based on a scientific, theoretical, or conceptual foundation [22,23,30,31], it is difficult to know whether any meet the specific self-management needs and expectations of older people with arthritic pain.

Several pain app systematic reviews have been undertaken, but none has focused specifically on the needs of older people with arthritic pain. The evaluation and reporting approaches used in these systematic reviews varied widely, with some reviews only providing a descriptive account of the pain app's features [23,31],

while others provide details of an evidence-based quality appraisal [22,30,32]. However, these quality appraisals were limited because the review excluded arthritis pain apps [30], focused on nonarthritic literature [22], and/or was based only on CBT pain management literature [32]. Another limitation is that most reviews have not considered the needs of older users [33,34] and/or utilized a quality assessment criteria based on an extensive arthritic pain self-management literature, leading to inconclusive results.

Usability

Although usability evaluations of health care applications have become increasingly prevalent in the recent years [35–38], there has been little research addressing usability evaluations of pain apps [30]. While usability of pain apps has been evaluated in a recent systematic review [30], it was limited to evaluation of only two pain apps and was based on ratings of middle-aged raters in an author-developed rating tool. No systematic evaluation of older adult–specific usability of pain apps has been undertaken. As the vast proportion of the arthritic pain population is comprised of older adults, an evidence-based quality and usability evaluation of pain apps considering older adults' technology-specific needs is necessary to help users make informed choices.

Objective

To appraise the quality and usability of currently available pain applications that could be used by community-dwelling older adults to self-manage their arthritic pain.

Methods

Systematic review methodology informed by three frameworks, namely 1) the World Health Organization Innovative Care for Chronic Conditions (ICCC; macro level) [39]; 2) the domains of chronic disease self-management (meso level) [40]; and 3) the elements of Stanford Program (micro level) [17,18], was adopted to appraise the quality and usability of pain apps (Figure 1).

Inclusion Criteria

English language pain self-management apps developed from 2007 onwards and including at least one symptom awareness function (i.e., pain assessment, pain recording, pain management recording, and/or recording other complaints) and one symptom management function (i.e., patient education, other symptoms, CBT approach, and/or physical exercise) were eligible for inclusion. An app with only one function (either symptom awareness or symptom management) was deemed unlikely to comprehensively assist with pain self-management activities and was therefore excluded. Apps focusing on migraine, dental, or gynecological pain were excluded as the management approaches for these conditions tend to be different than the management approach for arthritic pain.
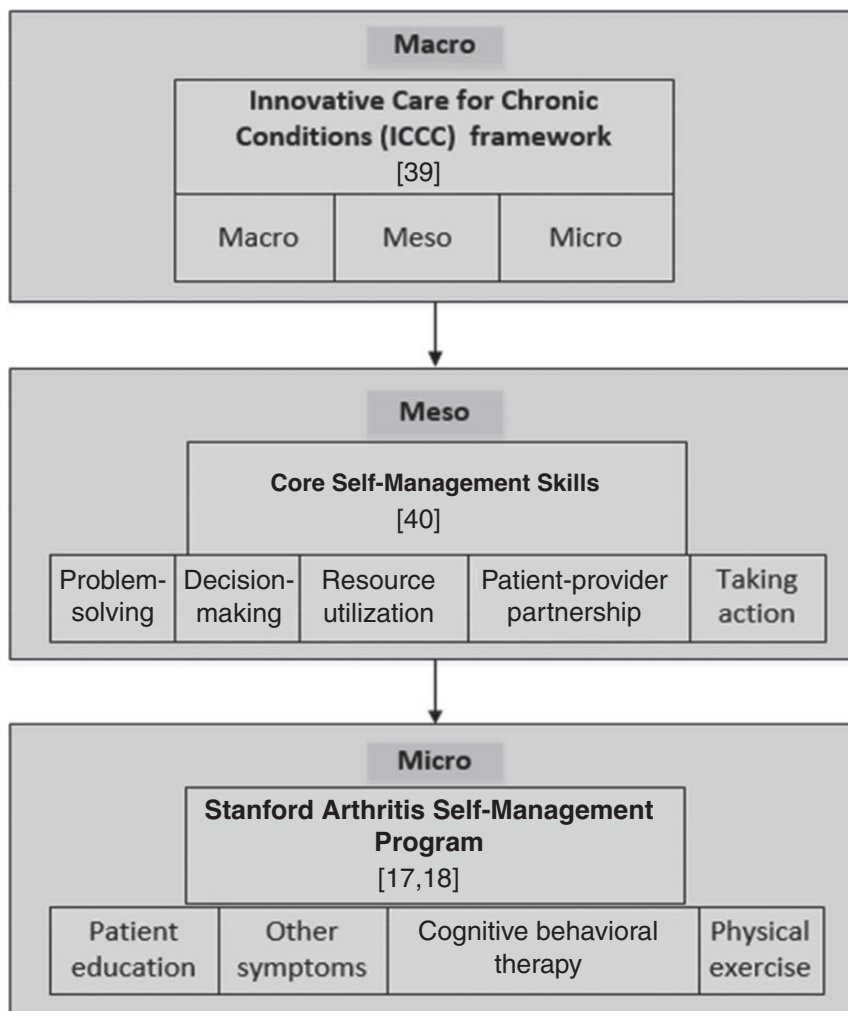
Figure 1 Guiding framework of this review.

Searches were conducted between 1st and 30th of May 2016 on two leading mobile operating systems that make up 99% of the global smartphone market (App Store for Apple and Google Play for Android) [41] using the following key words: pain, arthritis, osteoarthritis, back pain, and iPain. A Google web search using the phrase "pain app" was also conducted to ensure adequate coverage. Resultant apps were screened based on their name and description. As the resultant app list was potentially endless (similar to a Google search), we utilized the approach used in a previous review [42] and carried out the screening process until 20 consecutive apps yielded no new potentially relevant app. These apps were downloaded to an iOS (Apple iPhone 5S) or an Android device (Samsung Galaxy S5) for assessment against the inclusion criteria. Multiplatform apps were downloaded to the Apple device. Three reviewers (PB, TNJ, and JLP) assessed the eligibility of the resultant apps against the inclusion criteria. Inter-rater reliability of included/excluded apps was determined by calculating Cohen's kappa statistic for the primary author's

independent ratings (PB) against the two other authors (JP, TNJ). There was moderate to excellent agreement among raters (k = 0.595–1.00, $P < 0.001$) in the initial rating, and with subsequent discussion, full agreement was reached on all included/excluded apps. Apps meeting the inclusion criteria were saved for data extraction.

An app quality evaluation audit tool (Supplementary Data File 1) was developed a priori to evaluate app content quality. This audit tool was informed by the Stanford Program [17,43], Cochrane reviews [44,45], established arthritic pain management guidelines [46,47], and a randomized controlled trial (RCT) (refer to Table 1) [48]. Two key aspects of pain self-management, symptom monitoring (pain assessment and ability to document assessment findings) and symptom management (pain management concepts and strategies, promoted via education/instruction), were the focus of the quality evaluation. Each quality evaluation item in the quality evaluation tool was allocated one point if it was

Table 1 Overview of the app quality evaluation audit tool

Symptom Awareness (Pain Assessment and Awareness Function)

Pain diary
This section assessed if the app in question provided key functionalities expected in a pain diary, namely:
1. pain assessment recording,

2. pain management recording, and

3. recording of other symptoms and complaints.

These key components were derived from an earlier randomized trial study that developed and tested an electronic pain diary [48].

Symptom Management (Pain Management Function)

Patient education
This section assessed if the app in question included the following key components of the Stanford Program, namely:
1. education on important pain-related topics,

2. management of symptoms that commonly accompany pain,

3. CBT approach, and

4. physical activity.

These key components were then developed as sections with corresponding subsections designed to collect information on how each app delivers the component to the user. The items in the subsections were compiled based on recommendations from Cochrane reviews [44,45], established guidelines [46,47], or from best practice evidence such as the Stanford program itself [43]. However, not all of the items included within the subsections of each key component have established evidence to support their efficacy in pain self-management.

Usability Evaluation
This section assessed how usable the app in question is from the perspective of older users. The following components were assessed [36]:
1. comprehensibility,

2. presentation (image and text),

3. usability, and

4. general characteristics.

present ("Yes") and zero if not present ("No"). An aggregate score for each symptom monitoring and management subsection was calculated. Three reviewers (PB, JLP, and TNJ) independently rated each of the included apps using this quality evaluation audit tool.

The usability evaluation was carried out using the older adult–specific usability evaluation tool used in an earlier evaluation of diabetes apps [36]. This tool ranks four functionality criteria, namely comprehensibility, presentation, usability, and general characteristics, using a five-point Likert scale [36]. An overall usability score is calculated by averaging the scores of each of the functionality criteria (range = 1–5), with a score of 3.0 or greater reflecting acceptable usability [36]. General information about each app was extracted onto a Microsoft Excel table. The quality and usability score for each app is reported as the mean of each rater's score.

Results

Of the 433 apps identified, only four met the inclusion criteria (Figure 2). All of the apps were available in the Apple (iOS) platform; however, one (WebMD Pain Coach) [49] was downloaded to the Android device due to it repeatedly crashing on an Apple device. The Google web search yielded no additional apps.

App Characteristics

The summary of included apps is provided in Table 2. All of the apps were developed in high-income countries: two in the United States (Track + React, WebMD Pain Coach) [49,50], one in the United Kingdom (Pain Toolkit) [51], and one in Ireland (Rheumatoid Arthritis, Information, Support, and Education [RAISE]) [52]. All of the apps were developed in consultation with a health care authority or health professional. None of the apps required payment for download; however, one app (Pain Toolkit) [51] required either a UK-based general practitioner–provided token number or a payment of $7.99 (AUD) for full access.

Quality Evaluation

The app quality evaluation summary is presented in Table 3 (refer to Supplementary Data File 2 for raters' scores). All of the apps included a pain assessment function [49–52]; three featured a numeric rating scale (NRS) for pain intensity assessment that could be used as frequently as the user wished [49,50,52], whereas the fourth [51] included a body chart–based assessment of pain location, pain impact assessment, and questions on pain type that was only completed as part of the initial assessment. Two apps also included an option for recording analgesic(s) taken and other accompanying symptoms and/or complaints [49,50]. The Pain Toolkit [51] provided a free text option for users to enter information relating to their pain medication and the effect of nonpharmacological interventions employed.

All of the apps provided education on topics such as pain self-management principles and medication use [49–52]. However, the content is generic, with no
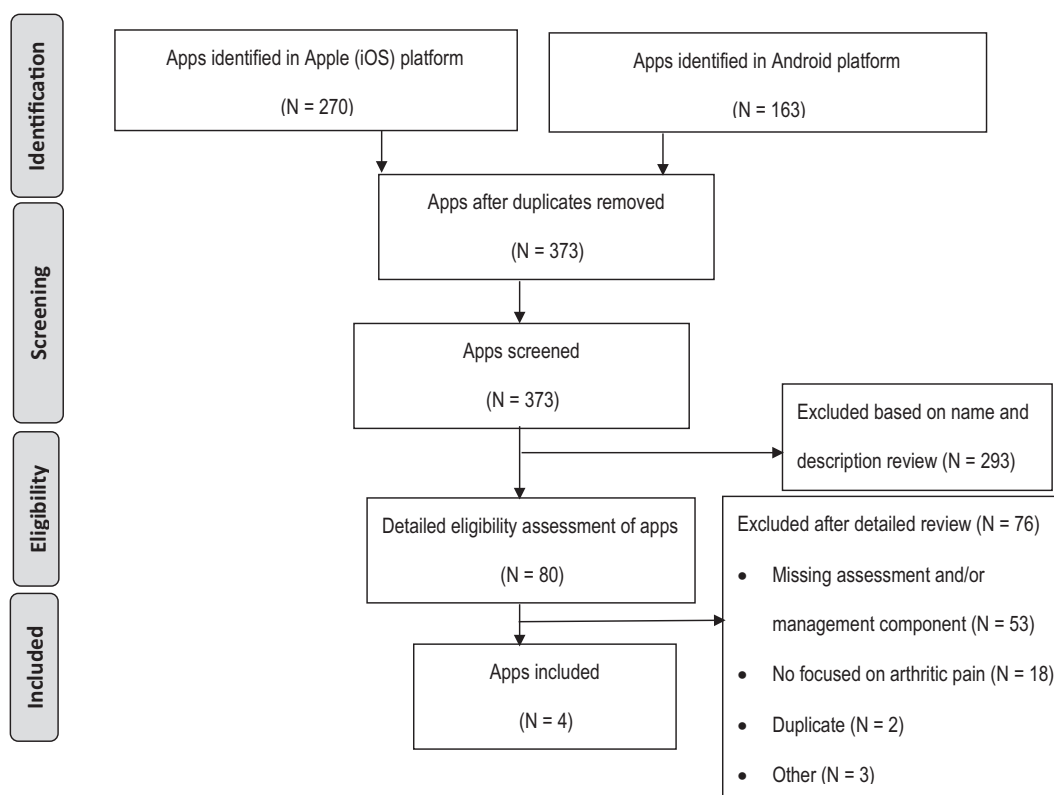
Figure 2 Flow chart of apps from search to inclusion.

capacity to be tailored as per individual need or preference. In addition, all four apps [49–52] encouraged users to regularly communicate their pain concerns with their health professionals and seek advice when contemplating a new pain management approach. Disease-related problem-solving was covered by three apps [49–52]. None of the apps highlighted strategies to minimize or address pain-related fear avoidance.

Information relating to the management of nutrition, general mood, depression, and anxiety was included in two apps [49,52]. Additionally, the RAISE [52] app also included information on fatigue management, and the WebMD Pain Coach [49] included comprehensive information on sleep management. The Track + React app [50] included information on management of sleep, fatigue, general mood, and nutrition, whereas the Pain Toolkit [51] only included information on sleep management.

The WebMD Pain Coach [49] integrated a number of CBT-based pain management approaches (5/8), including information on general relaxation, mindfulness meditation, distraction, imagery, and goal setting. The RAISE [52] and Pain Toolkit [51] apps both included information on general relaxation, goal setting, and activity pacing, with the Pain Toolkit [51] additionally including information on mindfulness meditation. The Track + React app [50] only covered goal setting and activity pacing.

While varying levels of physical exercise information were included in all of the apps, the WebMD Pain Coach [49] and RAISE [52] apps provide users with an option to create a personalized exercise program from a list of recommended stretching, isotonic, aerobic and aqua exercises. The RAISE app [52], in addition to detailing the World Health Organization's recommendation for duration and frequency of exercise for adults [46], also included a series of warm-up and cool-down exercises. The Pain Toolkit [51] provided information on stretching and aqua exercises and highlighted the need for an exercise program to be personalized as per individualized needs and capabilities. Several elements of the quality evaluation were not found in any of the included apps, such as education on fear avoidance principles, biofeedback treatment, and operant conditioning.

Usability Evaluation

WebMD Pain Coach was the only app to obtain a moderate usability score of above 3, while Track + React, RAISE, and Pain Toolkit all fell just below the acceptable moderate usability score of 3.

Discussion

This systematic review has demonstrated that a very small number of pain apps offer pain self-management strategies based on the arthritic pain self-management

Table 2 Summary of included apps

App Name	Developer	Cost/Pain Type	Assessment and Documentation Function	Management Function	Usability	Total Score*
WebMD Pain Coach [49]	WebMD	Free/all type	At least daily assessment and recording of pain using 11-point NRS. Option to record the name of analgesic taken (time stamped). Option to record other symptoms and complaints as desired. Score = 4.7/7	Provision of education on pain/self-management process, medication use, communication with health professionals and pain-related problem solving. Detailed information on sleep, nutrition, and psychological issues management. CBT-based pain management instruction on relaxation, mindfulness and meditation, distraction, imagery, and goal setting. Customizable exercise plan, with detailed information on stretching, isotonic, aerobic, and aqua exercises. Score = 23/32	Average general features (1.9/5) and presentation (2.9/5), moderate usability (3.4), and high comprehensibility (4/5). Score = 3.2/5	Quality = 27.7/39 Overall usability = 3.2/5
Track + React [50]	Arthritis Foundation US	Free/arthritis	At least daily assessment and recording of pain using 11-point NRS. Option to record the name of analgesic taken, nutrition, fitness, sleep, medication, overall feeling, fatigue, mood, stiffness, and joint function. Score = 4.5/7	Education provision on pain/self-management process, medication use, communication with health professionals and pain-related problem solving. Information on management of fatigue, sleep, nutrition, and affect. Inclusion of goal-setting function and information on activity pacing. Customizable stretching, isotonic, aerobic, and aqua exercise; warm-up, cool-down included. Score = 18/32	Poor general features (1.1/5), average presentation (2.3/5), moderate usability (3.2/5) and comprehensibility (3.6/5). Score = 2.7/5	Quality = 22.5/39 Overall usability = 2.7/5
RAISE [52]	St James Hospital + Arthritis Ireland	Free/rheumatoid arthritis	At least daily assessment and recording of pain and activity level using 6-point (0–5) NRS. Pain management approach documentation not included. Score = 1.2/7	Provision of education on pain/pain self-management process, medication use, communication with health professionals and pain-related problem solving. Information on fatigue, sleep, and psychological issues management. CBT pain management instruction on relaxation, goal setting, and activity pacing (20–30 minutes session). Videos of stretching, isotonic and aerobic exercise with warm-up and cool-down stages. Duration and frequency indicated. Score = 21.5/32	Poor general features (1.2/5), average presentation (2.8/5), moderate usability (3/5) and comprehensibility (3.6/5). Score = 2.9/5	Quality = 22.7/39 Overall usability = 2.9/5

(continued)

Table 2 Continued

App Name	Developer	Cost/Pain Type	Assessment and Documentation Function	Management Function	Usability	Total Score*
Pain Toolkit [51]	Pain Sense	$7.99/chronic pain	One of assessment of pain type and location, no intensity reporting offered. Health needs and pain impact measuring option. Option to record medication on the diary function of the app. Assessment and recording of other complaints not prompted. Score = 2.7/7	Provision of education on pain/pain self-management, medication use, communication with health professionals, and sleep management. CBT approach to pain management recommended via use of general relaxation, activity pacing, and goal setting. Personalized approach recommended for stretching and aqua exercise. Score = 14/32	Poor general features (1.2/5), average presentation (2.5) and usability (2.7/5), and high comprehensibility (4.2/5). Score = 2.8/5	Quality = 16.7/39 Overall usability = 2.8/5

*Mean scores of three raters.

literature. Additionally, there seems to be very little consideration of older adult–specific usability in currently available pain apps. Although the resultant app numbers were small, some valuable insights have been generated about the quality and usability of pain self-management apps, particularly in relation to the elements of the Stanford Program as detailed below:

Elements of the Stanford Program

Recording Diary Function

Despite the abundance of pain apps, very few promoted pain self-management practices in accordance with elements of the Stanford Program [18,40]. At a minimum, all of the included apps provided options to assess pain (pain intensity or pain type and location). While pain intensity assessment is noted to be one of the most common features of pain apps [30,31], this measure is less relevant than pain impact in the context of chronic arthritic pain [53,54]. Pain intensity score is known to be a poor indicator of clinically important pain [53], with little evidence of accuracy and effectiveness in improving delivery of care and outcome. Instead, pain impact assessment, which is a better indicator of chronic pain patients' treatment preferences, could be a more valuable addition to future pain apps, with a potential to guide appropriate self-management strategies [54].

Although international guidelines recommend that arthritic pain management plans include both pharmacological and nonpharmacological approaches [55,56], the latter seems to have received very little recognition among pain apps. While the recording of analgesic use was a prominent feature, the recording of nonpharmacological treatments as part of an active self-management plan is a noticeable gap in the majority of pain apps. By focusing disproportionately on analgesics, these apps may inadvertently lead to nonpharmacological strategies being underpromoted. In addition, poor access and limited availability of nonpharmacological pain self-management strategies such as mindfulness and tai chi, together with limited promotion of such approaches by primary care clinicians [57], could further contribute to the underutilization of these strategies among arthritic patients [58,59].

Patient Education

Pain education and self-management instructions were featured in all of the included apps. This approach adheres with the conceptual definition of the persistent pain self-management process where older adults are expected to acquire the knowledge and skills necessary to respond to and control their pain [60]. Furthermore, provision of the information and skills necessary to attain mastery over the care of one's health condition is the foundation of the patient empowerment process [61]

and is recommended in the self-management of chronic diseases such as diabetes [62].

It is interesting that the majority of the included pain apps provided information relating to nutrition management [49,50,52]. Although appropriate nutritional intake is an important component of healthy living among older adults [63], there is little evidence supporting a specific diet for pain self-management purposes. While nutritional interventions for older adults with reduced functionality may result in improved energy level, they fail to translate into improved functional outcomes [64].

Written learning content embedded within the majority of apps was the prime medium used to educate consumers. Only one of the apps integrated a different learning format, in the form of providing supplemental audiovisual material [51]. Although written communication is a widely used passive health information dissemination strategy, the addition of the audiovisual mode leads to relatively greater information recall [65]. Recall of health information is crucial if consumers are to effectively implement the recommended self-management instructions [66]. Optimizing learning opportunities in apps is crucial given that many older adults have low health literacy levels [67]. People with poor health literacy not only lack the necessary skills to understand and use health-related information [68], but are also known to have poorer recall [69]. Moreover, the cognitive and sensory changes that accompany the process of aging further amplify the challenges associated with teaching older adults new learning content [70].

CBT Approach to Pain Management

Although a CBT-based pain management approach is recommended for older adults as an adjunct or a firstline therapy if the patient prefers [5], most of the included apps only alluded to CBT approaches in very basic form (e.g., written instruction on relaxation or activity pacing). This finding is consistent with a recent review of adult pain apps, where features consistent with evidence-based CBT principles were present in very few apps [32].

As behavioral goal setting is an effective strategy supporting self-management behaviors [62], it was pleasing that CBT goal-setting approaches were incorporated within all of the included apps. This finding differs from earlier research, which found that goal setting was rarely included in pain apps [22,32]. It is unclear if CBT features have been underreported in previous app reviews or if this finding reflects recent advancement in technology that has led to increased inclusion of goal-setting features. Goal setting is prominently featured in physical activity [71] and weight loss [72] apps, with a corresponding indication from consumers of its desirability [73]. However, the role of goal setting in pain apps and the views of consumers of this feature ought to be explored. There is

also a need to explore the effectiveness of integrating CBT into pain apps as a recent RCT of a CBT-based app for depression has demonstrated clinically significant improvements [74].

Physical Exercise

The inclusion of some form of physical exercise component in all of the included app reflects the established recommendation to incorporate physical exercise in the pain management of older adults [5,46]. The importance of regular exercise in older adults with chronic pain and arthritis is supported by high-level evidence [46,47], yet few if any pain self-management apps have included all of these physical exercise recommendations.

The exclusion of tailored physical exercise prescription, including duration and frequency of movements by the majority of apps, is a notable gap that needs to be addressed in future pain self-management apps. A tailored physical exercise prescription that can be adapted according to the comorbidities, functionality, and safety profile of an individual user may not only assist older users to better self-mage their pain, but also help prevent falls and injury [75,76]. Additionally, providing information on the beneficial role of physical exercise in preventing falls may also encourage older users to engage effectively with their physical exercise prescription.

Usability

Overall, the older adult–specific usability of pain self-management apps could be classified as moderate at best. Functions important to older users such as enlarging the app screen size or font were not provided in any of the apps, indicating that these apps were developed without consideration of the visual and motor impairment prevalent among older adults, the group that forms the significant proportion of the pain population [77]. Consideration of the usability requirements of older adults is necessary in future pain app development endeavors; after all, provision of high-quality information in an app may be of no benefit it the usability needs of the target users are not met [78].

Technological Advances in the Future

Given smartphones' high-quality on-board sensors that can capture advance movement and sound-based assessment data [79], there are opportunities to integrate these features into future apps. Apps capable of assessing and interpreting sensor-based data in the future may assist cognitively impaired older adults and/or caretakers to better manage their pain. While sensor-based features have been utilized in screening and monitoring apps for depression [80] and sleep disorders [79], none has the capacity for electronic health information exchange between the users and their treating health professionals. Given the importance of the patient-clinician

Table 3 Quality evaluation summary of included apps as rated by two or more raters

	Quality Components	WebMD Pain Coach [49]	Track + React [50]	RAISE [52]	Pain Toolkit [51]
Recording/ diary function [48]	Daily NRS	✓	✓	✓	×
	Pharmacological pain management	✓	✓	×	✓
	Nonpharmacological pain management	×	×	×	✓
	Pain/pain self-management	✓	✓	✓	✓
	Fear avoidance	×	×	×	×
	Medication use	✓	✓	✓	✓
Patient education [43]	Communication with HP	✓	✓	✓	✓
	Problem solving	✓	✓	✓	×
	Fatigue	×	✓	✓	×
	Sleep	✓	✓	×	✓
Education on other symptoms [43]	Nutrition	✓	✓	✓	×
	Affect	✓	✓	✓	×
	Depression	✓	×	✓	×
	Anxiety	✓	×	✓	×
	Relaxation	✓	×	✓	✓
	Mindfulness, meditation	✓	×	×	✓
CBT pain management techniques [44,43,45]	Diversion, distraction	✓	×	×	×
	Imagery	✓	×	×	×
	Goal setting	✓	✓	✓	✓
	Biofeedback	×	×	×	×
	Activity pacing	×	✓	✓	✓
	Operant treatment	×	×	×	×
	Personalized	✓	✓	×	✓
	Warm-up, cool-down	×	×	✓	×
Physical exercise [43,46,47]	Stretching	✓	✓	✓	✓
	Isotonic	✓	✓	✓	×
	Isometric	×	×	×	×
	Aerobic	✓	✓	✓	×
	Aqua exercise	✓	✓	×	✓
	Duration	×	×	✓	×
	Frequency	×	×	✓	×

partnership as technology advances, building electronic health information exchange capacity into future pain apps will strengthen their utility.

Patient-recorded pain management data, if shared with clinicians, could not only assist with the development and/or refinement of an individualized pain management plan, but also facilitate technology use among older users [81]. However, as primary care clinicians will often be unable to deal with the large volumes of data generated by these technological interventions, caution should be exercised in data-sharing with clinicians to minimize data overload [82]. While future pain apps should prioritize electronic health information exchange, clinicians should be involved in setting up this process to ensure useful and practical presentation of the data [82].

Implications for Practice

The lack of clinician's involvement in development of pain-related apps and other health care apps has been

noted previously, indicating concerns about the accountability, accuracy, and reliability of the app contents, calling for increased regulatory oversight so as to safeguard patient welfare [30,31,83,84]. It is worth noting that all the apps included in this review (which had some merit based on the pain self-management literature) had some input from health care authorities/professionals. Although there is not enough evidence to suggest that apps developed with a clinician's involvement are superior to those developed without their input, such collaboration has the potential to inform the self-management and patient education inclusions to be appropriately well integrated and evidence based [23]. The involvement of pain experts should be considered in future pain app development endeavors.

Despite being considered important inclusions in a pain self-management plan [44,85,86], operant treatment, biofeedback, and fear avoidance education were not featured by any of the apps and were probably out of the scope of an app to deliver. This suggests that while

apps may be helpful adjuncts in the pain self-management process, the creation of the expert patient occurs when the patient is supported and empowered by their clinicians throughout the pain self-management journey [40]. Clinicians providing care to patients who utilize apps to facilitate their pain self-management process should be aware of the capabilities and limitations of the apps and provide appropriate support and education to these patients.

In addition, the inclusion of non-evidence-based components such as nutrition management in the apps indicates that clinicians should exercise caution in recommending or "prescribing" apps to their patients. There is a need for a health app rating system so that clinicians and consumers are able to easily appraise which app promotes the best available evidence for the purpose of pain self-management. Furthermore, a valid and reliable tool designed for quality and usability evaluation of pain self-management apps is necessary to further enhance this area of research.

Strengths and Limitations

Some limitations should be considered in interpreting our review's result. Firstly, as our searches were conducted in Australia, apps exclusively available to app stores of other countries could have been missed by our search. In addition, although searches were conducted in the two most popular app platforms (App Store and Google Play), some apps hosted exclusively in websites may have been missed in this review. Secondly, although the tools used to evaluate the quality and usability of the apps were evidence based, they are not validity- and reliability-tested; future work in testing the validity and reliability of these tools is warranted. Thirdly, this review did not involve any older adults in the quality appraisal and evaluation process, thereby limiting the review's potential to provide views of older adults who are the end users of the apps. Finally, although care was taken to rate the apps as objectively as possible, we acknowledge that some level of subjectivity or bias may have existed in rating the apps. The involvement of three raters and the reporting of the mean scores of the quality criteria were done to minimize this issue.

Nevertheless, this review also has notable strengths. The development and utilization of an evidence-based app quality evaluation tool to appraise the merit of currently available pain apps (paid and free) has allowed this paper to offer an evidence-based comparison of the capabilities of these apps. The quality evaluation tool can serve as a basic guide for future app development or an existing app refinement process. To our knowledge, this is the first review to investigate the older adult–specific usability of pain apps.

Conclusions

Despite availability of a large number of pain apps, this review has revealed that few offer a comprehensive pain self-management approach aligned with established evidence. Although a very small number of apps did provide pain self-management function, the range of included strategies did not seem to be comprehensive. The moderate-level older adult–specific usability across the included apps also indicates a need to consider the usability needs of the older population in future pain self-management app development endeavors.

Future work in the area of pain self-management should consider a collaborative venture between industry, health professionals, and end users where the app development process would include the following question: "What features and qualities should this app possess to support an effective pain self-management for older users?" In addition, as the features of smartphones continue to advance, developers of future pain self-management apps should consider incorporating these advance functions in the pain self-management apps with an option of real-time data sharing with the user's health care provider.

Supplementary Data

Supplementary Data may be found online at http://painmedicine.oxfordjournals.org.

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Appendix 3

App quality evaluation audit tool. This tool was developed by the DigiTech Pain project team and used to evaluate the content quality of the apps reviewed in the systematic review of pain self-management apps (study 1b).

App Quality Evaluation Tool

App Name	
Platform	
Date of download	
Developer	
Cost	
Target population	
Target pain type	

Reviewed by

Initial	
Date	

Quality evaluation tool

Pain assessment and documentation (Diary) aspect covered by the app [1]				
Pain assessment/management recording	At least daily 11-point NRS Scale for pain	Pain management process documentation	Recording of other symptoms and complaints	Score
☐ Yes (Provide details in the next columns) ☐ No (Proceed to components listed below)	☐ Yes ☐ No (Proceed to next column)	**Approach** / Score Pharmacological Analgesic taken — ☐ Yes ☐No Administration time — ☐ Yes ☐No Effects of analgesics — ☐ Yes ☐No Non-pharmacological Effects of other therapies — ☐ Yes ☐No	☐ Yes ☐ No (Now proceed below to educational components)	
/1	/1	/4	/1	/7

Patient education components covered by the app [2-5]				
Component 1 Important patient educational topics covered ☐ Yes (Provide details below) ☐ No (Proceed to next component)	**Component 2** Accompanying symptom management ☐ Yes (Provide details below) ☐ No (Proceed to next component)	**Component 3** CBT based pain coping skills ☐ Yes (Provide details below) ☐ No (Proceed to next component)	**Component 4** Physical exercise ☐ Yes (Provide details below) ☐ No (Proceed to next component)	

Component 1

Education topic		Score
Pain/pain self-management related education	☐ Yes ☐No	
Pain related fear avoidance	☐ Yes ☐No	
Medication use	☐ Yes ☐No	
Communication with health professionals	☐ Yes ☐No	
Disease related problem solving	☐ Yes ☐No	

Other relevant details:

Component 2 — Symptoms addressed

Symptoms		Score
Physical		
Fatigue	☐ Yes ☐No	
Sleep	☐ Yes ☐No	
Nutrition*	☐ Yes ☐No	
Psychological		
Affect- anger frustration, hopelessness etc.	☐ Yes ☐No	
Depression	☐ Yes ☐No	
Anxiety	☐ Yes ☐No	

Other relevant details:

Component 3 — CBT approaches included

Approaches		Score
Cognitive or Respondent treatment		
Relaxation (general)	☐ Yes ☐No	
Mindfulness/ meditation	☐ Yes ☐No	
Diversion/distraction	☐ Yes ☐No	
Imagery	☐ Yes ☐No	
Goal setting	☐ Yes ☐No	
Biofeedback	☐ Yes ☐No	
Activity pacing	☐ Yes ☐No	
Operant treatment	☐ Yes ☐No	

Other relevant details:

Component 4

Exercise plan		Score
Personalised	☐ Yes ☐No	
Involves warm up and cool down	☐ Yes ☐No	

Type of physical activity

Exercise type		Score
Stretching	☐ Yes ☐No	
Isotonic	☐ Yes ☐No	
Isometric	☐ Yes ☐No	
Aerobic	☐ Yes ☐No	
Aqua exercise	☐ Yes ☐No	
Total		/5

Duration and Frequency

Session Duration	Frequency per week	Score
20-30 minutes	3-4 days	
☐ Yes	☐ Yes	/2
☐ No	☐ No	0

Other relevant details:

/6	/7	/9	/10	/32

*Not evidence based but included in the Stanford Program based on no- low level evidence

A3

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Appendix 4

App usability evaluation tool. This tool was used to evaluate the older people specific usability of the apps reviewed in the systematic review of pain self-management apps (study 1b).

App Usability Evaluation Tool

App Name	
Platform	
Date of download	
Developer	
Cost	
Target population	
Target pain type	

Reviewed by

Initial	
Date	

Main Criteria	Sub-criteria	Assessment Criteria: Likert Scale (1 to 5)					Score
		1	2	3	4	5	
Comprehensibility — Use of understandable semantics		Does not apply at all				Does fully apply	
		1 ➝				5	
	Avoidance of foreign language and technical terms						/5
	Use of generally intelligible symbols and terms						/5
	If necessary, provision of additional explanations						/5
Simple comprehensibility and interpretability of displayed images and depictions		Does not apply at all				Does fully apply	
		1 ➝				5	
	Self-explanatory images and depictions, understandable without further support and explanations						/5
Simple, self-explanatory menu structures		Does not apply at all				Does fully apply	
		1 ➝				5	
	Easily understandable and internally consistent menu structures						/5
	Avoidance of strong hierarchical menu structures and too many functionalities						/5
Presentation (Image and Text) — Sufficient color contrast		Does not apply at all				Does fully apply	
		1 ➝				5	
	Clear, distinguishable colors for images and depictions or choice of color-neutral depictions						/5
	Avoidance of too glaring colors						/5
Large size of operating elements		Does not apply at all				Does fully apply	
		1 ➝				5	
	Sufficient size of screen as well as input and output fields						/5
Ability to adapt the size of operating elements and displayed images		Applicable or Not applicable					
	Ability to adapt size of operating elements and displayed images according to individual needs, capabilities, and preferences	Applicable =1 Not applicable=0					/1
Usability — Instant and easily understandable feedback		Does not apply at all				Does fully apply	
		1 ➝				5	
	Instant response to entered data, including easily understandable error						/5

			1	2	3	4	5	
		messages in case of erroneous data input						
Usability	Intuitive usability		1 Does not apply at all 1 ──────▶	2	3	4	5 Does fully apply 5	
		Ability to use the application without prior knowledge						/5
		Ease of learning						/5
		Fast achievement of a first feeling of success						/5
	Simple recognition of click-sensitive areas		1 Does not apply at all 1 ──────▶	2	3	4	5 Does fully apply 5	
		Simple distinction between click-sensitive and non-click- sensitive areas, also without prior knowledge of the features of the touchscreen technology.						/5
General Characteristics	High Fault tolerance/ efficient fault management		1 Does not apply at all 1 ──────▶	2	3	4	5 Does fully apply 5	
		Reducing probability of erroneous data input by limiting choice to meaningful values						/5
		Efficient proofreading mode and/or helpful user feedback, for example, in case of erroneous data input [27,30]						/5
	Password-protected services		Applicable or Not applicable					
		Avoidance of registration at online platforms (but partly contrary to data protection regulations)	Applicable =1 Not applicable=0					/1
Total score								/82

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Appendix 5

Summary of the quality and usability scores of each app included in the systematic review of pain self-management apps (study 1b), as scored by three raters (the doctoral student and two supervisors).

App scoring summary illustrating the scores of three raters

	JLP	TNJ	PB	Mean
WebMD Pain Coach				
QUALITY				
Pain assessment and documentation	5/7	4/7	5/7	4.7/7
Pain management	23/32	23/32	23/32	23/32
USABILITY				
Overall usability	3.9/5	2.4/5	3.2/5	3.2/5
Track + React				
QUALITY				
Pain assessment and documentation	4.5/7	5/7	4/7	4.5/7
Pain management	17/32	21/32	17/32	18/32
USABILITY				
Overall usability	2.8/5	2.7/5	2.6/5	2.7/5
Raise				
QUALITY				
Pain assessment and documentation	1.5/7	1/7	1/7	1/7
Pain management	23.5/32	20/32	21/32	21.5/32
USABILITY				
Overall usability	3.0	3.2	2.5	2.9/5
Pain Toolkit				
QUALITY				
Pain assessment and documentation	2/7	4/7	2/7	2.7/7
Pain management	14/32	16/32	12/32	14/32
USABILITY				
Overall usability	2.8	2.9	2.6	2.8/5

Appendix 6

Permission to use the figure depicting Efficacy expectation and outcome expectation (Bandura's self-efficacy theory). Depicted in this thesis as 'Figure 4.1', in the methods chapter (chapter 4).

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v1.9

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Appendix 9

The list of older people specific clubs approached with a request to share the DigiTech Pain project's recruitment poster to their members.

Organisations approached with invitation to participate in DigiTech Pain project

	Organisation/Clubs
	Listed in the OFA
1	Council on the Ageing (NSW)
2	Probus
3	Australian Retired Persons Association (ARPA)
4	Association of Independent Retirees (AIR)
5	Combined Pensioners and Superannuants Association (CPSA) of NSW
6	Older Men: New Ideas (OM:NI)
7	Older Women's Network (OWN)
	Other
8	Arthritis NSW
9	Rotary Club

Appendix 10

The DigiTech Pain project's recruitment poster.

Appendix 11

Screenshot of the DigiTech Pain project's Facebook page.

DigiTech Pain Project's Facebook page

Appendix 12

Participant Information and Consent Form designed for the recruitment of older people to the: phase I feasibility study (study 2a), and the qualitative sub-study (study 2b).

PARTICIPANT INFORMATION and CONSENT FORM
Using Digital health technology to optimise older people's Pain self-management capabilities: a mixed-methods ('DigiTech Pain') Project.

Introduction

You are invited to take part in the DigiTech Pain project because you experience ongoing osteoarthritic pain, are over 65 years of age and use a smartphone. Please read this information carefully and ask questions about anything that you don't understand or want to know more about. Participation in this research is voluntary. If you don't wish to take part, you don't have to. If you agree to participate in this study, you will be asked to sign the consent section.

What is the project about?

Osteoarthritic pain is very common among older Australians. Many older people living with arthritis will self-manage their pain by carrying out activities such as medication tracking and exercising. Some older people also use technologies including pain self-management apps.

While Apps are increasingly being used by all age groups, little is known about their suitability for older people. This study has been initiated by a team of clinical researchers [Professor Jane Phillips, Dr Toby Newton-John, and Ms Priyanka Bhattarai] to investigate older people's experiences of using a pain self-management App.

Who is undertaking the project?

This project is being conducted by Ms. Priyanka Bhattarai and will form the basis for the degree of Doctor of Philosophy (PhD) at The University of Notre Dame Australia, under the supervision of Professor Jane Phillips.

What will I be asked to do?

Participation in this project involves the following:
1. **First Meeting (M1) -** App download and questionnaire completion: With the assistance of one of the researchers, participants will be asked to download a freely available pain self-management App to their smartphone or tablet. The developers of the intervention App are not involved in this project so there is no known gain (financial or otherwise) to the App developers or to the research team from your involvement in this project. After the App download you will be asked to complete a questionnaire. It is estimated that this meeting will take up to 45 minutes and can be carried out face-to-face or via telephone.
2. **Over the next two weeks**: Participants will be asked to use the downloaded App (the way they want to use it).
3. **Second Meeting (M2)** - (Week 3): In the third week participants will be asked to take part in a telephone meeting to complete the follow-up study questionnaire.
4. **Interview (optional)** - After second meeting (M2): Participants will be invited to attend a one-on-one telephone interview to share their experiences of using the App. The interview will be audio recorded and could take up to 45 minutes.
5. **Clinician 5. Nomination (optional) -**You will be asked to nominate up to three health professionals who help you manage your pain and indicate if you agree to us contacting them with an invitation to participate in the study.

Are there any risks associated with participating in this project?

It is possible that you may experience discomfort during participation as a result of using the App, completing the questionnaire, or participating the interview. You will be monitored closely throughout the study period to ensure that participation does not lead to distress. Further, you are free to withdraw at any time. If these feelings persist after the study has ended, arrangements will be made for you to access support from the research team at no expense to you.

What are the benefits of the research project?

While this research intends to further knowledge in the area of pain self-management and may lead to improvement in future pain self-management practices, it may not directly benefit you.

What if I change my mind?

Participation in this study is voluntary. Even if you agree to participate, you can withdraw from the study at any time without discrimination or prejudice. *If you decide to withdraw, you can simply notify me via phone or email [0452518525/ Priyanka.Bhattarai1@my.nd.edu.au].*

Will anyone else know the results of the project?

The information collected from you will be de-identified, stored securely, and accessed only by the research team. This information will be held in strict confidence, and will only be made available if required by law. Publications resulting from this project will present the data in aggregate form and you will not be identified. The project data will be stored securely for five years after study completion and may be used in future research. The results of the study will be published as journal articles, a PhD thesis, and presented at relevant conferences.

Will I be able to find out the results of the project?

Once we analyse the information from this study we will get in touch with the organization/club via which we recruited you and offer to conduct a presentation session or provide a Newsletter with the summary of results. Alternately, if you wish to receive this information privately via the post/email we can organize that too. You can expect to receive this feedback in 12-18 months.

Who do I contact if I have questions about the project?

If you have any questions about this project please feel free to contact either myself [0452518525/ Priyanka.Bhattarai1@my.nd.edu.au] or my supervisor, Professor Jane Phillips [0295144822/ Jane.Phillips@uts.edu.au]. My supervisor and I are happy to discuss with you any concerns you may have about this study.

What if I have a concern or complaint?

This study has been approved by the Human Research Ethics Committee at The University of Notre Dame Australia (Approval 017049S). If you have a concern or complaint regarding the ethical conduct of this research project and would like to speak to an independent person, please contact Notre Dame's Ethics Officer at (+61 8) 9433 0943 or research@nd.edu.au. Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

How do I sign up to participate?

If you are happy to participate, please sign both copies of the consent form, keep one for yourself and mail the other to me in the envelope provided. Thank you for your time.

Yours sincerely,

Priyanka Bhattarai, PhD Candidate

The University of Notre Dame Australia

Phone: +61 0423 882 700 **|** Email: Priyanka.Bhattarai1@my.nd.edu.au

CONSENT FORM

Using Digital health technology to optimise older people's Pain self-management capabilities: a mixed-methods ('DigiTech Pain') Project.

- I agree to take part in this research project.
- I have read the Information Sheet provided and been given a full explanation of the purpose of this study, the procedures involved and of what is expected of me.
- I understand that I will be asked to:
  - o Download a pain self-management App to my smartphone or tablet. One of the investigators will help me do the download and setup. At this stage I will be asked to complete a questionnaire with the help of the study investigator. It is estimated that this meeting will take up to 45 minutes and can be carried out face-to-face or via telephone.
  - o Use the App (in the way I want to) for a period of two weeks.
  - o Complete the study questionnaire again after the two week period (via telephone)
  - o Take part in an audio recorded one-on-one telephone interview session to share my experiences of using the App (**optional**). This interview could take up to 45 minutes.
  - o Nominate up to three health professionals who help me manage my pain, and indicate if I agree to them being contacted with an invitation to participate in the study (**optional**).
- The researcher has answered all my questions and has explained possible problems that may arise as a result of my participation in this study.
- I understand that I may withdraw from participating in the project at any time without prejudice.
- I understand that all information provided by me is treated as confidential and will not be released by the researcher to a third party unless required to do so by law.
- I agree that any research data gathered for the study may be published provided my name or other identifying information is not disclosed.
- I understand that research data gathered may be used for future research but my name and other identifying information will be removed.

Name of participant			
Signature of participant		Date	

I would like to take part in the telephone interview to share my experience of using the App at a later date   ☐ [Optional]

I would be willing to provide the names of up to three health professionals who help me manage my pain   ☐ [Optional]

- I confirm that I have provided the Information Sheet concerning this research project to the above participant, explained what participating involves, and have answered all questions asked.

Signature of Researcher		Date	

Appendix 13

Participant Information and Consent Form designed for the recruitment of primary care and allied health clinicians to the qualitative interview study (study 3).

Participant Information and Consent Form- Clinician

PARTICIPANT INFORMATION and CONSENT FORM

Using Digital health technology to optimise older people's Pain self-management capabilities: a mixed-methods ('DigiTech Pain') Project.

Introduction

You are invited to take part in the DigiTech Pain project because you may be involved in helping older people in the community manage their arthritic conditions. This Participant Information and Consent Form tells you about the research project. Please read this information carefully and ask questions about anything that you don't understand or want to know more about. Participation in this research is voluntary. If you don't wish to take part, you don't have to. If you agree to participate in this study, you will be asked to sign the consent section.

What is the project about?

Osteoarthritic pain is very common among older Australians. Many older people living with arthritis will self-manage their pain by carrying out activities such as medication tracking and exercising. Some older people also use technologies including pain self-management apps. Pain self-management Apps could not only assist the pain self-management process but also provide the user with an option to share this data with their primary clinician.

While Apps are increasingly being used by all age groups, little is known about their suitability for older people. In addition, the views of primary-care clinicians, like yourself, on the use of apps by older people for pain self-management is also not well-known. This study has been initiated by a team of clinical researchers [Professor Jane Phillips, Dr Toby Newton-John, and Ms Priyanka Bhattarai] to investigate older people's experiences of using a pain self-management App, and to explore their primary care clinicians' perspective regarding the benefits or limitations of integrating this approach into their older patient's pain self-management strategy.

Who is undertaking the project?

This project is being conducted by Ms. Priyanka Bhattarai and will form the basis for the degree of Doctor of Philosophy (PhD) at The University of Notre Dame Australia, under the supervision of Professor Jane Phillips.

What will I be asked to do?

Participation in this research study involves taking part in an audio recorded one-on-one telephone interview session to share your perspective on use of App by older arthritic patients to help them self-manage their pain. This interview could take between 15-30 minutes and will be conducted via telephone.

Are there any risks associated with participating in this project?

It is possible that you may experience some level of discomfort during participation in the interview session. If you experience any discomfort during or after the interview please notify the research team immediately [0423 882 700/ Priyanka.Bhattarai1@my.nd.edu.au]. Further, you are free to withdraw at any time. If these feelings persist after the study has ended, arrangements will be made for you to access support from the research team at no expense to you.

What are the benefits of the research project?

While we intend that this research furthers knowledge in the area of pain self-management and may lead to improved self-management practices for people with arthritic pain in the future, it may not be of direct benefit to you.

What if I change my mind?

Participation in this study is voluntary. Even if you agree to participate, you can withdraw from the study at any time without discrimination or prejudice. *If you decide to withdraw, you can simply notify me via phone or email [0423 882 700/ Priyanka.Bhattarai1@my.nd.edu.au].*

Will anyone else know the results of the project?

The information collected from you will be de-identified, stored securely, and accessed only by the research team. This information will be held in strict confidence, and will only be made available if required by law. Publications resulting from this project will present the data in aggregate form and you will not be identified. The project data will be stored securely for five years after study completion and may be used in future research. The results of the study will be published as journal articles, a PhD thesis, and presented at relevant conferences.

Will I be able to find out the results of the project?

Once we have analysed the information from this study we will contact you via mail/email to share the findings of the study. You can expect to receive this feedback in 12-18 months.

Who do I contact if I have questions about the project?

If you have any questions about this project please feel free to contact either myself [0423 882 700/ Priyanka.Bhattarai1@my.nd.edu.au] or my supervisor, Professor Jane Phillips [02 9514 4822/ Jane.Phillips@uts.edu.au]. My supervisor and I are happy to discuss with you any concerns you may have about this study.

What if I have a concern or complaint?

The study has been approved by the Human Research Ethics Committee at The University of Notre Dame Australia (approval number 017049S). If you have a concern or complaint regarding the ethical conduct of this research project and would like to speak to an independent person, please contact Notre Dame's Ethics Officer at (+61 8) 9433 0943 or research@nd.edu.au. Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

How do I sign up to participate?

If you are happy to participate, please sign both copies of the consent form, keep one for yourself and mail the other to me in the envelope provided. Thank you for your time.

Yours sincerely,

Priyanka Bhattarai, PhD Candidate

The University of Notre Dame Australia

Phone: 0423 882 700 | Email: Priyanka.Bhattarai1@my.nd.edu.au

CONSENT FORM

Using Digital health technology to optimise older people's Pain self-management capabilities: a mixed-methods ('DigiTech Pain') Project.

- I agree to take part in this research project.

- I have read the Information Sheet provided and been given a full explanation of the purpose of this study, the procedures involved and of what is expected of me.

- I understand that I will be asked to take part in an audio recorded one-on-one telephone interview session to share my perspective on use of App by older arthritic patients to help them self-manage their pain. This telephone interview could take between 15-30 minutes and will be done at a time that is convenient for me.

- The researcher has answered all my questions and has explained possible problems that may arise as a result of my participation in this study.

- I understand that I may withdraw from participating in the project at any time without prejudice.

- I understand that all information provided by me is treated as confidential and will not be released by the researcher to a third party unless required to do so by law.

- I agree that any research data gathered for the study may be published provided my name or other identifying information is not disclosed.

- I understand that research data gathered may be used for future research but my name and other identifying information will be removed.

Name of participant			
Signature of participant		Date	

- I confirm that I have provided the Information Sheet concerning this research project to the above participant, explained what participating involves and have answered all questions asked of me.

Signature of Researcher		Date	

Appendix 14

List of all ethical amendments sought for the DigiTech Pain project.

Evidence of all relevant written communication trail is also included.

26 September 2017

Professor Jane Phillips & Ms Priyanka Bhattarai
School of Nursing
The University of Notre Dame, Australia
P.O Box 944
Broadway NSW 2007

Dear Jane and Priyanka,

Reference Number: 017049S

Project title: "Using Digital Health Technology to optimise Older People's pain self-management capabilities: A mixed methods 'DigiTech Pain Project'."

Your application for an amendment to your approved research project has been reviewed by the university's Human Research Ethics Committee in accordance with the *National Statement on Ethical Conduct in Human Research* (2007, updated May 2015). I advise that approval for your amendment has been granted conditional on the following issues being addressed:

- HREC approves displaying the recruitment poster in venues as outlined in amendment request 1 of the application.

- HREC approves advertising on the Arthritis Australia and other support group Facebook pages as outlined in amendment request 2 and 4, as long as the researchers do not become members of this group.

- Researchers to provide more information for how the "DigiTech Project" Facebook page will work and whether visitors to the page can be identified by the researchers. Provide a screenshot of the page or link to the page for the HREC to view.

Please send your response addressing each of the issues as listed above, including supporting information where applicable, to me at Natalie.Giles@nd.edu.au by **16 October**. Failure to respond and/or communicate by this time could result in a suspension of the ethical review of the project.

Yours sincerely,

Dr Natalie Giles
Research Ethics Officer
Research Office

cc: A/Prof Joanna Patching, SRC Chair, School of Nursing Sydney

Priyanka Bhattarai
University of Notre Dame Australia
School of Nursing, Sydney

Dr Natalie Giles
Research Ethics Officer
Research Office
The University of Notre Dame Australia
Fremantle Campus

Dear Natalie,

HREC Reference Number:017049S

Project Title: Using Digital health Technology to optimise older people's Pain self-management

capabilities: a mixed methods ('DigiTech Pain') Project.

The table below outlines the conditions/issues raised by the HREC and the researcher's response summary, including the location of the required amendment in the ethics application.

Condition / Issue Raised	Response to condition/issue
HREC requested information on 'DigiTech Project' Facebook page including a screenshot	A Facebook Page titled "DigiTech Pain Project" has been created by the student. The profile picture and the cover photo of this page displays the study's recruitment poster without the PhD student's direct contact details. This page is open for general public to connect and follow. The DigiTech Pain project is not a member of any support groups and is not connecting, following, or is *friend* with any potential participants. The screenshot of the DigiTech Pain Project Facebook page is attached for the HREC's review.

Yours sincerely,

Priyanka Bhattarai

DigiTech Pain Project's Facebook page

12 October 2017

Professor Jane Phillips & Ms Priyanka Bhattarai
School of Nursing
The University of Notre Dame, Australia
P.O Box 944
Broadway NSW 2007

Dear Jane and Priyanka,

Reference Number: 017049S

Project title: "Using Digital Health Technology to optimise Older People's pain self-management capabilities: A mixed methods 'DigiTech Pain Project'."

Your response to the conditions imposed by the university's Human Research Ethics Committee, has been reviewed and assessed as meeting all the requirements as outlined in the *National Statement on Ethical Conduct in Human Research* (2007, updated May 2015). I am pleased to advise that ethical clearance has been granted for this proposed amendment.

All research projects are approved subject to standard conditions of approval. Please read the attached document for details of these conditions.

On behalf of the Human Research Ethics Committee, I wish you well with your study.

Yours sincerely,

Dr Natalie Giles
Research Ethics Officer
Research Office

Cc: A/Prof Joanna Patching, SRC Chair, School of Nursing Sydney

From:	Natalie Giles <natalie.giles@nd.edu.au>
Sent:	29 November, 2017 4:29 PM
To:	Priyanka Bhattarai
Subject:	RE: Amendment application DigiTech Project

That's fine to go ahead Priyanka.

Best wishes

Kind regards
Natalie

Dr. Natalie Giles (PhD)
Research Ethics Officer | Research Office

The University of Notre Dame Australia | www.nd.edu.au | CRICOS Code: 01032F
33 Phillimore St (PO Box 1225), Fremantle, WA 6959
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In Office
Monday - Thursday 9.00am – 2.30pm

For more information and application forms and templates go to: http://www.nd.edu.au/research/ethics-and-integrity

From: Priyanka Bhattarai [mailto:priyanka.bhattarai1@my.nd.edu.au]
Sent: Wednesday, 29 November 2017 12:47 PM
To: Natalie Giles <natalie.giles@nd.edu.au>
Subject: Amendment application DigiTech Project

Hi Natalie,
 Hope this email finds you well. I am emailing you a request of ethical amendment to my PhD Project
(DigiTech Pain- 017049S).
 I have attached a completed amendment request form and also the PICF that needed minor change
(removal of the name of the intervention app that has been taken down).
It would be great if you could review the submission.
Please do not hesitate to contact me if anything else is required from my end regarding this.
Thank you
Priyanka

Important Information for Applicants

1. This application form is to be used by researchers when seeking to amend an already approved research project.

2. It is a condition of HREC approval that any proposed changes or amendments to the research project must be applied for using an Amendment application form and approved by the HREC before these may be implemented.

   Full HREC review research projects: If the original project was approved by the full HREC, amendment applications must also be approved by the full HREC (see HREC meeting dates and deadlines).

   Low Risk research projects: If the original project was considered 'low risk' amendment applications will be reviewed by a HREC sub-committee unless the proposed changes are not considered 'low risk' according to the National Statement.

3. Download a new form from the HREC - ethics application forms webpage to ensure that you are using the most current version of this form.

4. Handwritten applications will not be accepted.

5. Type an X in checkboxes that apply.

6. Provide all necessary attachments where indicated.

7. The *National Statement on Ethical Conduct in Human Research (2007, updated 2014)* (NS) provides the primary guidelines for research involving human participants.

8. Other national guidelines can be found at the HREC - Useful Links page.

9. UNDA research policies can be found at the HREC - Policies and Guidelines page.

10. Your completed amendment application can be sent directly to the Research Ethics Officer for review by the HREC.

11. AMENDMENTS TO YOUR RESEARCH PROJECT MUST NOT COMMENCE UNTIL WRITTEN APPROVAL HAS BEEN PROVIDED BY THE HREC.

12. The HREC will not grant retrospective ethics approval.

Request for an Amendment to an Approved Research Project.

1. Project Title:

> Using Digital health Technology to optimise older people's pain self-management capabilities: a mixed methods ('DigiTech Pain') project

2. HREC reference number: 017049S

3. HREC approval date: 6.6.2017

4. Researcher Details:

a) Chief Investigator/Supervisor:

Name:	Prof Jane Phillips		
Mailing Address:	P O Box 123, Ultimo, NSW 2007		
Email:	Jane.Phillips@uts.edu.au	Phone:	9514 7241

b) Co-Investigator/Student:

Name:	Ms Priyanka Bhattarai		
Mailing Address:	5/47 Alt St, Ashfield NSW 2131.		
Email:	priyanka.bhattarai1@my.nd.edu.au	Phone:	0423 882 700

5. Project Status:

Provide a short lay summary of your original project and its current status.

> The DigiTech project aims to explore the feasibility of using an App to help community based older people better manage their arthritic pain. Included in this program of research is a Phase I pre-post-test intervention study (Study 1) that aims to evaluate the feasibility and acceptability of a freely available pain self-management app (RAISE). This project is currently open for recruitment, and six participants are currently recruited to the app feasibility trial.
>
> DigiTech project also includes a clinician study (Study 3) which aims to evaluate the views of primary care clinicians about integration of an app into their older patient's pain self-management regime. The planned (and ethics approved) method to approach primary care clinicians was to seek referrals from older participants of Study1.

6. Amendment Request:

List the requested changes including any changes to the original approved project design.

[Please attach documentation as necessary]

This amendment application is seeking approval to expand our recruitment method by utilising the following three additional distribution approaches:

1. Snowballing approach: We would like to ask the participants of Study 3 (clinicians) to refer us to any of their colleagues who may have interest in taking part in this study

2. Professional network: The investigator team of this project are experienced clinicians and have working relationships with various primary health care professionals. We would like to invite clinicians in our professional networks to share Study 3's participation invite with others.

   Within this approach, we will strictly use "an arm's length approach" where the referring contact will get me in touch with the potential participant, but they will not do the consenting or recruiting for the project team. Therefore, the referring contact will remain out of the consenting and active recruiting process.

3. Peak bodies of various health professions: We would also like to invite health professionals caring for older people living with arthritis in the community including:
   a. General practitioners (Royal Australian College of General Practitioners (RACGP)
   b. Practice nurses (Australian Primary Health Care Nurses Association)
   c. Physiotherapists (Australian Physiotherapy Association)
   d. Chiropractors (Australian Chiropractors Association)
   e. Psychologists (Australian Psychological Society)
   f. Exercise physiologist (Exercise and Sports Science Australia)

1. Amendment Justification:

Provide an explanation of the reasons for these changes.

Our past attempts of recruitment to the clinician study (Study 3) has been met with challenges such as very low rate of referrals from older participants of Study 1, and no response from the primary care clinicians who were sent the invitation letter to participate in Study 3.

The reason we opted for older participant's referral of their clinicians was with an intention of boosting recruitment; not to have an "older person-clinician dyad". The data required to answer Study 3's research questions, does not necessarily have to be limited to the clinicians who are in the role of caring or supervising the participants of Study 1. As recruitment of primary care clinicians, especially GPs, in research studies has been known to be very challenging, we are proposing these proactive measures to enhance our recruitment process.

2. Risks to Participants:

Do these amendments introduce new risks to participants?

YES   X   NO

If YES, please outline the new risks the proposed changes may create for participants and provide an explanation for how these new risks will be managed.

9.   Participant Information:

Do these amendments necessitate changes to the:

Participant Information Sheet	X YES	NO
Consent Form	X YES	NO

[If YES please attach the revised documents]

PICF is attached.

10.   Declaration:

I certify that the above information is accurate and that the project will continue to be carried out in an acceptable and ethical manner and in accordance with the original HREC approved protocol and any approved amendments.

Name of Researcher	Signature of Researcher	Date
Prof Jane Phillips		23. 7. 2018
Ms Priyanka Bhattarai		23.7.18
Dr Toby Newton-John		24/7/2018

Priyanka Bhattarai

Hi Priyanka

Actually, I think that's fine to go ahead. It's a pretty minor change, only involving asking professionals to invite people to participate. I don't believe it requires further HREC review.

Kind regards
Natalie

Dr. Natalie Giles (PhD)
Research Ethics Officer | Research Office

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Do you need more research ethics information or do you need an ethics application form? Check out the Research Ethics & Integrity webpage

Do you want to be up to date with the latest research news at UNDA? Check out the Research Office Newsletter

Are you a Fremantle or Broome researcher and looking for a workshop to attend? Check out the Fremantle/Broome Workshop Schedule

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Dear Natalie,
I am emailing you to submit a small amendment request relating to my PhD project [DigiTech Pain project-HREC reference: 017049S].
It would be great if you could review this amendment request.
Please do not hesitate to contact me if you require anything else with regards to this submission.
Thank you
Priyanka
Priyanka Bhattarai
BN Hons, PhD Candidate
The University of Notre Dame Australia
School of Nursing | PO Box 944
Broadway NSW 2007 Australia
Mob: +61 0423 882 700 Email: Priyanka.Bhattarai1@my.nd.edu.au Twitter: @priankabh

Appendix 15

Data collection tools used in the phase I feasibility study (study 2b).

Pain outcomes Case Report Form

THE UNIVERSITY OF
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Using Digital health technology to optimise older people's Pain self-management capabilities: a mixed-methods ('DigiTech Pain') Project.

[HREC Approval Number: 017049S]

Pain Outcomes Measurement Case Report Form	
Participant ID	
Date data collection commenced	____ / ____ / _____
Date data collection Completed	____ / ____ / _____
Research Personnel Initials	____ ____
Date data entered	____ / ____ / _____

1903

Date: ☐☐ / ☐☐ / ☐☐
(month) (day) (year)

Subject's Initials : _____

Study Subject #: ☐☐☐☐

Study Name: _____
_____
Protocol #: _____
PI: _____
Revision: 07/01/05

Brief Pain Inventory (Short Form)

1. Throughout our lives, most of us have had pain from time to time (such as minor headaches, sprains, and toothaches). Have you had pain other than these everyday kinds of pain today?

☐ Yes ☐ No

2. On the diagram, shade in the areas where you feel pain. Put an X on the area that hurts the most.

Front   Back

Right   Left   Left   Right
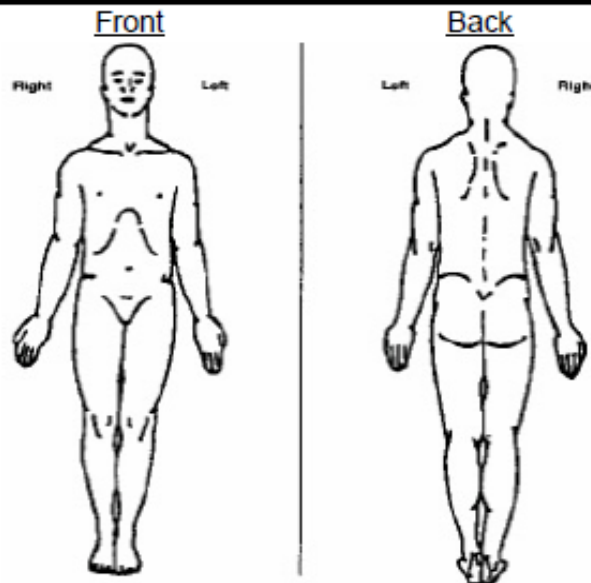
3. Please rate your pain by marking the box beside the number that best describes your pain at its worst **in the last 24 hours.**

☐ 0   ☐ 1   ☐ 2   ☐ 3   ☐ 4   ☐ 5   ☐ 6   ☐ 7   ☐ 8   ☐ 9   ☐ 10
No   Pain As Bad As
Pain   You Can Imagine

4. Please rate your pain by marking the box beside the number that best describes your pain at its least **in the last 24 hours.**

☐ 0   ☐ 1   ☐ 2   ☐ 3   ☐ 4   ☐ 5   ☐ 6   ☐ 7   ☐ 8   ☐ 9   ☐ 10
No   Pain As Bad As
Pain   You Can Imagine

5. Please rate your pain by marking the box beside the number that best describes your pain on the average.

☐ 0   ☐ 1   ☐ 2   ☐ 3   ☐ 4   ☐ 5   ☐ 6   ☐ 7   ☐ 8   ☐ 9   ☐ 10
No   Pain As Bad As
Pain   You Can Imagine

6. Please rate your pain by marking the box beside the number that tells how much pain you have right now.

☐ 0   ☐ 1   ☐ 2   ☐ 3   ☐ 4   ☐ 5   ☐ 6   ☐ 7   ☐ 8   ☐ 9   ☐ 10
No   Pain As Bad As
Pain   You Can Imagine

1903

Date: ☐☐ / ☐☐ / ☐☐
(month)   (day)   (year)

Subject's Initials : _____

Study Subject #: ☐☐☐☐

Study Name: _____
_____
Protocol #: _____
PI: _____
Revision: 07/01/05

7. What treatments or medications are you receiving for your pain?

☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐
☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐☐☐☐☐☐☐☐☐

8. In the last 24 hours, how much relief have pain treatments or medications provided? Please mark the box below the percentage that most shows how much relief you have received.

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
No Relief										Complete Relief

9. Mark the box beside the number that describes how, during the past 24 hours, pain has interfered with your:

A. General Activity

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
Does Not Interfere   Completely Interferes

B. Mood

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
Does Not Interfere   Completely Interferes

C. Walking ability

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
Does Not Interfere   Completely Interferes

D. Normal Work (includes both work outside the home and housework)

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
Does Not Interfere   Completely Interferes

E. Relations with other people

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
Does Not Interfere   Completely Interferes

F. Sleep

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
Does Not Interfere   Completely Interferes

G. Enjoyment of life

☐0 ☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7 ☐8 ☐9 ☐10
Does Not Interfere   Completely Interferes

A15

(i)   Pain Self-Efficacy Questionnaire Short Form (PSEQ-2)

Pain Self-Efficacy Questionnaire—Two-Item Short Form (PSEQ-2)

Michael K. Nicholas, PhD, Brian E. McGuire, PhD, and Ali Asghari, PhD

Please rate how **confident** you are that you can do the following things <u>at present</u>, **despite the pain.** To indicate your answer circle one of the numbers on the scale under each item, where 0 = not at all confident and 6 = completely confident.

For example:

```
     0        1        2        3        4        5        6
```

Not at all confident   Completely confident
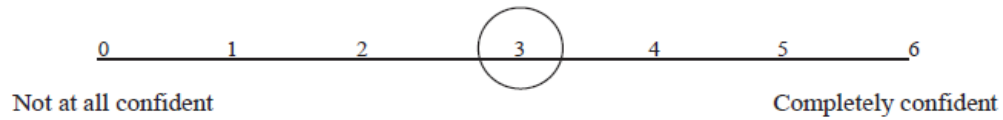
Remember, this questionnaire is not asking whether or not you have been doing these things, but rather **how confident you are that you can do them at present, <u>despite the pain.</u>**

1. I can do some form of work, despite the pain ("work" includes housework and paid and unpaid work).	0 Not at all confident	1	2	3	4	5	6 Completely confident
2. I can live a normal lifestyle, despite the pain.	0 Not at all confident	1	2	3	4	5	6 Completely confident

Interpretation guide: A person with a score of 5 or less might be considered in need of help with their confidence in functioning in the presence of their pain. A score of 8 or higher reflects a desirable level of pain self-efficacy or confidence in functioning in the presence of pain.

ONLINE TECHNOLOGIES SELF-EFFICACY SCALE (OTSES)

Thank you for agreeing to fill out this questionnaire. The following questions ask how confident you feel with using online technologies (such as Internet, email, etc.)

If you do not have much computer/ App use experience, just complete the questionnaire to the best of your knowledge. DO NOT WORRY! Remember that each section begins with the statement "I would feel confident..." performing an activity, and not "I have done it before." It does not matter whether you have had experience with the activities described. We would like to find out what your perceptions are performing the activities below. There are no right or wrong answers, just answer as accurately as possible.

Please read the directions below and then fill in ALL items

The survey requires you to indicate your level of confidence with the statements below by writing an 8 or a 4 in each box from "Very Confident" to "Not Confident At All". If you do not know what a statement means, choose "Not Confident At All."

A) Questions about using the internet (Internet competencies)				
I would feel confident……	Very Confident	Somewhat Confident	Not Very Confident	Not Confident At All
1. Opening a web browser (e.g. internet explorer or Google Chrome)				
2. Reading text from a web site				
3. Clicking on a link to visit a specific website				
4. Accessing a specific web site by typing the address (URL)				
5. Bookmarking a web site				
6. Printing a web site				
7. Conducting an Internet search using one or more keywords				
8. Downloading (saving) an image from a website to a disk				
9. Copying a block of text from a web site and pasting it to a document in a word processor				
B) Questions about chatting "live" via a synchronous chat system such as a Net-Meeting or web-chat.				
I would feel confident……	Very Confident	Somewhat Confident	Not Very Confident	Not Confident At All
10. Providing a nickname within a synchronous chat system				
11. Reading messages from one or more members of the chat system				
12. Answering a message or providing my own message in a synchronous chat system (one-to-many interaction)				
13. Interacting privately with one member of the synchronous chat system (one-to-one interaction)				

C) Questions about using an e-mail system such as Mail, or Outlook to communicate with friends, instructors, or other group members who are not online at the same time.				
I would feel confident……	Very Confident	Somewhat Confident	Not Very Confident	Not Confident At All
14. Logging on and off an e-mail system				
15. Sending an e-mail message to a specific person (one-to one interaction)				
16. Sending one e-mail message to more than one person at the same time (one-to- many interaction)				
17. Replying to an e-mail message				
18. Forwarding an e-mail message				
19. Deleting messages received via e-mail				
20. Creating an address book				
21. Saving a file attached to an e-mail message to a local disk and then viewing the contents of that file				
22. Attaching a file (image or text) to an e-mail message and then sending it off				
D) Questions about posting a message to a newsgroup, a bulletin board, or on the discussion board of a conferencing system where participants are not online at the same time				
I would feel confident……	Very Confident	Somewhat Confident	Not Very Confident	Not Confident At All
23. Signing on and off an asynchronous conferencing system				
24. Posting a new message to an synchronous conferencing system (creating a new thread)				
25. Reading a message posted on an asynchronous conferencing system				
26. Replying to a message posted on an asynchronous conferencing system so that all members can view it				
27. Replying to a message posted on an asynchronous conferencing system so that only one member can view it (reply to sender)				
28. Downloading (saving) a file from an asynchronous conferencing system to a local disk				
29. Uploading (sending) a file to an asynchronous conferencing system				

End of Pain Outcomes CRF

Demographics and clinical Survey

THE UNIVERSITY OF
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Using Digital health technology to optimise older people's Pain self-management capabilities: a mixed-methods ('DigiTech Pain') Project.

[HREC Approval Number: 017049S]

Sample characteristics Case Report Form	
Participant ID	
Date data collection commenced	____ /____ /_____
Date data collection Completed	____ /____ /_____
Research Personnel Initials	____ ____
Date data entered	____ /____ /_____

SECTION 1. DEMOGRAPHIC INFORMATION

Date of Birth _ _/_ _/_ _ _ _	Age _ _ _ Years	Gender M ❑ F ❑	With whom do you live?(Tick all that apply) Spouse ❑ Children ❑ Alone ❑ Other _____

SECTION 2. COMORBIDITIES Charlson Comorbidity Index (Charlson et al. 1987)

Do you have any of the following medical conditions? Tick all that apply

Condition		Condition		Condition	
Myocardial Infarction	❑	Hemiplegia	❑	Metastatic solid tumor	❑
Congestive heart failure	❑				
Peripheral disease	❑	Moderate or severe renal disease	❑		
Cerebrovascular disease	❑				
Dementia	❑	Diabetes with end organ damage	❑		
Chronic Pulmonary Disease	❑			AIDS	❑
Connective tissue disease (arthritis)	❑	Tumor with metastasis	❑		
Peptic ulcer disease	❑				
Mild liver disease	❑	Leukemia	❑		
Diabetes without end organ damage	❑	Lymphoma	❑		

Total Score =

Do you have a diagnosis of psychological conditions such as depression or anxiety?
Yes ❑ No ❑ Prefer not to answer ❑
If Yes, please indicate

SECTION 3. MEDICATION USE

Do you take any prescribed medications?

Yes ❑ No ❑

If YES – what are your CURRENT medications?

	Drug Name	Used for
1		
2		
3		
4		
5		
6		
7		
8		

Do you use any other products such as vitamins, herbal medicines, supplements not prescribed by a doctor?
Yes ❑ No ❑
If yes, please list them here

	Drug Name	Used for
1		
2		
3		
4		
5		
6		
7		
8		

SECTION 4. PERFORMANCE STATUS
Australian-modified Karnofsky Performance Scale (AKPS) (Abernethy et al. 2005)

Please check *ONLY ONE RESPONSE* that is most accurate for you *AT THIS TIME.*

Normal, no complaints, no symptoms of disease	❑
Able to carry on normal activity, minor symptoms of disease	❑
Normal activity with effort, some symptoms of disease	❑
Care for self, unable to carry on normal activity or do active work	❑
Require occasional assistance but able to care for most of personal needs	❑
Require considerable assistance for personal care	❑
Disabled, require special care and assistance	❑
Severely disabled, require continuous nursing care	❑

These questions refer to your activities just within the past month.

LIFE-SPACE LEVEL	FREQUENCY					INDEPENDENCE	SCORE
During the past four weeks, have you been to....	How often did you get there?					Did you use aids or equipment? Did you need help from another person?	Level X Frequency X Independence
Life-space Level 1... Other rooms of your home besides the room where you sleep? Yes 1 / No 0	Less than 1/week 1	1-3 times/ week 2	4-6 time/ week 3	Daily 4		1 = Personal assistance 1.5 = Equipment only 2 = No equipment or personal assistance	
Score	___ X		_____			X	_____ Level 1 Score
Life-Space Level 2... An area outside your home such as your porch, deck or patio, hallway (of an apartment building) or garage, in your own yard or driveway? Yes 2 / No 0	Less than 1/week 1	1-3 times/week 2	4-6 time/ week 3	Daily 4		1 = Personal assistance 1.5 = Equipment only 2 = No equipment or personal assistance	
Score	_____ X		_____			X	_____ Level 1 Score
Life-Space Level 3... Places in your neighbourhood, other than your own yard or apartment building? Yes 3 / No 0	Less than 1/week 1	1-3 times/week 2	4-6 time/ week 3	Daily 4		1 = Personal assistance 1.5 = Equipment only 2 = No equipment or personal assistance	
Score	___ X		_____			X	_____ Level 1 Score
Life-Space Level 4.... Places outside your neighbourhood, but within your town? Yes 4 / No 0	Less than 1/week 1	1-3 times/week 2	4-6 time/week 3	Daily 4		1 = Personal assistance 1.5 = Equipment only 2 = No equipment or personal assistance	
Score	_____ X		_____			X	_____ Level 1 Score
Life-Space Level 5.... Places outside your town? Yes 5 / No 0	Less than 1/week 1	1-3 times/week 2	4-6 time/week 3	Daily 4		1 = Personal assistance 1.5 = Equipment only 2 = No equipment or personal assistance	
Score	_____ X		_____			X	_____ Level 1 Score
	TOTAL SCORE (ADD)						Sum of Levels

Please list the equipment or mobility aids that you used:

SECTION 5. SOCIAL SUPPORT

UCLA Three item Lonliness Scale (Hughes et al. 2004)				Do you receive assistance from your family or friends in managing your pain?
The next questions are about how you feel about different aspects of your life. For each one, tell me how often you feel that way.				Yes ❑ No ❑
	Hardly ever	Some of the time	Often	If yes, please indicate the type of assistance below:
How often do you feel that you lack companionship?	1	2	3	
How often do you feel left out?	1	2	3	
How often do you feel isolated from others?	1	2	3	

SECTION 6. TECHNOLOGY USE

Which of the below devices do you own ? (Tick all that apply)

Desktop Computer	❑
Laptop Computer	❑
Tablet Computer (ipad, Galaxy Tab etc)	❑
Smartphone	❑
Smartwatch/activity tracker	❑
Other Please specify: _____	❑

How often do you use your smartphone or tablet computer? (Only select one)
At least:

_____ Minutes everyday
_____ times per week
_____ times a month
Rarely ❑
Other _____

Please list five most common activities you carryout using you smartphone or tablet computer

1	
2	
3	
4	
5	

Have you ever used a Pain self-management App?

Yes ❑	No ❑
What was the name of the App? _____	
How long ago did you download it? _____	
Do you currenlty use it in a regular basis? Yes ❑ No ❑	

What do you expect an ideal pain self-management App to offer you in assisting your pain self-management?

SECTION 7. HEALTH PROFESSIONAL CONTACT

Could you please indicate up to three health professionals that play a key role in you pain self-management process?
Yes ❑ No ❑
If Yes, Please provide details below

	Health Professional Name	Profession	Contact details/Place of practice
1			
2			
3			

Would you agree to us contacting the above mentioned health professionals with an invitation to participate in a short interview session?
Yes ❑ No ❑

References:

1. Charlson, M.E., et al., *A new method of classifying prognostic comorbidity in longitudinal studies: development and validation.* Journal of chronic diseases, 1987. **40**(5): p. 373-383.

2. Abernethy, A.P., et al., *The Australia-modified Karnofsky Performance Status (AKPS) scale: a revised scale for contemporary palliative care clinical practice [ISRCTN81117481].* BMC palliative care, 2005. **4**(1): p. 1.

3. Stalvey, B.T., et al., The Life Space Questionnaire: A measure of the extent of mobility of older adults. Journal of Applied Gerontology, 1999. 18(4): p. 460-478.

4. Hughes, M.E., et al., *A short scale for measuring loneliness in large surveys results from two population-based studies.* Research on aging, 2004. **26**(6): p. 655-672.

End of Sample Characteristics CRF

Appendix 16

Interview guide used to provide structure to the semi-structured interviews conducted with older people in the qualitative sub-study (study 2b).

Interview guide- Older People

THE UNIVERSITY OF NOTRE DAME AUSTRALIA

Using Digital health technology to optimise older people's Pain self-management capabilities: a mixed-methods ('DigiTech Pain') Project.

QUALITATIVE INTERVIEW WITH OLDER PEOPLE- INTERVIEW GUIDE

- Can you tell me about your experience of using the App during the two-week trial period?

- Do you think the App assisted your regular pain self-management process?

    o If Yes- How

    o If No- Why do you think that was the case?

- What do you think would have been beneficial to have in addition to what the App offered?

- Did you encounter any challenges or problems in using the App?

- Were the features of the App easy to use and navigate?

- What features of the App did you find to be most useful? And, why?

- What was the least important feature of the App? And, why?

- What encouraged you to use the App?

- Were there anything that particularly discouraged you to use the App?

- Did you receive assistance to use the App?

- Would you recommend using an App for pain management to others? Why/why not?

- Is there anything else you would like to share with us?

Appendix 17

Interview guide used to provide structure to the semi-structured interviews conducted with primary care and allied health clinicians of study 3.

Interview guide- Clinician

THE UNIVERSITY OF
NOTRE DAME
AUSTRALIA

Using Digital health technology to optimise older people's Pain self-management capabilities: a mixed-methods ('DigiTech Pain') Project.

QUALITATIVE INTERVIEW WITH CLINICIAN- QUESTION ROUTE

- Can you tell me tentatively what proportion of your patients are older people with arthritic pain?

- How do you generally facilitate these patient's pain self-management process?

- Do you think there is a role an App could play in assisting these patient's pain self-management regime?

    o If Yes- How

    o If No- Why do you think that is the case?

- As a primary care clinician do you think an App could offer any assistance to you in formulating or facilitating pain self-management plans of older patients with arthritic pain?

- Do you think advance App features such as the ability to transfer participant's data to you real-time, or the possibility to communicate with patients via app (sending, reminders, prompts to exercise etc.) could be beneficial?

- What features do you think an optimal pain self-management app designed for older people should include so it could assist community based pain self-management practices?

- Would you recommend using an App for pain management to your older arthritic patients? Why/why not?

- Is there anything else you would like to share with us?

Appendix 18

The full ethics approval of the DigiTech Pain project, provided by the University of Notre Dame, Human Research Ethics Committee.

6 June 2017

Prof Jane Phillips & Ms Priyanka Bhattarai
School of Nursing
The University of Notre Dame, Australia
P.O Box 944
Broadway NSW 2007

Dear Jane and Priyanka,

Reference Number: 017049S

Project title: "Using Digital Health Technology to optimise Older People's pain self-management capabilities: A mixed methods 'DigiTech Pain Project'."

Your response to the conditions imposed by the university's Human Research Ethics Committee, has been reviewed and assessed as meeting all the requirements as outlined in the *National Statement on Ethical Conduct in Human Research* (2007, updated May 2015). I am pleased to advise that ethical clearance has been granted for this proposed study.

All research projects are approved subject to standard conditions of approval. Please read the attached document for details of these conditions.

On behalf of the Human Research Ethics Committee, I wish you well with your study.

Yours sincerely,

Dr Natalie Giles
Research Ethics Officer
Research Office

Cc: A/Prof Joanna Patching, SRC Chair, School of Nursing Sydney

Appendix 19

Publication: Feasibility evaluation of a pain self-management app-based intervention among older people living with arthritic pain: study protocol

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Feasibility evaluation of a pain self-management app-based intervention among older people living with arthritic pain: study protocol

Priyanka Bhattarai[1*], Toby R. O. Newton-John[2] and Jane L. Phillips[3]

Abstract

Background: Optimal management of chronic arthritic pain experienced by older adults involves applying active self-management strategies every day. Cost-effective and innovative strategies to help build older people's pain self-management capability are required. This study protocol is designed to evaluate the feasibility, acceptability, and preliminary outcomes of a pain self-management app among older people living in the community with arthritic pain.

Methods/design: This is a phase I feasibility study. A pre-post test study design will be used to trial a freely available pain self-management app named Rheumatoid Arthritis Information Support and Education ("RAISE") for 14 days. Thirty community-dwelling older people living with arthritic pain who use a smartphone will be recruited from (1) various community-based social clubs/organizations/groups or (2) via Facebook groups with potentially high number of older members. In addition, snowballing sampling approach will also be utilized.

These participants will trial the RAISE app, which was selected following a systematic evaluation of all available chronic pain apps by the investigator team. A face-to-face or telephone-based meeting will be organized with all consenting participants in order to seek their informed consent, download and set up the intervention app on their mobile device, be provided with app training, and complete the pre-test data (Time 1 (T1)). Participants will be asked to use the RAISE app as desired for 14 days. Post-test data collection (Time 2 (T2)) will occur on day 15. Data collected includes participant's demographic and clinical information, pain scores, pain self-efficacy, and online technology self-efficacy. Participants will be invited to take part in a semi-structured telephone interview at T2 to explore their experiences of using the app.

An evaluation of patterns of app use, recruitment, retention, attrition rates, and analysis of the missing data will inform the study and intervention feasibility. Preliminary outcomes are participant's pain intensity and interference, pain self-efficacy, and online technology self-efficacy.

Discussion: This study will help us better understand the feasibility and acceptability of using this novel intervention among community-dwelling older people living with arthritic pain. The results will also help inform future pain app studies.

Trial registration: Australia New Zealand Clinical Trials Registry: ACTRN12617000921381.

Keywords: Older adults, Pain management, Arthritis, Smartphone, App, Technology

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Background

Unrelieved pain is one of the most common health conditions affecting the majority of older people (those aged over 65 years) [1–3]. Globally, about 70% of older adults suffer from arthritis-related pain [2, 3]. Although the global economic impact of arthritis remains unknown, it is estimated to cost high-income countries between 1–2.5% of their gross national product [4]. As most older people live in the community, self-management strategies are central to improving their unrelieved chronic pain and minimizing the adverse impact of pain on their lives [5, 6]. Active self-management involves (i) medical management (i.e., medication adherence, dietary modification), (ii) behavior modification (i.e., modifying activities of living, physical, and recreational activities), and (iii) managing emotion (i.e., dealing with fear, frustration, and anger) [7]. Building patients' capacity to self-manage pain is underpinned by effective instruction, education, and support, augmented with regular medical, nursing, and/or allied health follow-up. Self-management strategies are central to maximizing effective coping with pain and minimizing the adverse impact of pain on older people's lives [5, 6]. While structured pain self-management programs have traditionally been grounded in face-to-face coaching approaches, there has been a growing interest in the use of technology-mediated self-management intervention to promote and support self-management.

Although younger people outnumber older people in terms of technology engagement, the uptake of new technology among older people is increasing rapidly [8]. The proportion of older people using smartphones has more than doubled since 2014 [9], with over 40% of people aged over 65 years now owning a smartphone [10]. A growing proportion of older people regularly use the internet and source online health information [8]. While digital technology uptake among older people of today is increasing and is yet to reach saturation, the next generations of older people ("baby boomers") who have grown old with digital technology are likely to be even familiar users. Given this reality, there will be more opportunities to use digital technology-facilitated approaches to reach and meet the needs of the world's rapidly growing and aging population.

Since the introduction of the smartphone in 2007, its subsequent widespread adoption has fueled the development of a range of health-related applications (apps) that can be accessed from these computerized mobile handsets [11]. Smartphone apps use software that interact with users on an individual basis [12]. Health-related apps form a significant proportion of all apps. Although exercise and wellness apps form the major proportion of the health app landscape, self-management apps for chronic conditions, including pain, are growing [13]. There are currently over 350 pain self-management apps offering pain assessment recording, pain information, and pain self-management plans available

on the internet, and this number is expected to increase [14, 15]. While several recent systematic reviews have evaluated the quality of currently available pain-related apps [14–17], only one review has examined the quality and usability of arthritic pain self-management apps for older people [13]. This review identified that only 4 of the available 373 pain apps offered pain self-management advice and support in accordance with the Stanford Arthritis Self-Management Program and reflected current arthritic pain management evidence [13].

There is a paucity of pain app evidence that is applicable to older people, with most studies focusing primarily on younger people's management of their chronic pain [18–20]. The two app-based interventions tested among older people have both focused on areas outside of pain, such as strength training [21] or falls [22]. As older people with chronic pain indicate a willingness to learn and use smartphones and apps for pain self-management [23, 24], the feasibility, acceptability, and effectiveness of using a pain app to help older people better self-manage their arthritic pain warrant further investigation.

Aim

The aim of this study is to evaluate the feasibility, acceptability, and preliminary outcomes of a pain self-management app among older people living in the community with arthritic pain.

Method

Design

This is a phase I feasibility study. Based on the Medical Research Council's continuum of evidence structure, this study is classed as a phase I study [25, 26]. Studies classed as phase I are designed to improve the understanding of components of an intervention and their interrelationships. Qualitative testing is recommended for use in these studies so as to facilitate the understanding of how the intervention might work [25]. It is, however, important to note that development and evaluation of a complex intervention is not always a sequential or linear process, and these interventions may work best if they are tailored to local settings instead of a uniform/standardized approach [26].

Feasibility studies are used to determine whether an intervention is appropriate for further evaluation [27]. Adhering to the conceptual framework outlined by Eldridge and colleagues [28], this study could be classed under "feasibility studies that are not pilot studies." Feasibility studies differ from pilot studies as they are carried out before a main study so as to estimate important parameters required to design the main study, whereas a pilot study is a smaller version of the main study carried out to evaluate if all of the components of the main study can work together [29].

Participants

This study aims to recruit 30 older people living with arthritic pain, who use a smartphone or a tablet device, and who meet the following inclusion criteria:

- Living in the community;
- Aged 65 years or over;
- Presence of arthritic pain for ≥ 3 months (participant reported);
- Ability to read and write in English;
- Ownership of a smartphone/tablet-computer;
- Ability to give written informed consent

Exclusion criteria include the following:

- Presence of cancer pain
- Under end-of-life care pathways
- Living in an institutional home

Setting and procedure for recruitment

The screening, recruitment, and consenting process for this study will be carried out by one of the investigators (PB). Prospective participants will be sought from various older people's club/associations/groups, including Facebook groups across Metropolitan and Regional New South Wales (NSW), Australia. This approach of recruitment is considered because many older Australian utilize their free time keeping active and participating in leisure activities by engaging in social clubs [30]. With over 60% of community-dwelling older Australians involved in a social or support group [31], members of older people-specific social clubs and organizations are expected to be a fair representation of the target population of this project.

Each club/association/group will be approached with a written invitation to participate. Utilizing a snowballing sampling approach, club members will be asked if they could provide a referral to any other club/organization/group that could be contacted with an invitation to participate. Interested clubs/organizations/groups will be asked to circulate the study's poster among their members in paper or electronic form. Groups that meet in person will be offered an on-site presentation to promote the study and share the invitation to participate.

To facilitate online recruitment, a designated study Facebook page will be created. Administrators of interested Facebook-based groups will be asked to upload the study's poster on the group's Facebook page on behalf of the investigator team. Utilizing a snowballing sampling approach will enable study participants to share our study invite among their networks and to refer us to any contacts who they think may have interest in participating.

The first contact with potential participants will be made via one of the three following approaches: (i) during the on-site presentation, (face-to-face contact), (ii)

when interested participants contact the investigator responding to the recruitment poster (telephone, email, or via Facebook), (or iii) when a face-to-face contact (prospective participant, club member, or study participant) provides a referral to another prospective participant (telephone or email contact).

Each potential participant will be asked the following three questions to assess if they meet the eligibility criteria: (a) Have you experienced arthritic pain for over 3 months? (b) Are you over 65 years of age? (c) Do you live in the community setting (not in an institutional home like residential aged care facility)? Participants answering "Yes" to all of the three questions will be considered eligible to participate in the study. Those meeting the eligibility criteria will be provided with a brief verbal overview of the study including a clear indication that there is no direct incentive to them in participating in this study. This will be followed by the provision of the written Participant Information and Consent Form. Potential participants will be prompted to ask any questions regarding the implications of participation before signing the consent form. After this time point, potential participants will be advised to get in touch with the study team when they are ready to provide their written consent. This could happen on the same meeting session (or day) of information provision, or could be up to 2 weeks before the end of the recruitment period.

Sample size

As this is a phase I feasibility study, a sample size calculation is not appropriate. However, consistent with other comparable studies [32, 33], $N = 30$ will be the target recruitment figure.

Intervention

The intervention to be tested in this study is the free, widely available and downloadable pain self-management app named Rheumatoid Arthritis Information Support and Education ("RAISE") [34]. The selection was made based on our recent systematic review of the quality and older people-specific usability of all available pain apps identified on the web as of 30 May 2016 [13]. The WebMD Pain Coach app [35] generated the highest quality and usability score [35]; however, this app has recently been removed from the public domain. The app scoring the second highest score RAISE [34] will be selected for evaluation in this study. Written permission has been obtained from the developers of the RAISE app for its use in this study.

The RAISE app

The RAISE app has been designed by the collaborative effort of the Rheumatology Department of St. James Hospital in Ireland and Arthritis Ireland for the self-management of

arthritic pain [36]. The features of the RAISE app could be broadly classed as encompassing the following functions:

- *Assessment and documentation:* The RAISE app offers an option to assess pain in a 0–5 Numeric Rating Scale (NRS) and keeps a time-stamped record of the NRS score. This pain intensity scale can be used as frequently as the user desires. Users can also record their activity level on a 0–5 NRS, and
- *Pain self-management education:* The RAISE app provides education on a range of different topics relating to pain self-management such as a provision of education on pain/pain self-management processes, medication use, and communication with health professionals and pain-related problem-solving. Information on fatigue, sleep, and the management of distress along with CBT pain management instructions on relaxation, goal-setting, and activity pacing (20–30 min session) are provided. Finally, there are videos of stretching, isotonic and aerobic exercise with warmup and cooldown stages with the duration and frequency of exercise also indicated.

Intervention delivery

A meeting (face-to-face or via telephone) will be organized with all consenting participants in order to download and set up the RAISE app on the participant's mobile device, provide participants with app training and brief them to use the app for 14 days, and collect the pre-test data (Time 1 (T1)). Participants will be shown all of the features of the app and then guided to navigate through the features of the app until they are comfortable using it. In addition, participants will be advised to contact one of the investigators if they require any assistance in using the app throughout the 14-day period.

A wireless-enabled device (wireless internet dongle) will be purchased and used for downloading the app to the face-to-face meeting participant's device so that they do not have to use their mobile phone's data allowance for the app download. If a face-to-face meeting is not feasible, and the participant is willing and able to use their own wireless or mobile internet for the app download, this session will be carried out over the phone (telemeeting). Participants will be advised to use the RAISE app as desired for the next 14 days. It is important to note that this study is not prescriptive in terms of how often participants will use the app. They receive brief training on how to use the intervention app to ensure they are comfortable with using it; however, the frequency with which they use it is up to them.

Study outcomes

For the purpose of this study, following three preliminary outcomes will be measured before and after the intervention: (1) pain severity and interference, (2) pain self-efficacy—

described as confidence people with ongoing pain have in performing activities while in pain [37], and (3) online technology self-efficacy—described as confidence in using various kinds of online technology [38]. In addition to these preliminary outcomes, this study will also measure the following feasibility outcomes: (1) recruitment, refusal, and attrition rates; (2) proportion and patterns of missing data; and (3) ability to recruit 30 participants within 6 months of recruitment commencement.

Data collection

Data collection will be carried out by one of the investigators who is a registered nurse with a Bachelors of Nursing (Honors) qualification and is currently undertaking a doctoral degree. She has over 5 years experience of working in healthcare research environment across various aged and chronic care trials in the aged care and hospital setting.

Data will be collected using the following questionnaires (refer Table 1):

1. Pain outcomes Case Report Form (CRF)—This CRF includes three valid and reliable outcomes measurement questionnaires, namely the Brief Pain Inventory-short form [39], the short form Pain Self-Efficacy Questionnaire (two-item scale) [40, 41], and the Online Technology Self-Efficacy Questionnaire [38].
   a. The Brief Pain Inventory (BPI)-short form—The BPI-sf is a validated, widely used, self-administered questionnaire developed to assess the severity of pain and the impact of pain on daily functions [39].
   b. Short form Pain Self-Efficacy Questionnaire (PSEQ-2)—The PSEQ-2 is a valid and reliable two-question tool designed to assess the confidence people with ongoing pain have in performing activities while experiencing unrelieved pain [40, 41]. This tool is deemed to be a robust measure of pain self-efficacy [42].
   c. Online Technologies Self-Efficacy Scale (OTSES)—The OTSES is a valid tool that is designed to measure an individual's self-efficacy in using online technologies [38].
2. Demographic and clinical survey—The survey captures participants' demographic, social, and health-related information and includes the Charlson Comorbidity Index [43], the Life-Space Assessment questionnaire [44], and the Australian-modified Karnofsky Performance Scale [45].

Data collection commenced in July 2018 and will continue for 6 months or until all of the data has been collected for the 30th participants, whichever occurs first.

Table 1 Data collection tool and time points

Tool	Day 0 (T1)	Day 15 (T2)
Demographic and clinical survey captures the following:	✓	✗
• Participant's demographic information, medication use details, social support, technology use pattern, and clinician details		
• Comorbidity: Charlson Comorbidity Index		
• Mobility: Life-Space Assessment questionnaire		
• Performance status: Australian-modified Karnofsky Performance Scale		
Pain outcomes measurement Case Report Form includes the following:	✓	✓
• The Brief Pain Inventory-short form		
• Pain Self-Efficacy Questionnaire-short form (two-item scale)		
• Online Technology Self-Efficacy Questionnaire		

Qualitative sub-study

All participants will be invited to take part in a semi-structured telephone interview at the end of the intervention period. The semi-structured interviews will focus on evaluating the acceptability of the intervention. Participants will be specifically asked about the pattern of app use, including frequency and timing, and their experiences, attitudes, and perspectives on integrating the RAISE app into their pain self-management strategy. Participant's perceptions of the barriers and facilitators to successful use of the intervention app, as well as their willingness and concerns regarding its use, will also be explored. The semi-structured interview will be carried out via telephone. It is anticipated that the interviews will last for approximately 30–45 min. The interviews will be audio recorded and transcribed verbatim for analysis.

Statistical analysis

This study will utilize the IBM Statistical Package for Social Science (SPSS) software for management and analysis of data. Descriptive statistics will be used to synthesize the sociodemographic data of the participants. Frequencies and percentages will be reported for categorical variables, normally distributed continuous variables will be presented as mean and standard deviations, and median and interquartile range will be reported for non-normally distributed continuous variables. Participant's pre-test self-reported pain data (pain intensity and pain interference), pain self-efficacy, and online technology self-efficacy will be compared with their post-test reports.

Qualitative analysis

The qualitative data will be managed using NVivo software. Coding and classification of the data will be carried out to make sense of the collected data and to highlight the features and messages of the semi-structured interviews [46]. Data analysis will be carried out using an inductive process of thematic content analysis. The transcribed interviews will be read and re-read so as to promote immersion in the data

and close examination of the interview content. Preliminary themes and sub-themes will be generated and continually refined.

Data integration and synthesis

Integration of data will take place after the completion of qualitative data collection. The data will be integrated through a triangulation approach [47]. A "coding matrix" will be developed listing the findings from the quantitative and the qualitative study, followed by critical evaluation to find out if the findings from the two studies agree (convergence), if they offer same information on the same issue (complementarity), or if they contradict each other (dissonance) [47]. The aim of this integration process is to develop "meta-themes" that will enable the creation of a composite picture of the whole phenomenon of interest. Based on this integration, a series of recommendations will be made to inform future pain app studies.

Ethical considerations

The ethical approval for this study was obtained from The University of Notre Dame Australia Ethics Committee (approval number: 017049S). This study is also registered in the Australia New Zealand Clinical Trials Registry (ANZCTR) under the trial ID: ACTRN12617000921381.

Data management plan

Study data will be recorded in electronic and hard copy form for the purpose of study administration and for the collection of participant data.

Electronic recording

An Excel spreadsheet will be created to store participants' confidential contact information together with their allocated study ID. This will be the only link between each participant and their study ID. This linkage of information is necessary to carry out the post-test data collection, to organize the semi-structured interviews with interested

participants, and in cases where a participant later wishes to withdraw from the study and wants their data removed.

The audio recording of the semi-structured interviews will also be transcribed in electronic form (Microsoft Word file). Each interviewee will be provided with a study ID, and any identifiable information that may be present in the audio recording will be de-identified in the transcription process before transferring the data to NVivo software. These files will be stored in the researcher's password-protected laptop computer and saved within password-protected folders for added security. All data entry work will be carried out by one of the investigators.

Hard copy recording
The consent forms of each participant will be obtained in hard copy or paper form. In addition, the pre-post test data will also be collected in hard copy form. The hard copy of the participant's consents will be stored in a locked cabinet securely and separately from their study data.

All of the data storage will be done in a locked cabinet securely at the principal investigator's office. The access to the study data will be provided only to the investigator team. At the completion of the study, all study material (electronic and hard copy) will be reconciled and stored as per the relevant state regulation regarding research data retention and disposal of that time.

Dissemination
Data analysis will start immediately after the data collection period. The result of this study will be published in peer-reviewed journals and presented in relevant conferences.

Discussion
This phase I feasibility study will make an important contribution to determining the feasibility and acceptability and building the evidence base concerning the use of pain self-management apps for older people living with arthritic pain. In addition to being the first study to evaluate the feasibility and acceptability of a pain self-management app in the older population, this study will also provide preliminary insights into the impact of a self-management app in older people's pain and self-efficacy-related outcomes. Given the globally aging population, the prevalence of chronic pain, an upward trend of smartphone adoption among older people, and the paucity of evidence in the area of pain self-management apps among older people, this study aims to address an important evidence gap.

Several limitations of this study should be considered. Firstly, this study is not prescriptive in terms of how often participants are to use the app. They will receive a brief training on how to use the intervention app to ensure they are comfortable with using it; however, the frequency with which they use it is up to them. This could lead to non-uniform app use pattern among the participants.

However, as we intend to evaluate the feasibility and acceptability of the pain self-management app as it resembles the "real-world" situation, the varying pattern of app use will be considered and evaluated in a qualitative sub-study with the participants (reported elsewhere). Secondly, there is a possibility of selection bias as we aim to recruit via social clubs and associations which could exclude those who are less socially active and involved. To minimize this potential, we have also opted for snowballing recruitment approach where referrals to non-members from participating clubs/individuals are followed-up adequately for inclusion. However, with the utilization of snowballing sampling approach, it will be challenging to appropriately capture the refusal rate resulting from snowballing, and this will be a limitation of this study.

Despite the above-noted limitations, findings from this study will be relevant in informing future arthritic pain self-management research and similar app development endeavors. The findings of this study are expected to help develop a set of recommendations that could inform policymakers, clinicians, app developers, and consumers when developing, selecting, or implementing a pain self-management app.

Publisher's Note

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Appendix 20

Publication: Apps for Older People's Pain Self-Management: Perspectives of Primary Care and Allied Health Clinicians

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Apps for Older People's Pain Self-Management: Perspectives of Primary Care and Allied Health Clinicians

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Abstract

Background. Chronic arthritic pain is one of the major causes of physical suffering and disability among older people. Primary care and allied health clinicians use various approaches to help their older clients better manage their arthritic pain. The growing uptake of technology among older people offers the potential for clinicians to integrate an arthritic pain app into their patients' self-management plans. This study explored the perspectives of Australian primary care and allied health clinicians regarding the use of pain self-management apps to help their older patients/clients better manage their arthritic pain. **Methods**. Qualitative design using a semistructured interview approach. Interviews were conducted via telephone with primary and allied health clinicians (N = 17) across Australia. **Results**. The overarching theme underlying participants' views on integration of apps into older people's pain self-management strategy was that this approach is an idealistic but uniquely challenging endeavor. Four subthemes emerged, namely: 1) self-management apps are a potentially useful tool but require careful consideration; 2) clinicians' involvement is crucial yet potentially onerous; 3) no single app is right for every older person with arthritic pain; and 4) patient data access is beneficial, but caution is needed for real-time data access. **Discussion**. The predominant clinician perspective of integrating apps into their older patients/clients' pain self-management strategies was that this approach is an idealistic but uniquely challenging endeavor. Apps were seen as having potential to support various aspects of patients' self-management behaviors; however, there were notable concerns with regards to the challenges inherent in this approach for both clinicians and older users (patients/clients).

Key Words: Older Adults; Smartphone; App; Primary Care; Allied Health; Pain Management

Introduction

Despite population aging and the growing burden of noncommunicable diseases, health care and technological advances are enabling more older people (>65 years) [1,2] to live at home [3–5]. Many older people have multiple comorbidities and varying levels of symptom burden and disability that they need to manage [6]. Arthritis is a common cause of unrelieved pain and suffering, experienced by 20–46% of community-dwelling older people [7], and accounts for 4% of all Australian general practitioner (GP) consults [8,9]. Chronic pain forms a significant proportion of primary care clinicians'

workload, with one of three older people consulting a GP due to their pain [6,8]. Innovative and cost-effective approaches to support pain self-management behaviors of community-dwelling older people are required, including the use of pain self-management applications or "apps."

The multidimensional process of pain self-management commences when the older person experiencing pain perceives the need to take control of their pain and is willing and able to do so. Effective pain self-management requires older people to be aware of their own responses to painful symptoms [10] and to

regularly assess their pain, manage their analgesic intake, modify their lifestyle and help-seeking behavior [11], and seek regular primary and allied health review. Increasing numbers of older people are adopting smartphones [12], and are keen to utilize this modality to self-manage their pain [13–15]. The advanced computing features of smartphones and tablet computers present new opportunities to improve health outcomes by empowering patients to assume a more active role in monitoring and managing their health via a partnership with their clinicians [16].

Pain self-management apps offer a range of functions, such as recording pain assessments, providing pain-related information, and generating pain self-management plans. Although a recent systematic review [17] evaluating the efficacy of apps in the management of any type of pain across all ages indicated this approach to be beneficial, the majority of participants were younger people (one out of 15 included studies had a mean participant age >65 years), limiting the applicability of this finding to older people living with chronic pain. However, the growing number of recent study protocols [18,19] suggests that evaluation of the feasibility and efficacy of apps among older people for their chronic pain management is a growing area of interest.

Although evidence indicates enthusiasm among primary care clinicians in applying smartphone technology to care for older people with noncancer pain [20], their views about integration of apps into their community-dwelling older patients' pain self-management regimes remain unknown. As apps become more ubiquitous in health care, exploring primary care and allied health clinicians' views about the current and future roles of apps as part of an arthritic pain self-management intervention requires further exploration.

Positioning this Qualitative Study
This qualitative study reports on the findings of interviews with primary care and allied health clinicians caring for community-dwelling older people living with arthritic pain.

Aim
To explore the attitudes and perspectives of primary care and allied health clinicians regarding the integration of pain apps into their older arthritic patients' pain self-management strategies.

Methods

Design
A qualitative study using semistructured interviews.

Methodological Orientation
This qualitative study is part of the DigiTech Pain Project, designed to evaluate the feasibility of integrating pain apps in older people's pain self-management regimes [18]. Guided by a constructivist worldview, this study considers knowledge to be produced by understanding the social world of the participant [21]. This allows for significance to be placed on meaning and interpretation of the knowledge, while acknowledging that these meanings are often socially constructed [21]. In this study, knowledge is generated based on the views of clinicians, which are founded on their interactions with older patients/clients.

Setting
Primary care.

Recruitment of Participants
A purposive sampling method [22] was utilized to recruit primary care and allied health clinicians registered with the Australian Health Practitioner Regulation Agency as "health professionals." An invitation to participate was circulated via the following three approaches:

1. Participants of the pre/post-test app trial [18] were asked to nominate three clinicians who help them with their pain self-management.
2. Electronically via advocacy groups/associations representing the health professions listed below:
   a. General practitioners (Royal Australian College of General Practitioners);
   b. Practice nurses (Australian Primary Health Care Nurses Association);
   c. Physiotherapists (Australian Physiotherapy Association);
   d. Chiropractors (Australian Chiropractors Association);
   e. Psychologists (Australian Psychological Society);
   f. Exercise physiologists (Exercise and Sports Science Australia).
3. Professional networks of the study team.

Referrers were advised to inform their networks to contact the study team (PB via e-mail or phone) if they had any questions or wished to participate in the study. Potential participants were asked to contact the study team (instead of the study team approaching them) to minimize risk of persuasion or influence. Written consent was obtained from eligible participants before scheduling the interview.

Research Team
The interdisciplinary research team included a registered nurse with experience in digital health research and a background in chronic and palliative care research (PB); an experienced clinical academic nurse researcher with a background in palliative care and mixed-methods and clinical trials research (JLP); and a clinical academic psychologist with specialization in pain self-management, who is also an expert in the social aspects of chronic pain (TNJ).

Data Collection

Data were collected via telephone interviews between October and December 2018. An interview guide comprising various open-ended questions guided the interviews (Supplementary Data). All interviews were conducted by one researcher (PB) and were audio-recorded and professionally transcribed by an external transcription service. The interviewer also took detailed field notes, which were cross-compared with the interview transcripts. The interviewer kept a reflective journal and made entries after each interview to exercise critical self-reflection and to minimize any bias that the interviewer's position may pose. Data collection continued until no new insights were generated.

Data Analysis

The NVivo 12 software package was used to manage the qualitative data. An inductive thematic analysis approach was utilized for data analysis [23]. One researcher (PB) read and re-read the transcripts and field notes to achieve data familiarization, followed by identification of recurring themes and open coding of the content. A hierarchical coding approach was adopted utilizing branching arrangement of subcodes (child code) created under each code (parent code). This process was constantly cross-validated with the team (JLP and TNJ) to ensure coding validity. Any discrepancies in coding were discussed by the research team and resolved via consensus. No formal reliability statistics were calculated. Recurring data patterns and themes were identified using the constant comparison method [24].

Ethical Considerations

Ethical approval was granted by The University of Notre Dame Australia Ethics Committee (01749S0). All participants provided written consent. Participants were informed that participation was voluntary and that they could withdraw from the study at any time. No reimbursement was provided for participation. Data were de-identified to ensure confidentiality. Reporting of this study adheres to the Consolidated Criteria for Reporting Qualitative Research (Supplementary Data) [25].

Results

Data were collected from 17 primary care and allied health clinicians, including general practitioners (N = 4), physiotherapists (N = 8), clinical psychologists (N = 2), an osteopath (N = 1), an emergency department physician (N = 1), and a specialist pain physician (N = 1) (Table 1). Participants were spread across Australia, with the majority being based in New South Wales (N = 10). Most participants were female (N = 10; 59%), with a mean age of 45.8 years (±10 years). Over half of the participants worked full-time (N = 11), and the mean number of years in practice was 20 (±10). The mean duration of the interview was 23.4 minutes.

The overarching theme underlying participants' views on integration of apps into older people's pain self-management strategy was that this approach is an idealistic but uniquely challenging endeavor. Four subthemes emerged, namely: 1) self-management apps are potentially useful tools but require careful consideration; 2) clinicians' involvement is crucial yet potentially onerous; 3) no single app is right for every older person with arthritic pain; and 4) patient data access is beneficial, but caution is needed for real-time data access.

Potentially Useful Self-Management Tool but Requires Careful Consideration

Most participants were positive about the integration of apps into older people's pain self-management strategies.

> I think generally the concept of tools like app being useful in self-management of chronic disease is definitely one that would seem to have traction on.... I can really see the potential in that. (HP01, 57, M, GP)

Participants were open toward recommending pain self-management apps to their older patients.

> I think I would [recommend a pain self-management app]. I guess I would have to know how aware they [patients] are with technology and if they are using smartphones or not. I think if they were and they seemed like they are the right kind of person and they are interested to learn, I think I would definitely recommend it. (HP06, 30, F, GP)

However, this positivity was accompanied by concerns about the challenges inherent with app utilization in an older population.

> There are a lot of barriers to using apps.... Apps can be quite intimidating and overwhelming to the older person. A lot of my clients won't even let me assist them to set up an alarm on their phone for their medications, because it all sounds too difficult. (HP11, 31, F, Physio)

App as an Empowerment Tool

The integration of apps into the pain self-management process was considered to empower older people by fostering a sense of responsibility and engagement.

> Most people want something to do. They want to feel as though they are doing something actively towards helping their pain. And that [using an app] is a way of engaging them in an activity that can help them get mastery, or at least help them feel like they are doing something towards their self-management. (HP02, 54, F, Clinical Psychologist)

Table 1. Participant demographics

Characteristic	Classification	N = 17
Gender	Female	10
	Male	7
Age	Mean (SD), y	46 (±10)
	Median (IQR), y	47 (21)
Discipline	Medicine	6
	Physiotherapy	8
	Clinical psychology	2
	Osteopathy	1
Years of practice	≤10	3
	10–20	6
	20–30	5
	>30	3
Highest level of education	Graduate diploma	2
	Undergraduate	5
	Postgraduate	10
Employment status	Full-time	11
	Part-time	6
Practice setting	Public	6
	Private	9
	Community	2
Percentage of older patients/clients with arthritis	≤25	5
	26–50	8
	>50	4

IQR = interquartile range.

Participants considered apps to be a helpful educational tool that could facilitate digital delivery of point-of-care information and instructions to older people, instead of using paper-based action plans.

> I guess in the past we've always relied on paper plans to help guide people in what they do, like the "COPD Action Plan." So, I guess that sort of stuff could be incorporated into an app for arthritis. (HP06, 30, F, GP)

An app's ability to share data with clinicians was perceived as a potential motivator, which could improve patients' adherence to the self-management instructions.

> If we could look at their [patients'] practices and they knew we could look at their practices, I think they might be more keen to engage [in self-management]. (HP10, 41, M, Physio)

Digital Familiarity Still an Unmapped Territory for Older People

Although participants acknowledged the increasing uptake of smart devices among older people, they were unsure if this has yet translated into increased user engagement with apps.

> A lot of older clients are getting mobile phones and smartphones, but of my clients who have a mobile phone, probably 60% of them only use it for calling or texting. Not many use it for its other features, and it can be quite overwhelming and intimidating to them to think about using an app. (HP11, 31, F, Physio)

However, there was an acknowledgement that this situation is continually changing and that clinicians should be open to such engagements.

> I think I'm seeing more and more of my clients with mobile phones and smartphones.... The proportion of my clients with mobiles that are over the age of even 70, they have the phones! I think, we could be utilizing it more.... We should be using it to our advantage. (HP11, 31, F, Physio)

The complexity involved in downloading and purchasing apps was raised as an important element in the context of user burden when considering app use by the older group.

> It's not just about usability; it's the actual process: "Do I know my apple ID and password...? No, I don't. Now I need to reset it. I don't know how to reset it. Ooh...wait, I don't have a credit card saved on my device." All this stuff that comes with the mandatory download of something from an app store. (HP16, 33, F, Physio)

Clinicians' Involvement Is Crucial yet Potentially Onerous

Participants perceived that integration of apps into older people's pain self-management regime will be taxing on clinicians' time.

First, participants considered it crucial to assess their patients for suitability of app use.

> Yeah, I think some people just shouldn't go down that rabbit hole because they are already there. They already over-focus on the negative: the pain.... If you give them an outlet to complain more about the pain, they'll take it.... I think you just have to be really careful with who accesses the app. (HP11, 31, F, Physio)

Second, participants noted a range of factors they would consider if they had to identify and recommend a pain self-management app for their patient.

> I think I would want to see a level of evidence–based endorsement in the literature. So, I would be looking for...a clear endorsement of a particular app from a recognized authority and some evidence base for it. (HP01, 52, F, GP)

This meant that participants had to download the app and familiarize themselves with it before recommending it to their patients.

> The problem with recommending an app for patients is you have to be familiar [with the app]. Making sure myself or other clinicians using an app will have adequate training to know all the functions. Because, if recommending things you don't necessarily agree with, then we

probably shouldn't be recommending the app. (HP06, 30, F, GP)

Consequently, time constraints in relation to app use were noted by participants.

Most of the work that I do with these apps is outside of the consultation time. I am finding myself needing more and more time at the end of the day. (HP09, 59, M, Osteopath)

No Single App Is Right for Every Older Person with Arthritic Pain

Participants reinforced the importance of personalizing care and that no single pain management approach is right for everyone.

The ability of an app to offer personalization in relation to self-management skill-building was considered important.

Exercise should be tailored to the individual, and if…not, there's a risk that [they] could be doing something that's inappropriate. (HP10, 41, M, Physio)

This suggestion of personalization extended to the types of self-management strategies that are suitable and preferred by each user, suggesting that an app had the potential to be a companion tool that assisted older people to build their cognitive behavior therapy (CBT) and physical exercise–based skills.

Maybe some kind of goal setting with that. I would suggest physical activity of course, and then some way to track their progress toward that goal and maybe some reward system when they achieve that goal. (HP05, 35, F, Physio)

Things like meditation, mindfulness, relaxation, that side of it. Something like that in an app would be really great. (HP11, 31, F, Physio)

Apps were considered capable of offering prompts and motivation to exercise, providing accurate instructions to exercise, and being an exercise support/progress-monitoring tool for older people.

I think videos of the exercises are very useful because I do often go back to clients and as much as we write it out and draw it out for them, you do often go back and they have been doing it wrong or they have been a bit confused about it. So I think videos are a really useful tool. I think videos of the clients doing it themselves are even more useful. (HP11, 31, F, Physio)

In addition, successful integration of apps was perceived to be very much dependent upon its user-friendliness, ease of use, and intuitiveness.

I guess user-friendliness is probably the main thing. If it's not user-friendly then it is probably not going to be

something that they [patients] are going to engage with. (HP10, 41, M, Physio)

Age-related limitations and challenges such as poor vision and dexterity were also considered important when thinking of suggesting an app to an older person.

Some patients in this demographic you are addressing have limited ability to manipulate a handheld device to work some of these things, so that's a bit of a catch 22. (HP09, 59, M, Osteopath)

Patient Data Access Considered Beneficial, but Caution Needed for Real-time Data Access

The capability of apps to collect and share various patient assessment data was perceived to be beneficial. Participants were interested in a range of different data points.

Quite accurate measure of activities and also the pain relief and a quite accurate picture of how much pain relief and when they are taking it…. It's also quite useful to know what's happening to people's activity levels and what they do with their pain. So, for example, you can see that people's movements going up, and mood decreasing, and at the same time the pain is increasing. That leads you down the set of ideas that what happens if the pain was going up and down? Then that leads you down a certain set of ideas. That would be really useful. (HP03, 47, M, GP)

However, participants were mindful of the possibility of the data overload that might be brought on by this level of data sharing from the app, especially with the real-time data-sharing feature.

You wouldn't want to be in the position where you were having lots of data sent your way that you are meant to be looking at outside consultations. If you weren't being appropriately reimbursed. GPs are not going to go for that. (HP13, 57, F, GP)

Consequently, most participants wished to access (and review) aggregated patient data, preferably during the consult.

I find summaries of recent data much more useful, so what I mean is – I don't know what people are doing on a day-to-day basis, but that doesn't really tend to give me anything that I need to know. But having a summary of what happened is useful. (HP03, 47, M, GP)

Discussion

This study adds to the growing empirical literature on the use of pain self-management apps. Various factors

that should be considered before and during the integration of apps into older people's pain self-management strategy from the perspectives of primary care and allied health clinicians have been identified, many of which have not been previously reported.

In line with the growing evidence on the role of apps in self-management of various chronic illnesses [26,27], clinicians of this study perceived apps to be useful in facilitating the pain self-management process of older people. Patient empowerment is considered one of the critical elements of any self-management intervention [28]. Apps were considered capable of empowering older users by helping them to assume responsibility for aspects their care, become more knowledgeable, and subsequently be committed to their treatment regimens [28]. However, this optimism was accompanied by a feeling of ambivalence when considering the digital familiarity of older people. These concerns relating to low-level proficiency in app download and use among older people reflect the published literature with studies conducted in the United States [29], Hong Kong [30], and Germany [31] that reported low levels of technical readiness and computer literacy among older adults [30,31].

Growing concerns about the quality of health-related apps are known to cause uncertainty among clinicians in recommending these apps to their patients [32]. An app's ability to be a good vehicle of electronic information and instruction relay makes it useful but at the same time highlights the concern among clinicians regarding the quality of the app's content [33,34]. Clinicians of this study similarly felt a need to personally evaluate the evidence base and credibility of the developer/endorser of the app. Consequently, the pressure this puts on the clinicians' existing workload was a reasonable concern. This concern resonates with reports in the literature [35,36] indicating that making apps mainstream demands a considerable time commitment from clinicians. The literature also points toward the potential risks of this modality [32], indicating a need for individualized suitability assessment before an app is recommended to patients, which confirms the perceptions of clinicians in this study. However, when considering older people with a possibility of cognitive decline, a preliminary assessment on commencement of app use may not suffice. Instead, ongoing technical support and regular assessment of their ability to appropriately engage may be required.

Ease of use (use requiring minimal effort), is a preferred design feature of disease self-management apps [34,37], including pain apps [38]. However, when considering older users, this concept extends beyond intuitive and user-friendly design to considerations of unique needs related to aging [34,39]. This view was confirmed by the clinicians of this study with recommendations regarding the inclusion of exercise personalization features. Although the recent guideline on arthritis management details the value of personalized regular physical exercise

[40], lack of access to a personal coach or ability to develop one's own personalized training regime remains a well-known barrier to exercise engagement [41,42]. Given this reality, apps with advanced personalized exercise prescription features may be able to offer an acceptable way of facilitating evidence-based physical exercise therapy for older people. Furthermore, the clinician's suggestion of integrating various CBT-based approaches into the app is largely aligned with the published evidence on elements of a comprehensive pain self-management plan [43,44].

Apps' potential to share patient data with clinicians has been widely lauded in the context of chronic disease self-management [45,46], where regular communication with and support from clinicians are considered beneficial. Previous studies exploring the views of people with chronic conditions [34,47] and primary care providers [20] on the data-sharing features of apps have similarly valued this capability. In line with this evidence, the clinicians of this study also perceived access to patients' data to be beneficial in their care-planning and -provisioning process. The data points of interest to the clinicians were mostly related to the assessment and documentation of pain and analgesia intake and physical activity tracking, which also confirms the reports of the literature [20]. As clinicians play a pivotal role in helping patients accept and adhere to pain self-management treatments and plans [48], their interest in patients' self-management activity–related data is understandable.

However, this openness toward data access was correspondingly balanced by some level of cautiousness. In line with previously published literature [20], clinicians were cognizant of the challenges of potentially unlimited access to patient data, including the need to consider its value and systems regarding its management [49]. In addition, there was some uncertainty regarding how this level of data access by clinicians could impact the patient and their behaviors. Although patients in general are open to sharing their self-assessment data with clinicians via an app [34,47], some authors consider clinicians' ability to scrutinize their patients' actions and communications on a very fine-grained level to be unnecessarily intrusive [50]. Pain app studies involving older people who use the data-sharing feature of the app are needed to better understand this area.

Implication for Practice

Based on the findings of this study, the following recommendations for practice are made:

- Clinicians need to be well supported to review, identify, and recommend pain self-management apps suitable for their older clients/patients.
- As the systematic integration of apps into clinical care requires a considerable time investment, there should be a clear discussion around reimbursements of clinicians from the health systems level.

- Future pain self-management apps should offer personalized tailoring to meet the needs and preferences of users with different pain types and self-management needs.
- Although access to patient data generated via apps could enable improved monitoring and management of older people, clinicians may benefit from health systems–level policies and procedures outlining appropriate management and use of such data.

Implication for Research and Development

Future research should focus on evaluating the value-added nature of smartphone apps, that is, evaluating their unique and advanced features that can potentially help to enhance the pain self-management process. Furthermore, to gain a comprehensive understanding of this area, studies investigating the feasibility of apps among older people are warranted.

Future pain app development work should consider a co-design approach involving academic experts in pain self-management, experts in technology implementation, primary and allied health clinicians, and older people to ensure the app is rigorously built, as well as relevant and effective. These recommendations agree with the newly published report [51] outlining a research agenda on mobile health technology for chronic pain management in older adults.

Strengths and Limitations

Several limitations of this study should be considered. First, the sample was small, nonrandom, and limited to primary care and allied health clinicians within Australia. Therefore, the findings may not be generalizable to other settings or areas with different data accessibility patterns and laws. Second, the profession-specific breakdown of the sample is uneven, with small numbers of participants from some disciplines and higher numbers from others. Therefore, our findings reflect the collective perspective of primary care and allied health clinicians, rather than the perspective of a single discipline. Finally, although there was nothing in the data to suggest a selection bias, we cannot discount the possibility that providers who chose to take part may have differed in some important ways from those who did not. For example, recruited providers may have had a greater affinity for technology or viewed the implementation of mobile health strategies more positively than those who did not take part.

Conclusions

A range of factors that should be considered before and during implementation of a pain self-management app into older people's pain self-management regimes has been identified and discussed in this paper. Ultimately, we hope that the findings of this study can help inform the development of future pain self-management apps where due consideration is given to the needs of older people and their clinicians. There is a possibility that apps could offer a cost-effective and time-efficient method to assist primary care and allied health clinicians in planning and implementing pain self-management care plans for their older patients, while also improving patient outcomes.

Supplementary Data

Supplementary data are available at *Pain Medicine* online.

Authors' Contributions

All three authors (PB, TNJ, and JLP) contributed to the concept and design of this study and to the manuscript preparation.

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Appendix 21

Electronic print of a media article relating to the clinician interview study (study 3), published in the 'Australian Doctor Plus'

Australian Doctor Plus is an online platform sharing news summaries, opinion pieces, and expert guidance.

6MINUTES **NEWS**

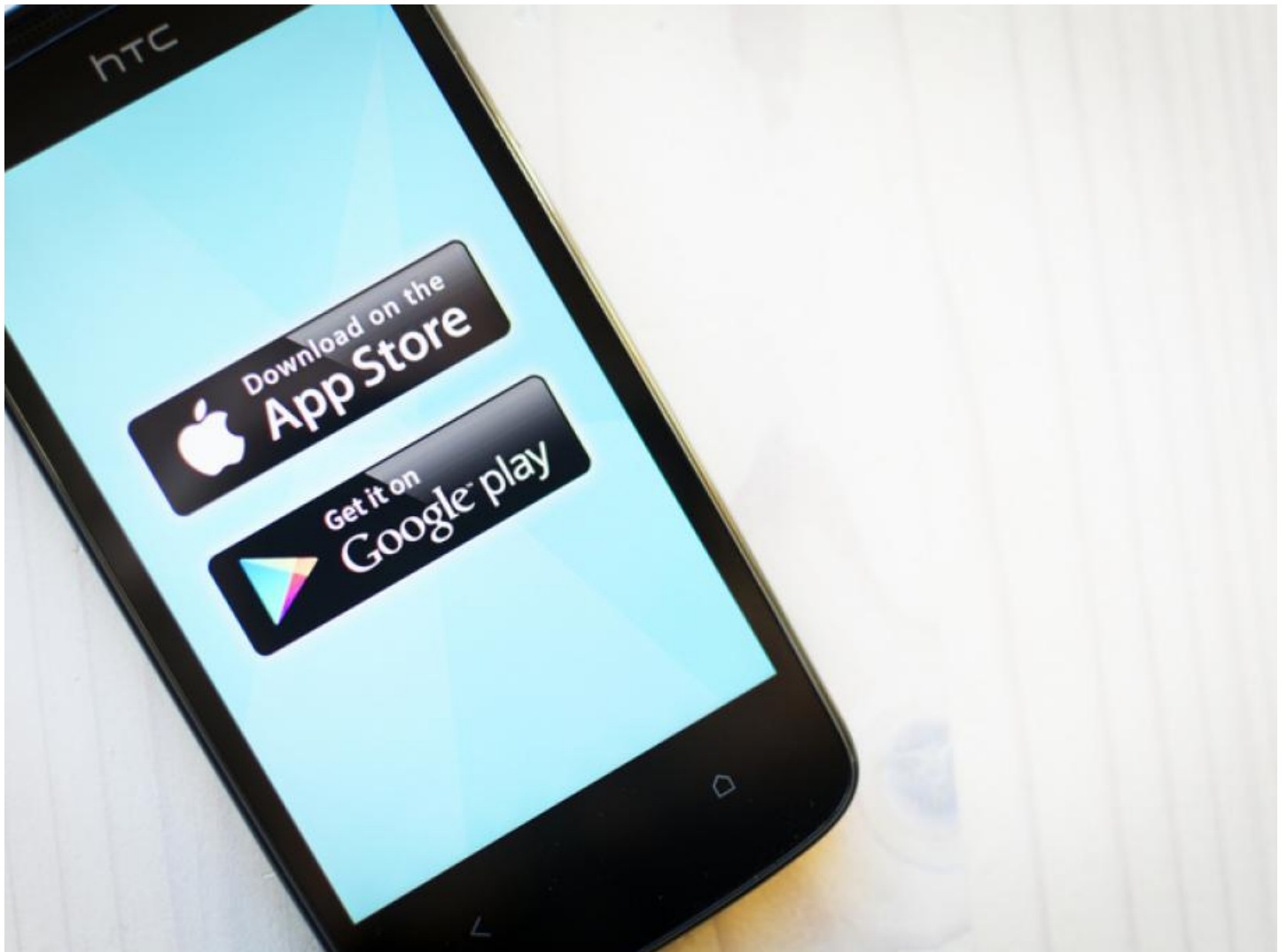# GPs sceptical of pain apps for older patients

Chief among their concerns was patients' ability to use the software

13th September 2019

By Clare Pain |

0 Comments

Australian GPs, doctors and allied health professionals have reservations about the suitability of pain management apps for older patients with arthritic pain, a small study shows.

Seventeen clinicians involved in treating arthritic pain in the over-65s were interviewed about the potential for patients to use smartphone apps to help manage their pain.

Interviewees included four GPs, an emergency doctor, a specialist pain physician, eight physiotherapists, two clinical psychologists and an osteopath.

Their common view was that the idea of using pain-management apps in older patients was idealistic and would be challenging to put into practice.

Among their concerns were making sure they were recommending high-quality apps, the ability of older patients to use them and reimbursement for managing any associated data.

> One GP said: "I think I would want to see a level of evidence-based endorsement in the literature. So I would be looking for … a clear endorsement of a particular app from a recognised authority."

A physio added: "Apps can be quite intimidating and overwhelming to the older person. A lot of my clients won't even let me assist them to set up an alarm on their phone for their medications because it all sounds too difficult."

Meanwhile, another GP said: "The problem with recommending an app for patients is you have to be familiar [with the app]. Making sure myself or the other clinicians will have adequate training to know all the functions. Because if you're recommending things you don't necessarily agree with, then you probably shouldn't be recommending the app."

A third GP said: "You wouldn't want to be in the position where you were having lots of data sent your way that you are meant to be looking at outside consultations if you weren't being appropriately reimbursed. GPs are not going to go for that."

But they did have a few positive things to say too.

"[It would be] quite useful to know what's happening to people's activity levels and what they do with their pain," a GP said.

A clinical psychologist said: "Most people … want to feel as though they are doing something actively towards helping their pain. [Using an app] is a way of engaging them in an activity where they can get mastery or at least help them feel like they are doing something towards their self-management."

The authors said they hoped the particular needs of older patients and their clinicians would be taken into account when designing pain management apps.

More information: *Pain Medicine* 2019