

Engaging Self-Management with a Low Back Pain App

in Manual Labor Workers

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Abstract

Background: Chronic low back pain is an extremely common condition in an occupational health setting. Among manual labor workers, chronic non-specific LBP can lead to loss of function, loss of income, and fear-avoidance behavior.

Aim: The aim of this project was to use electronic mobile application to assist manual labor workers with chronic back pain to increase their functional levels and to decrease illness behavior.

Methodology: This pilot project used a quasi-experimental pretest-posttest design. Manual labor workers with non-specific low back pain were recruited from a kitchen cabinetry manufacturing company. The four-week intervention included utilization of a de-novo created mobile application that contained educational materials and links to various exercise routines. The degree of physical disability and fear avoidance beliefs were measured pre and post intervention by using the Oswestry Disability Index (ODI) and the Fear-Avoidance Beliefs questionnaire (FABQ) respectively.

Results: Six participants participated in this study. All participants were males with a prolonged duration of low back pain (almost 5 years). There was a non-significant decrease in the physical disability ($p = 0.068$) score and a significant reduction in the avoidance beliefs ($p = 0.027$) score.

Implications: Electronic mobile applications should be included in the treatment management plans to reduce avoidance behaviors. Future research should focus on the role of applications on reduction of physical disabilities and preventing progression to chronic low back pain.

Keywords: low back pain, self-management, mobile health applications

Engaging Self-Management with a Low Back Pain App in Manual Labor Workers

According to the National Institute of Neurological Disorders and Stroke, about 80 percent of adults in the United States experience low back pain at some point in their lifetimes (2017). This condition affects men and women equally (2017). It is the most common cause of job-related disability and a leading contributor to missed days at work (National Institute of Neurological Disorders and Stroke, 2017). Low back pain is a common injury reported in occupational medicine, a field tasked with the goal of decreasing disability and loss of productivity (United States Department of Labor, n.d.-a).

Recommendations from clinical practice guidelines (CPGs) on treating low back pain often have a heavier focus on medical interventions. Yet, there is agreement amongst the CPGs to include psychosocial interventions for low back pain to complement the more traditional medical treatments (O'Connell, Cook, Wand, and Ward, 2016). An example of an intervention targeting the psychosocial aspect of low back pain is the promotion of self-management. This project evaluated the effectiveness of a mobile health application in promoting self-management among manual labor workers with low back pain.

Background and Significance

The Institute of Medicine (IOM) and the Occupational Health and Safety Administration (OSHA) recognized the significant impact of back pain. IOM and OSHA pushed for initiatives to reduce back pain because of its substantial effects on global, financial, and workplace factors.

Institute of Medicine

The IOM identified pain as a public health challenge. The national costs of chronic pain were \$635 billion each year (2011). In response, the IOM published a blueprint which quoted

the following:

1. Medical treatment for back pain had a cost of \$30.3 billion in 2007 (Soni, 2010).
2. LBP resulted in a loss of 149 million days-of-work per year (Freburger et al., 2009).
3. There was an estimated cost of greater than \$100 billion annually, two-thirds of which were from decreased wages and productivity (Freburger et al., 2009).
4. The Centers for Disease Control and Prevention (2009) reported disability from all causes had estimated costs of \$300 billion annually, with back/spine problems being one of the top causes.

Recognizing the need to address the public health burden of low back pain, the IOM issued a set of recommendations on management of this condition. One of these recommendations by the IOM was education and “promotion of self-management to individualize care to each patient” (IOM, 2011, p. 8).

Occupational Safety and Health Administration

OSHA focuses on providing a safer work environment through tracking workplace injuries and illnesses. OSHA sets and enforces standards in response to trends in workplace injuries. They also provide training, outreach, education, and assistance (United States Department of Labor, n.d.-b). They require employers with more than ten employees to keep a record of serious work-related injuries and illnesses (The United States Department of Labor, n.d.-c). Recordable injuries include those that require medical treatment beyond first aid and/or resulting in days away from work, restricted work, or transfer to another job (The United States Department of Labor, n.d.-c).

Low back pain is a common complaint seen in the work setting. It can result from falls,

fractures, strains, or repetitive motions. To illustrate the prevalence of work-related low back pain, national data on injuries and illnesses reported by employers to OSHA is next discussed.

Bureau of Labor Statistics

OSHA reporting requires employers to indicate the nature of injury when reporting new injury occurrences. OSHA publishes this data across all industries. Low back pain is a nonfatal occupational injury. It is not reported separately on its own, but is reported under the categories of sprains, strains, and tears or soreness and pain. The Bureau of Labor Statistics reported the following for 2017:

1. Manufacturing industries had the second highest number of nonfatal occupational injuries (394.6 thousand) by private industry sector (Bureau of Labor Statistics, 2018).
2. Sprains, strains, and tears had the highest nature of injury with an incidence rate of 35 per 10,000 full-time workers (Bureau of Labor Statistics, 2018). The second highest was soreness and pain which had an incidence rate of 17.1 per 10,000 full-time workers (Bureau of Labor Statistics, 2018).

These statistics showed manufacturer workers are involved in workplace injuries. It also showed sprains, strains, and tears and soreness and pain were the predominant nature of injury.

Occupational Health

The goals for employees with low back pain are to decrease disability and return the individual promptly to full-duty work. The longer the pain and physical limitations linger, the higher impact of low back pain on an individual's home life, everyday activities, and psychosocial well-being (Mansell, Hall, & Toomey, 2016). Prolonged return-to-work can lead to financial loss, job loss, physical limitations, and catastrophizing (Mansell et al., 2016).

According to the Fear avoidance model (FAM), when an individual experiences pain, they believe the activity may be causing further damage or more pain (Vlaeyen, Crombez, & Linton, 2016). This leads to negative thought processes, such as catastrophizing, and can progress to maladaptive behaviors such as fear of movement and avoidance behavior (Mansell et al., 2016).

Anecdotally, similar concerns were identified by the co-investigator working in the occupational health setting. These concerns include personal financial burden (e.g. wage loss, potential for job loss), penalties and restrictions (e.g. employee wages for light duty, risk of OSHA penalties, legal fees), and compensation by insurance carriers (e.g. cost of treatments, specialists visits).

Needs Assessment

As a challenging public health concern, back pain has been addressed across the spectrum from global, national, state, and local entities. Globally, countries have established CPGs for low back pain. There were numerous published research studies conducted at varied settings across the world on back pain. Nationally in the United States, there is the IOM and governmental bodies such as the National Institute of Neurological Disorders and Stroke. On a state and local level, research was conducted in healthcare institutions, medical practices, or communities. Most of the focus was on interventions tackling the medical aspect of care (e.g. NSAIDs, physical therapy). Translation of non-medical research into practice is yet to be actualized and sustained.

Global Response

CPGs on low back pain were developed by experts from the United States, United Kingdom, and Canada. It was a global effort to provide evidence-based recommendations on treatment of low back pain. For the most part, these CPGs were heavily focused on the medical

aspect of care, though patient education was consistently recommended amongst the CPGs. Despite the availability of CPGs, their recommendations have not been implemented into a routine practice. There were many barriers for CPGs uptake. Provider-level barriers included unawareness and low familiarity with CPGs. Additionally, the recommendation on self-management lacked specific details, resulting in inconsistencies in their use. When used appropriately, CPGs helps clinicians formulate individualized treatment for those with low back pain.

The reviewed CPGs all agreed upon advising patients with low back pain to stay active and resume their normal activities as soon as possible. Staying on bedrest longer than the immediate period can prolong the time to recovery, a fact often unbeknownst to the individual. Yet, it is human nature to avoid activities that may cause pain. Individuals often avoid activities that cause pain, thinking that it is harming them since it is the cause of their pain. This avoidance behavior was the key element in the theory known as the Fear Avoidance Model (Vlaeyen, Crombez, & Linton, 2016). In this model, once avoidance behavior takes hold, it remains persistent and continues to feed into pain-related fear (Vlaeyen et al., 2016).

Psychosocial interventions were needed to address avoidance behavior since medical treatments were not sufficient on its own. Support showing the importance of addressing the psychological impact was found in the study by Yang, Haldeman, Lu, and Baker (2016). They reported the impact of low back pain on psychosocial factors indicated significant associations of low back pain with work-family imbalance, exposure to hostile work, and job insecurity (Yang et al., 2016).

In a prospective, longitudinal study by Volker, Zijlstra-Vlasveld, Brouwers, van Lomwel, and van der Feltz-Cornelis (2015), at the focus was the return-to-work phenomena of patients

with low back pain. The authors concluded that identified self-efficacy and illness behavior were strong predictors of full return to work. Self-efficacy is an individual's belief on his or her ability to succeed in a specific behavior. Since self-efficacy and illness behavior were noted to be strong predictors, they recommended interventions focusing on the psychosocial aspects. In fact, Volker et al. (2015) found that when only medical interventions were applied, it took participants longer to return to their full duty capacity. Interventions should aim to increase self-efficacy and decrease illness behavior (Volker et al., 2015). The study concluded that both medical and psychosocial interventions should be implemented.

National Response

The IOM's blueprint for action also addressed approaches to pain management. One of the recommendation focuses on "promotion of self-management to individualize care to each patient" (IOM, 2011, p. 8). Other recommendations focused on pain management, furthering research, education on healthcare providers, assessing patient barriers, and insurance reimbursement (IOM, 2011).

State and Local Response

The use of mobile health applications, or apps, has proven to be effective in chronic conditions such as diabetes and asthma by promoting self-management behaviors. In a systematic review by Whitehead and Seaton (2016), using mobile apps were compared to paper-based interventions as a self-management tool. The study showed a positive benefit on symptom management with the use of apps. The effect was more pronounced when the mobile apps was used together with weekly support. In contrast, the review found that frequent clinical input (e.g. office visits, face-to-face counseling) by itself was not effective in changing symptom management (Whitehead & Seaton, 2016).

Similar results were reported in the qualitative study by Anderson, Burford, and Emmerton (2016). According to this study, there was a greater self-awareness of their chronic conditions with the use of health apps by incorporating self-management. Constant stimulation to propagate usage of the app is essential for self-management when managing chronic conditions (Anderson et al., 2016). An app can provide this constant stimulation through educational modules and interactive features. On the downside, participants reduced app usage when their goals for their chronic conditions (e.g. glycemic control, minimizing asthma exacerbations, decreased pain levels) were achieved (Anderson et al., 2016).

Project Proposal

The literature shows that motivation through self-management, avoidance of catastrophizing and reinforcing education were key to limiting physical disability and improving functional activities in patients with non-specific back pain. The goal of the project was to promote self-management in employees experiencing low back pain. This app included educational modules with recommendations based on CPGs and from the National Institute of Neurological Disorders and Stroke. Its success aimed to validate the use of a self-management app as a non-pharmacological intervention when treating low back pain.

SWOT Analysis

Determining the strengths, weaknesses, opportunities, and threats (SWOT) was essential for this project. Such an analysis aided in the planning stage to determine strategies on how best to implement change into practice. The SWOT analysis allowed capitalization on the strengths and opportunities. By identifying weaknesses and strength in advance, action steps was formulated and implemented.

Strengths. There was critical support from key stakeholders, including the owners of the company and their top management. Also, the project site had over 100 employees, most of whom worked as manual laborers. Since there were over 100 employees engaged in manual labor, there was an increased probability there were workers with low back pain as opposed to a site that had only 20 employees. The availability of CPGs to formulate evidence-based practice recommendations for the app was a strength. This body of knowledge provided credibility to the educational modules of the app. Another strength was providing the app for free. Participants were more inclined to participate with the provision of a free educational app. Lastly, the current cultural norms of technology use were a strength. Smart phones or devices are widely used across generations. This aided in accessibility to the internet and for its mobility.

Weaknesses. The identified weaknesses in this project were based mostly on workers' factors. The project's inclusion criterion was having current back pain. If a worker consented to the project, they were essentially admitting they had low back pain. Workers may have felt reluctant to admit physical disability. Another weakness was that fear of activity (avoidance behaviors) may have taken root. Workers may have already believed that physical activity caused their pain, thus would have been reluctant to participate. Other weaknesses was unfamiliarity with technology and low health literacy. Workers may have found it difficult to navigate their smart phones or devices, and read more complex content. Lastly, there was no control over the utilization of the app by the workers. They may have consented to participate in the project, but usage of the app and perform the recommended activities was not guaranteed.

Opportunities. The opportunities of this project stemmed from data-rich evidence supporting use of technology to improve self-management of low back pain. This included the recognition of the IOM on the importance of promoting self-management for pain. It also

included the body of literature supporting the use of apps for self-management of chronic conditions. Lastly, the ability to provide tech support on the app was a feature offered by the app development site.

Threats. The threats of this project were related to the app itself, the tools being used, and outside influencing factors. The app itself is a threat since there is a possibility that the app may not function as intended, as a self-management tool. The app may glitch or crash, deterring workers from using it.

Problem Statement and Clinical Question

Adult manual labor workers with low back pain need to return to their optimal physical functioning. Delayed healing can lead to loss of function, loss of income, and fear-avoidance behavior.

Thus, the clinical question guiding this project was: Does a low back pain mobile health application promote effective self-management in adult manual labor workers with low back pain over a four-week period?

Aims & Objectives

The overarching goal of this project was to reduce disability in manual workers with low back pain.

There were two aims of this project. The first aim was to determine the effect of providing a low back pain app to manual labor workers on physical functioning. The second aim was to determine the effect of providing a low back pain app to manual labor workers on fear avoidance beliefs. The objectives to meet these aims were the following:

- Created a phone application based on evidence-based recommendations that reduce physical disability in manual workers with low back pain
- Conducted an individual question-answer session with study participants on the purpose and the use of the app
- Assessed the effect of the low back pain app on physical functioning using the Oswestry Low Back Pain Disability Questionnaire, also known as the Oswestry Disability Index (ODI), before using the app and after 4 weeks of its use.
- Assessed the effect of the low back pain app on fear avoidance beliefs using the Fear Avoidance Beliefs Questionnaire (FABQ) before using the app and after 4 weeks of its use.

Review of Literature

Search Strategy

For the purpose of conducting literature review, several databases were searched: PubMed, CINAHL, Medline (through Ovid), Essential Evidence Plus, and National Center for Biotechnology Information (NCBI). The key words included *self-management*, *low back pain*, and *mobile health application*. The search terms of *low back pain* resulted in 15,912 articles, *self-management* 18,708 articles, and *mobile health application* 1,402 articles. By combining these search terms, removing duplicates, and limiting database searches to articles published between 2014 and 2019, the resulting number of articles was 296. The articles were reviewed and included if participants were patients. The search was limited to articles written in English. After review of abstracts, 13 articles were deemed relevant to the clinical question (see Appendix A). These articles were critically appraised using the Johns Hopkins appraisal tool.

Treatment Recommendations

Evidence on Treatment Recommendations. The articles discussed in this section provided recommendations on treatment of low back pain.

O'Connell et al. (2016) published a narrative review on three clinical practice guidelines. These CPGs were the 2016 NICE guidelines on low back pain and sciatica (UK), 2015 Evidence-Informed Primary Care Management of Low Back Pain (Canada), and 2007/2009/2017 Diagnosis and Treatment of Low Back Pain (USA). There were common recommendations across these CPGs. Providers needed to give advice to stay active and return to normal activities as soon as possible and educate on an expected course of low back pain to reduce fear or catastrophizing (O'Connell et al., 2016). Pharmaceutical recommendations included the use of NSAIDs, caution with opioids for short-term use, and against or caution with antidepressants (O'Connell et al., 2016). Other recommendations included not using imaging for non-specific low back pain, exercise therapy, and inclusion of more than one type of intervention such as self-management and psychological approaches (O'Connell et al., 2016). There was a consensus for surgery on refractory back pain with radicular symptoms.

There were inconsistencies in recommendations amongst the CPGs. These included the use of interventional or injection treatments and the type of surgery to perform (e.g. spinal fusion, interspinous spacers). The CPGs also varied in the advisement on the use of TENS, back belts, corsets, and acupuncture. The medications that were not consistently recommended across the CPGs were tricyclic antidepressants, SSRIs, acetaminophen, long-term use of opioids, herbal treatments (O'Connell et al., 2016).

O'Connell et al. (2016) recognized there were local differences in culture and healthcare delivery which allows for interpretive differences. CPGs had inconsistencies on the scope of the

guideline such as advisement on the use of herbal treatments. Lastly, there were barriers to clinical guideline implementation including personal factors, guideline factors, and external factors.

Qaseem, Wilt, McLean, and Forciea (2017) formulated a clinical practice guideline using the American College of Physicians' grading system. The CPG was based on recommendations on a systematic review of randomized controlled trials and systematic review published through April 2015 and with updated searches through November 2016.

Qaseem et al. (2017) reported that most with acute or subacute low back pain improve over time regardless of treatment. For this reason, it was strongly recommended to start with nonpharmacologic treatment such as superficial heat, massage, acupuncture. Clinicians should inform and reassure patients with acute or subacute low back pain usually improves over time. Patients should also be advised of all subtypes of low back pain, to maintain their normal activities, and remain physically active as much as they can tolerate.

Qaseem et al. (2017) identified areas that they found did not have enough evidence. There was insufficient evidence for treatment of radicular low back pain, most physical modalities, treatment specific to patient populations, and on disability or return to work.

In a systematic review for clinical practice guidelines by Wong et al. (2017), 10 high quality guidelines focused on protocols for low back pain were appraised. The protocols appraised were for those with or without radiculopathy and included noninvasive treatment modalities. The Appraisal of Guidelines for Research and Evaluation II (AGREE II) was used to assess the development and reporting of guidelines.

For acute, nonspecific low back pain, education should include the expected course of recovery, effective self-care options for pain management, advising on early return to work

activities, staying active, and avoiding bedrest or inactivity (Wong et al., 2017). Wong et al. (2017) also found the definition of chronic back pain differed between studies. Some studies indicated timeframes of more than four weeks, six weeks, and three months.

All the guidelines reviewed by Wong et al. (2017) agreed on certain interventions for acute nonspecific low back pain. This included evidence-based education on the expected course of recovery and effective self-care options for pain management. Another is the advisement on early return to work activities, staying active, and avoiding bedrest or inactivity. The recommendations on medication use was to include Paracetamol (Acetaminophen) or NSAIDs if indicated and muscle relaxants up to 2 weeks (Wong et al., 2017). Lastly, spinal manipulation with self-care was advised.

A limitation of the systematic review was the exclusion of non-English guidelines. This may cause inherent bias in the results. Low back pain management recommendations may differ depending on the guidelines used. Wong et al. (2017) surmised this was due to the differing definitions of the time intervals between acute to chronic back pain.

The randomized control study by Yang et al. (2019) looked at the effects of self-management on pain, self-efficacy, disability level, and health-related quality of life. The treatment group had self-management plus physiotherapy ($n = 4$), whereas the control group had physiotherapy only ($n = 4$). Participants were included if they were diagnosed with chronic low back pain and were 18 years old and above. Yang et al. (2019) used the visual analog pain scale, the Pain Self-Efficacy Questionnaire (PSEQ), the Roland Morris Disability Questionnaire (RMDQ), and the SF36 (quality of life) tools.

There was no statistically significant difference in pain level between nor within the intervention group and control groups. Report of bodily pain showed improvements within

group effects ($p = .046$) and between group effects ($p = .008$) (Yang et al., 2019). Pain self-efficacy showed a significant between group effect ($F = 7.31, p = 0.035$) (Yang et al., 2019). After analyzing SF36-VT as a covariant, the resulting adjusted PSEQ between-group effect was no longer significant, though the interaction effect was significant ($p = 0.008$) (Yang et al., 2019).

The results supported the inclusion of self-management in managing low back pain. The effects of self-management plus physiotherapy versus physical therapy alone was studied. It was reported there was an improvement in mental health within ($p = .017$) and between group ($p = .013$) (Yang et al., 2019). This reinforced the recommendation to address both the psychosocial and medical aspects when treating low back pain.

A limitation of the study was the small sample size ($N = 8$). Another is the short treatment duration of four weeks, nor did it allow for follow-up on long term effects. Lastly, those who did not have a smartphone were excluded.

Evidence on non-pharmacological interventions. Treatment of low back pain should incorporate self-management and education.

Self-management as a psychosocial intervention. The reviewed evidence focused on treatment of low back pain. The majority of CPGs had a heavy focus on medical interventions. Additionally, there was agreement among the CPGs to include more than one type of intervention. O'Connell et al. (2016) and Yang et al. (2019) supported the use of self-management as an intervention that provides a psychological approach to low back pain treatment.

Education on low back pain and reassurance. Education and focusing on non-pharmacologic treatment were advised by O'Connell et al. (2016), Qaseem et al. (2017), and

Wong et al. (2019). For acute, nonspecific low back pain, education should include the expected course of recovery, effective self-care options for pain management, and staying active (Wong et al., 2017). Clinicians were to advise patients in all subtypes of low back pain to maintain their normal activities and remain physically active as much as they can tolerate. This was echoed in the systematic review by Wong et al. (2017).

Predictive Factors and Mediators

Evidence on Predictive Factors and Mediators. Predictive factors are a finding that can be used to help predict whether an individual will respond to a specific treatment. Mediators are intermediary factors that indirectly cause or relate to a condition.

An integrative review by Mansell et al. (2016) examined 21 studies across 4 systematic reviews on self-management with persistent back pain. Their study focused on behavior change and effect sizes on pain and disability. According to the Social Cognitive Theory, self-efficacy, a person's environment, and outcome expectancies will impact their behavior (Mansell et al., 2016). Threatening this is the phenomenon of the fear avoidance model. When pain was experienced, negative thought processes such as catastrophizing leads to fear of movement and avoidance behavior due to belief that movement may cause further damage or more pain. To prevent the fear avoidance behavior, education was warranted. This education should include advice that movement was essential to improved function and would not lead to further damage, but rather it would reduce disability and improve physical function (Mansell et al., 2016). Mansell et al. (2016) cautioned that self-management interventions may have benefits, but there were inconsistencies with its effectiveness amongst the studies they reviewed. The variable definitions of self-management can explain some inconsistencies as they led to different interventions and targets. The methodology of the reviewed studies was noted to have patients

and providers that were not blinded and allocation was not often concealed (Mansell et al., 2016). Only some studies reported an intention-to-treat analysis. Lastly, follow-up rates were less than 85% (Mansell et al., 2016).

Benyapa et al.'s (2018) study used a cross-sectional, correlational design to develop a causal model of self-management in those with chronic low back pain. The study participants were from seven hospitals in Thailand and were 30 to 60 years old ($N = 174$). The study measured self-management, self-efficacy, knowledge, physical function, and social support. The Self-Management scale (SM scale) measured self-management behavior in those with chronic low back pain. The Belief in Treatment Effectiveness Scale (BTES scale) assessed self-efficacy for chronic low back pain. The Low Back Pain Knowledge Questionnaire (LKQ) examined the individual's specific knowledge about their condition. The study measured the ability to perform self-management tasks with the Modified Self-Efficacy for Chronic Low Back Pain Management Scale (MSE-CMS). Physical functioning was determined by the Modified Barthel Activity of Daily Living Index (ADLs) and the Chula Activity of Daily Living (instrumental ADLs). The Social Support Questionnaire (SSQ) looked at the participant's social support. Benyapa et al. (2018) found that 33% of the variance in self-management is directly affected by self-efficacy, social support, low back pain knowledge, and belief in treatment effectiveness. A high self-efficacy had a positive influence on performance of self-management tasks. Those who believed in chronic low back pain treatment effectiveness adhered to treatment and exhibited performed self-management behavior. Another finding of the study showed that having knowledge of low back pain supported decisions incorporating self-management behavior. In addition, support from family, friends, and healthcare providers was correlated to a change in behaviors for self-management (Benyapa et al., 2018). There were limitations in the study. The sample included

those with three subtypes of chronic low back pain and may have influenced self-management. Also, using MBAI and Chula ADLs to measure physical function has not been tested for those with chronic low back pain. Lastly, generalizability is limited due to the convenience sampling.

Kawi (2014) used a cross-sectional, descriptive design to study self-management, self-management support, and pain-related variable in patients with provider-diagnosed nonmalignant chronic low back pain. The participants were recruited from four primary care clinics in Nevada and included if 18 years old or older ($N = 120$). The variables being evaluated were self-management, views on chronic illness management, functional disability, and mental health. Self-management was measured by the Patient Activation Measure (PAM) short form. The Patient Assessment of Chronic Illness Care (PACIC) tool was used to measure viewpoints on chronic illness management. Functional disability was assessed by the Oswestry Disability Index (ODI) version 2.1a. Participant's mental state was determined by the Mental Health Inventory tool. Kawi (2014) found self-management support was significantly correlated with self-management and is essential in activating patients. The study (Kawi, 2014) also noted self-management was facilitated by patient-perceived support through encouragement from healthcare professionals. Education on physical activity included maintaining physical activity, exercising, and proper body mechanics. The influence of education was significant ($F = 3.672, p = .008$) (Kawi, 2014). This was in addition to other advice such as keeping a healthy lifestyle, making good nutrition choices, and alternatives for pain led to self-management behaviors (Kawi, 2014). The average ODI score ($M = 46.10, SD = 18.10$) of the participants of the study aligns with a score of severe disability (Kawi, 2014). There are some limitations in generalizability due to the convenience sampling. The use of PAM and PACIC is new to chronic low back pain population.

Jung and Jeong (2016) looked at the relationship between motivation and education on self-management using a non-experimental cross-sectional approach, descriptive design with mediation analysis. This study was conducted in a physical therapy and rehabilitation clinic in Seoul, South Korea. Patients were included if they had physician-diagnosed nonmalignant chronic low back pain and ages 20 years old or older ($N = 120$). The tools used in the study assessed pain, self-management behaviors, depression, social support, and situational motivation (Jung & Jeong, 2016). Pain was measured pain by the numerical scale. A descriptive self-report survey looked at self-management behavior. The study used the Center for Epidemiologic Studies Depression Scale to assess for depression. The Multidimensional Scale of Perceived Social measured social support. Intrinsic and extrinsic types of situational motivation was examined with the Situational Motivation Scale.

Jung and Jeong (2016) found motivation to affect self-management. They found that motivation completely mediated the relationship between education and self-management in individuals with chronic back pain. In the first analysis, the effect of the predictor self-management education was significant ($B = 7.360, p = .013$) and accounted for 5.1% of the variance in motivation. In the second analysis, self-management education's effect on self-management was significant ($B = 3.773, p = .019$) and accounted for 4.6% of the variance. In the third model, when including motivation, the effect of self-management education on behavior decreased, showing non-significant effects of self-management education ($B = 1.945, p = .184$), but significant for motivation's effects on self-management behavior ($B = .248, p < .001$). This supported the utilization of interventions that address both motivation and education to facilitate self-management (Jung & Jeong, 2016). The limitations of the study were due to the characteristics of a convenient sample and self-reporting. The study was in a rehabilitation clinic

in South Korea. This limits generalizability to other settings and countries. The tools used were self-reported. This can introduce recall bias and social desirability bias concerns.

Predictive Factors and Mediators. These articles evaluated predictive factors and mediators of low back pain, noting the impact of motivation and self-efficacy. Self-management was facilitated by motivation, education, high self-efficacy, and advisement on movement.

Self-efficacy and self-management. High self-efficacy was found to be an essential predictive factor in the studies by Mansell et al. (2016) and Benyapa et al. (2018).

Self-efficacy was found to be a strong predictor, as well as a mediator, of disability and pain outcomes in low back pain populations (Mansell et al., 2016). Similarly, Benyapa et al. (2018) noted having a high self-efficacy had a positive influence on performance of self-management tasks. Those who believed in chronic low back pain treatment effectiveness adhered to treatment and exhibited self-management behavior. Finally, the study found that having knowledge of low back pain supported decisions incorporating self-management behaviors.

Education, motivation, and self-management behaviors. Mansell et al. (2016) discussed the phenomenon of the fear avoidance model. Preventing this phenomenon starts with education which should include advice that movement was essential to improved function (Mansell et al., 2016). Kawi (2014) and Benyapa et al. (2018) both found the positive influence of education on self-management. In Kawi's study (2014), the influence of education to maintain physical activity was significant ($F = 3.672, p = .008$). Benyapa et al. (2018) had the same recommendation of education, noting that having knowledge of low back pain supported

decisions incorporating self-management behavior. Support from family, friends, and healthcare providers was correlated to a change in behaviors for self-management.

Variance was addressed in the studies by Benyapa et al. (2018) and Jung and Jeong (2016). When factoring self-efficacy to the recommendations of education and the individual's belief in treatment effectiveness, it was found to directly affect self-management, explaining 33.00 % of the variance (Benyapa et al., 2018). Likewise, Jung and Jeong (2016) found motivation to affect self-management. Jung and Jeong (2016) found that motivation completely mediated the relationship between education and self-management in individuals with chronic back pain. Thus, motivation was essential to self-management behavior of individuals with chronic back pain. Self-management was facilitated by interventions that addressed both motivation and education (Jung & Jeong, 2016).

Effects of support on self-management behaviors. Echoing the findings in Benyapa et al. (2018) on the positive effects of social support, Kawi (2014) found self-management support was significantly correlated with self-management and was essential in activating patients. Kawi (2014) found that self-management on chronic low back pain was facilitated by patient-perceived support through provision of information and advice from healthcare professionals.

Self-management Apps

Evidence on Self-management Apps. Self-management apps for low back pain are available commercially. There were several studies that evaluated the effects of using self-management apps.

In a randomized control study by Irvine et al. (2015), they assessed the level of engagement in behaviors intended to help or prevent back pain. Their study consisted of

participants recruited from four companies, including trucking, manufacturing, technology, and a corporate headquarters. Inclusion criteria were participants 18 to 65 years old who experienced low back pain within the past three months. Participants were included if they were employed at least half time, retired, or a family member of an employee at one of the four collaborating companies. The study compared two treatment arms to a control arm. One treatment arm used the FitBack app ($n = 197$). The second arm was the alternative care group. This group received e-mails with links to internet resources ($n = 197$). The control arm ($n = 197$) received neither and was contacted only to do the assessments. Their outcome measures included physical, behavioral, and work-related factors. Physical factors included pain, physical functionality, quality of life, and well-being. Their behavioral tools looked at prevention-helping behaviors, patient activation, behavioral intentions, self-efficacy, attitudes towards pain, catastrophizing of pain, and knowledge. The work-related tools assessed work limitations and presenteeism.

The current adjusted back pain status was a significant predictor for both the treatment vs. control (OR 1.72, 95% CI 1.11-2.68, $p = .02$) and treatment vs. alternative care (OR 1.60, 95% CI 1.03-2.50, $p = .035$) (Irvine et al., 2015). Subjects in the alternative care group were 1.6 times more likely to report current back pain than subjects in the FitBack treatment group and subjects in the control group were 1.7 times more likely to report current back pain than subjects in the FitBack treatment group (Irvine et al., 2015). Group differences in back pain was statistically significant at 16 weeks between FitBack treatment group and control group $F = 4.41$ (Irvine et al., 2015). Physical outcome measures were statistically significant at both 8 weeks ($F = 5.88$, $p = .003$) and 16 weeks ($F = 6.76$, $p = .001$) between FitBack treatment group and control (Irvine et al., 2015).

Behavioral outcomes measures assessed the level of engagement in behaviors intended to help or prevent back pain. These behavioral outcomes showed statistically significant differences in engagement at eight weeks between the treatment group using an app vs. control group ($F = 33.83, p = .017$) and the treatment group vs. alternative care group ($F = 9.32, p = .017$) (Irvine et al., 2015). The difference of treatment group was evident even at 16 weeks between the control group ($F = 46.81, p = .009$) and the alternative care group who were e-mailed links to information ($F = 6.88, p = .025$) (Irvine et al., 2015). Patient activation of patients in taking care of their low back pain was significant at 8 weeks between the treatment group vs. control group ($F = 28.75, p = .003$) though not when comparing to the alternative care group (Irvine et al., 2015). At 16 weeks, the difference in patient activation of the treatment group was significant between the control group ($F = 54.83, p = .002$) and the alternative care group ($F = 7.08, p = .027$) (Irvine et al., 2015). Tests looking at worker productivity and presenteeism was significant for the FitBack group when comparing to the control group ($F = 3.65, p = .027$) (Irvine et al., 2015). The FitBack group worker productivity and presenteeism was significant only at 16 weeks when compared to the alternative care group ($F = 3.36, p = .036$) (Irvine et al., 2015).

There were limitations of the study. E-mail reminders to the treatment group were sent if initial messages were not opened resulting in a potential for response rate bias. Another limitation is the self-report nature of the study. Self-reporting was used in determining eligibility and in their assessments. Generalizability was limited since participants tended to be employed, educated, and in middle-class. Internet availability may have been a limiting factor in those who have lower income, are less educated, in homes without Internet service, or without access to the program.

The randomized control study by Riva et al. (2014) examined the effects of an app with interactive features ($n = 27$) and compared it to the control group ($n = 24$). The control group only had access to the library, first aid, and FAQ sections. Participants were 18 years old or older and had back pain for at least three months. They were recruited through their health care providers from clinics and rehabilitation centers in Canton Ticino, Switzerland. The study measured the effects on pain, medication misuse, physical activity, and patient empowerment.

There was a statistically significant decrease in pain levels at 8 weeks only, within both the intervention group ($t = -1.5, p = .001$) and the control group ($t = -1.7, p = .001$) (Irvine et al., 2015). This was attributed to a wear out effect where there was a decrease in website use between 4 weeks and 8 weeks. At the end of the 8 weeks, participants in the intervention group attributed their improvement on back pain to the website more than the control group ($t = 1.6, p = .001$), used the website more ($t = 0.8, p = .05$), and visited more pages on the website ($t = 2.2, p = .001$) (Irvine et al., 2015). Physical exercise decreased within the intervention group and within the control group at 4 weeks and 8 weeks. Riva et al. (2014) found patient empowerment was increased significantly within the intervention group at 4 weeks ($t = 0.8, p = .05$) and at 8 weeks ($t = 0.8, p = .01$), whereas there were no significant changes within the control group. A limitation was the small group size. Also, the two-month timeframe was too short. Another limitation was a lack of specificity on what caused the differences amongst the groups.

Chhabra et al. (2018) conducted a randomized control trial in India. The study compared the treatment effects with the Snap care app treatment arm ($n = 45$) and the control arm ($n = 48$) of usual or conventional care. Conventional care consisted of medication, physical therapy, and home exercises. Participants were individuals 18 years of age and older with mechanical low back pain persisting for over 12 weeks with or without radicular symptoms. These participants

were prescribed at least some level of daily physical activity, medicines, and reported regular use of an Android mobile device with internet access. The dependent measures were disability measured by Modified Oswestry Disability Index (MODI), pain measured by numerical pain scale, and current symptoms measured by Current Symptoms Scale (CSS). They found that both the treatment group and control group recorded a decline in their disability index, measured by the Modified Oswestry Disability Index (MODI) (Chhabra et al., 2018). The decline for the app group was significantly greater (Chhabra et al., 2018). Using ANCOVA with the baseline score set as the covariate, a 2×2 mixed model ANCOVA yielded a main effect for time, $F(1, 90) = 4.739, p = 0.032$ and a significant interaction effect $F(1, 90) = 9.053, p = 0.003$ (Chhabra et al., 2018). The paired t -test was used to assess the change in symptom scores and activity levels in the App group, from baseline to 12-weeks of app usage. They used the Current Symptom Scale which showed a statistically significant ($p < 0.05$) decrease with improvements in each component (sleep, mood, mobility, ADL, distance walked). The percentage of respondents that reported poor sleep reduced from 33% to 4%, those reporting poor mood decreased from 31% to 9%, and restricted physical activity was reported by only 4% respondents after 12 weeks as opposed to 64% at baseline (Chhabra et al., 2018). Generalizability was limited due to the study being conducted in India. Another limitation was the Current Symptom Scale was only available from app group since data was collected through the app. Lastly, collection methods changed from baseline for both groups. Collection at baseline was in person and later conducted through telephone interview for post intervention.

Lo et al. (2018) recruited users of a free artificial intelligence-embedded mobile app called “Well Health”. This app gave tailored exercise rehabilitation programs. It was downloadable in the United States, United Kingdom, and China. Participants were included if

they had neck and low back pain within the past three months and if they were 18 to 65 years old. The study assessed if the app increased adherence to therapeutic exercises, affected pain level, or reduced the need for other interventions by using a 14-item questionnaire. The reported time spent on therapeutic exercises as per the AI-embedded mobile app were 22.2% (35/158) 1 day, 24.1% (38/158) 1 week, 25.9% (41/158) 1 month, 14.6% (23/158) 3 months, and 13.3% (21/158) 6 months or more (Lo et al., 2018). Of the 142 (89.9%) participants who indicated spending time reading the education material, 123 (77.8%) indicated the material encouraged them to do the exercise program (Lo et al., 2018). Lo et al. (2018) reported an overall reduction in the numeric pain rating scale from 6 before using the app to 4 after its use (95% CI 1.18-1.81, $p = .04$). There was a greater pain reduction noted in those who used it for 6 or more months (from 6 to 3). Of all users, self-perceived improvement was reported in 65%, with 58.6% in those who used the app for 3 months, and 71.1% for 6 months. Usage of other interventions was reduced. About 24.1% did not receive any other intervention while using the app. There were some limitations of the study. There should be caution due to the nature of self-reported data. The eligibility criteria were self-reported. If inaccurate, it may have affected their responses to the intervention. There could have been recall bias with a retrospective study design. Sample bias may have been present since those who consented to be in the study were most likely to participate in the app in the first place. Also, the functional aspect was not studied. Thus, it cannot be determined if the decrease in pain led to an increase in function.

In a retrospective cohort study by Huber et al. (2017), they evaluated the effects of self-management with an app on self-reported pain level. The study recruited users of Pro app subscribers before 2017, via online channels (e.g. Facebook, Google Ads, company homepage). These users were from Germany, Austria, and Switzerland. Participants in the study were 18

years or older with back pain, denied any red flag indicators, and had self-reported sufficient levels of physical fitness. The app contained a multidisciplinary biopsychosocial rehabilitation program for back pain. Huber et al. (2017) reported reduced pain ratings in patients with acute, subacute, and chronic low back pain from baseline ($M = 4.80$, $SD = 1.95$) to the last day of use ($M = 3.75$, $SD = 1.76$). This was a statistically significant reduction $t(158) = 6.21$, $p < .001$, with a moderate effect size, $d = 0.56$ (Huber et al., 2017). The longer an app was used, there was a statistically significant reduction in pain among the individual participant, $t(19) = 3.75$, $p = .001$. Between-group analysis showed a statistically significant greater reduction in pain among those who completed the full 12-week program compared to all users, $t(177) = 2.71$, $p = .007$ (Huber et al., 2017). There were limitations in the study. The retrospective design did not allow adjustment of self-report pain levels for any potential spontaneous improvement of pain levels. Another limitation was a high dropout rate over time. There were 68.3% participants remaining at 4 weeks, 32.3% at 8 weeks, and 17.8% at 12 weeks for unknown reasons (Huber et al., 2017). Due to the study design, it was unclear if participants got better spontaneously or due to use of the app. Baseline physical activity could not be assessed, also due to the study design.

Effects of a Self-management App. The studies looking at the app's effects on low back pain showed varied results with pain. Yet there are more consistent results with fear avoidance behaviors and physical functioning using apps as a self-management tool.

Patient engagement and activation. The use of a self-management app was noted to increase patient engagement and activation in the studies by Irvine et al. (2015) and Riva et al. (2014). In Irvine et al.'s study (2015), the significant difference when compared to the alternative care group was seen with longer use.

Irvine et al. (2015) reported on significant differences of patient activation at 8 weeks between the treatment group vs. control group ($F = 28.75, p = .003$). The treatment group did not show a significant effect on patient activation when compared to the alternative group until 16 weeks ($F = 7.08, p = .027$) (Irvine et al., 2015).

Similar findings were reported by Riva et al. (2014). Patient empowerment was increased significantly within the intervention group at 4 weeks ($t = 0.8, p = .05$) and at 8 weeks ($t = 0.8, p = .01$), whereas there were no significant changes within the control group (Riva et al., 2014).

Physical outcomes and disability. The studies by Chhabra et al. (2018), Irvine et al. (2015), and Lo et al. (2018) found that using an app for self-management showed an overall decline in disability and improved physical outcomes. Chhabra et al. (2018) found that both the treatment group and control group recorded a decline in their disability index, measured by the Modified Oswestry Disability Index (MODI). The decline for the app group was significantly greater (Chhabra et al., 2018). There were significant reductions in poor sleep, poor mood, and restricted physical activity.

Similar findings were noted in the studies by Irvine et al. (2015) and Lo et al. (2018). Irvine et al. (2015) also reported physical outcome measures (e.g. current back pain, day-to-day activities, mood, productivity at work) were statistically significant at both 8 weeks ($F = 5.88, p = .003$) and 16 weeks ($F = 6.76, p = .001$) between the treatment group and control group. Likewise, Lo et al. (2018) noted self-perceived improvement was reported in 65% of participants, with 58.6% in those who used the app for 3 months, and 71.1% for 6 months.

Self-report of pain. Using an app for self-management led to inconsistent results when it came to pain. The only consistent trend was that an individual's self-report of pain decreased the longer the app was used.

Huber et al. (2017) evaluated the effects of self-management with an app containing a multidisciplinary bio-psychosocial rehabilitation program for back pain, noting reduced pain in patients with acute, subacute, and chronic low back pain. The longer an app was used, the more there was a noted reduction in pain, especially in those participants who completed the full 12-week program.

The effects of a long use of an app was also reported by Lo et al. (2018) and Riva et al. (2014). In the study by Lo et al. (2018), there was an overall reduction in the numeric pain rating from 6 before using the app to 4 after its use (95% CI 1.18-1.81, $p = .04$) with the greater reduction noted in those who used it for longer than six months. Riva et al. (2014) attributed statistically significant decrease in pain levels at eight weeks only to the wear-out effect, where there was a decrease in website use between four weeks and eight weeks.

The app's effect on pain was inconsistent in the study by Yang et al. (2019). In their study, there was no statistically significant difference in pain level between and within the intervention and control groups.

Looking at pain from a slightly different aspect, Irvine et al. (2015) found that subjects in the alternative care group were 1.6 times more likely to report current back pain than subjects in the app treatment group. Subjects in the control group were 1.7 times more likely to report current back pain than subjects in the app treatment group (Irvine et al., 2015). Group differences in back pain were statistically significant at 16 weeks demonstrating the app's effects when used for a longer duration.

Summary of the Evidence

Several studies provided evidence on treatment of low back pain. Self-management was supported as an intervention to address the non-medical aspect of low back pain. Additional studies focused on predictors and mediators of low back pain. Encouragement of motivation and self-efficacy combined with education led to effective self-management behaviors. Healthcare provider's support had a positive effect on self-management as well. In addition, there were studies that showed that self-management of low back pain resulted in a decrease in pain, a reduction in fear avoidance behaviors, and improved physical functioning.

Low Back Pain App

Development of the App

This Low Back Pain app was developed by the co-investigator through a paid membership with Swiftic (Swiftic, n.d.) app development site. The educational modules included information about low back pain, structures of the lower back, risk factors and causes of low back pain, red flag signs, types of diagnostic testing, types of providers, at-home treatments, non-pharmacologic treatments, pharmacologic treatments and their potential risks, preventative measures, links to an external site with exercises to do at home, and references used in developing the app. All references used in development was included within the app, listing reliable resources such as the National Institute of Neurological Diseases and Stroke (2017) and primary research used in development of the American College of Physician's clinical practice guidelines on non-invasive treatment on low back pain (Qaseem et al., 2017). All pictures in the development of the app were obtained through google search and from free, non-copyrighted sources.

Testing of the App

The app was beta-tested by an occupational medicine physician, four nurse practitioners, two nurses, two computer science specialists, and two lay persons without health-related nor computer-related backgrounds. The healthcare providers who tested the app provided feedback on app content. The testers with computer science backgrounds provided feedback as an end-user on navigating through the app. Feedback provided by the lay persons was obtained to make sure the app was understandable to the participant without neither health-related nor computer-

related knowledge. The final version of the Low Back Pain App can be found in Appendix B.

Theoretical Framework

Knowledge-to-Action Model

Theoretical frameworks are models of change to guide the practical application of translating knowledge into practice (White, Dudley-Brown, & Terhaar, 2016). One such framework was the Knowledge-to-Action (KTA) model developed by Graham et al. (2006). Graham et al. (2006) purposefully coined the term “action” as opposed to “practice” to account for its usability across industries which stands to use new knowledge, contrasting the implication of “practice” being confined to the clinical setting. The KTA model emphasized the action part of evidence translation by focusing on activities that needed to be developed in applying new knowledge to the targeted setting (White et al., 2016).

The KTA model is a synthesis of work in which planned action theories are used to develop deliberate activities to facilitate change, allowing feedback among all the phases and between both the knowledge creation and the action cycles (White et al., 2016). Graham et al. (2006) listed the seven phases in a KTA cycle as:

1. Identify a problem that needs addressing; identify, review, and select the knowledge or research relevant to the problem
2. Adapt the identified knowledge or research to the local context
3. Assess barriers to using the knowledge
4. Select, tailor, and implement interventions to promote the use of knowledge
5. Monitor knowledge use
6. Evaluate the outcomes of using the knowledge

7. Sustain ongoing knowledge use

The KTA model was chosen since it provides a structure to translate evidence-based knowledge into practice and can be applied to many settings (White et al., 2016). Since this DNP project was applying evidence-based knowledge to promote self-management, the KTA model was appropriate. It provided a stepwise approach on how to apply the new knowledge of using an app to self-manage low back pain by formulating actions that facilitated change (see Appendix C).

Application of the KTA Model

The first step of the KTA model was identifying a problem and selecting the relevant research (Graham et al., 2006). The problem of managing the psychosocial aspect of low back pain identified led to the PICO question: Does a low back pain mobile health application promote effective self-management in adult manual labor workers with low back pain over a four-week period? A literature search was performed using combinations of the terms *self-management*, *low back pain*, *mobile health*, and *influence* (plus *self-management*) in PubMed, CINAHL, Ovid, Essential Evidence Plus, and National Center for Biotechnology Information (NCBI) e-mail updates published between 2014 and 2019. Articles focusing on self-management of back pain or chronic conditions using an app or electronic device within the last five years were used for knowledge evidence gathering. The evidence supported the implementation of interventions beyond those that are health-focused interventions, such as self-management to increase self-efficacy and decrease illness behavior (Volker et al., 2015). It also supported the use of a mobile health app to facilitate self-management as it led to greater self-awareness of their condition and constant stimulation which the app can provide (Anderson et al., 2016).

The second step of the KTA model was adapting the identified knowledge or research to the local context (Graham et al., 2006). For this step, the knowledge evidence gathered from the review of literature was applied to employees in a manufacturer work setting. This project used a self-management app in manual labor workers at a kitchen cabinetry manufacturing and distribution site in a facility in North-Central New Jersey that employs over 100 employees.

The third step of the KTA model was assessing barriers to using the knowledge (Graham et al., 2006). In this DNP project, a barrier would include convincing the company's management on the benefits of the low back pain app, as well as imparting the negatives of not implementing the intervention, sustaining enthusiastic support for the intervention, and even discouragement on coercing employee participation. Participant barriers included the comfort level of participants with using mobile health apps, having a device that supported the use of the app, engaging the participants in utilizing the app, and maintaining retention of consented participants.

Another barrier was formulating an app that was useful and was easy to use. Gagnon, Ngangue, Payne-Gagnon, and Desmartis (2016) found that the most important factors for participant usage of a mobile app were usefulness and ease of use of the technology. A finding in a systematic review by Whitehead and Seaton (2016) was that self-management apps led to significant improvements in symptom control if the use of mobile apps involved weekly support. Thus, the technological barriers included formulating the app to achieve its intended purpose with content based on evidence-based practice, providing a user-friendly and engaging app, while maintaining a functional app throughout the intervention period with technical support as needed. Using low back pain guidelines and information from the National Institute of Neurological Diseases and Stroke (2017), the app provided educational modules.

The fourth step was selecting, tailoring, and implementing interventions to promote the use of knowledge (Graham et al., 2006). After development of a low back pain app, establishing the project's protocols, approval by the Institutional Review Board (IRB), and implementation of the app at the project site was completed. Consented participants filled out a demographic's questionnaire (see Appendix D) and administered questionnaires at baseline and again after four weeks app usage. These questionnaire were the self-report measurement tools of ODI (see Appendix E) and FABQ (see Appendix F). The ODI was developed by Fairbank and Pynsent (2000) to measure the physical disability and functioning in those with spinal disorders. The FABQ was developed by Waddell, Newton, Henderson, Somerville, and Main (1993) based on theories of fear and avoidance behavior, used specifically to assess the beliefs of patients with low back pain and how physical activity and work affected their low back pain. After completing these questionnaires at baseline, the app was downloaded to the participants' phones.

The fifth step was monitoring knowledge use (Graham et al., 2006). This was done by quantifying the number of app downloads and number of days in a week the participants used the app. On the day of consenting, the co-investigator assisted in downloading the app to the participant's mobile device, thus allowing the quantification of downloads. To monitor usage, weekly e-mails was sent at the end of each week requesting the participant reply back with a single digit indicating the number of days the app was used that week.

The sixth step was evaluating the outcomes of using the knowledge (Graham et al., 2006). To measure the effects of the intervention, the same measurement tools used at baseline was re-administered as a posttest four weeks after the app's download by the participant. The data obtained was be analyzed statistically with the SPSS program. The nonparametric test called the Wilcoxon Signed-Ranks test for the ODI and FABQ were used.

The seventh step was sustaining ongoing knowledge use (Graham et al., 2006). The low back pain app could be maintained and updated as the clinical guidelines are changed. Yet, according to Anderson et al. (2016), participants reduce their usage when their goals were achieved and there were no new self-management techniques to benefit from. With this in mind, the app may be used mostly for acute episodes of low back pain, exacerbations, or for maintaining core stability. In addition, the project's findings were disseminated to the academic community and its application could be expanded to other industries with manual labor workers (e.g. healthcare workers involved in patient handling).

The KTA model helped guide the project from the initial phase of identifying the problem, through the subsequent phases of selecting the intervention, implementing the intervention, evaluating its effects, and determining actions for sustaining the knowledge use. Using the KTA model provided a framework to organize thoughts derived from new knowledge into action. The framework highlighted manageable action steps to drive the translation of gathered new knowledge of using a low back pain app for self-management into knowledge use among manual labor workers. Successful application across industries could lead to some ease in the burdens of back pain and in some cases, prevent back pain from becoming chronic pain.

Methodology

Design of Project

The proposed pilot project used a quasi-experimental pretest-posttest design. This project evaluated the effectiveness of a low back pain app on promoting self-management. Effectiveness was measured by assessing the app's effects on physical disability, functional activities, and fear avoidance beliefs using questionnaires administered to the participants before

and after the implementation of the app.

Setting

The setting for this project was a kitchen cabinetry manufacturing and assembly company located in a metropolitan north-central town in New Jersey. The company employed over 100 employees, most of whom work as manual laborers.

Study Population

The population for this project included a purposeful sample of adult, 18 years or older, male manual labor workers from the kitchen cabinetry factory experiencing any degree of low back pain. Inclusion criteria included fluency in reading and writing in English, had an app-capable mobile device with internet access, and an e-mail address.

Those who had spinal surgery or had symptoms down their legs could have a more severe back problem. Exclusion criteria was prior spinal surgery, pain unrelieved by rest, or having current symptoms of numbness, tingling, or pain down the legs. Contraindications to participating in the exercises included severe pain, conditions of the heart or lungs that makes physical activity unsafe, or injury or pain in any other part of the body.

This was a pilot project. All participants who met inclusion criteria were included. The total number of subjects screened was 50 manual labor workers. All participants who met the inclusion and exclusion criteria was included ($n = 18$). Out of the 18 participants who consented, six completed the 4-week intervention period.

Subject Recruitment

Information about the project addressing low back pain with an app was disseminated via a recruitment flyer (see Appendix G) posted in the bulletin board in the staff kitchen. This staff kitchen served as their break room. In addition, an on-site recruitment session by the co-investigator was held in the conference room. During this on-site recruitment session, questions were answered on the project and consents were obtained once all questions were satisfactorily answered. It was emphasized that participation was voluntary, and participation would not have any positive nor negative sequelae at work. During this on-site visit, participants' e-mails was obtained and added to a private distribution list.

Recruitment and consenting were done on-site on the same day by the co-investigator. The co-investigator administered an Eligibility to Participate questionnaire (see Appendix H) and reviewed the responses using an Eligibility Screening Answer Key (see Appendix I) to determine if the inclusion criteria were met and the exclusion criteria were absent. When deemed by the co-investigator eligible to consent, consenting procedure was conducted.

Consenting was done at least half an hour after recruitment on-site. At this visit, administration of three pre-intervention questionnaires (demographics, ODI, FABQ) was completed, after which participants was assisted with downloading the low back pain app.

Consent Procedure

The IRB Adult Consent form was used, and a copy can be found in Appendix J. Consent forms was available 30 minutes after the recruitment phase at the facility. Participants was given the opportunity to ask questions. Additional questions beyond this day could have been e-mailed to the dedicated e-mail LowBackPainApp@gmail.com though no questions on consent were received. This dedicated e-mail was assessable only to the co-investigator on a password-

protected dedicated computer. The co-investigator could have been contacted by phone at the dedicated line [REDACTED] though no calls were received. Again, participants were informed that participation was voluntary and would not affect their employment. They were informed of what was to be expected (downloading of app, app content), risks, clearing with private medical provider if needed, and that they could have withdrawn at any time.

Risks and Harm

The potential risks or harm were minimal, but potentially included physical, emotional, and data safety. There was potential physical harm with performing certain physical activities. Participants would have needed to consult with their private medical provider if there were any concerns to participating and would have been advised to stop immediately if pain worsened. If the participant did not have a private medical provider, the participant could have provided a list of local urgent care centers (see Appendix K) though no participant requested this information. Emotional harm could have occurred if participants developed fear of resuming physical activity. In this event, participants could have consult with their private medical provider. There was potential for compromising safety on data. Although this risk was mitigated by the fact that participants' information was de-identified and the connection to the de-identified information was maintained for the shortest amount of time to obtain the post-intervention results. Once the post-intervention results were obtained and connected to the pre-intervention results, the participants' link was destroyed.

Subject Costs and Compensation

There was no cost to the participants. The low back pain app was free and would continue to be publicly available after the project was completed, until May 2020. There was not

any compensation for the participants of this project. Light refreshments was served during the on-site visits for consenting and at the post-intervention visit.

Study Intervention

The following were the steps during the intervention period:

- Phase 1: Recruitment and consenting
 - Recruitment and consenting in person on same day. As aforementioned, a recruitment flyer was posted in the staff kitchen bulletin board. Once IRB approval was granted, the flyer was posted with the confirmed dates of November 11, 2019 and December 9, 2019 for the on-site visits. Using the conference room, the co-investigator answered questions during the on-site recruitment session. Recruitment flyers was made available to interested employees.
 - The dedicated e-mail for this project, LowBackPainApp@gmail.com, was used for subsequent e-mail communications (see Appendix L) after the on-site visits. Additional questions beyond the on-site recruitment day could have been e-mailed or discussed via phone to [REDACTED]. All participants identities were maintained confidential in e-mail communications. Only the co-investigator had access to this e-mail account, the contents of which remained confidential and password-protected known only to the co-investigator.
 - Consenting took place on the same day as the recruitment day, but at a minimum of 30 minutes after recruitment. At this visit, consenting of participants using the IRB Adult Consent form was done. The co-

investigator emphasized participation was voluntary and decisions of participation would not affect their employment. An opportunity to ask questions was allotted prior to obtaining consent. They were informed of what was to be expected (downloading of app, app content), risks, clearing with private medical provider if needed, and that they could have withdrawn at any time. A sequential ID number was assigned upon consent and entered onto an encrypted passcode-protected spreadsheet. The master link was kept on a dedicated passcode-protected file in a passcode-protected computer, kept in a RU cloud based storage. Completed consents will be stored in a locked cabinet at 65 Bergen St, Newark, NJ 07107.

- Phase 2: Pre-intervention questionnaires (demographics, ODI, FABQ questionnaires)
 - Pre-intervention questionnaires was handed out to consented participants at the on-site visit. They were identifiable only by the assigned sequential ID number the co-investigator wrote on the top of the questionnaires.
 - The pre-intervention questionnaires included the demographic, ODI, and FABQ questionnaires. These were handed out on at the on-site visit right after consent.
 - The pre-intervention questionnaires remained with the co-investigator until the scores were calculated by the co-investigator and entered into a data spreadsheet. After data was collected, original questionnaires will be

kept in a separate locked cabinet at 65 Bergen St, Newark, NJ 07107.

- Phase 3: Four-week intervention period (app in use)
 - Assistance with downloading the low back pain app was provided on-site at the initial visit.
 - An introductory e-mail was sent later that night introducing the app contents and advised the participants to use the app at least three times a week.
 - At the beginning of each week during the 4-week intervention period, a reminder was sent to the consented participants. In addition, there was mid-week quick reminders to use the app.
 - At the end of the week, participants was asked to reply back with how many days the app was used.
 - All e-mail communications ended with a signature advising participants to report back any app-related issues promptly as well as immediately ceasing any activities that caused increased pain and report back to their private medical provider. A copy of the e-mail signature, introductory, weekly, mid-week, and end of the week e-mail templates can be found in Appendix L.
- Phase 4: Post-intervention questionnaires (ODI and FABQ)
 - At the end of the four-week intervention period, a final on-site visit was made. The post-intervention ODI and FABQ questionnaires was

administered.

- The master link was on site to allow the linking of pre-intervention and post-intervention questionnaires to the specific participant ID. The master link was immediately destroyed after this connection was obtained.
- The questionnaires were calculated by the co-investigator and these scores entered into the SPSS database. After data was collected, original questionnaires will be kept with the consent forms in the locked cabinet at 65 Bergen St, Newark, NJ 07107.

Outcomes

The project outcomes were measured by the ODI AND FABQ questionnaires, both of which were chosen as they fit the population. Thus, the data analyzed and measured included the demographics, ODI, and FABQ questionnaires. Analyzing the demographic data provided the project's sample characteristics. Analyzing the ODI and FABQ scores showed if there were significant changes in ODI and FABQ scores after the four-week intervention of using the app.

Demographic data. The demographic data was collected with the demographic questionnaire in Appendix D. This questionnaire provided data on the characteristic of this sample population. This included age, gender, ethnicity, highest level of education, marital status, length of time worked in their role, length of time with low back pain, and comfort level with using apps on their smart device (Likert-like scale).

Oswestry Low Back Pain Disability questionnaire. The ODI was a ten-section questionnaire, developed by Fairbank and Pynsent (2000) to measure the physical disability and functioning in those with spinal disorders. The test-retest reliability ranged from 0.84 to 0.94

and the Cronbach α is 0.71 to 0.87 (Vianin, 2008). Permission to use the ODI questionnaire was obtained through ePROVIDE Mapi Research Trust (ePROVIDE, n.d.).

The ten sections were Likert scales from 0 (no limitation of function) to 5 (severe limitation of function). Details on scoring was found in the user manual for the questionnaire (ePROVIDE, n.d.). In each section, if the first statement was marked, it was scored 0 ranging to 5 for the last statement. Each section can score up to 5 points and when with all sections totaled can be out of a total possible raw score of 50 points. The total raw scores did not need to be adjusted if a question was not answered since the co-investigator ensured all the questions were answered. The adjusted score was expressed as a percentage by dividing the score by the total possible raw score of 50 and then multiplying by 100. The resulting percentage was the index score, of which the lower the score, the better the functioning.

Interpretation was detailed in the user manual (ePROVIDE, n.d.). An index score of 0% to 20% indicated minimal disability, 21% to 40% moderate disability, 41% to 60% severe disability, 61% to 80% crippled, and 81% to 100% bed-bound or consider exaggerating.

Fear Avoidance Beliefs Questionnaire. The FABQ was a non-proprietary, 16-question Likert scale between two subscales developed by Waddell, Newton, Henderson, Somerville, and Main (1993). It was based on theories of fear and avoidance behavior, used specifically to assess the beliefs of patients with low back pain and how physical activity and work affected their low back pain (Waddell et al., 1993). It had a test-retest reliability of 0.97 (Physiopedia, n.d.). It's correlation coefficient with another measure of fear avoidance called Tampa Scale of Kinesiophobia for the work subscale was 0.53 and for the physical activity was 0.76 (Physiopedia, n.d.).

The two subscales were the Physical Activity subscale (FABQPA, items 2, 3, 4, 5) and the Work subscale (FABQW, items 6, 7, 9, 10, 11, 12, 15) for a total of 66 possible points. Each subscale was graded separately by summing the responses for the respective scale items (0 – 6 for each item with responses for each item scored from 0 for completely disagree to 6 for completely agree. For scoring purposes, only four of the physical activity scale items were scored (24 possible points) and only seven of the work items were scored (42 possible points). There was no procedure to adjust for incomplete items, so all items were confirmed to be answered. The higher the final score, the higher the degree of fear avoidance beliefs. For the FABQW subset, a score greater than 34 was considered a high score and for FABQPA subset, a score greater than 15 was considered a high score (Physiopedia, n.d.).

Project Timeline

The anticipated timeline for this project is as follows (see Appendix M):

- Low Back Pain App Development: February 2019 to July 2019
- Projection planning: March 2019 to June 2019
- Project proposal: July 2019 to August 2019
- IRB submission: August 2019
- IRB approval: November 2019
- Pre-test and intervention: November 11, 2019 to December 9, 2019
- Post-test and data analysis: December 2019
- Project write-up: December 2019 to January 2020
- Presentation and poster: January 2020

Resources Needed and Economics

The costs associated with this project was the sole responsibility of the co-investigator. The co-investigator's cost included the cost for the app's development, the SPSS program, the light refreshments served during the on-site visits, the costs of printing materials for the recruitment flyer and questionnaires, and the cost for the poster presentation. The project budget is in Appendix N.

Evaluation Plan

Evaluation of the project's knowledge use was through monitoring the number of downloads of the app and its usage through the number of times accessed. Usage of the app was quantified by the participant who was asked to reply to an e-mail with the number of days they used the app that week.

To evaluate the effects of the app, the FABQ and ODI questionnaires were re-administered at the end of the four-week intervention period. These results was compared to the pre-intervention results.

Data Analysis Plan

The SPSS statistics program was used for the data analysis. The demographic data of the participants was analyzed with descriptive statistics. The change over four weeks of the ODI and FABQ scores was be analyzed with the non-parametric pretest-posttest statistics called Wilcoxon Signed-Ranks test.

Demographic data

The demographic questionnaire provided data on age, gender, ethnicity, highest level of

education, marital status, length of time worked in their role, length of time with low back pain, and comfort level with using apps on their smart device (Likert-like scale). Since age, length of time worked in their role, and length of time with low back pain are continuous variables, both frequencies and the mean was analyzed using the statistical program SPSS. The characteristics of highest level of education and comfort level with using apps on their smart device are ordinal variables for which frequencies were analyzed. Lastly, the variables of gender, ethnicity, marital status are nominal variables for which frequencies were run in SPSS.

ODI and FABQ questionnaires

The scores for both the ODI and FABQ questionnaires were continuous values. Due to the low sample size of participants who completed the intervention period ($n = 6$), SPSS was used to run the nonparametric test called the Wilcoxon Signed-Rank Test for both the ODI and the FABQ.

Data Maintenance and Security

Participants were provided a sequential ID number by the co-investigator and written on the questionnaires administered. The master list linking the participant to the sequential ID number was kept in an encrypted passcode-protected excel file in a passcode-protected computer, kept in a RU cloud based storage . The questionnaire will be stored in a separate locked cabinet at 65 Bergen St, Newark, NJ 07107 after results were calculated and entered onto the data file. Post-intervention results were logged with the same sequential ID number. Data was de-identified once the data collection was complete. The master link at this point was destroyed. All data was destroyed in accordance with Rutgers University guidelines upon

completion of the project and closure of the IRB. Hard copies of consents and data will be stored in office 1127 at the School of Nursing at Rutgers University at 65 Bergen Street, Newark, NJ 07107.

All e-mail correspondences through LowBackPainApp@gmail.com was accessible only to the co-investigator for the app project on a passcode-secured dedicated laptop. All sent e-mail correspondences were permanently deleted at the end of each week. All received e-mail correspondences were recorded for app usage and then immediately deleted permanently.

Results

Out of 18 workers who originally consented to participate in the study, only six participants completed the 4-week app intervention. Thus, there was a 66.7% attrition rate. There were no missing data.

Sample Characteristics

The sample characteristics of gender, ethnicity, highest level of education, and marital status were nominal data. SPSS was used to analyze their respective frequencies. The ratio data includes age, number of years with low back pain, and number of years in their role for which frequencies and mean were analyzed. The sample characteristics can be found in Table 3.

The average age of the participants was 29 years old ($M = 29$, $SD = 4.0$, range: 23-34). All six participants were male. The majority were Asian or Pacific Islander (50.0%), followed by Black or African American (33.3%), and Hispanic or Latino (16.7%). The highest education achieved was high school (83.3%) with only one with a college education (16.7%). The marital status of the participants was either single, never married (50.0%) or married (50.0%). Participants worked in their roles an average of 3.1 years ($M = 3.1$, $SD = 2.0$, range: 0.6-6). Low

back pain was experienced by participants an average of 4.9 years ($M = 4.9$, $SD = 2.2$, range: 1.5-7). All participants indicated they were very comfortable using apps.

Table 3

Participant Characteristics

Characteristic	Mean(SD)	n	%
Age	29(4.0)		
20 to 30 years old		4	66.7
31 to 40 years old		2	33.3
Gender			
Males		6	100.0
Females		0	0.0
Ethnicity			
Hispanic/Latino		1	16.7
Black or AA		2	33.3
Asian/PI		3	50.0
Highest Education			
High School		5	83.3
College		1	16.7
Marital Status			
Single, never married		3	50.0
Married		3	50.0
Job Title			
Dock Customer		4	66.7
Support Team		2	33.3
Years on the Job	3.1(2.0)		
Years with LBP	4.9(2.2)		
Comfort Using Apps			
Very Comfortable		6	100.0

App Usage

Evaluation of knowledge use was measured by the participant's self-report on the number of days per week they logged into the app (see Table 4 and Figure 4). In Week 1, participants used the low back pain app an average of 3.5 days, with a range of 2 to 5 days in the week. The

average app usage in Week 2 was 2.5 days, with a range of 2 to 3 days. In Week 3, the average app usage was 0.8 days, ranging from 0 to 2 days of usage. In Week 4, the average app usage was 1.2 days, ranging from 0 to 2 days of usage.

Table 4

App Usage per Week

	Mean	n	%
Week 1	3.5		
2 Days		1	16.7
3 Days		2	33.3
4 Days		2	33.3
5 Days		1	16.7
Week 2	2.5		
2 Days		3	50.0
3 Days		3	50.0
Week 3	0.8		
0 Days		5	83.3
1 Day			
2 Days		1	16.7
Week 4	1.2		
0 Days		3	50.0
1 Day			
2 Days		3	50.0

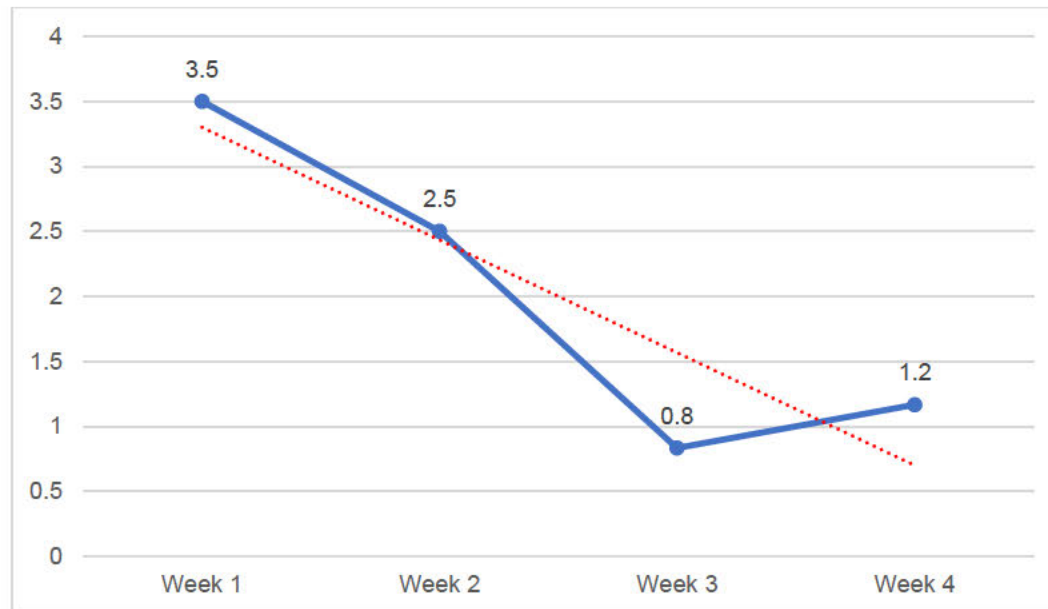


Figure 4. The average number of days per week the app was used by participants.

ODI and FABQ scores

Due to the small sample size, $n = 6$, SPSS was used to analyze the two related samples (pretest and posttest) for both the ODI and FABQ scores with the nonparametric Wilcoxon Signed-Ranks Test. Alpha levels were set to 0.05.

ODI scores. There was a non-significant decrease in the median post-test FABQ scores compared to the median pre-test scores ($Z = -1.826, p = 0.068$). The negative ranks were 4, indicating most (66.7%) participants scored lower on posttest compared to pretest ODI scores. There were 2 ties (33.3%) in which there was no change between the pretest and posttest scores. See Figure 5 of mean ODI scores and Tables 5, 6, and 7 for the statistical analysis of ODI and FABQ scores.

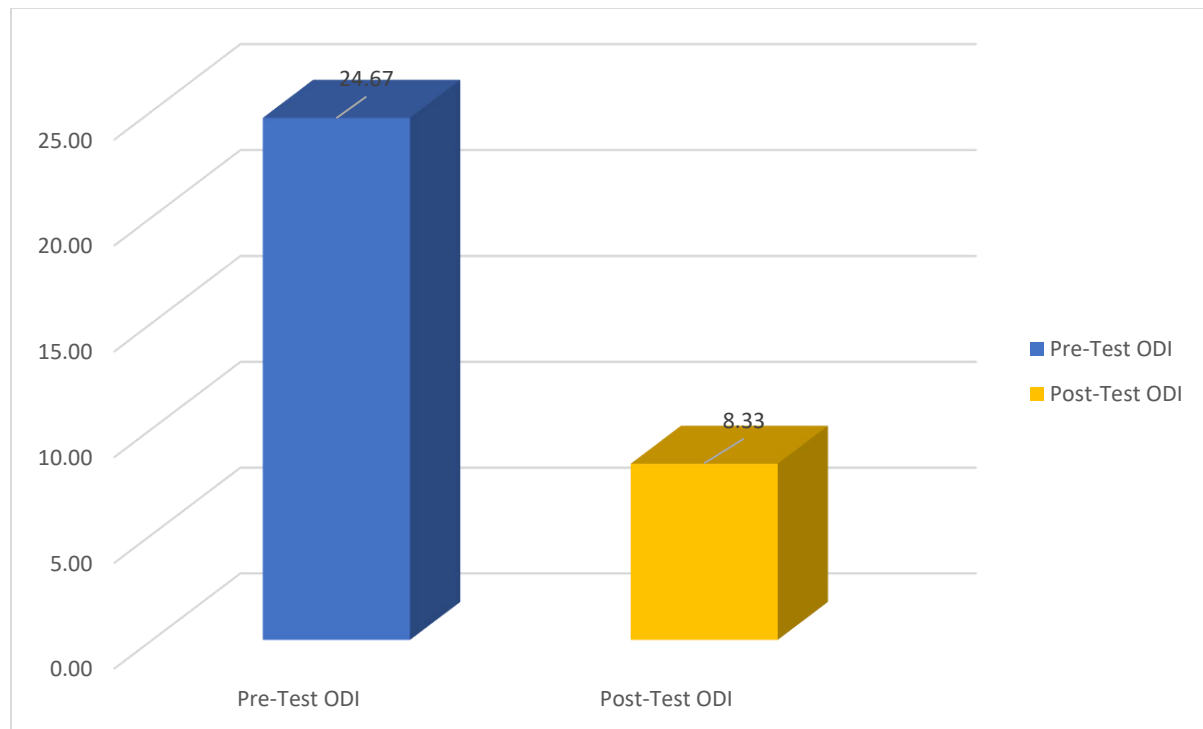


Figure 5. Mean pre-test and post-test ODI scores.

Table 5

ODI and FABQ Descriptive Statistics

	N	Mean	Std. Deviation	Minimum	Maximum
Pretest ODI score	6	24.67	14.17	6.00	42.00
Posttest ODI score	6	8.33	4.97	2.00	16.00
Pretest FABQ score	6	27.00	14.42	9.00	46.00
Posttest FABQ score	6	7.50	5.86	0.00	15.00

Table 6

Wilcoxon Signed Ranks Test

		N	Mean Rank	Sum of Ranks
Posttest ODI score - Pretest ODI score	Negative Ranks	4 ^a	2.50	10.00
	Positive Ranks	0 ^b	0.00	0.00
	Ties	2 ^c		
	Total	6		
Posttest FABQ score - Pretest FABQ score	Negative Ranks	6 ^d	3.50	21.00
	Positive Ranks	0 ^e	0.00	0.00
	Ties	0 ^f		
	Total	6		

a. Posttest ODI score < Pretest ODI score

b. Posttest ODI score > Pretest ODI score

c. Posttest ODI score = Pretest ODI score

d. Posttest FABQ score < Pretest FABQ score

e. Posttest FABQ score > Pretest FABQ score

f. Posttest FABQ score = Pretest FABQ score

Table 7

Test Statistics^a

	Posttest ODI score – Pretest ODI score	Posttest FABQ score – Pretest FABQ score
Z	-1.826 ^b	-2.207 ^b
Asymp. Sig. (2-tailed)	.068	.027

a. Wilcoxon Signed Ranks Test

b. Based on positive ranks.

FABQ scores. There was a statistically significant decrease in the median posttest FABQ scores compared to the median pretest scores ($Z = -2.207, p = 0.027$). The negative ranks were 6, indicating all participants scored lower on posttest compared to pretest FABQ scores. See Figure 6 for mean FABQ scores and Tables 5, 6, and 7 for the statistical analysis of ODI and FABQ scores.

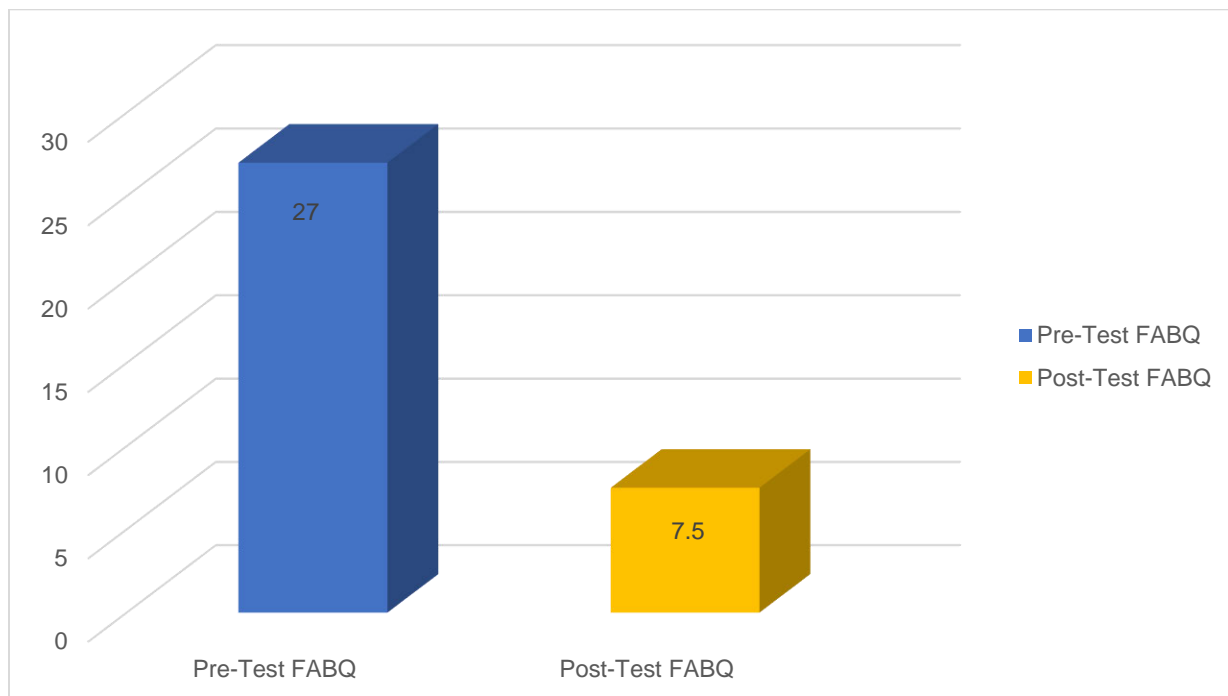


Figure 6. Mean pre-test and post-test FABQ scores.

Discussion

App Usage

Knowledge use was evaluated by monitoring the number of days the app was used per week. The app usage was self-reported by each participant at the end of each week via e-mail and all needed second e-mail reminders to respond with their app usage. This can be a limitation

due to the potential for response rate bias, a concern also noted in the study by Irvine et al. (2015) in which they also sent e-mail reminders if initial messages were not opened.

Overall, there was a downward trend on the number of days per week the app was used by the participants. The third week had the lowest usage out of the four weeks, which could be attributed to it coinciding with a major holiday. Similarly, Riva et al. (2014) observed a wear out effect, in which there was a decrease in website use and a decrease in physical exercise over time.

App Intervention Effects on ODI and FABQ

The effects of using the low back pain app over four weeks was measured by comparing the pre-intervention and post-intervention ODI and FABQ scores. The aim of this project was to provide self-management using a low back pain app and evaluate its effects on physical functioning and fear avoidance behaviors. The app was anticipated to lead to positive findings in managing the psychosocial aspect of low back pain.

ODI. The ODI tool measured physical functioning and is a percentage expressed as an index score. The lower the index, the better the functioning. At baseline, the participants had moderate disability, with the ODI falling between 21% to 40% ($M = 24.67$, $SD = 14.17$). After the 4-week app intervention period, the participants dropped into the minimal disability, with the ODI falling between 0% to 20% ($M = 8.3$, $SD = 5.0$). This change was not statistically significant ($Z = -1.83$, $p = 0.068$). Thus, the null hypothesis was retained.

These results were in contrast to the improvement in physical functioning found in the studies by Chhabra et al. (2018), Irvine et al. (2015), and Lo et al. (2018). On the other hand, the shorter intervention period of this project may have contributed to this divergence. Chhabra's

intervention period was 12 weeks, Irvine was 8 to 16 weeks, and Lo's was 3 to 6 months. A longer intervention period is suggested for future studies.

FABQ. The FABQ tool assessed patients' beliefs on how physical activity and work affected their low back pain (Waddell et al., 1993). The lower the score, the lower the degree of fear avoidance beliefs. There was a statistically significant decrease ($Z = -2.207, p = .027$) in the FABQ score after the 4-week app intervention ($M = 7.50, SD = 5.86$) from baseline ($M = 27.00, SD = 14.42$). In contrast to the ODI, the null hypothesis was rejected for FABQ.

The significant decrease in FABQI scores means that the participants attributed their physical activities to their low back pain to a lesser degree. This decrease in their perceptions may in turn lead to earlier resumption of normal activities and decrease the likelihood that illness behavior takes hold. These findings point to the significant impact of education. The importance of education on low back pain and illness management was noted in the studies by Kawi (2014) and Benyapa et al. (2018). Benyapa's cross-sectional correlation study tested their hypothesized causal models of self-management in patients with chronic low back pain. The participants ($N = 174$) in Benyapa's study were recruited from seven Thailand hospitals and administered questionnaires that measured self-management, self-efficacy, knowledge, physical function, and social support. Kawi's (2014) participants ($N = 120$) were recruited from four primary care clinics in Nevada and measured self-management, views on chronic illness management, functional disability, and mental health. Kawi (2014) noted the significant influence of education as well as advisement on keeping a healthy lifestyle and making good nutrition.

Both studies found the positive influence of education on self-management. Kawi's study (2014) noted the significant influence of education to maintain physical activity. Likewise,

Benyapa et al. (2018) had the same recommendation of education. Having knowledge of low back pain supported decisions incorporating self-management behavior (Benyapa et al., 2018).

Process Evaluation

The process evaluation of this low back pain app project includes the number of downloads of the app to assess usage, the number of times the app was used per week by the participants, the number of completed ODI questionnaires, and the number of completed FABQ tool.

There were 18 participants who consented during the on-site visit. The app was downloaded onto each participant's phone ($n = 18$). All 18 participants completed the demographic, ODI, and FABQ questionnaires right after consent was obtained. At the final on-site visit, there were 6 remaining participants who completed the ODI and FABQ questionnaires.

After the first week of using the app, only 12 participants e-mailed back on their app usage. After the second week, the same 12 replied back. After the third week, 7 of the remaining 12 participants replied back. After the final week, one participant did not reply back, resulting in 6 participants who remained.

Facilitators, Barriers, and Consequences

The key facilitators in achieving the project's objectives included critical input from the project chair and team member, availability of beta-testers for the app, and the initial support from the project site's leadership. Formulation of the app was a laborious endeavor and required input from the project team and beta-testers. Lastly, the initial support from the project site's leadership (i.e. owner/CEO, Vice President of Operations) was absolute.

Barriers that impacted the project was a temporary change in the project site's leadership that led to wavering support of the project at the conclusion of the 4-week intervention period. The length of time from the initial commitment from the project site to the commencement of the project was 11 months. At the conclusion of the intervention phase, the acting-CEO was initially reluctant to let the study continue and did not want the posttest questionnaires to be filled out on site. Another barrier was the misperception of some workers that their responses would be made known to their employer and also discomfort with answering questions related to their sexual activity. These barriers may have contributed to the 67% attrition rate. Lastly, the convenience sampling and the subsequent characteristics limits generalizability.

A potential unintended consequence would be an increase in participants reporting work injuries. This could be a positive consequence for an enlightened employee, but a negative one for the employer. The realization that their pain may be work-related could be due to reading how repetitive activities can lead to low back pain injuries and also from the FABQ questionnaire asking questions about work-related injuries and worker's compensation claims.

Implications and Recommendations

The use of a low back pain app for self-managing has the potential for significant changes for clinical practice, healthcare policy, quality and safety, and education. Addressing the psychosocial aspect of low back pain through self-management has been proven in other conditions to lead to positive disease-specific outcomes. Even though the ODI results were non-significant, self-management with an app should be explored with a longer intervention period than the 4-weeks in this project.

Clinical Practice

Low back pain treatment in occupational medicine is focused heavily on the medical interventions. Incorporating self-management into treatment algorithms is recommended to address the multi-factorial nature of low back pain and how it affects an employee in their work setting. Encouragement from treating providers coupled with a self-management app can lead to patient activation and engagement.

Patient activation and engagement is supported with an educational self-management app. The app can reinforce the education by the treating providers beyond the in-person visit. Additionally, the app can list resources such as approved exercise protocols for their current stage of low back pain (e.g. acute, subacute). Another resource the app can list is their company's Employee Assistant Program (EAP). Employees who are having a hard time dealing with their low back pain would benefit from having this information readily available. Reaching out to EAP can connect the employee to mental health professionals who may provide another avenue of addressing the psychosocial aspect of low back pain.

Another recommendation is for this industry is to incorporate some of the ODI and FABQ questions into their routine clinical assessment. Periodic assessment using the ODI can help the provider assess their current physical functioning. Knowing their evolving level of physical functioning can lead a clinician to reassess their treatment plan and change as needed. Periodically using the FABQ questions into a routine clinical assessment can help identify employees who may need more aggressive management to address their psychosocial needs.

Healthcare Policy

A goal of HealthyPeople 2030 is to “create social, physical, and economic environments that promote attaining full potential for health and well-being for all” and across multiple sectors

(ODPHP, 2020). As recommended by clinical practice guidelines and IOM, adding interventions to address the psychosocial aspect of low back pain will lead to better health outcomes for this population, thereby having significant impacts on healthcare quality. With consistent positive effects and improvement, healthcare policies can integrate this recommendation into the treatment plans as a standard of care in treating individuals with low back pain.

Institutional policies for healthcare can integrate self-management as a recommendation into treatment plans not just for occupational medicine but across disciplines. Incorporating self-management in such a fashion maintains its importance and perpetuates its utilization as a standard of care. In the historically resistant world of occupational medicine, institutional mandate for using self-management modalities allows for acceptance in a predominantly medicine-focused setting. Ultimately, this supports policies that integrate psychosocial interventions at the workplace.

Another recommendation is the formulation of standardized mobile health apps for medical conditions. For example, the National Institute of Health already has health information for the general consumer. They could house self-management apps for conditions such as diabetes, asthma, and low back pain to name a few.

Quality and Safety

Addressing the psychosocial aspect of low back pain by promoting self-management can improve the quality and safety at the workplace. Using a holistic approach in the management of patients by addressing interventions beyond just the medical aspect of care leads to improved employee outcomes. Employees overall would be empowered and feel they have a role in

getting back to at work. This in turn prevents catastrophizing and lessens the likelihood that fear-avoidance behaviors take root. It may prevent a certain subset from falling from the acute low back pain state to a subacute or even chronic low back pain state.

Employers will also have an increase in quality and safety indicators. For the employer, this means a reduction in the reported loss days and restricted work-days to OSHA.

Occupational health has its own unique potential cost savings. In addition to the above, financial reliefs for worker's compensation includes paying out less for out of work wages, prolonged medical treatments for physical therapy, specialist visits, and invasive surgeries. As a result, for the employees, success will lead to a lesser burden of wondering if they have loss of wages or even loss of job protection.

Employers will show a decrease in the wages spent. These wages are from loss of productivity of an injured worker and the wages spent paying for working in a restricted duty position among employers who accommodate restricted duties. Thus, the financial gains include decrease in wage replacement, decrease in loss of productivity, and a decrease in medical treatment payouts.

Better control with chronic low back pain and decreasing the time of acute low back pain has implications beyond the improved quality of life for this population. There will be a lesser financial burden to the \$635 billion each year reported by the IOM and on the \$60 billion annually from decreased wages and productivity. Pharmacologic therapies and prescription costs would decrease. Physical therapy intervention may require lesser duration or frequency. Expensive treatments such as epidural injections and even surgery for intractable symptoms may be avoided for a select group especially as there are many living quality functional lives with chronic pain even when surgery was recommended.

Education

Education on self-management and other approaches to target the psychosocial aspects of their disease process can be at the student, clinician, institution, and population levels.

Self-management is a treatment modality that can be included in nursing and medical curriculum so clinicians will have early exposure to its benefits. It can be integrated into clinical care plans formulated during the clinical rotations. Focusing on the self-management from such an early stage is important to increase its utilization. It also perpetuates a holistic approach to managing patients.

Another recommendation are educational modules that provide CMEs on self-management. These modules can review what self-management is, its benefits, how to use it as an intervention, and available resources to use this modality into their current practice. These educational modules can be self-learning through professional journals and online modules.

Additional education is required for institutions. Acceptance of self-management can be challenge if its benefits remain unknown to an industry such as occupational health. The IOM can play a role in targeting institution-based education on self-management techniques. Self-management techniques such as the educational mobile health apps can be part of recommendation for other interventions to complement their care.

Self-management can be a topic of discussion in occupational health conferences. Speakers can use this venue to disseminate the benefits of engaging patients for self-management behaviors. Tailoring its use in this setting can be a challenge considering the medical intervention-focused nature of treating occupational conditions. Occupational health professionals can use the information gained in these conferences and apply it to their respective settings.

Sustainability

Sustaining this knowledge of self-management and psychosocial interventions is essential in perpetuating its importance. Sustainability approaches can target a broader audience, the project site, and future studies.

Using the knowledge gained from the positive outcomes of a self-management app, this contributes to the body of knowledge of its benefits in treating chronic conditions. These strategies of self-management and psychosocial interventions can be applied to various medical conditions and diagnosis. It is already being used in diabetes, asthma, hypertension, and chronic conditions. It can be expanded to conditions beyond these. These methods can also be applied to acute conditions that if left unchecked, can lead to a chronic condition.

Continuing this self-management app intervention for the project site is made possible by having the app available. In this case, the app will be deactivated by the end of May 2020. Employees can be redirected to other apps that are already commercially available. Ideally, employers should provide this to employees as part of their employee benefits.

Legacy projects can design a longer intervention period of at least 12 weeks. It would also be optimal if the mobile app has the ability to use push notifications and designed with app activities which foster continued engagement. Also, a future study can use an app that can automatically monitor app usage so that recall bias can be avoided. Lastly, future studies should look at whether acute conditions can also benefit from self-managing the condition with the use of a mobile app, especially in conditions at risk of becoming chronic. Chronic conditions may be preventable if a timely self-management app is successful in targeted care.

On a personal level, future studies can be presented and developed in an occupational health setting targeting employees of a healthcare system. The study can apply the desired

changes as aforementioned, especially a longer intervention period. These findings can be disseminated in various ways beyond the institution.

Dissemination

Dissemination of this project on a self-management app for low back pain will begin at the local level. A paper write-up will be completed detailing the project in its entirety as per the requirements of the Rutgers Doctor of Nursing Practice program. Second, a presentation to Rutgers faculty and students will be scheduled to present the project from proposal to project results and implications for the future. Lastly, the project will be presented at a poster board presentation.

Broader audiences can be reached by publishing in nursing, orthopedic, and rehabilitation journals. Speaking at conferences such as the Practicing Clinicians Exchange is another potential avenue of disseminating to a broader audience.

For dissemination among occupational health, publications in occupational health such as the Workplace Health & Safety journal published by the American Association of Occupational Health Nurses can be pursued. Another avenue to disseminate the information to the occupational health audience is a presentation at the annual conference by the National Association of Occupational Health Professionals and the American Occupational Health conferences. Poster boards at the conferences is an additional avenue of dissemination at these events.

Lastly, in the context of realizing health care has the highest incident rates of work-related injuries and illnesses, the information can be presented to key stakeholders and members at the American Hospital Association's annual membership meeting. Convincing key stakeholders of its low cost and high return is essential to getting hospitals to get on board with

integrating into the occupational health departments in their respective hospitals and thereby start tackling the daunting task of combating this industry's workplace injuries.

Summary

Occupational health is a field where an employee is treated according to their injured body part or parts. Thus, the ability to practice holistically in a field such as occupational health is a task that should be taken up on. Utilizing medical and psychosocial interventions in this and other fields should be a standard, rather than an exception. Support of interventions based on these scientific underpinnings and recommendations based on evidenced-based practice have guided this DNP change project. Applying the leadership skillsets expected of a DNP is essential in facilitating this change project. The use of technology in this DNP project sought to transform healthcare in occupational health.

Though the results of this DNP project had mixed results than what was anticipated, the potential benefits of implementing non-medical treatments cannot be discounted. Psychosocial interventions such as self-management are still valuable considerations for clinical practice, healthcare policy, education, and quality and safety.

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Appendix A

Review of Literature

Table 1

Review of Literature

EBP Question: In adult manual labor workers with low back pain, does a low back pain app promote effective self-management?

Date: March 17, 2019

Article Number	Author and Date	Evidence Type	Sample Size, Sample, Setting	Study Findings That Help Answer the EBP Question	Observable Measures	Limitations	Evidence Level, Quality
1	Chhabra, Sharma, & Verma (2018)	Research-Randomized Control Trial	N = 93; Treatment group (app), n = 45; Conventional treatment (medicine, PT, home exercises), n= 48) 18 years of age and older with mechanical LBP persisting for over 12 weeks with or without radicular symptoms,	Both the treatment group (used app Snapcare app) and control group (conventional usual care) recorded a decline in their disability index, measured by the Modified Oswestry Disability Index (MODI), but the decline for the App group was significantly greater. Using ANCOVA with the baseline score set as the covariate, a 2×2 mixed model ANCOVA yielded a main effect for time, $F(1, 90) = 4.739, p = 0.032$ and a significant interaction effect $F(1, 90) = 9.053, p = 0.003$.	Disability measured by MODI, pain measured by numerical pain scale, and current symptoms measured by CSS Independent variables= Snap care app or usual care	Generalizability is limited due to the study being conducted in India. Current Symptom Scale only available from app group since data was collected through the app. Collection methods changed from baseline for both groups, where at baseline was in person	Level I, Quality Good (B)

			<p>prescribed at least some level of daily physical activity, medicines, and regular use of an Android mobile device with internet access</p> <p>India</p>	<p>The paired <i>t</i>-test was used to assess the change in symptom scores and activity levels in the App group, from baseline to 12-weeks of app usage.</p> <p>The CSS showed a statistically significant ($p < 0.05$) decrease with improvements in each component (sleep, mood, mobility, ADL, distance walked). The percentage of respondents that reported poor sleep reduced from 33 to 4%, those reporting poor mood decreased from 31 to 9%, and restricted physical activity was reported by only 4% respondents after 12 weeks as opposed to 64% at baseline.</p>		<p>and post intervention data collection was through telephone interview. Other factors such as medication use, adherence to treatment may affect physical Activity and thereby the disability index of the participants.</p> <p>There is a possibility of response bias due to the self-report questionnaires which could have led participants overestimating or underestimating the severity of their condition.</p>	
2	Huber, Priebe, Baumann,	Research-Retrospective Cohort Study	N = 180	Self-management with an app containing a multidisciplinary	Numerical pain scale	The retrospective design did not allow adjustment	Level III, Quality

	Plidschun, Schiessl, & Tölle (2017)		<p>18 years or older with back pain, no red flag indicators for back pain, and self-reported sufficient levels of physical fitness</p> <p>Users of the Pro app recruited via online channels (Facebook, Google Ads, company homepage) of subscribers before 2017</p> <p>Germany, Austria, and Switzerland</p>	<p>biopsychosocial rehabilitation program for back pain reduced pain ratings in patients with acute, subacute, and chronic low back pain from baseline ($M = 4.80$, $SD = 1.95$) to the last day of use ($M = 3.75$, $SD = 1.76$) was found to be a statistically significant reduction $t(158) = 6.21$, $p < .001$, with a moderate effect size, $d = 0.56$.</p> <p>The longer an app was used, there was a statistically significant reduction in pain among the individual participant, $t(19) = 3.75$, $p = .001$. Between-group analysis showed a statistically significant greater reduction in those who completed the full 12-week program compared to all users, $t(177) = 2.71$, $p = .007$.</p>		<p>self-report pain levels for any potential spontaneous improvement of pain levels.</p> <p>The dropout rate over time was expectedly high, with 68.3% remaining at 4 weeks, 32.3% at 8 weeks, and 17.8% at 12 weeks for unknown reasons.</p> <p>Due to the design study, it was unknown if participants got better spontaneously or due to use of the app.</p> <p>Baseline physical activity could not be assessed.</p>	Good (B)
3	Irvine, Russell,	Research-	N = 597; treatment group	Current adjusted back pain status was a significant	Back Pain (yes/no)	Potential for response rate bias	Level III,

	<p>Manocchia, Mino, Glassen, Morgan, Gau, Birney, Ary (2015)</p>	<p>Randomized Control Trial</p>	<p>(FitBack app), n = 197, Alternative care group (e-mails with links to internet resources), n = 197, Control arm, n = 197</p> <p>18 to 65 years old living in the United States</p> <p>Employed at least half time, retired, or a family member of an employee at one of the four collaborating companies.</p> <p>Have experienced low back pain within the past 3 months.</p>	<p>predictor for both the treatment vs. control (OR 1.72, 95% CI 1.11-2.68, $p = .02$) and treatment vs. alternative care (OR 1.60, 95% CI 1.03-2.50, $p = .035$).</p> <p>Subjects in the alternative care group were 1.6 times more likely to report current back pain than subjects in the FitBack treatment group and subjects in the control group were 1.7 times more likely to report current back pain than subjects in the FitBack treatment group.</p> <p>Group differences in back pain was statistically significant at 16 weeks between FitBack treatment group and control group $F = 4.41$.</p> <p>Physical outcome measures were statistically significant at both 8 weeks ($F = 5.88$, $p = .003$) and 16 weeks ($F = 6.76$, $p = .001$)</p>	<p>Physical:</p> <ul style="list-style-type: none"> - Multidimensional Pain Inventory Interference Scale (MPI) and the Interference Scale of the Brief Pain Inventory (10-item) -Dartmouth CO-OP (Dartmouth Primary Care Cooperative Information Project) scale (9-item) <p>Behavioral:</p> <ul style="list-style-type: none"> -Prevention-Helping Behaviors (4-item) <p>Worksite:</p> <ul style="list-style-type: none"> -Work Limitations Questionnaire (WLQ) (4-item) -Presenteeism (6-item) 	<p>as they sent reminder e-mails to the treatment group if initial messages were not opened.</p> <p>Caution is advised also due to the self-report nature of the study, present even when determining eligibility. This can also lead to social desirability bias.</p> <p>Generalizability is limited since they note participants tended to be employed, educated, and in middle-class, also factoring into internet availability as opposed to those who have lower income, less</p>	<p>Quality Good (B)</p>
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				<p>between FitBack treatment group and control.</p> <p>Behavioral outcomes measures which assessed the level of engagement in behaviors intended to help or prevent back pain showed statistically significant difference at 8 weeks between the treatment group vs. control group ($F = 33.83, p = .017$) and the treatment group vs. alternative care group ($F = 9.32, p = .017$). The difference of treatment group was evident even at 16 weeks between the control group ($F = 46.81, p = .009$) and the alternative care group ($F = 6.88, p = .025$).</p> <p>Patient activation of patients in taking care of their low back pain was significant at 8 weeks between the treatment group vs. control group ($F = 28.75, p = .003$) though not when comparing to the</p>	<p>Other Constructs:</p> <ul style="list-style-type: none"> -Patient Activation Measure (PAM) (10-item) Theory of Planned Behavior <p>Constructs:</p> <ul style="list-style-type: none"> -Knowledge (4-item) -Behavioral Intentions (14-items) -Self- Efficacy (13-item) -Attitudes towards pain (10-item) -Catastrophizing of Pain (4-item) 	<p>educated, or in homes without Internet service to access the program.</p>	
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				<p>alternative care group. On the other hand, at 16 weeks, the difference of treatment group was significant between the control group ($F = 54.83$, $p = .002$) and the alternative care group ($F = 7.08$, $p = .027$).</p> <p>Tests looking at worker productivity and presenteeism was significant for the FitBack group when comparing to the control group ($F = 3.65$, $p = .027$) and to the alternative care group ($F = 3.36$, $p = .036$) but only at 16 weeks.</p>			
4	Riva, Camerini, Allam, & Schulz (2014)	Research-Randomized Control Trial	<p>N = 51; treatment group (interactive features included), n = 27; control group (Library, First Aid, FAQ only), n = 24</p> <p>Recruited through their</p>	<p>Patient empowerment was increased significantly within the intervention group at 4 weeks ($t = 0.8$, $p = .05$) and at 8 weeks ($t = 0.8$, $p = .01$), whereas there were no significant changes within the control group.</p> <p>Physical exercise decreased within the intervention group and</p>	<p>Outcome Measures:</p> <p>Psychological Empowerment Scale (measures patient empowerment)</p> <p>Short Questionnaire to Assess Health-Enhancing</p>	<p>Small group size</p> <p>Control group had some use of the website, with the difference between interactive features</p> <p>Two-month timeframe too short</p>	Level III, Quality Low (C)

			<p>health care providers</p> <p>18 years old or older</p> <p>Had back pain for at least 3 months</p> <p>Clinics and rehabilitation centers in Canton Ticino, Switzerland (native Italian-speaking)</p>	<p>within the control group at 4 weeks and 8 weeks.</p> <p>There was a statistically significant decrease in pain levels at 8 weeks only, within both the intervention group ($t = -1.5, p = .001$) and the control group ($t = -1.7, p = .001$). This was attributed to a wear out effect where there was a decrease in website use between 4 weeks and 8 weeks.</p> <p>At the end of the 8 weeks, participants in the intervention group attributed their improvement on back pain to the website more than the control group ($t = 1.6, p = .001$), used the website more ($t = 0.8, p = .05$), and visited more pages on the website ($t = 2.2, p = .001$).</p>	<p>Physical Activity (measures physical exercise)</p> <p>Prescription Medication Use and Perception of Risk Instrument (measures medication misuse)</p> <p>Chronic Pain Grading Scale (0-10 pain scale)</p>	<p>Lack of specificity in which it is unable to determine what caused the differences</p>	
5	<p>Yang, Wei, Ge, Meng, & Zhao</p> <p>(2019)</p>	<p>Research-Randomized Control Trial</p>	<p>N = 8; treatment group (self-management plus physiotherapy),</p>	<p>There was no statistically significant difference in pain level between nor within the intervention group and control groups.</p>	<p>Visual Analog Scale (VAS) to measure pain</p> <p>Pain</p>	<p>Small sample size</p> <p>Short treatment duration</p>	<p>Level III, Quality Low (C)</p>

			<p>n = 4; control group (physiotherapy only), n = 3 4 males, 4 females</p> <p>18 years old or above</p> <p>Physician-diagnosed chronic low back pain (>3 months)</p>	<p>Pain self-efficacy showed a significant between group effect ($F = 7.31$, $p = 0.035$) and after analyzing SF36-VT as a covariant, the resulting adjusted PSEQ between-group effect was no longer significant, but the interaction effect was significant ($p = 0.008$).</p> <p>There was no statistically significant difference in physical disability after adjusting for SF36-VT as a covariant.</p> <p>Report of bodily pain showed improvements within group effects ($p = .046$) and between group effects ($p = .008$).</p> <p>Mental Health showed improvements within group effects ($p = .017$) and between group effects ($p = .013$).</p>	<p>Self-Efficacy Questionnaire (PSEQ) to measure the self-efficacy of patients</p> <p>Roland Morris Disability Questionnaire (RMDQ) to measure disability level</p> <p>SF36 to measure health-related quality of life</p>	<p>No follow-up on long term effects</p> <p>Excluded those who do not have a smartphone</p>	
6	Lo, Lei, Li, Huang, & Tong (2018)	Research-Observational Retrospective cohort	<p>N = 158</p> <p>18 to 65 years old</p>	<p>Reported time spent on therapeutic exercises as per the AI-embedded mobile app were 22.2% (35/158) 1 day, 24.1% (38/158) 1</p>	<p>Evaluation questionnaire (14-item) to assess if app increased</p>	<p>Caution with the nature of self-reported data</p>	<p>Level III, Quality Low (C)</p>

			<p>119 male, 39 females</p> <p>Had neck and low back pain within past 3 months</p> <p>Users of a free artificial intelligence-embedded mobile app that gives tailored exercise rehabilitation program called “Well Health” downloadable in US, UK, and China</p>	<p>week, 25.9% (41/158) 1 month, 14.6% (23/158) 3 months, and 13.3% (21/158) 6 months or more.</p> <p>Of the 142 (89.9%) participants who indicated spending time reading the education material, 123 (77.8%) indicated the material encouraged them to do the exercise program.</p> <p>There was an overall reduction in the numeric pain rating scale from 6 before using the app to 4 after its use (95% CI 1.18-1.81, $p = .04$) with the greater reduction noted in those who used it for 6 or more months (from 6 to 3).</p> <p>Of all users, self-perceived improvement was reported in 65%, with 58.6% in those who used the app for 3 months, and 71.1% for 6 months.</p> <p>Usage of other interventions was reduced,</p>	<p>adherence to therapeutic exercises, affected pain level, and reduced need for other interventions</p>	<p>Recall bias with the retrospective study design</p> <p>Sample bias since those who participated in the study were most likely to have been more likely to participate</p> <p>Adherence cannot be generalized to the long-term adherence to therapeutic exercise</p> <p>Did not record dropout rate</p> <p>Eligibility criteria is self-reported, so if inaccurate, it may affect their responses to the intervention</p>	
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				reporting 24.1% did not receive any other intervention while using the app.		Functional aspect not studied so cannot determine if the decrease in pain led to increase in function	
7	Jung, M. J., and Jeong, Y. (2016)	Research-Nonexperimental Cross-Sectional, Descriptive design with mediation analysis	<p>N = 120 20 years old or older Significant demographics include 75.8% females, 68.3% married, 63.3%, unemployed, and 48.3% are older than 65 years</p> <p>Physician-diagnosed nonmalignant chronic low back pain</p> <p>Physical Therapy and Rehabilitation Clinic in Seoul, South Korea</p>	<p>According to the study, motivation completely mediated the relationship between education and self-management. In the first analysis, the effect of the predictor self-management education was significant ($B = 7.360$, $p = .013$) and accounted for 5.1% of the variance in motivation. In the second analysis, self-management education's effect on self-management was significant ($B = 3.773$, $p = .019$) and accounted for 4.6% of the variance. In the third model, when including motivation, the effect of self-management education on behavior decreased, showing non-significant effects of self-management education ($B = 1.945$, $p = .184$), but</p>	<p>Situational Motivation Scale (assess intrinsic and extrinsic types of situational motivation)</p> <p>Self-management behavior measured by a descriptive self-report survey (Sim)</p> <p>Pain measured by numerical rating scale</p> <p>Center for Epidemiologic Studies Depression Scale (measure depression)</p>	<p>Convenient sample-characteristics of the participants limit generalizability</p> <p>Measured outcomes depended on self-report</p> <p>Recall bias and social desirability bias concerns with self-report</p>	Level III, Quality Good (B)

				<p>significant for motivation's effects on self-management behavior ($B = .248, p < .001$).</p> <p>Motivation is essential to self-management behavior of individuals with chronic back pain.</p> <p>Interventions should address both motivation and education to facilitate self-management.</p>	Multidimensional Scale of Perceived Social Support (measures social support)		
8	Kawi (2014)	Research Nonexperimental, cross-sectional, descriptive design	<p>N = 120 18 years old and above</p> <p>More females (68.3%), single (60.8%)</p> <p>Disabled, unable to work 44.2%, unemployed 25.0%, employed 30.8%</p> <p>Had provider-diagnosed</p>	Self-management support was found to be significantly correlated with self-management and is essential in activating patients. The influence of education was significant ($F = 3.672, p = .008$) and those that focused on physical activity included maintaining physical activity, exercising, and proper body mechanics, in addition to other advice such as keeping a healthy lifestyle, making good nutrition choices, and alternatives for pain.	<p>Patient Activation Measure (PAM) short form to measure self-management</p> <p>Patient Assessment of Chronic Illness Care (PACIC) to measure viewpoints on chronic illness management</p>	<p>Limited generalizability</p> <p>Convenience sampling</p> <p>Use of PAM and PACIC is new to chronic low back pain population</p>	Level III, Quality Good (B)

			<p>nonmalignant Chronic low back pain</p> <p>4 Primary care clinics in Nevada</p>	<p>Self-management on chronic low back pain was facilitated by patient-perceived support through encouragement and from healthcare professionals as well as provision of information and advice.</p> <p>Disability was perceived in patients' responses to the Oswestry Disability Index ($M = 46.10$, $SD = 18.10$) averaging a score of severe disability.</p>	<p>Oswestry Disability Index (ODI) version 2.1a to measure functional disability</p> <p>Mental Health Inventory (MHI-5) to measure mental health state</p> <p>4 open-ended questions</p>		
9	Benyapa, Wanchai, Tipaporn, Khanokporn, & Torphong (2018)	Research Cross-sectional, correlational design	<p>N = 174</p> <p>30 to 60 years old, mean 48.78</p> <p>Has diagnosis of chronic low back pain</p> <p>Female 67.24%, employed 40.80%, agriculturalists 22.99%</p> <p>7 hospitals in Thailand</p>	<p>Self-efficacy, social support, low back pain knowledge, and belief in treatment effectiveness directly affected self-management and explains 33.00 % of the variance in self-management.</p> <p>High self-efficacy has a positive influence on performance of self-management tasks.</p> <p>Those who believed in chronic low back pain treatment effectiveness</p>	<p>Self-Management scale (SM scale) to measure self-management behavior in those with chronic LBP</p> <p>Belief in Treatment Effectiveness Scale (BTES scale) to assess self-efficacy for chronic LBP</p>	<p>Sample included those with three subtypes of chronic low back pain- may have influenced self-management</p> <p>Using MBAI and Chula ADLs to measure physical function may be unsuitable for those with chronic low back pain.</p>	Level III, Quality Low (C)

				<p>adhered to treatment and exhibited performed self-management behavior.</p> <p>Having knowledge of low back pain supported decisions incorporating self-management behaviors.</p> <p>Support from family, friends, and healthcare providers is correlated to making decisions and change in behaviors for self-management.</p>	<p>The Low Back Pain Knowledge Questionnaire (LKQ) to assess specific knowledge about LBP</p> <p>Modified Self-Efficacy for Chronic Low Back Pain Management Scale (MSE-CMS) to measure the ability to perform self-management tasks</p> <p>Modified Barthel Activity of Daily Living Index (MBAI) to measure ADLs of physical function</p> <p>Chula Activity of Daily Living Index (Chula ADLs) to assess</p>	Limited generalizability	
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					instrumental activities of daily living (IADLs) of physical function		
					Social Support Questionnaire (SSQ), measures social support		
10	Mansell, Hall, & Toomey (2016)	Non-Research Integrative Review	21 studies across 4 systematic reviews	<p>Self-management interventions may have benefits, but there are inconsistencies.</p> <p>Basing the intervention on a theoretical rationale can be of benefit.</p> <p>Fear avoidance model (FAM)- when experiencing pain, negative thought processes such as catastrophizing leads to fear of movement and avoidance behavior that they believe may cause further damage or more pain.</p> <p>In self-management, to reduce disability and</p>	<p>Effect sizes on pain</p> <p>Effect sizes on disability</p>	<p>The variable definitions of self-management can explain some inconsistencies as they can lead to different interventions and targets.</p> <p>The methodology of the studies was noted to have the following:</p> <ul style="list-style-type: none"> -patients and providers were not blinded -allocation was not often concealed -only some studies reported 	V, B GOOD

				<p>improve physical function, teaching should focus on: -movement will not lead to further damage -movement is key to improved function.</p> <p>According to the Social Cognitive Theory- self-efficacy, person's environment, and outcome expectancies will impact their behavior.</p> <p>Self-efficacy is a strong predictor and mediator of disability and pain outcomes in low back pain populations.</p>		<p>an intention-to-treat analysis -follow-up rates were less than 85%</p>	
11	<p>Wong, Côté, Sutton, Randhawa, Yu, Varatharajan, . . . Taylor-Vaisey (2017)</p>	Systematic Review for Clinical Practice Guidelines	<p>High quality guidelines in English language utilizing a systematic search or critical appraisal methods. Guidelines of protocols for adults and/or children with</p>	<p>Chronic back pain definitions differed between >4 weeks, >6 weeks, and >3 months.</p> <p>Interventions recommended by all guidelines for acute nonspecific LBP: 1. Evidence-based education on expected course of recovery and effective self-care options for pain management.</p>	Appraisal of Guidelines for Research and Evaluation II (AGREE II) – used to assess the development and reporting of guidelines; 23 items among 6 quality-related domains	<p>The use of Paracetamol/ Acetaminophen in recent RCT found its use did not improve recovery time.</p> <p>Excluding non-English guidelines may cause inherent bias in the results.</p>	III, C HIGH

			low back pain with or without radiculopathy, including noninvasive treatment modalities; 10 guidelines; United Kingdom, North America	2. Advising on early return to work activities, staying active, and avoiding bedrest or inactivity. 3. Medication recommendations to include Paracetamol or NSAIDs if indicated and muscle relaxants up to 2 weeks. 4. Spinal manipulation with self-care option.		Low back pain management recommendations may differ depending on the guidelines used. This is due to the differing definitions of the time intervals between acute to chronic back pain.	
12	Qaseem, Wilt, McLean, & Forciea (2017)	Non-Research Clinical Practice Guideline	American College of Physicians USA	Strong recommendation to start with nonpharmacologic treatment (e.g. superficial heat, massage, acupuncture) since most with acute or subacute low back pain improve over time regardless of treatment. Strong recommendation in those with chronic pain to begin with nonpharmacologic treatment (e.g. exercise, multidisciplinary rehabilitation, acupuncture, mindfulness-based stress	Using ACP grading system, based on recommendations on a systematic review of randomized controlled trials and systematic review published through April 2015, updated searches through November 2016	Evidence insufficient for treatment of radicular low back pain Evidence insufficient for most physical modalities Evidence insufficient for treatment specific to patient populations Evidence on disability or	Level IV, Quality High

				<p>reduction, tai chi, yoga, motor control exercise, progressive relaxation, electromyography biofeedback).</p> <p>Clinicians should inform and reassure patients with acute or subacute low back pain usually improves over time.</p> <p>Clinicians should advise patients in all subtypes of low back pain to maintain their normal activities and remain physically active as much as they can tolerate.</p>		return to work lacking	
13	O'Connell, Cook, Wand, & Ward (2016)	Narrative Review Of Clinical Practice Guidelines	<p>Low Back Pain Clinical Guidelines:</p> <p>1. 2016 NICE Guideline on Low Back Pain and Sciatica NG59 (UK)</p> <p>2. 2015 Evidence-Informed Primary Care Management of</p>	<p>Recommendations across the guidelines:</p> <p>1. Advice to stay active and return to normal activities as soon as possible</p> <p>2. Educate on an expected course of low back pain to reduce fear/ catastrophizing</p> <p>3. Pharmacological- use of NSAIDs, caution with opioids for short-term use,</p>	n/a	<p>There are local differences in culture and healthcare delivery which allows for interpretive differences.</p> <p>There might be inconsistencies on the scope of the guideline such as the use of herbal treatments.</p>	Level V, Quality High

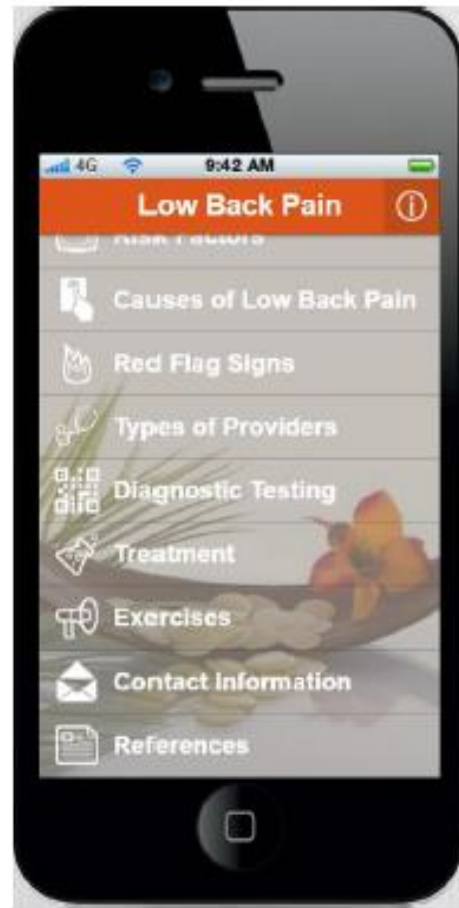
			<p>Low Back Pain (Canada)</p> <p>3. 2007/2009/2017 Diagnosis and Treatment of Low Back Pain: A Joint Clinical Practice Guideline from the American College of Physicians and the American Pain Society (USA)</p>	<p>against or caution with antidepressants</p> <p>4. Exercise therapy recommended, but no spinal traction</p> <p>5. More than one type of intervention, including self-management and psychological approaches</p> <p>6. Surgery for non-resolving radicular symptoms</p> <p>7. Against use of imaging for non-specific low back pain</p> <p>Inconsistencies between guidelines on:</p> <p>1. Interventional/injections recommendations differed</p> <p>2. Surgery (spinal fusion, interspinous spacers)</p> <p>3. Use of TENS, back belts, and corsets</p> <p>4. Use of tricyclic antidepressants, SSRIs, acetaminophen, long-term</p>		<p>There are barriers to clinical guideline implementation (personal factors, guideline factors, and external factors).</p>	
--	--	--	--	---	--	---	--

				use of opioids, herbal treatments			
				5. Acupuncture			

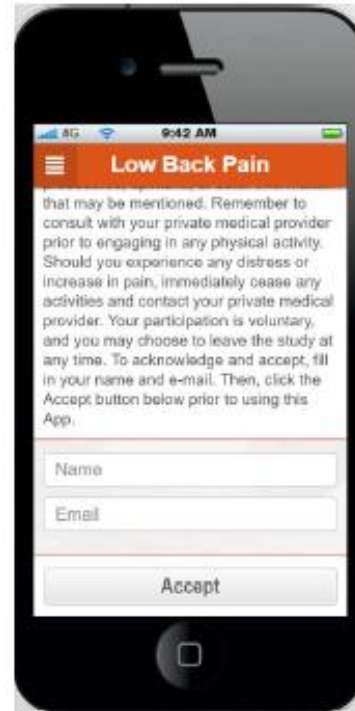
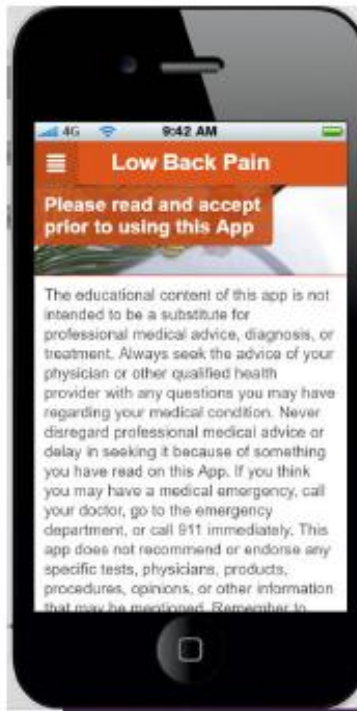
Appendix B

Low Back Pain App Screenshots

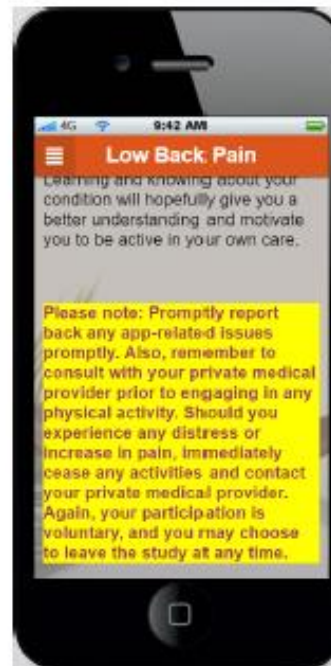
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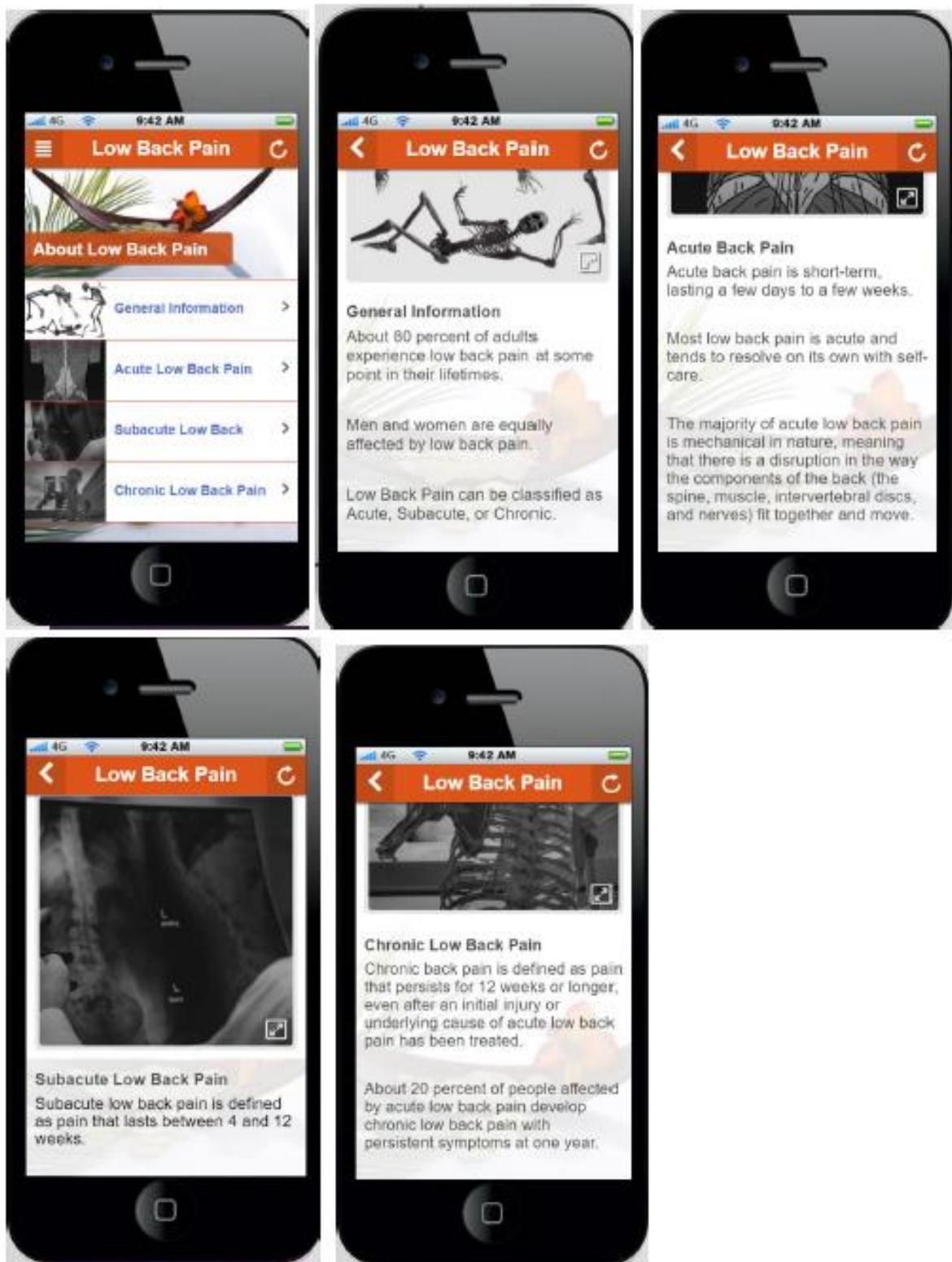


Section 1: Agreement Form

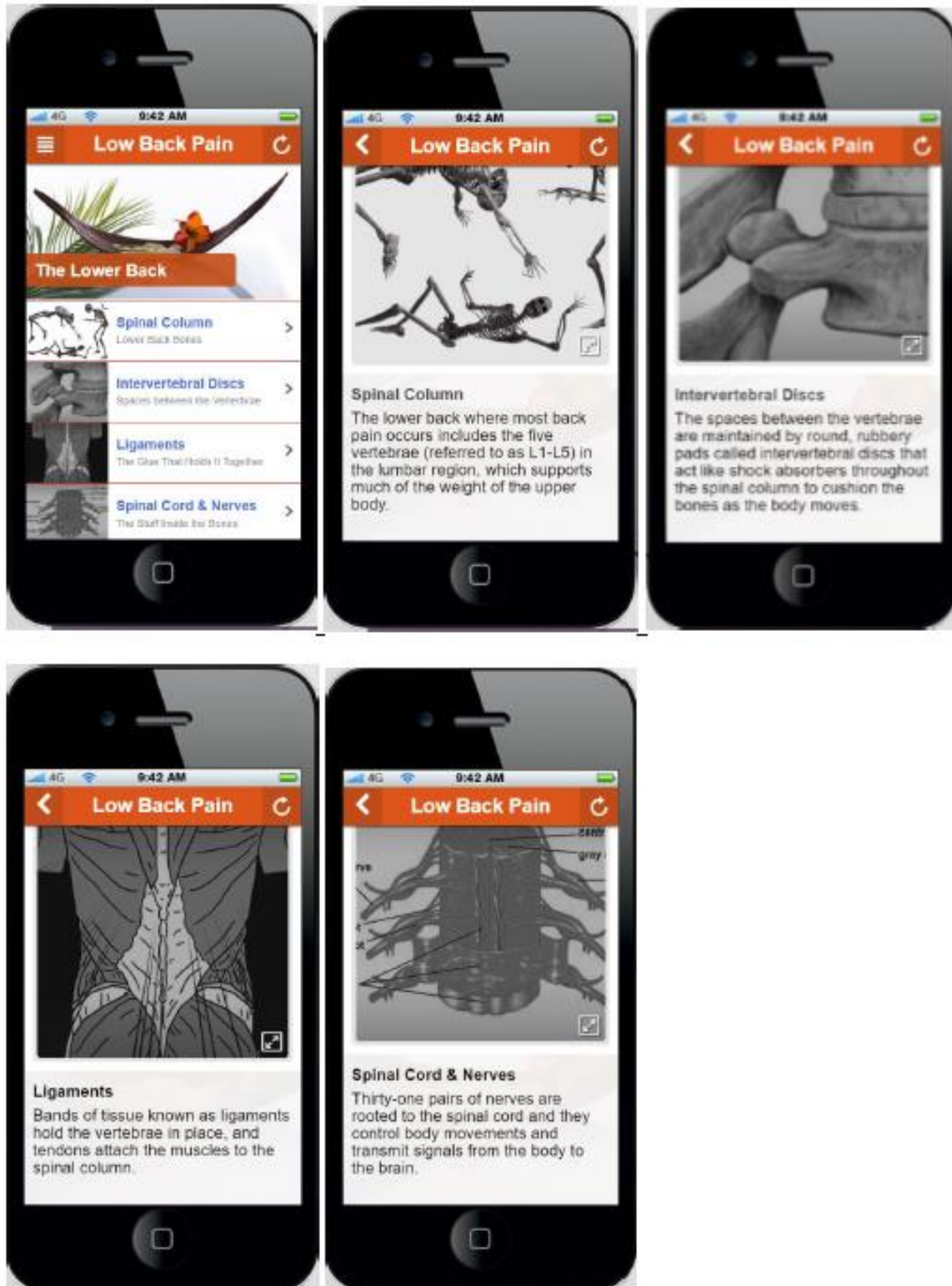


Section 2: About This App

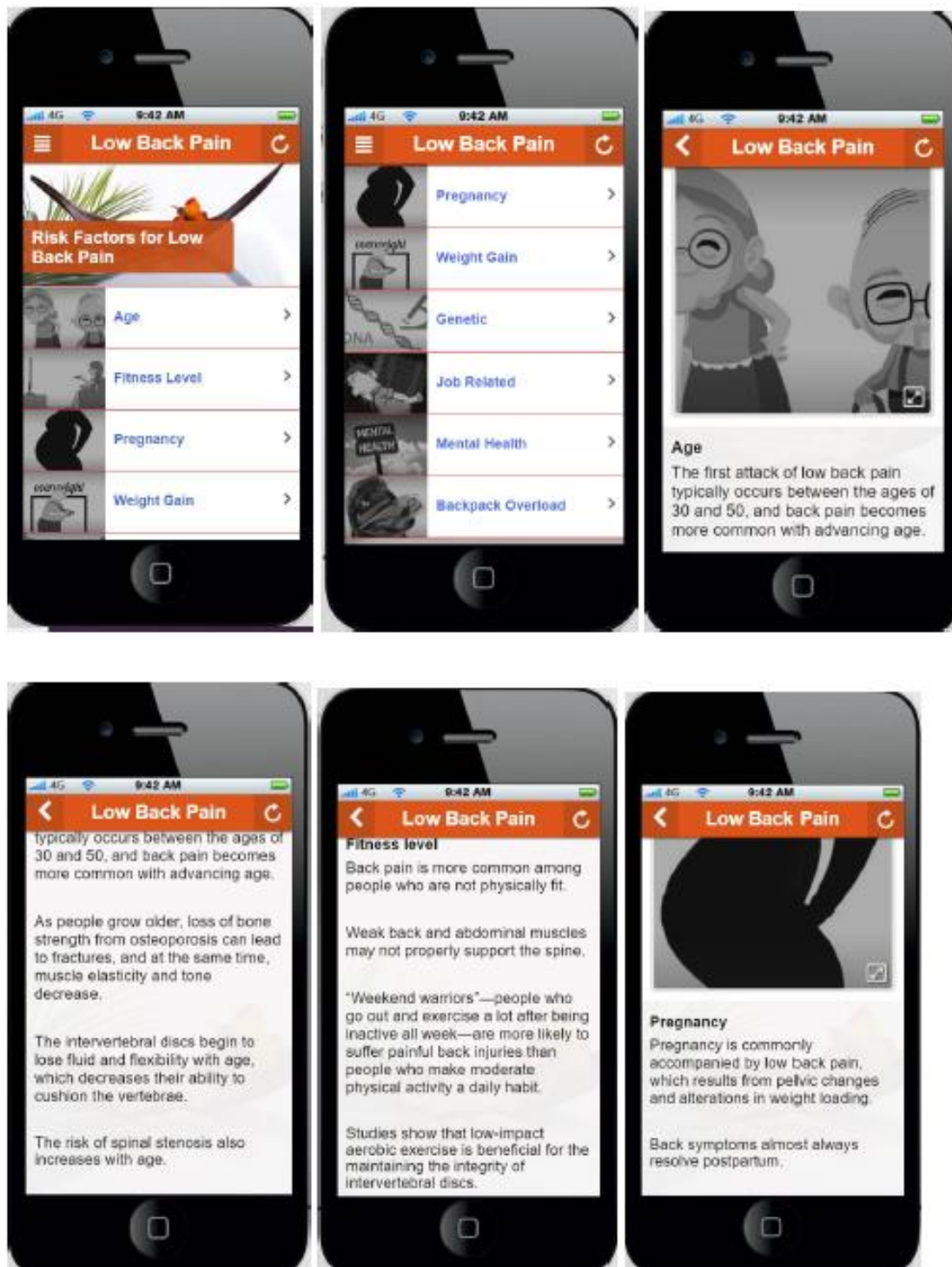


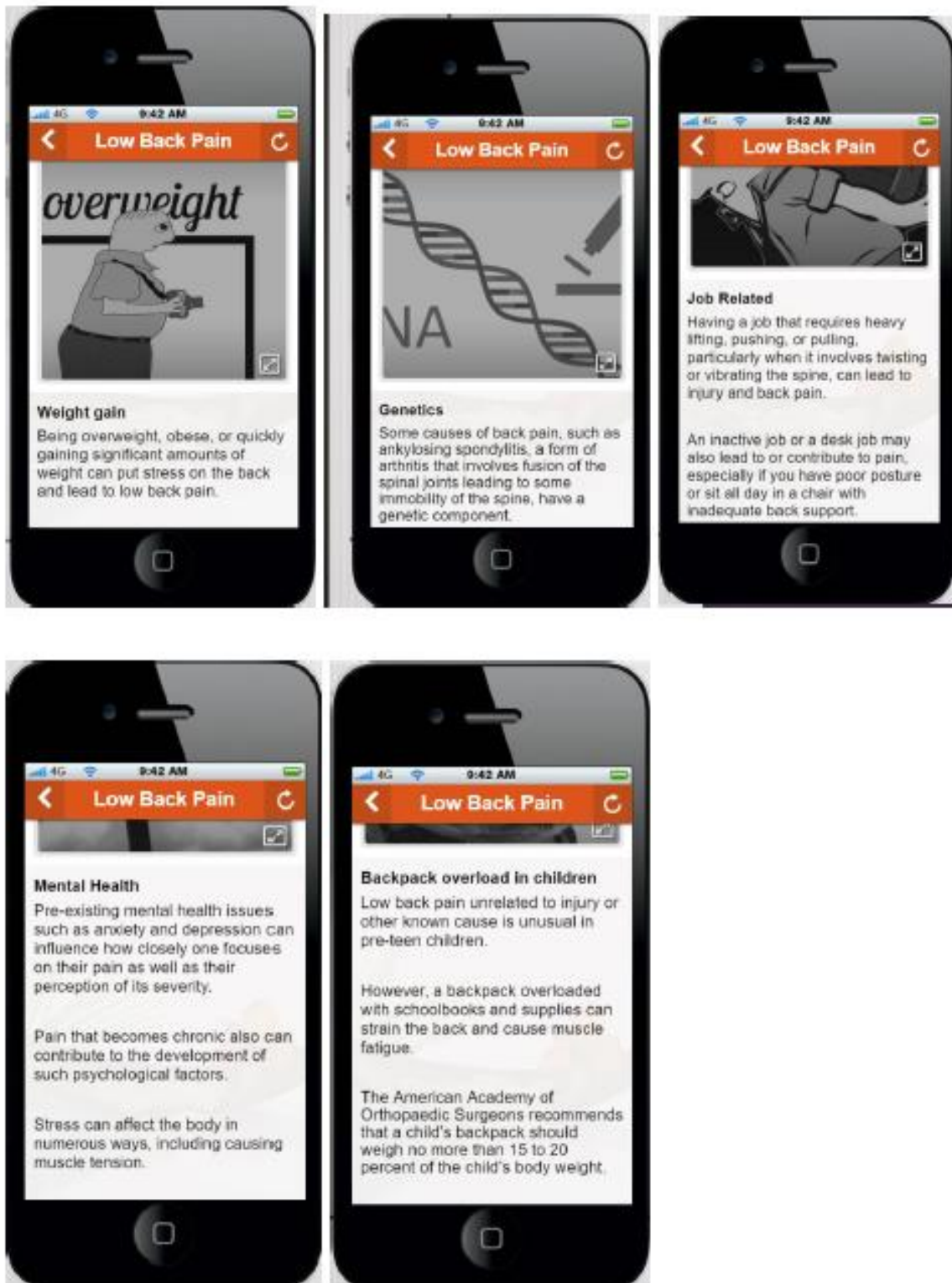
Section 3: About Low Back Pain

Section 4: Structure of the Lower Back

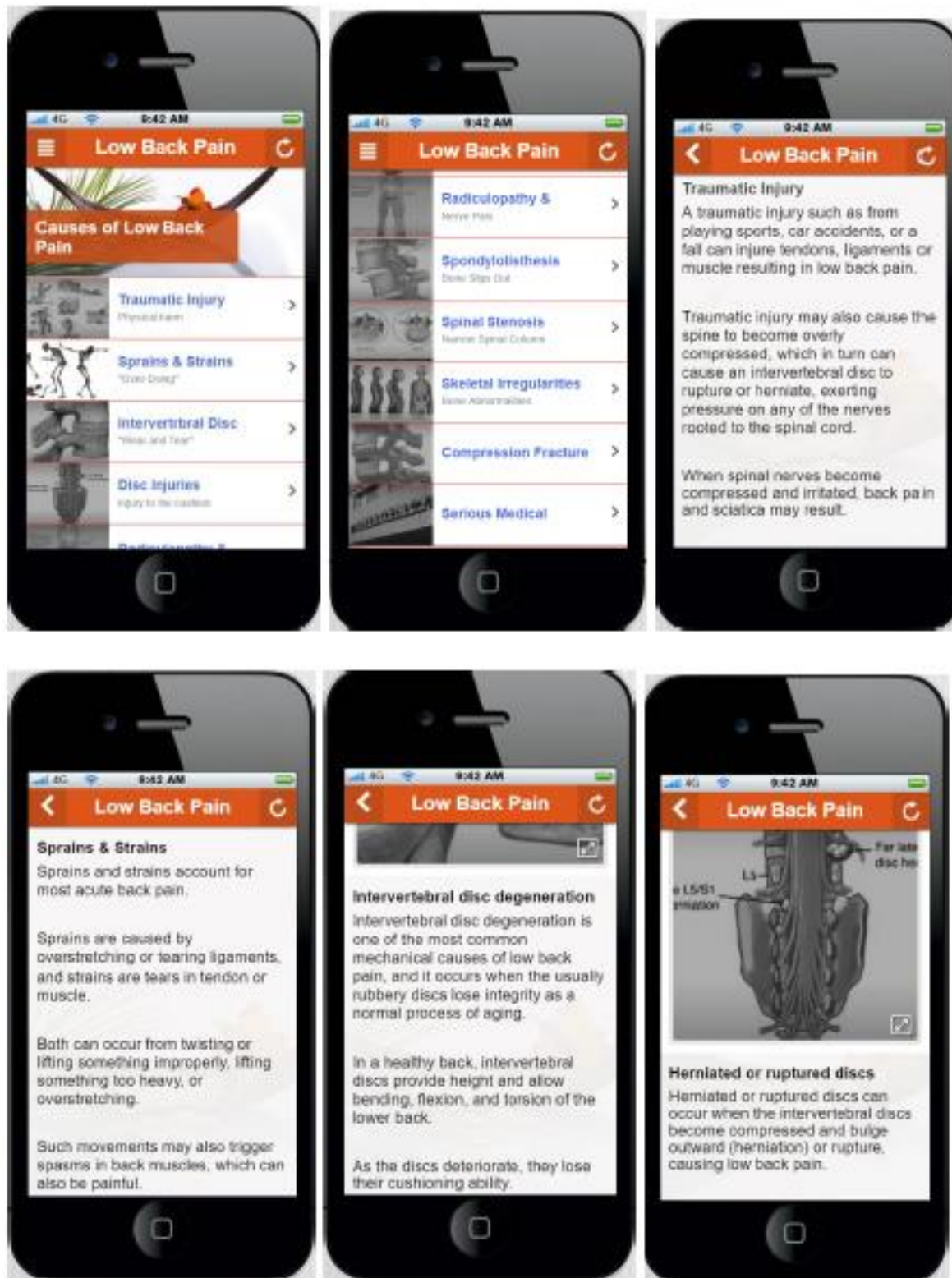


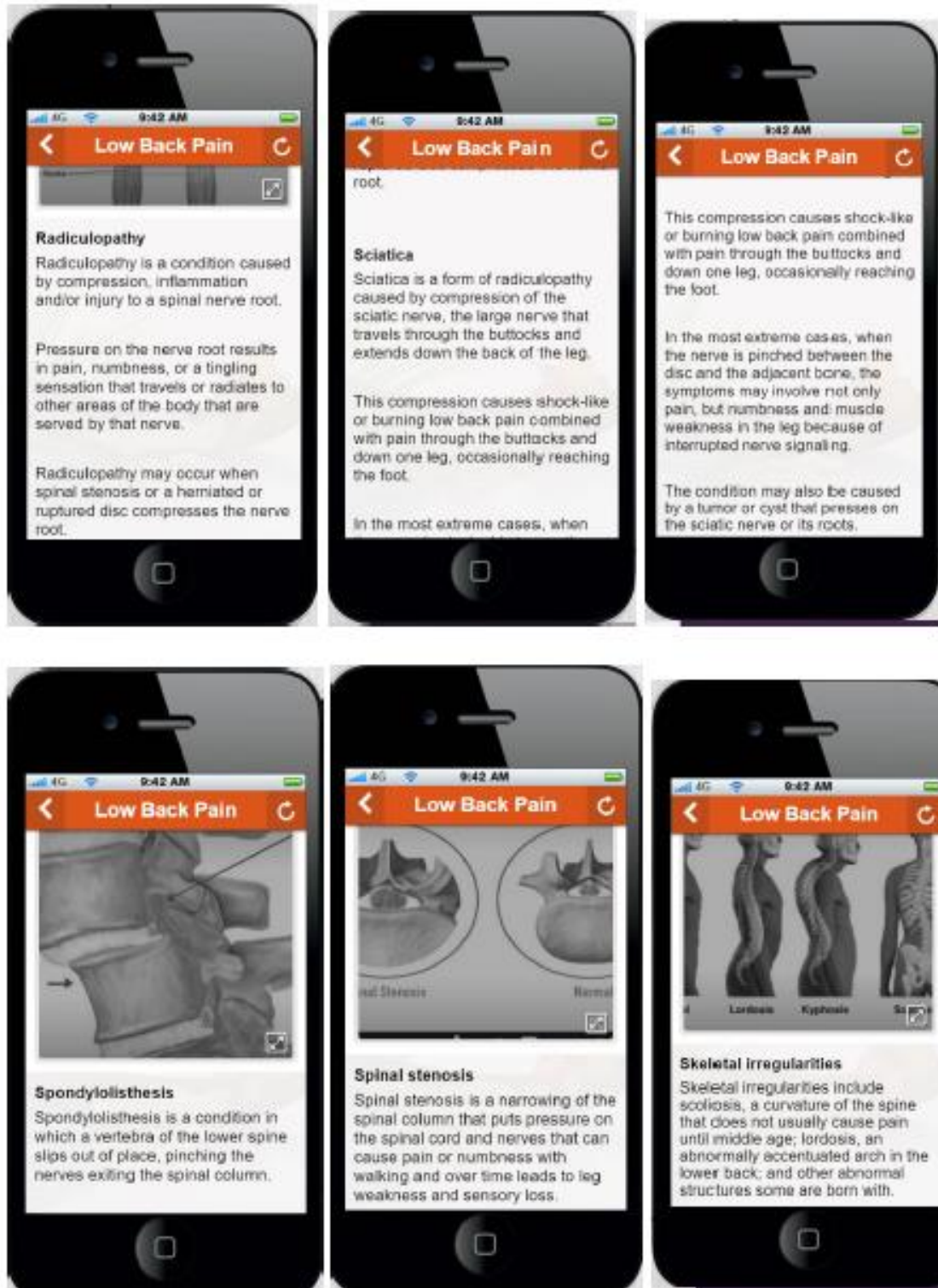
Section 5: Risk Factors

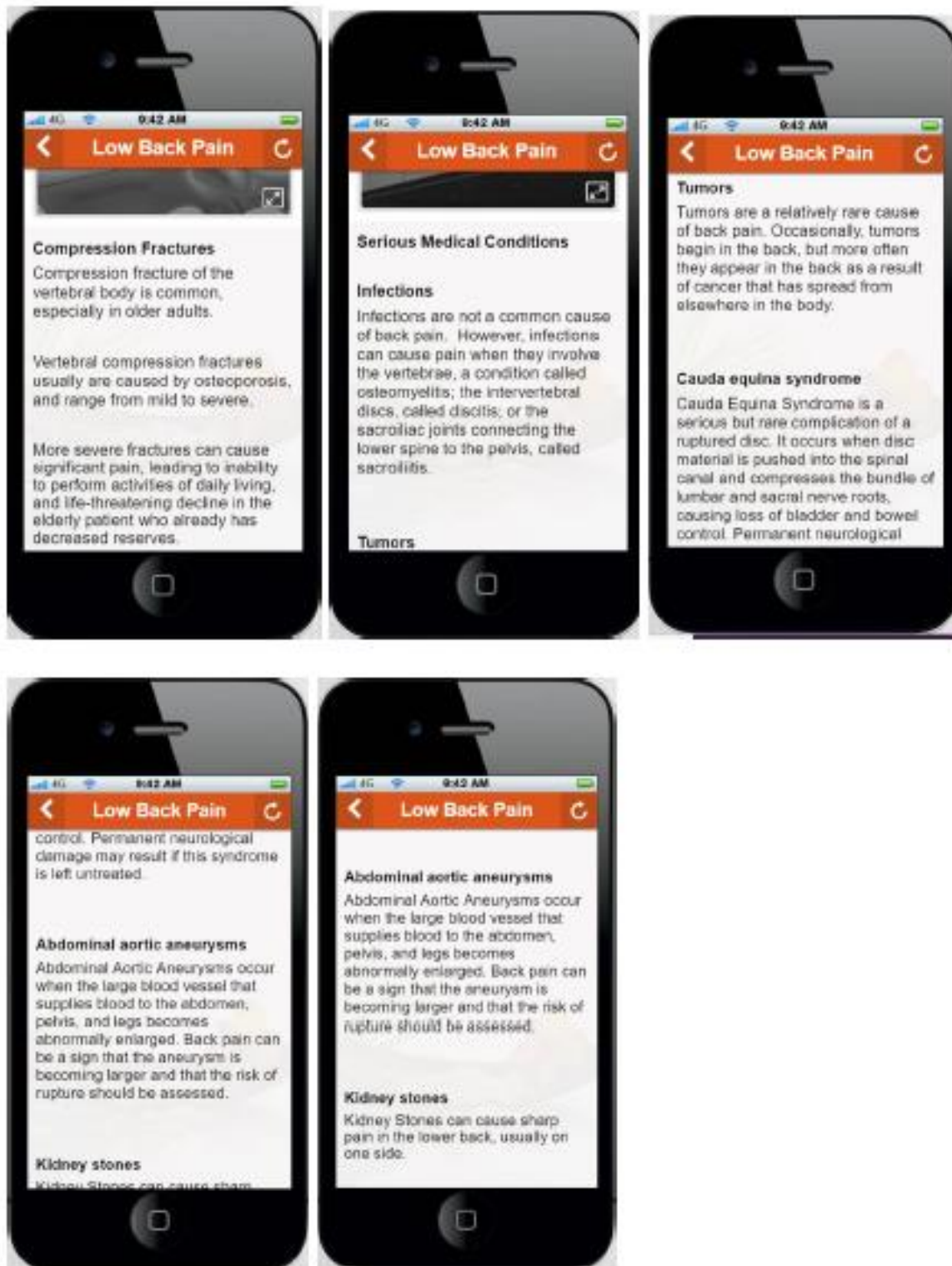




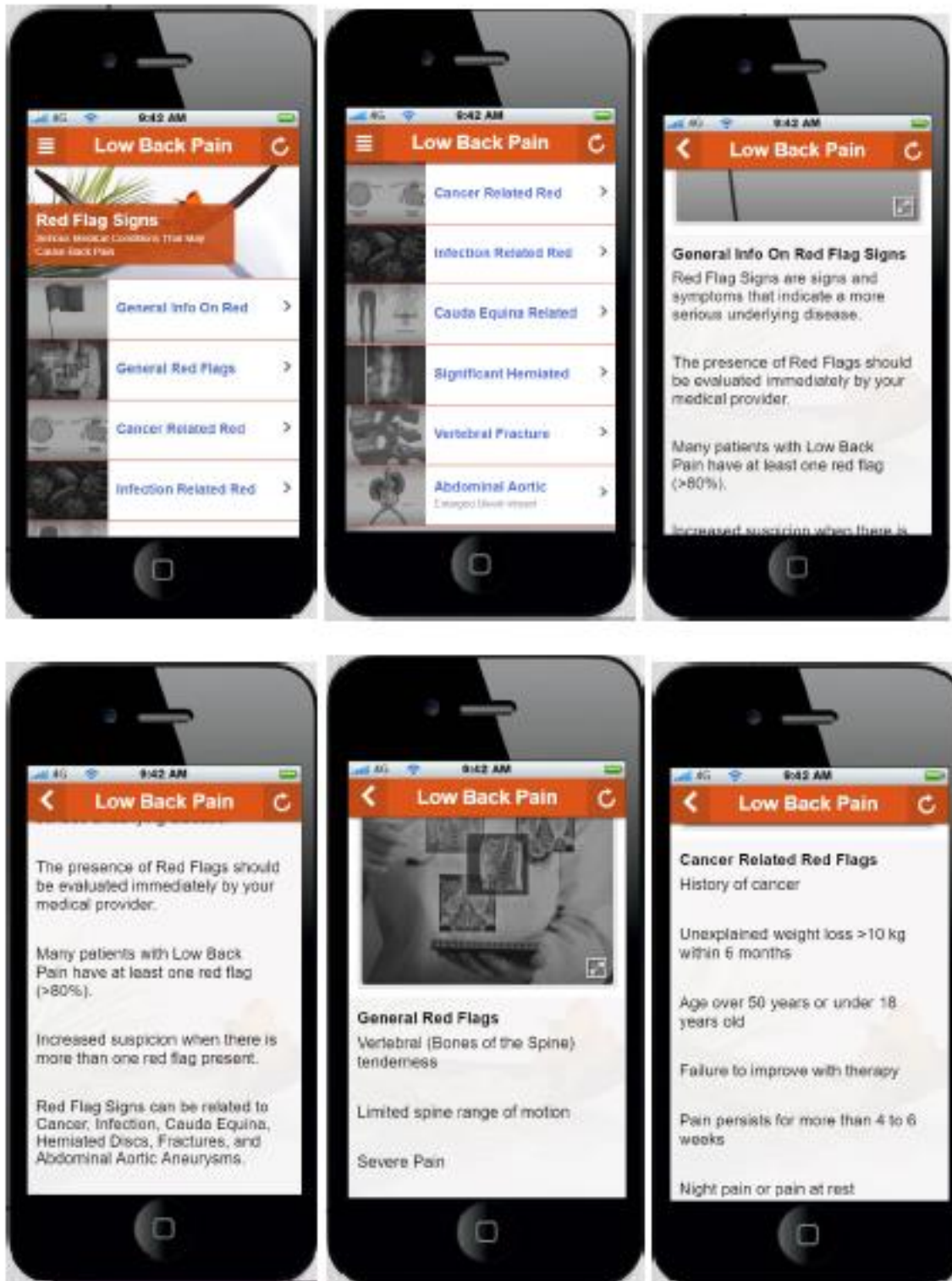
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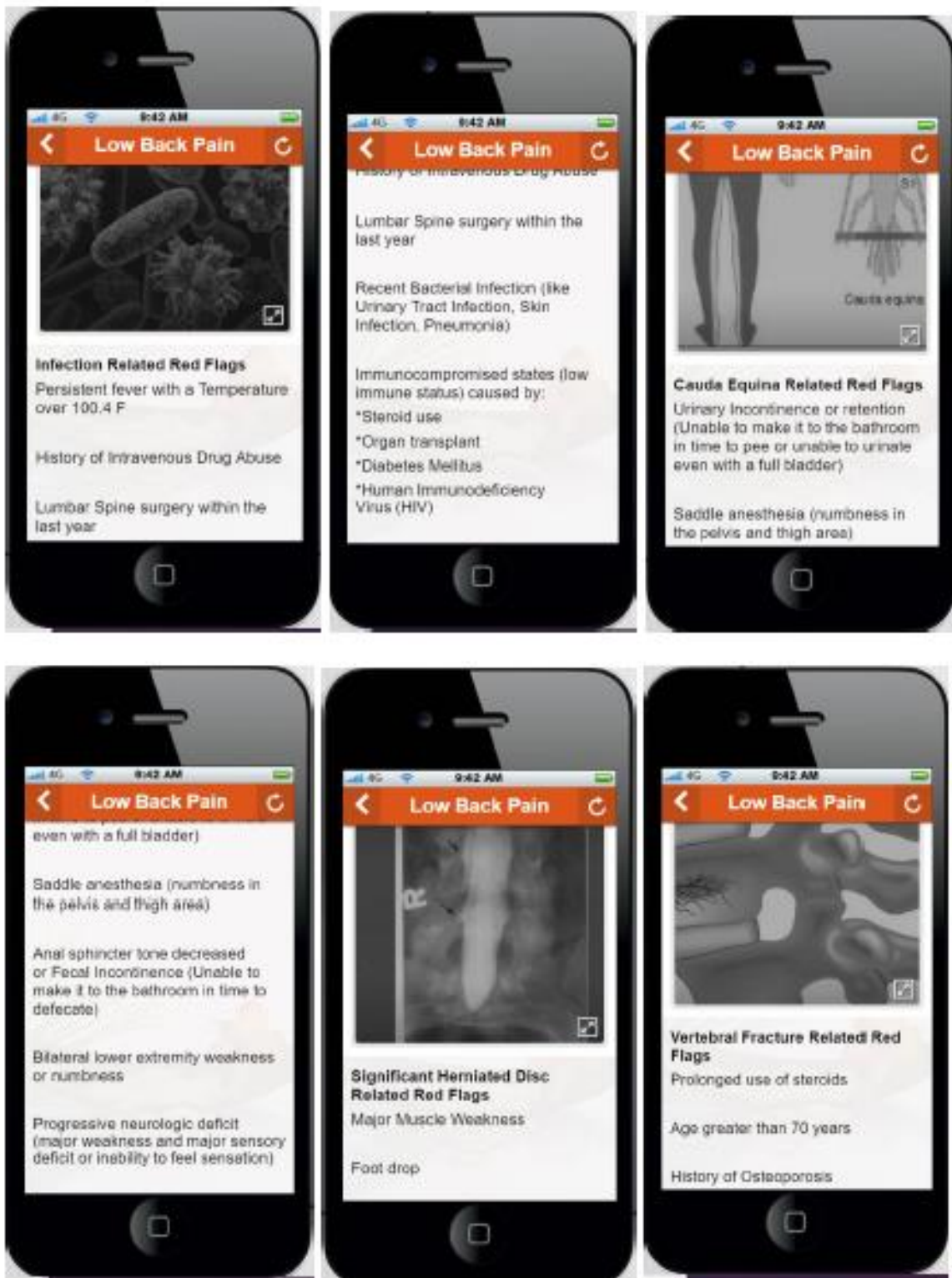


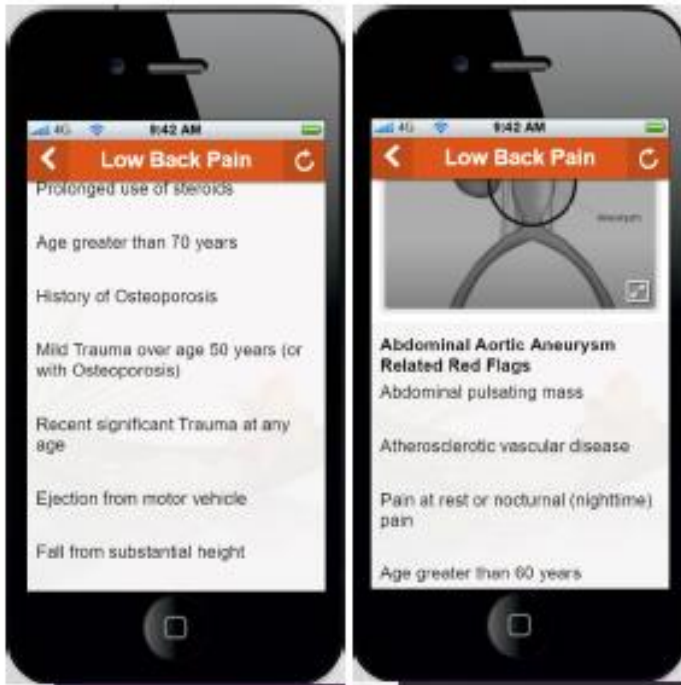




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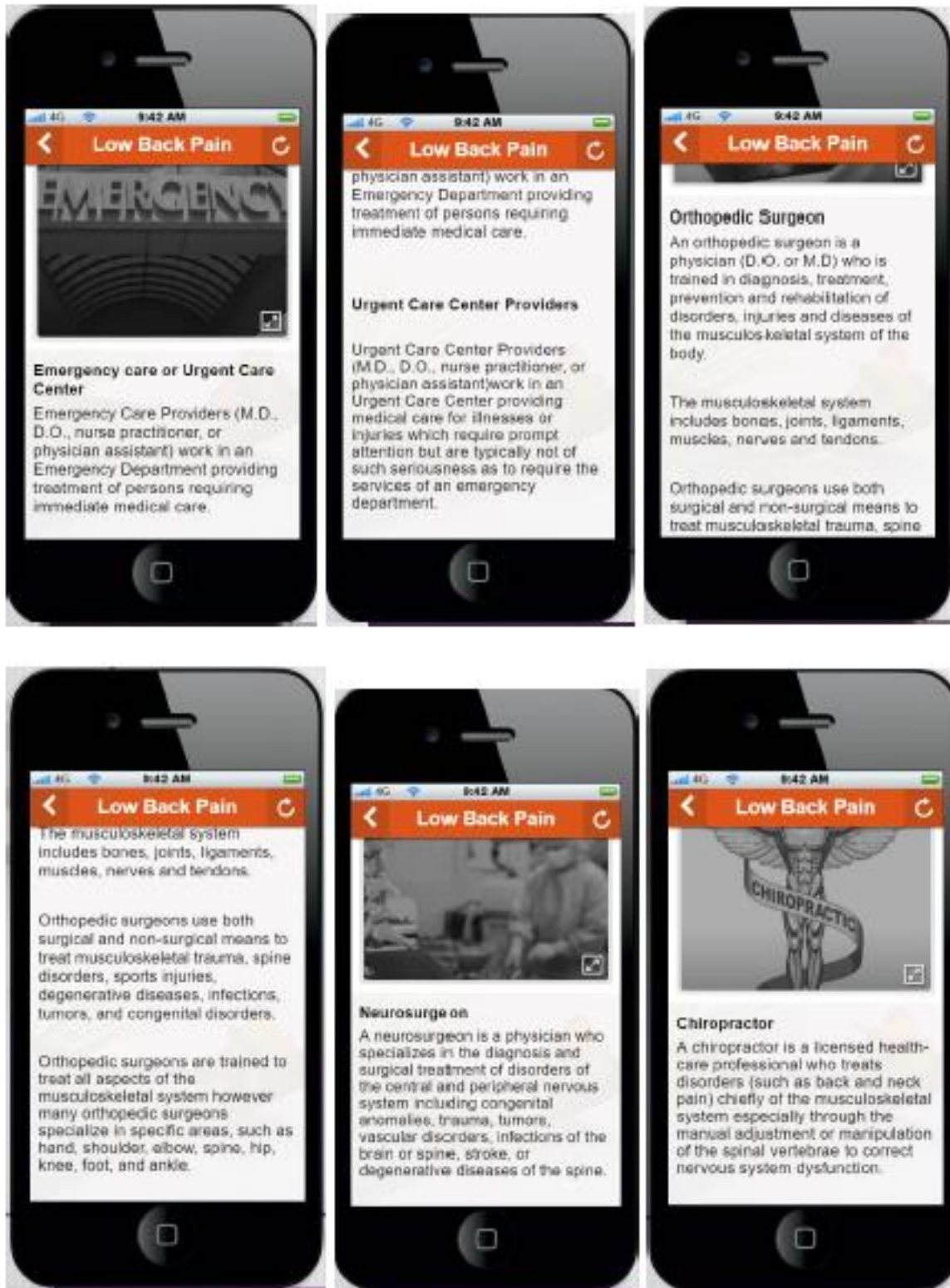


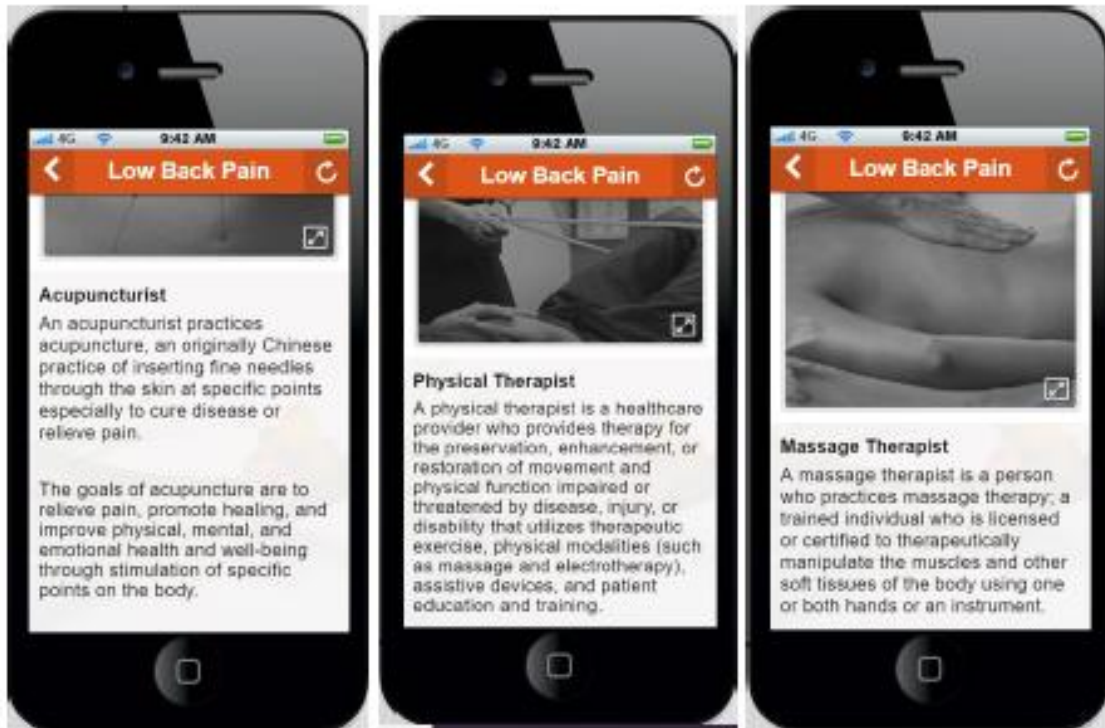




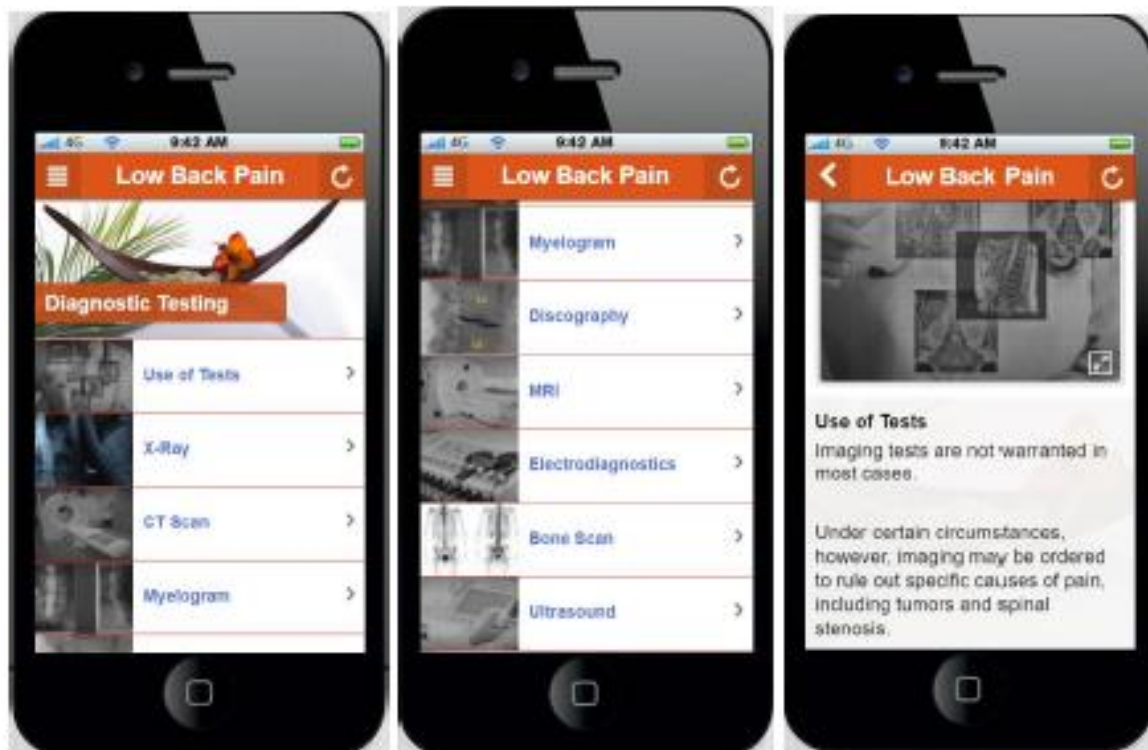
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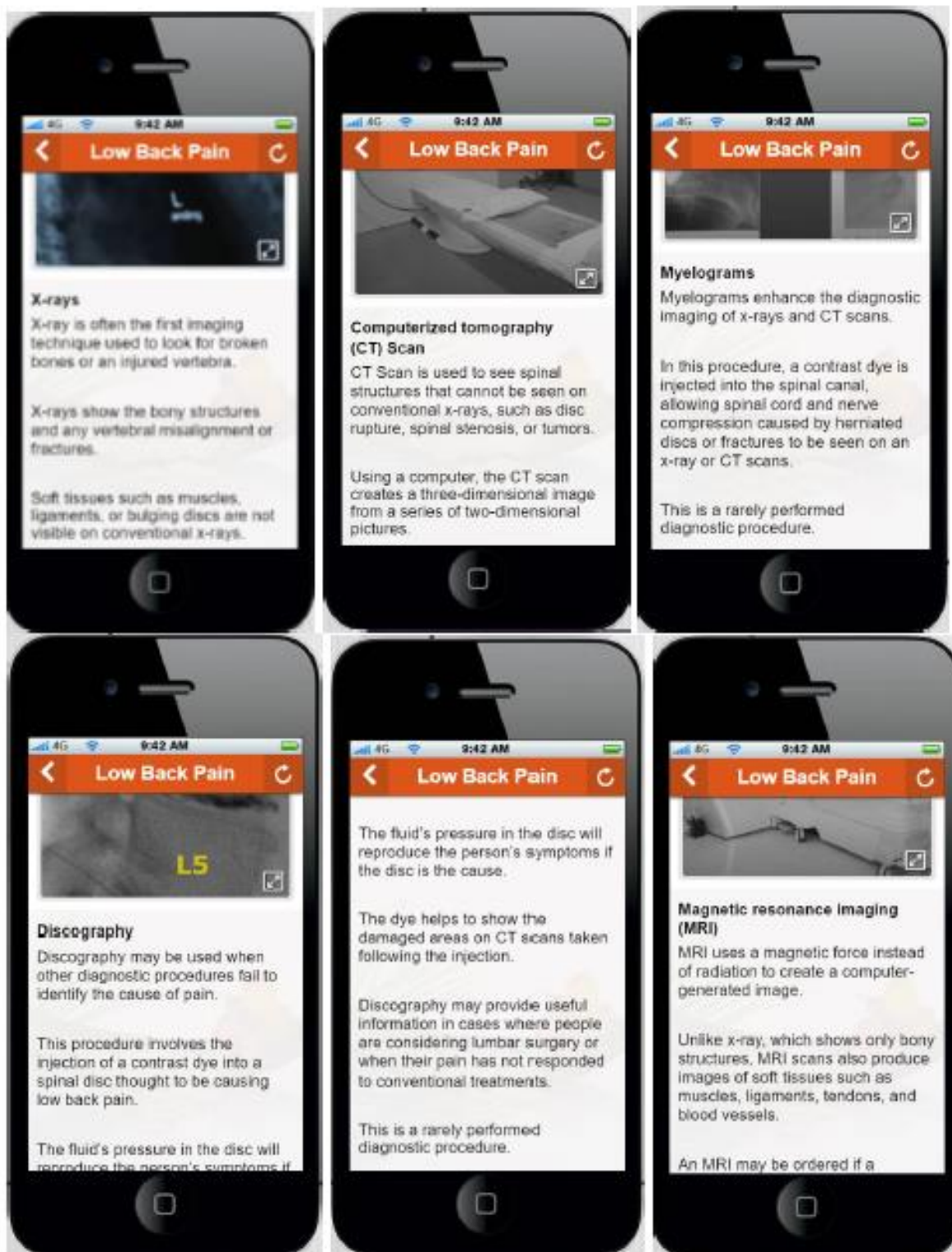


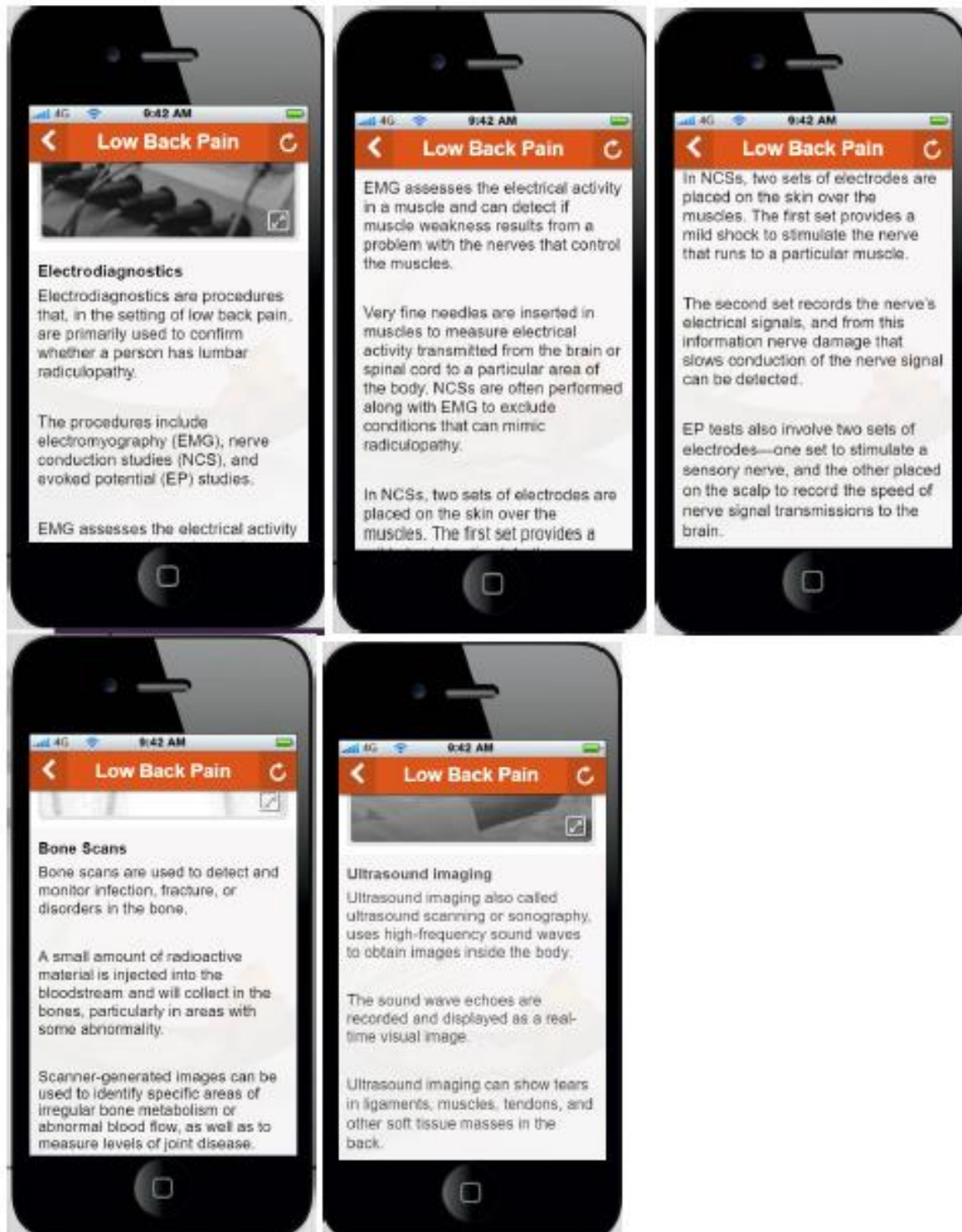




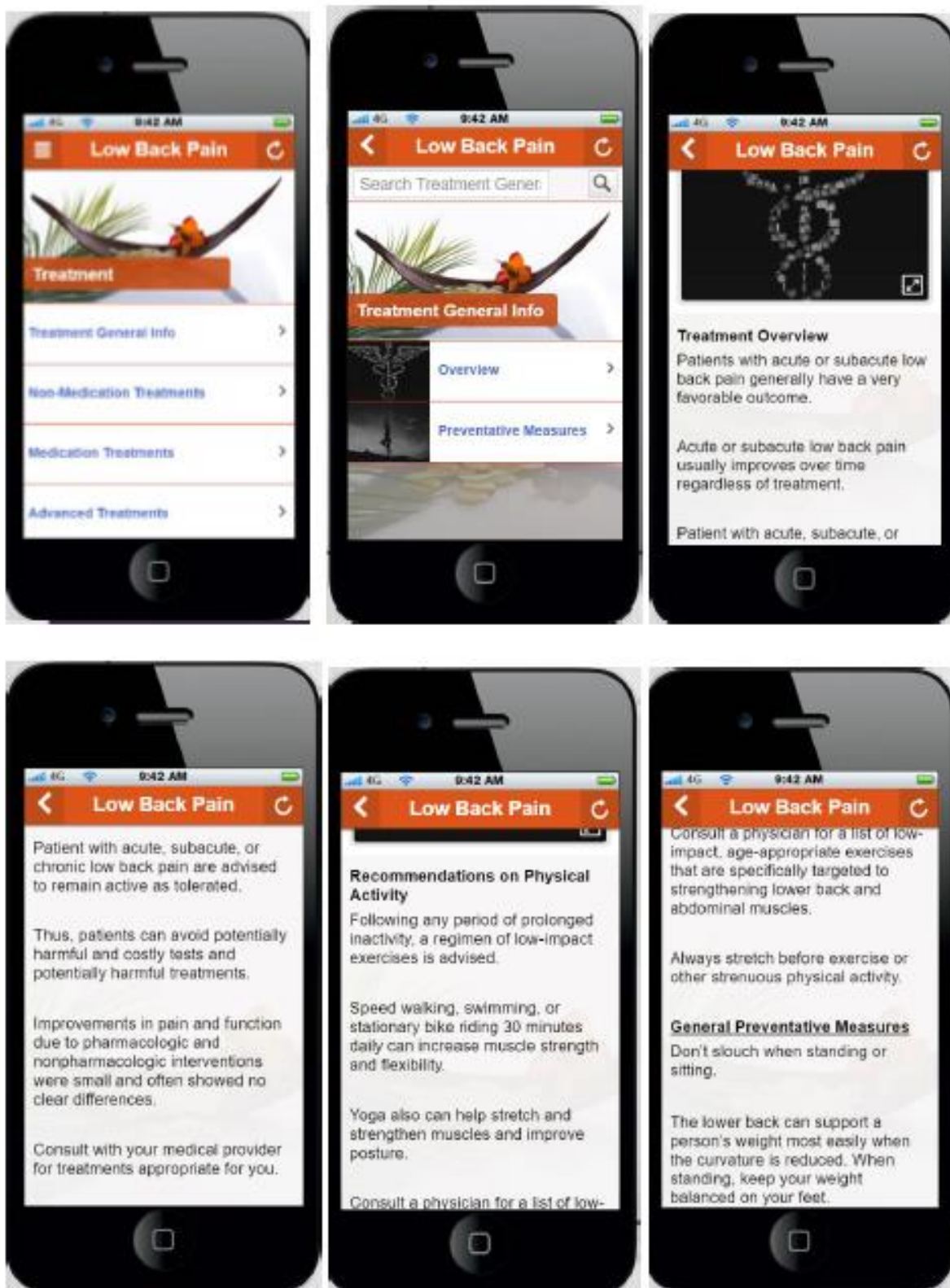
Section 9: Diagnostic Testing

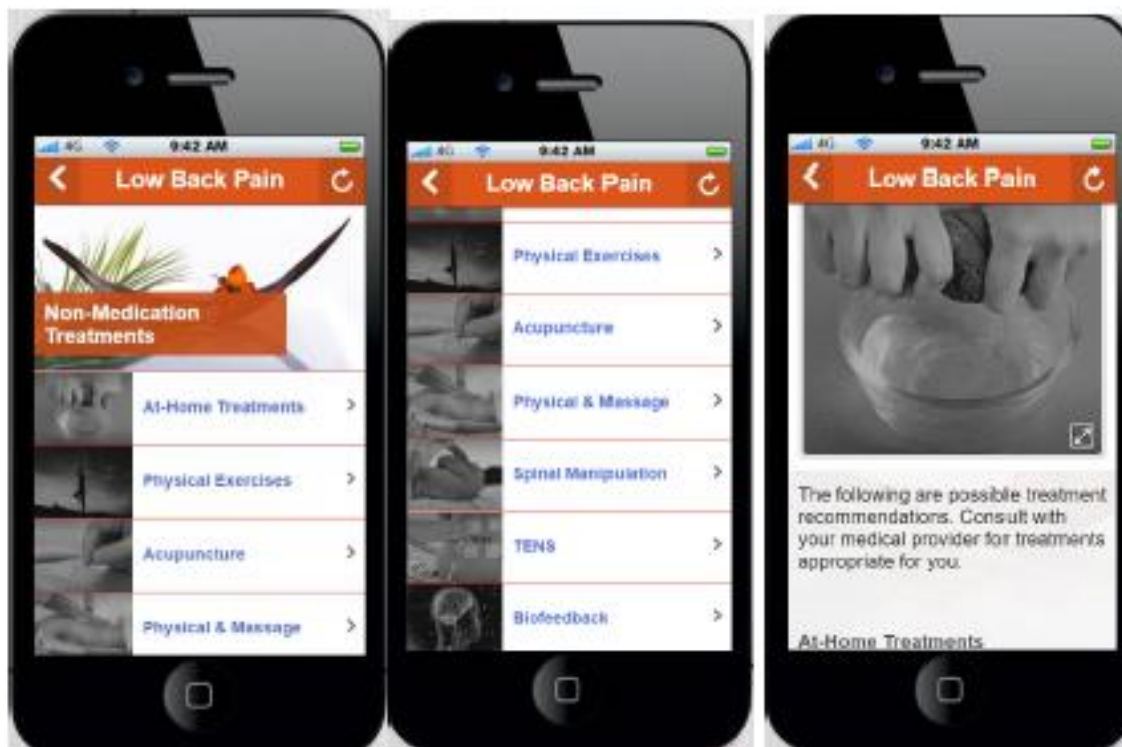
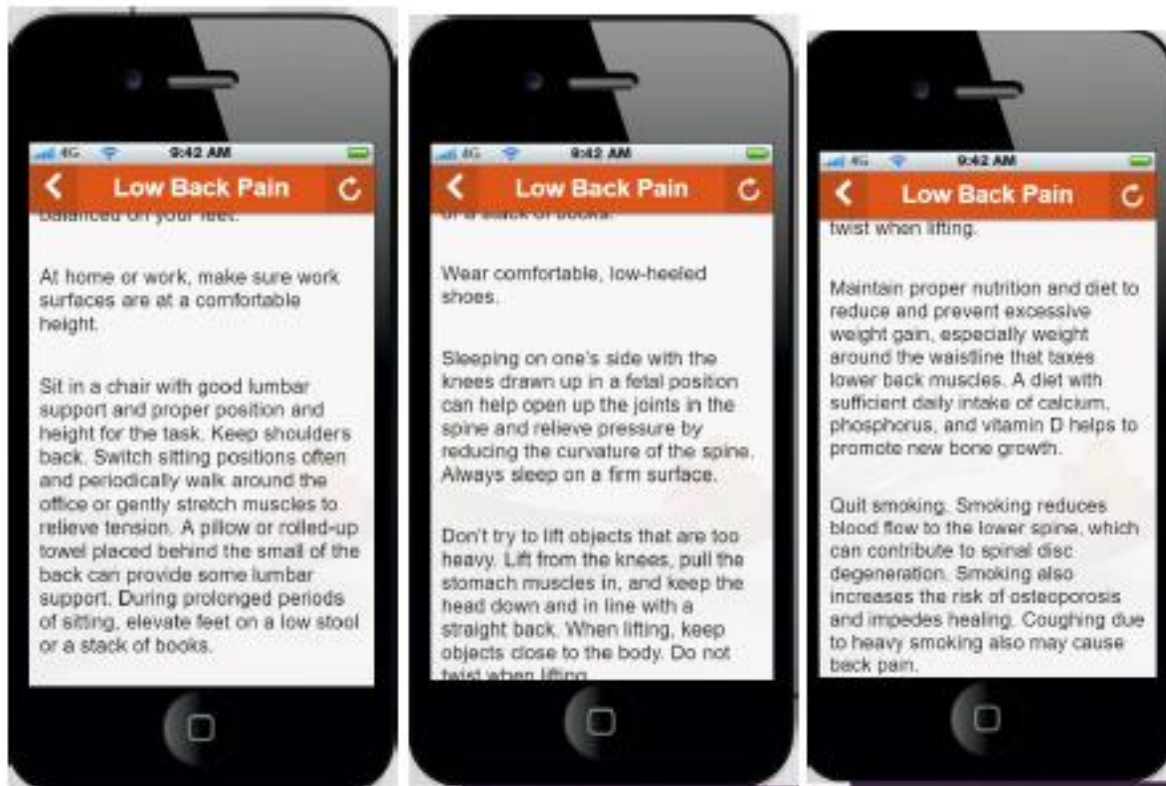


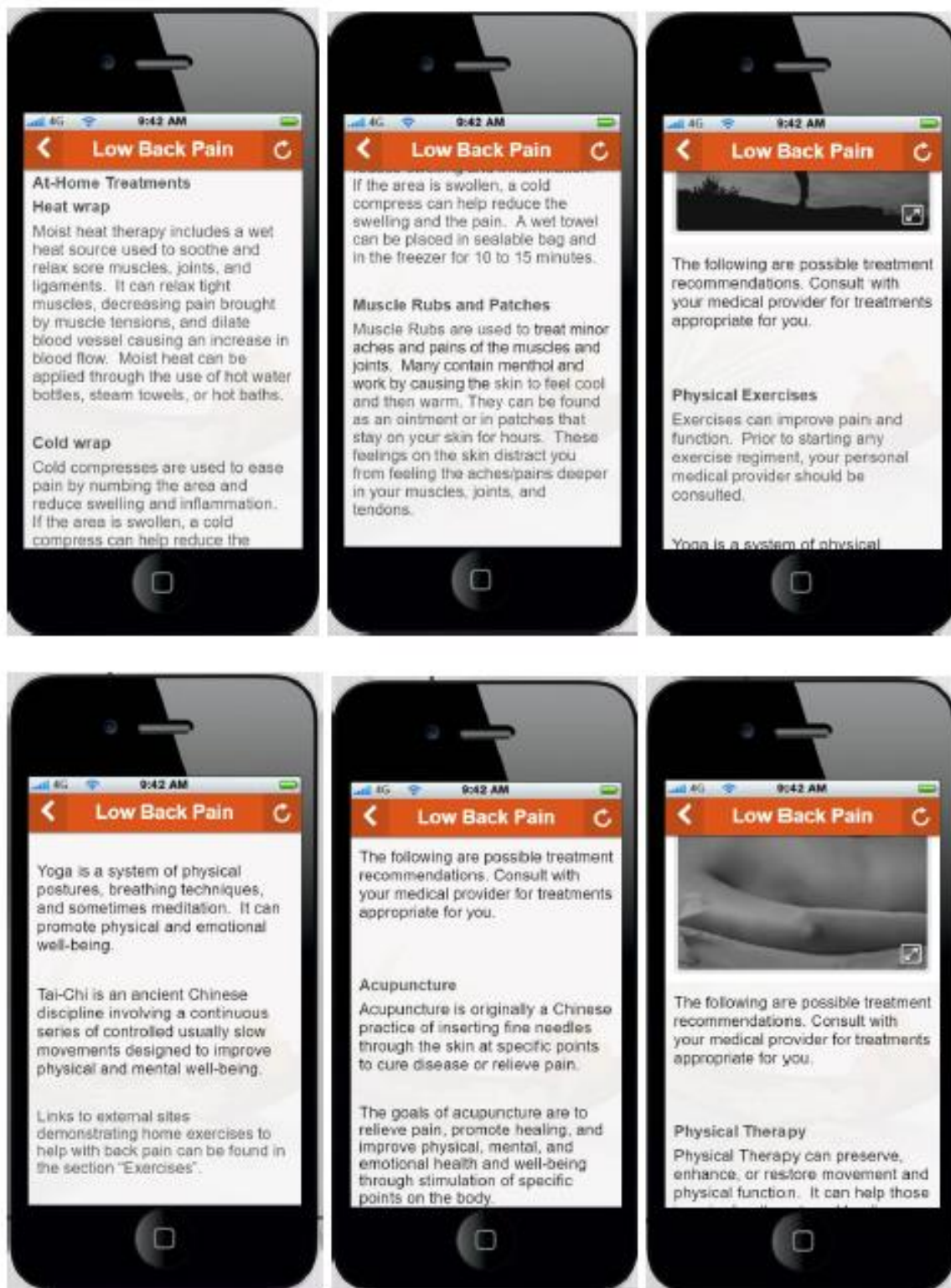


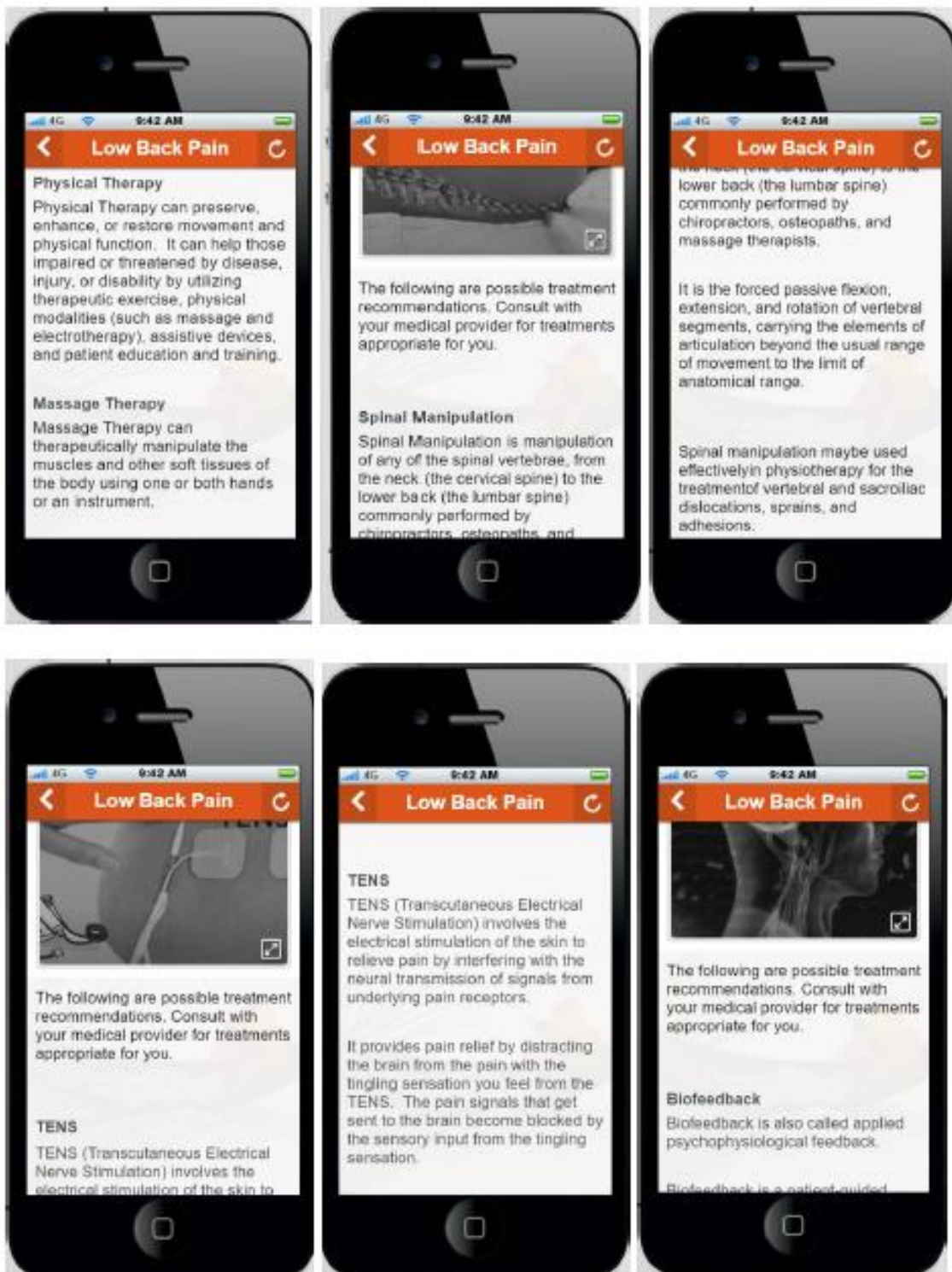


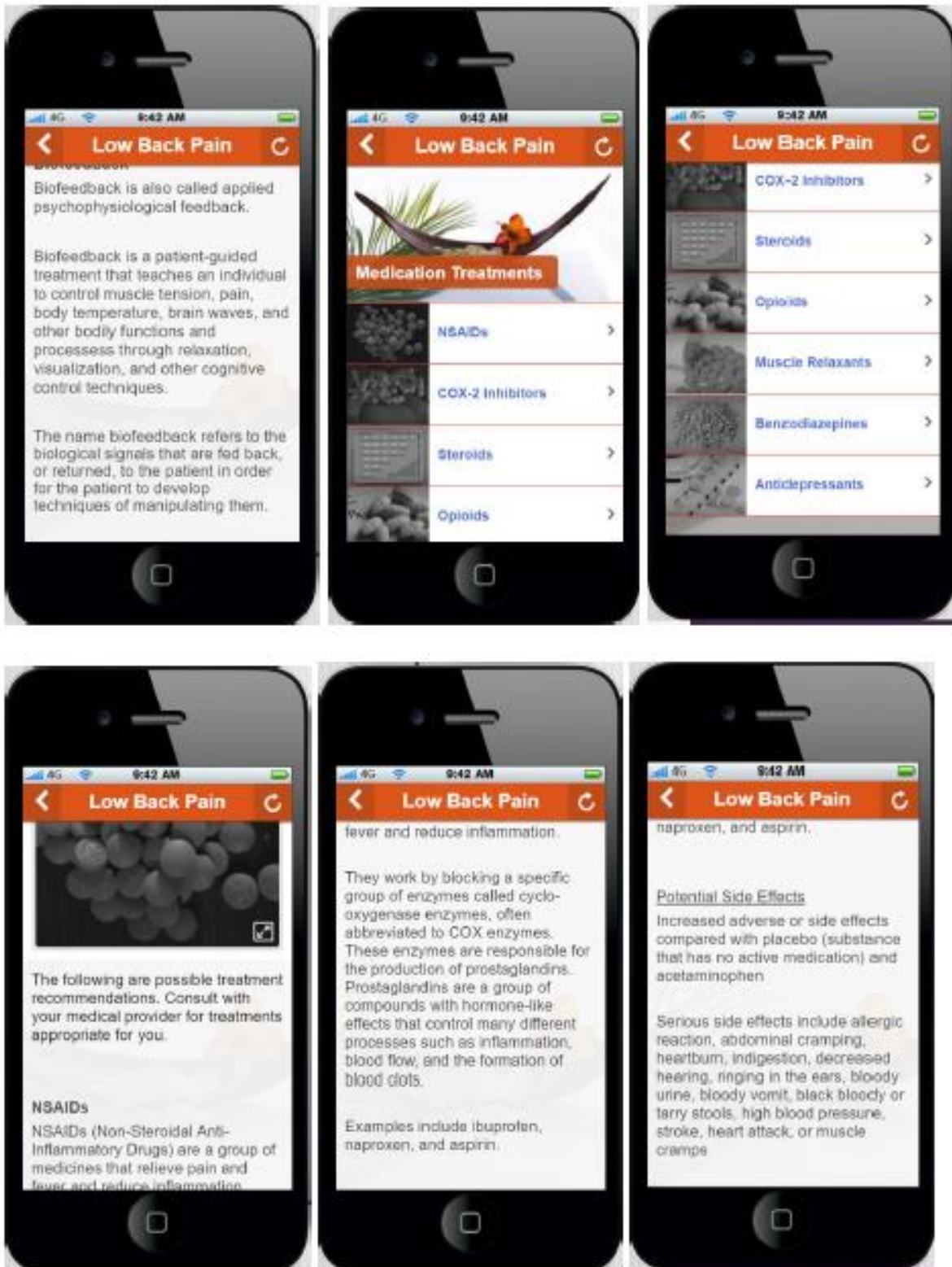
Section 10: Treatment

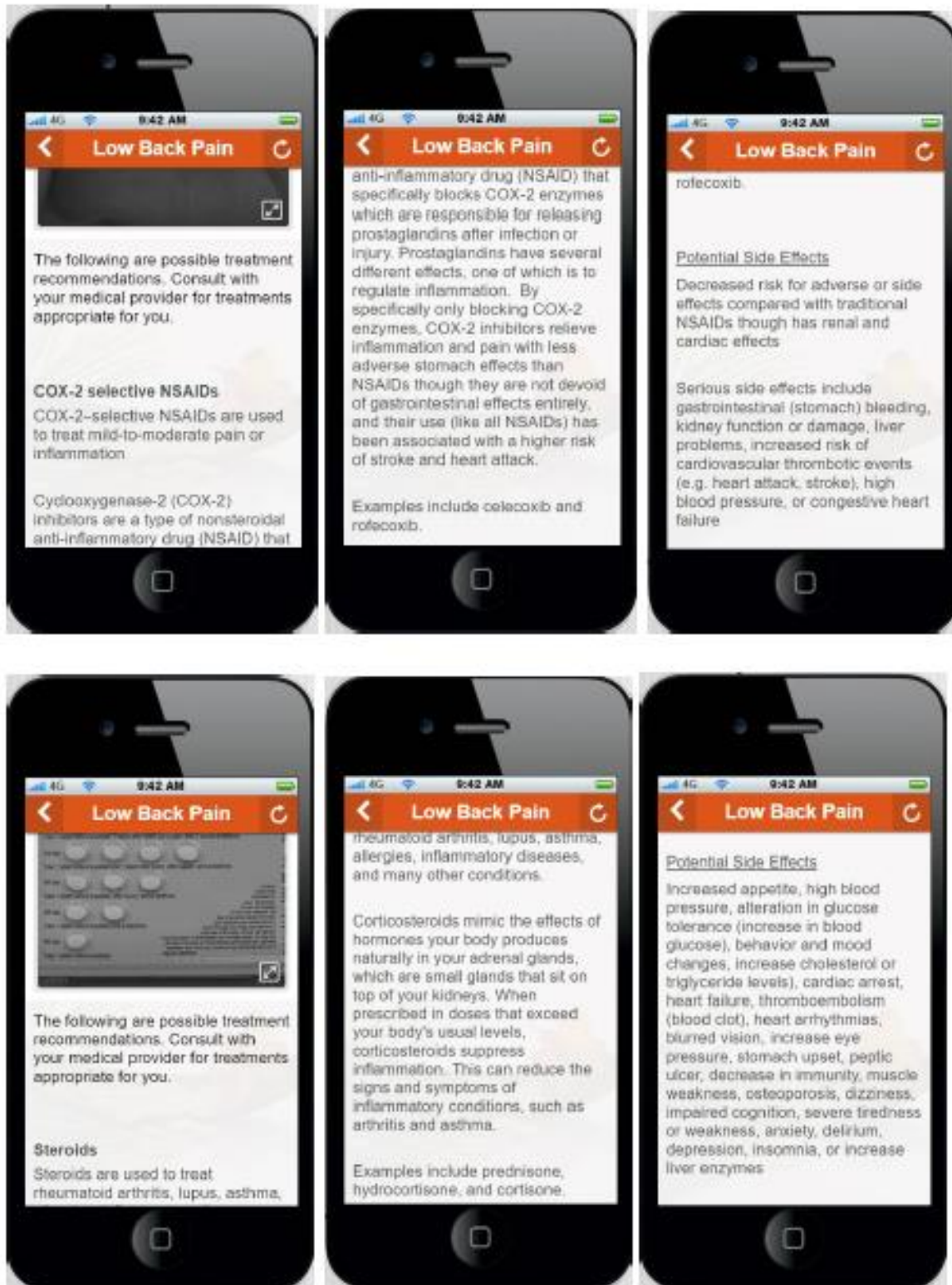


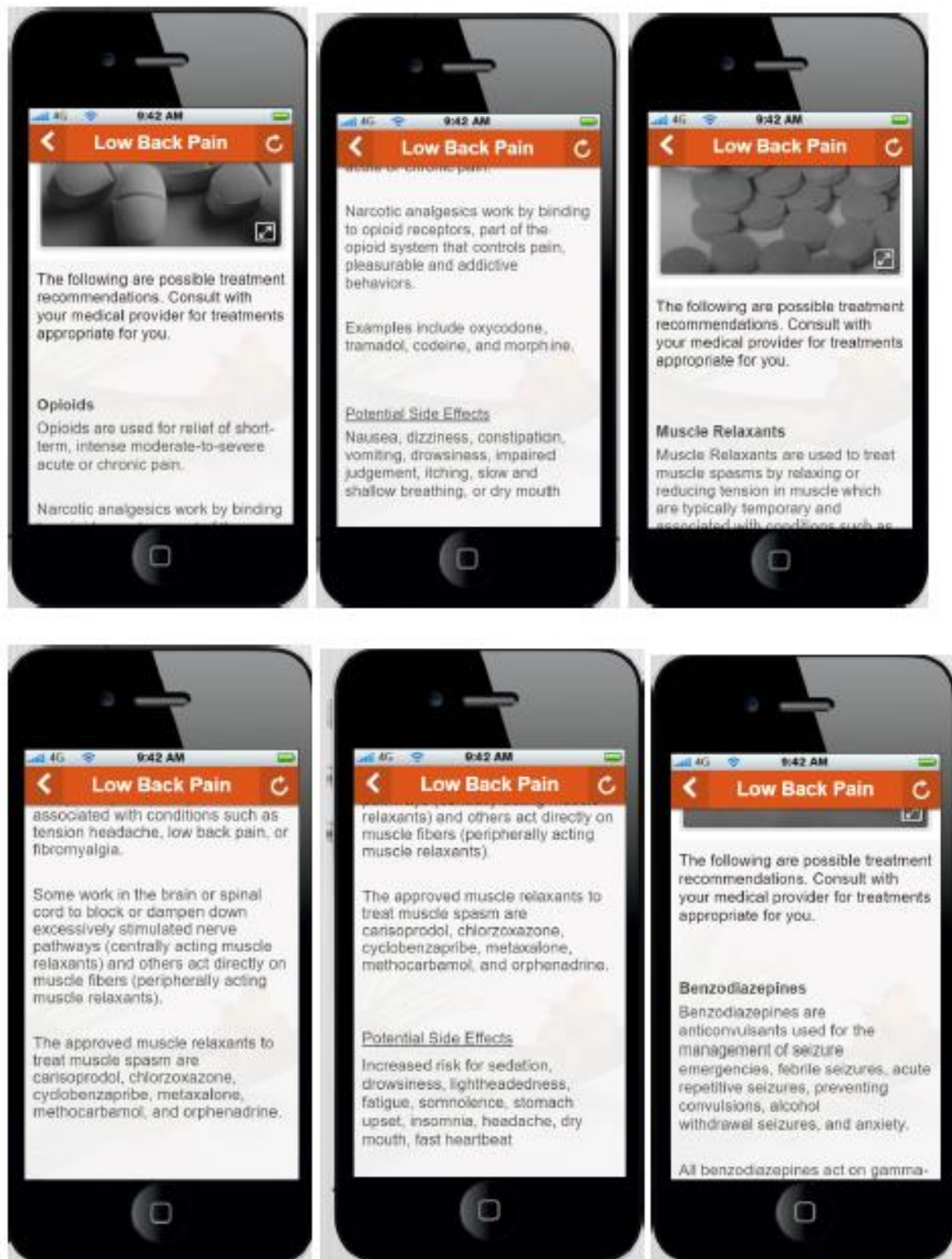


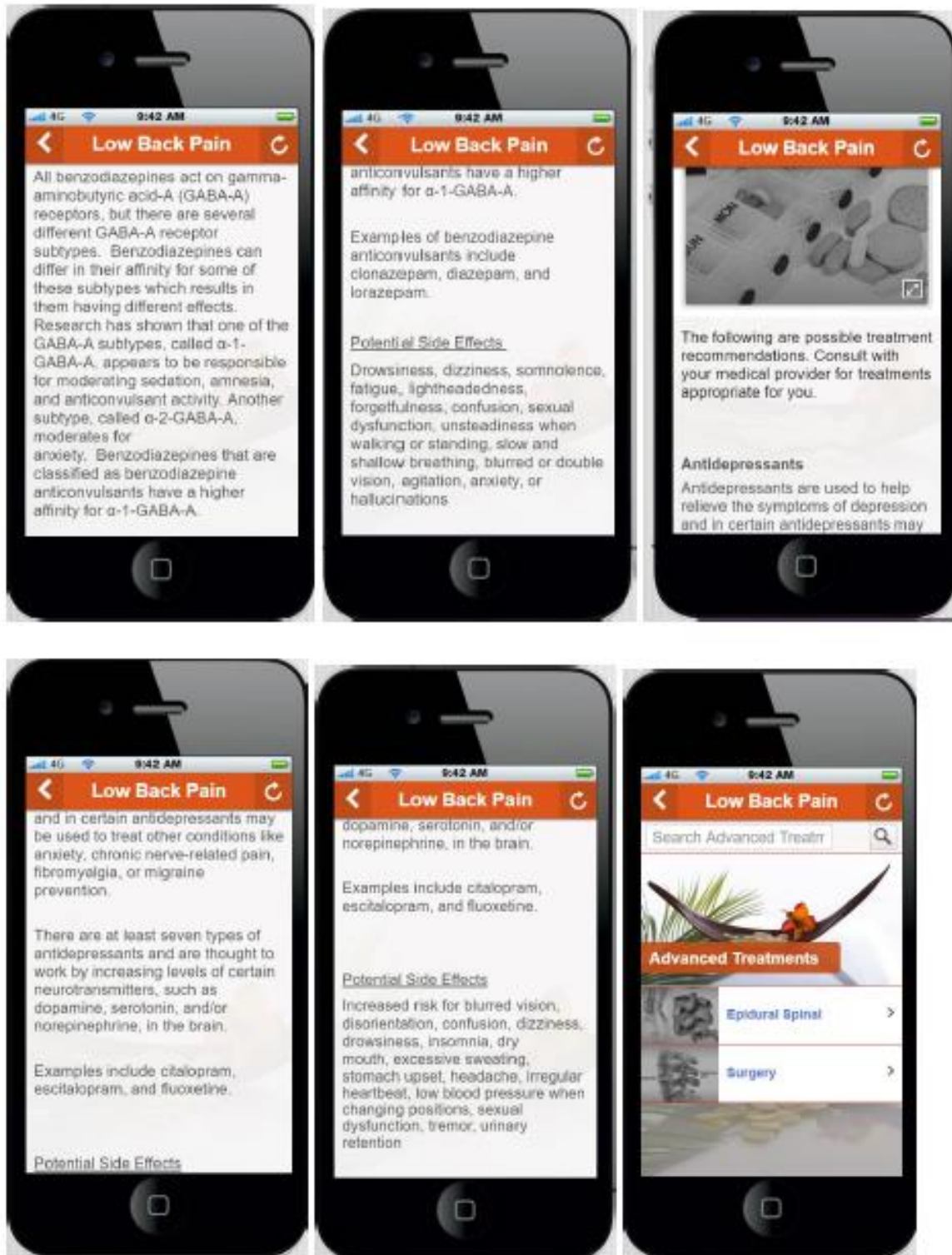


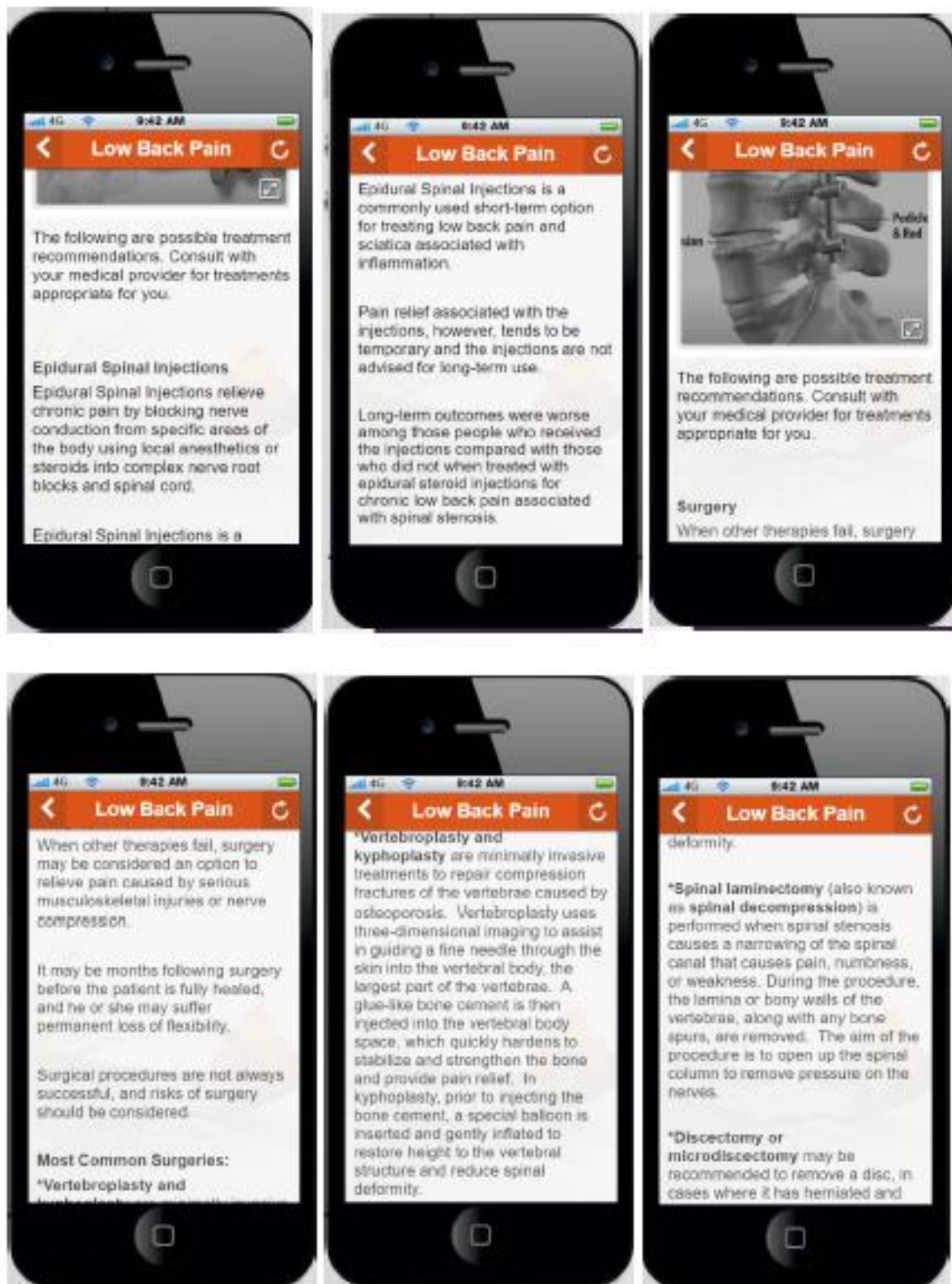


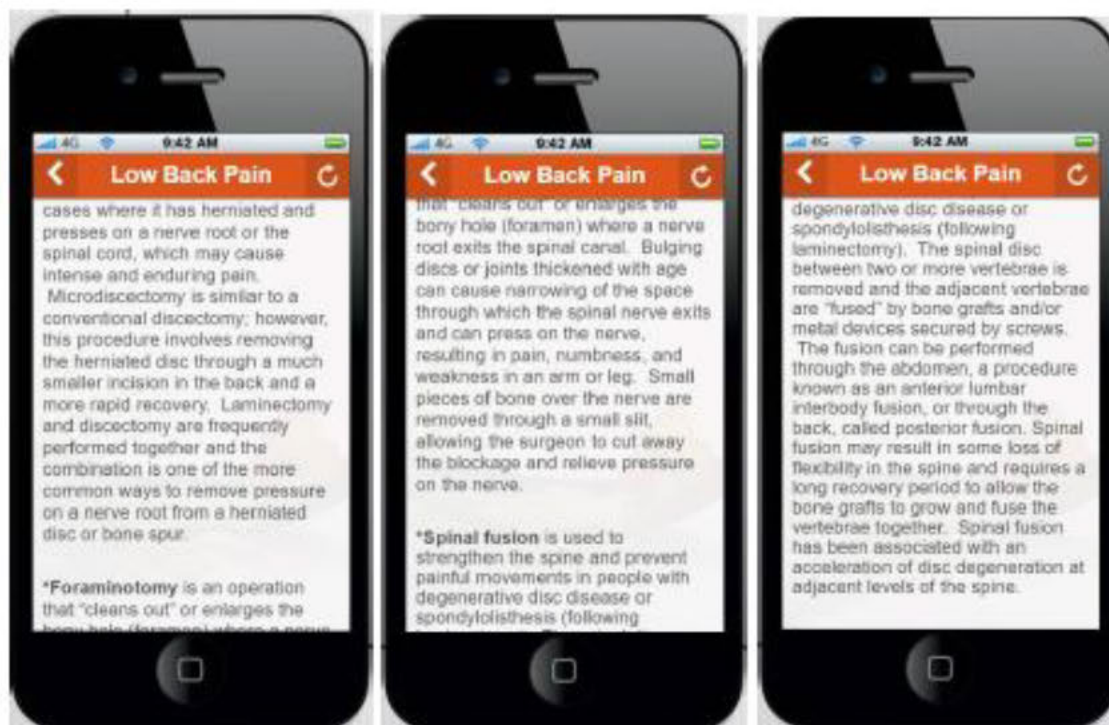












Section 11: Exercises



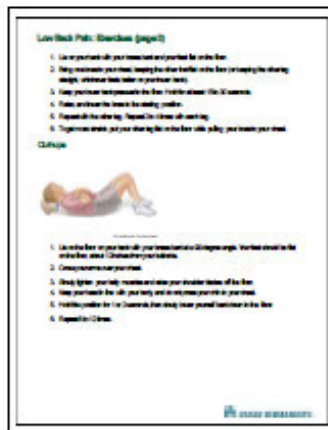
Kaiser Permanente Exercises



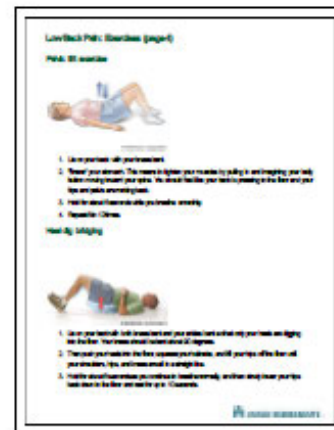
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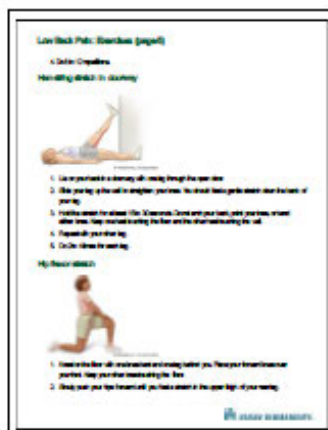
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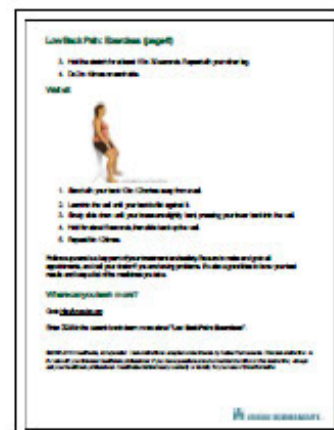
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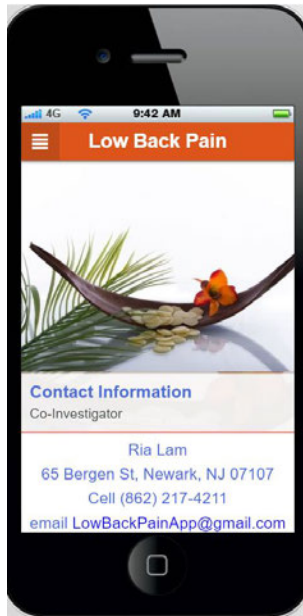


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6

Section 12: Contact Information



Section 13: References



Appendix C

Application of the KTA Model

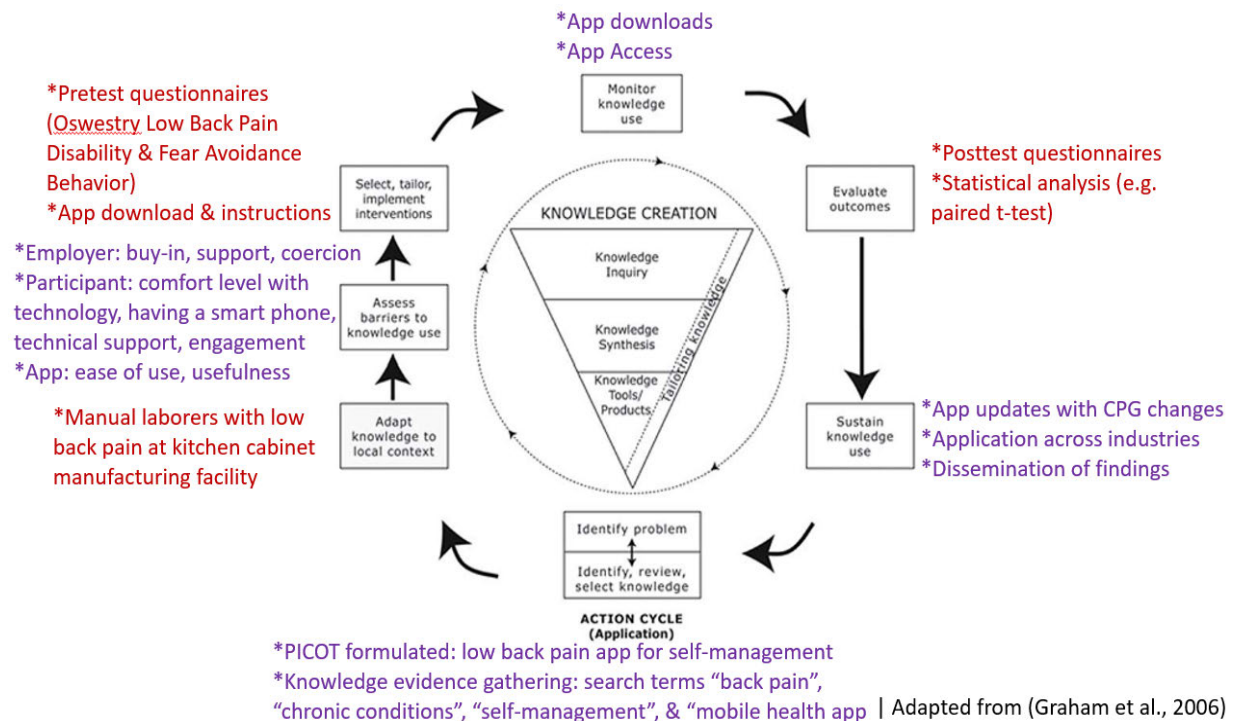


Figure 1. Application of the KTA Model to the Self-Management App Project. Adapted from "Lost in knowledge translation: Time for a map?", by I. D. Graham, J. Logan, M. B. Harrison, S. E. Straus, J. Tetroe, W. Caswell, and N. Robinson, 2006, *Journal of Continuing Education in the Health Professions*, 26(1), p. 19.

Appendix D

Demographics Questionnaire



Participant ID # _____

Demographics Questionnaire

1. How old are you? _____ years old

2. What is your gender?

- ☐ Male
- ☐ Female
- ☐ Other

3. What is your ethnicity?

- ☐ White
- ☐ Hispanic or Latino
- ☐ Black or African American
- ☐ Native American or American Indian
- ☐ Asian / Pacific Islander
- ☐ Other _____

4. What is your highest level of education?

- ☐ Middle School
- ☐ High School
- ☐ College
- ☐ Graduate



Participant ID # _____

- ☐ Post-graduate
 - ☐ Doctorate
 - ☐ Other
5. What is your marital status?
- ☐ Single, never married
 - ☐ Married
 - ☐ Widowed
 - ☐ Divorced
 - ☐ Separated
6. What is your job title at your work? _____
7. How long have you worked at your job? _____
8. How long have you had low back pain? _____
9. How comfortable are you using apps on your smart phone or device?
- ☐ Very comfortable
 - ☐ A little comfortable
 - ☐ Neutral
 - ☐ A little uncomfortable
 - ☐ Very uncomfortable

Appendix E

Oswestry Low Back Disability Questionnaire – ODI Version 2.1a

This questionnaire is designed to give us information as to how your back (or leg) trouble affects your ability to manage in everyday life.

Please answer every section. Mark one box only in each section that most closely describes you today.

Section 1 - Pain intensity

- ☐ I have no pain at the moment.
- ☐ The pain is very mild at the moment.
- ☐ The pain is moderate at the moment.
- ☐ The pain is fairly severe at the moment.
- ☐ The pain is very severe at the moment.
- ☐ The pain is the worst imaginable at the moment.

Section 2 - Personal care (washing, dressing, etc.)

- ☐ I can look after myself normally without causing additional pain.
- ☐ I can look after myself normally but it is very painful.
- ☐ It is painful to look after myself and I am slow and careful.
- ☐ I need some help but manage most of my personal care.
- ☐ I need help every day in most aspects of my personal care.
- ☐ I do not get dressed, I wash with difficulty and stay in bed.

Section 3 - Lifting

- ☐ I can lift heavy weights without additional pain.
- ☐ I can lift heavy weights but it gives me additional pain.
- ☐ Pain prevents me from lifting heavy weights off the floor but I can manage if they are conveniently positioned, e.g. on a table.
- ☐ Pain prevents me from lifting heavy weights but I can manage light to medium weights if they are conveniently positioned.
- ☐ I can only lift very light weights.
- ☐ I cannot lift or carry anything at all.

Section 4 - Walking

- ☐ Pain does not prevent me from walking any distance.
- ☐ Pain prevents me from walking more than one mile.
- ☐ Pain prevents me from walking more than a quarter of a mile.
- ☐ Pain prevents me from walking more than 100 yards.
- ☐ I can only walk using a cane or crutches.
- ☐ I am in bed most of the time and have to crawl to the toilet.

Section 5 - Sitting

- ☐ I can sit in any chair as long as I like.
- ☐ I can sit in my favorite chair as long as I like.
- ☐ Pain prevents me from sitting for more than 1 hour.
- ☐ Pain prevents me from sitting for more than half an hour.
- ☐ Pain prevents me from sitting for more than 10 minutes.
- ☐ Pain prevents me from sitting at all.

Section 6 - Standing

- ☐ I can stand as long as I want without additional pain.
- ☐ I can stand as long as I want but it gives me additional pain.
- ☐ Pain prevents me from standing for more than 1 hour.
- ☐ Pain prevents me from standing for more than half an hour.
- ☐ Pain prevents me from standing for more than 10 minutes.
- ☐ Pain prevents me from standing at all.

Section 7 - Sleeping

- ☐ My sleep is never interrupted by pain.
- ☐ My sleep is occasionally interrupted by pain.
- ☐ Because of pain I have less than 6 hours sleep.
- ☐ Because of pain I have less than 4 hours sleep.
- ☐ Because of pain I have less than 2 hours sleep.

- ☐ Pain prevents me from sleeping at all.

Section 8 - Sex life (if applicable)

- ☐ My sex life is normal and causes no additional pain.
- ☐ My sex life is normal but causes some additional pain.
- ☐ My sex life is nearly normal but is very painful.
- ☐ My sex life is severely restricted by pain.
- ☐ My sex life is nearly non existent because of pain.
- ☐ Pain prevents me from having any sex life at all.

Section 9 - Social life

- ☐ My social life is normal and causes me no additional pain.
- ☐ My social life is normal but increases the degree of pain.
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g. sport, etc.
- ☐ Pain has restricted my social life and I do not go out as often.
- ☐ Pain has restricted my social life to home.
- ☐ I have no social life because of pain.

Section 10 - Traveling

- ☐ I can travel anywhere without pain.
- ☐ I can travel anywhere but it gives me additional pain.
- ☐ Pain is bad but I am able to manage trips over two hours.
- ☐ Pain restricts me to trips of less than one hour.
- ☐ Pain restricts me to short necessary trips of under 30 minutes.
- ☐ Pain prevents me from traveling except to receive treatment.

*Figure 2. Oswestry Low Back Disability Questionnaire. From "The Oswestry Disability Index", by J.C. Fairbank and P.B. Pynsent, 2000, *Spine*, 25(22), pp. 2940-2952.*

Appendix F

Fear-Avoidance Beliefs Questionnaire

Here are some of the things which other patients have told us about their pain. For each statement please circle any number from 0 to 6 to say how much physical activities such as bending, lifting, walking or driving affect or would affect *your* back pain.

	Completely disagree	1	2	3	4	5	6 Completely agree
1. My pain was caused by physical activity.....	0	1	2	3	4	5	6
2. Physical activity makes my pain worse.....	0	1	2	3	4	5	6
3. Physical activity might harm my back.....	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse.....	0	1	2	3	4	5	6

The following statements are about how your normal work affects or would affect your back pain

	Completely disagree	1	2	3	4	5	6 Completely agree
6. My pain was caused by my work or by an accident at work.....	0	1	2	3	4	5	6
7. My work aggravated my pain.....	0	1	2	3	4	5	6
8. I have a claim for compensation for my pain.....	0	1	2	3	4	5	6
9. My work is too heavy for me.....	0	1	2	3	4	5	6
10. My work makes or would make my pain worse.....	0	1	2	3	4	5	6
11. My work might harm my back.....	0	1	2	3	4	5	6
12. I should not do my normal work with my present pain.....	0	1	2	3	4	5	6
13. I cannot do my normal work with my present pain.....	0	1	2	3	4	5	6
14. I cannot do my normal work till my pain is treated.....	0	1	2	3	4	5	6
15. I do not think that I will be back to my normal	0	1	2	3	4	5	6

work within 3 months.								
16. I do not think that I will ever be able to go back 0	1	2	3	4	5		6	
to that work.....					5			

Scoring

Scale 1: fear-avoidance beliefs about work – items 6, 7, 9, 10, 11, 12, 15.

Scale 2: fear-avoidance beliefs about physical activity – items 2, 3, 4, 5.

Figure 3. Fear-Avoidance Beliefs Questionnaire. From “A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability,” by G. Waddell, M. Newton, I. Henderson, D. Somerville

Appendix G

Recruitment Flyer



RUTGERS

School of Nursing

RESEARCH PARTICIPANTS NEEDED

Study: Self-Management App for Low Back Pain



Principal Investigator, Dr. Irina Benenson from Rutgers School of Nursing is conducting a research study about self-managing your low back pain using a mobile health application. Using sources from evidence-based research and established institutions, this app will have informative educative modules and advisement to help you manage your low back pain. The self-management app addresses the psychosocial aspect of low back pain. The goal is to determine if using this app has an effect on physical functioning and fear-avoidance behaviors in manual laborers.

Participants will be given access to download the low back pain app to your smart phone or device for use during the **4-week study period starting MONDAY, NOVEMBER 11, 2019.**

Participation is voluntary. As a participant in this study, you will be asked to participate in:

- 1) Questionnaires prior to the start of the study
- 2) Download and use the low back pain app for 4 weeks
- 3) Reply to end of the week e-mails on app usage with a single number (#days used)
- 4) Questionnaires at the end of the study

To be eligible to participate, you must be at least 18 years old or older, have some degree of low back pain, fluent in reading and writing English, work as a laborer in your job, have an app-capable mobile device with internet access, and an e-mail address.

You cannot participate if you had spinal surgery, nor if you currently have either numbness, tingling, pain in your legs, pain unrelieved by rest, severe pain, injury or pain in any other body part, and conditions of the heart or lungs that makes physical activity unsafe.

An on-site recruitment session and consenting with the availability to ask questions face-to-face is scheduled for **MONDAY, NOVEMBER 11, 2019.** Light refreshments will be served. All on-site visits will be held at the staff kitchen at [REDACTED]

Contact: Dr. Irina Benenson (Principal Investigator)

[REDACTED]

Contact: Ria Lam (Co-Investigator)

[REDACTED]

e-mail: LowbackPainApp@aol.com

Rutgers, The State University of New Jersey

Appendix H

Eligibility to Participate Screening Questionnaire



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School of Nursing

Screen # _____

Eligibility to Participate Screening Questionnaire

Part I

Are you at least 18 years or older?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you <i>currently</i> have some degree of low back pain?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Are you fluent in reading and writing English?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you work in a role doing manual labor?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have an app-capable mobile device with internet access?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have an e-mail address?	<input type="checkbox"/> YES <input type="checkbox"/> NO

Part II

Have you ever had spinal surgery?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have any numbness, tingling, or pain in your legs?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have pain unrelieved by rest?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have any severe pain?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have an injury or pain in any other body part?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have any conditions of the heart or lungs that makes physical activity unsafe?	<input type="checkbox"/> YES <input type="checkbox"/> NO

Appendix I

Eligibility to Participate Answer Key


RUTGERS

School of Nursing

Screen # _____

Eligibility to Participate - Answer Key for Study Team

Part I

Are you at least 18 years or older?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you <i>currently</i> have some degree of low back pain?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Are you fluent in reading and writing English?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you work in a role doing manual labor?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have an app-capable mobile device with internet access?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have an e-mail address?	<input type="checkbox"/> YES <input type="checkbox"/> NO
STUDY TEAM: STOP if there are any NO responses. Respondent does not meet inclusion criteria. If all YES responses, proceed to Part II.	

Part II

Have you ever had spinal surgery?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have any numbness, tingling, or pain in your legs?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have pain unrelieved by rest?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have any severe pain?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have an injury or pain in any other body part?	<input type="checkbox"/> YES <input type="checkbox"/> NO
Do you have any conditions of the heart or lungs that makes physical activity unsafe?	<input type="checkbox"/> YES <input type="checkbox"/> NO
STUDY TEAM: STOP if there are any YES responses. Respondent has exclusion criteria. If all NO responses, proceed to consenting.	

Appendix J

Consent Form



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CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: Engaging Self-Management with a Low Back Pain App in Manual Labor Workers
Principal Investigator: Irina Benenson, DNP, FNP-C

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help the participant decide whether the participant wants to take part in this study. It is the participant's choice to take part or not.

The purpose of the research is to determine if using a phone application (app) for self-management of low back pain has an effect on physical functioning and fear avoidance beliefs in manual labor workers.

Self-management is active participation by a patient in his or her own health care decisions and interventions through education and guidance of professional caregivers to promote his or her own optimal health or recovery. It is a form of treatment that addresses the non-medical aspect of low back pain.

The low back pain app was developed by the co-investigator using expert resources and research articles. The app includes information about low back pain, structures of the lower back, risk factors and causes of low back pain, red flag signs, types of diagnostic testing, types of providers, at-home treatments, non-medication treatments, medication treatments and their potential risks, preventative measures, links to external sites with exercises to do at home, and references used in developing the app. All references used in development is included within the app from reliable resources. This app was validated through beta testing by a physician, nurse practitioners, nurses, computer science specialists, and lay persons without health nor computer-related backgrounds.

If the participant wishes to take part in the research and is screened to be eligible by the co-investigator, the participant will be asked to fill out questionnaires. The first questionnaire will be taken before using the app and then a second time after four weeks of using the app. After these questionnaires are completed the first time, the low back pain the app will be downloaded to the participant's phone.

The participant will be asked to fill out questionnaires for demographics, fear-avoidance behaviors (Fear Avoidance Beliefs Questionnaire), and disability and physical functioning (Oswestry Low Back Pain Disability Questionnaire also known as Oswestry Disability Index). The scores for each questionnaire will be looked at to see if there are changes in the participant's beliefs on fear avoidance behavior and/or on the participant's physical functioning. Fear avoidance behavior is based on the theory that a person with pain is avoiding activity due to believing that activity causes the participant's pain.

The participant will receive regular emails communicating suggestions on areas to review in the app. Also, participants will be asked to send a weekly response on how many days they logged into the app and used it. After 4 weeks of using the app, participants will again fill out the Fear Avoidance Beliefs and Oswestry Disability index questionnaires.



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The participant's time in the study will take 20 minutes to complete the survey, 10 minutes to download the app, time spent using the app at least 3 times per week and for a total 4 weeks of using the app, 1 minute to reply back to weekly end of the week e-mails with a single number representing the number of days app was used for that week, and then 20 minutes to complete the final questionnaires.

Possible harms or burdens of taking part in the study may be physical, emotional, and risk related to data safety. There is potential physical harm with performing certain physical activities. Should the participant's pain worsen, stop the activity immediately and consult with the participant's private medical provider. If the participant does not have a private medical provider, the participant can be provided a list of local urgent care centers. Emotional harm may occur if participants develop fear of resuming physical activity. In this event, participants should consult with their private medical provider. There is potential for the participant's data safety being compromised. Participants' information will be de-identified with the connection to the de-identified information maintained for the shortest amount of time to obtain the post-intervention results. Once the scores are obtained, the link of the participant to the data will be destroyed. Possible benefits of taking part may be having a portable app educating the participant on low back pain to help manage the participant's low back pain, encourage the participant to resume normal activities earlier, improve physical functioning, and decrease fear-avoidance behaviors.

An alternative to taking part in the research study is seeking medical treatment only with the participant's private medical provider. The participant's alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of the participant if the participant choose to take part in it. If the participant has any questions now or during the study, the participant should feel free to ask them and should expect to be given answers the participant completely understands. After all of the participant's questions have been answered and the participant wishes to take part in the research study, the participant will be asked to sign this consent form. The participant is not giving up any of the participant's legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this study?

Dr. Irina Benenson is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Irina Benenson may be reached at [REDACTED] and 65 Bergen St, 1115, Newark, NJ 07107.

The Principal investigator or another member of the study team will also be asked to sign this informed consent. The participant will be given a copy of the signed consent form to keep.

Why is this study being done?

This study is being done to determine if using a self-management app for low back pain has an effect on physical functioning and fear avoidance beliefs. Self-management and prior studies have shown it is



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effective with other medical conditions. By having the manual laborer self-manage their low back pain, the study will look at whether it leads to less fear of being active even when experiencing pain. It will also look at whether those who use the app to self-manage their low back pain will lead to improvements in their everyday physical activities and reducing disability or physical limitations.

Who may take part in this study and who may not?

Adult, 18 years or older, male and female workers who currently has any degree of low back pain and works in a manual labor role from the kitchen cabinetry factory. The participant must be fluent in reading and writing English, have an app-capable phone or mobile device with internet access, and an e-mail address.

Those who have spinal surgery or have symptoms down their legs could have a more severe back problem. The participant cannot participate in the study if the participant ever had back surgery, nor if the participant has any numbness, tingling, pain in the legs, pain unrelieved by rest, or pain anywhere other than the participant's lower back. The participant cannot participate in exercises if there is severe pain, injury, or pain in any other body part, nor if there are conditions of the heart or lungs that makes physical activity unsafe.

Why have I been asked to take part in this study?

The participants are being asked to take part in this study because this study is looking for workers in a manual labor role and experiencing current low back pain. Manual labor workers experiencing low back pain may not be able to carry through their job safely and can lead to further injury or inability to continue working their normal role. Also, employees in manufacturer roles have the second highest incident rate for a work-place injury. As a participant with an app-capable phone with internet access, the participant has the ability to download and use the app for your educational purpose during the study.

How long will the study take and how many subjects will take part?

The total number of subjects to be screened is 50 manual labor workers. All participants who meet inclusion criteria will be included. The project will aim to recruit at least 25 participants.

Participants are expected to take part in the study for 4 weeks total.

The participant's time in the study will take 20 minutes to complete the survey, 10 minutes to download the app, time spent using the app at least 3 times per week and for a total 4 weeks of using the app, 1 minute to reply back to weekly end of the week e-mails with a single number representing the number of days app was used for that week, and then 20 minutes to complete the final questionnaires.

What will I be asked to do if I take part in this study?

1. The co-investigator will administer and review your responses to questions to determine eligibility to participate. If deemed eligible to participate by the co-investigator, the consenting procedure will be done.
2. If the participant meets the criteria, the participant will be asked to sign a consent form to participate in this study and provide an e-mail address.
3. After the participant consents to participate, the participant will be given 3 questionnaires to complete. This includes a questionnaire of the participant's demographic information (e.g. age, gender, education), the Oswestry Disability Low Back Pain questionnaire looking at the participant's physical function and abilities, and a Fear-Avoidance Behaviors questionnaire looking at the participant's beliefs about how the participant's pain affects the participant's physical activity or work.
4. After completing the questionnaires, the participant will be expected to connect to the internet and download the low back pain app onto the participant's phone or mobile device.
5. The participant will use the app and review the app at least 3 times a week for a total of 4 weeks.



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6. An e-mail will be sent out at the beginning of each week to remind the participant to use it with suggestions on what sections to look at with e-mail reminders mid-week to use the app.
7. At the end of each week, the participant will receive an e-mail asking for the participant to reply back with a single number representing the number of days the participant used the app for that week.
8. At the end of the 4 weeks, the participant will be given 2 paper questionnaires to complete. This includes the 2 questionnaires the participant completed before downloading the app, the Oswestry Disability Low Back Pain questionnaire on the participant's physical functioning and the Fear-Avoidance Behaviors questionnaire on the participant's beliefs about how the participant's pain affects the participant's physical activity or work.

What are the risks of harm or discomforts I might experience if I take part in this study?

The potential risks or harm are minimal, but may include physical, emotional, and risks related to data safety. There is potential physical harm with performing certain physical activities. If a participant's pain worsens, he or she must stop immediately and consult with their private medical provider. If the participant does not have a private medical provider, the participant can be provided a list of local urgent care centers.

Emotional harm may occur if participants develop fear of resuming physical activity. In this event, participants should consult with their private medical provider. If the participant does not have a private medical provider, the participant can be provided a list of local urgent care centers.

There is potential for the participant's data safety being compromised. The participant's information will be de-identified and a link to the participant's information will be passcode-protected and available only to the research team members. This connection to the de-identified information will be maintained for the shortest amount of time to obtain the scores of the participant's questionnaires to compare them to the participant's original responses. Once all scores are obtained and recorded, connecting it to the participant's original score, this link will be destroyed.

Are there any benefits to me if I choose to take part in this study?

The benefits of taking part in this study include having access to an app that educates the participant on low back pain. The app will help inform the participant of the participant's condition and provide information on home exercises the participant can do if approved by the participant's private medical provider. Taking an active participation in the participant's care may lead to an improvement in physical functioning and lessen the occurrence of fear-avoidance behaviors. However, it is possible that the participant may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?

The following alternative treatments are available if the participant choose not to take part in this study: Seek medical treatment only with the participant's private medical provider. The participant's alternative is not to take part in this study.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the course of the study, the participant will be updated about any new information that may affect whether the participant is willing to continue taking part in the study. If new information is learned that may affect the participant after the study or the participant's follow-up is completed, the participant will be contacted.



Will I receive the results of the research?

In general, we will not give the participant any individual results from the study. If we find something of urgent medical importance to the participant, we will inform the participant, although we expect that this will be a very rare occurrence. This may include the scores of the participant's questionnaires looking at the participant's physical disability and the participant's beliefs about low back pain and fear-avoidance behaviors so the participant can follow-up with the participant's private medical providers. The participant will be notified by confidential e-mail after analysis of research data are concluded, which may take up to six months.

Will there be any cost to me to take Part in this study?

There will be no cost to the participant. The low back pain app will be free and will be available for the participant's continued use at no cost until May 2020. The app will no longer be available starting June 1, 2020.

Will I be paid to take part in this study?

The participant will not be paid to take part in this study.

How will information about me be kept private or confidential?

All efforts will be made to keep the participant's personal information in the participant's research record confidential, but total confidentiality cannot be guaranteed.

Participants will be provided a sequential identification (ID) number by the co-investigator. This ID number will be written on the questionnaires administered. These questionnaires will be administered by the co-investigator. Aside from the ID number, the questionnaires will not have information that can identify the participant as the participant. This link between the ID number assigned to the individual participant, called a master link, will be kept in an encrypted passcode-protected excel spreadsheet in the co-investigator's dedicated computer. This computer is only accessible to the co-investigator, locked with a passcode, and in a RU cloud-based storage.

The completed paper questionnaires will be stored in a locked cabinet at the principal investigator's location in office 1127 at the School of Nursing at Rutgers University at 65 Bergen Street, Newark, NJ 07107. Once the questionnaires are scored and entered into a spreadsheet database, the questionnaires and the master link at this point will be destroyed. All data will be destroyed in accordance with Rutgers University guidelines upon completion of the project and closure of the IRB. Hard copies of consents and data will be stored in office 1127 at the School of Nursing at Rutgers University at 65 Bergen Street, Newark, NJ 07107.

All e-mail correspondences will be through LowBackPainApp@gmail.com. This e-mail account will be accessible to the co-investigator only on the passcode-secured dedicated computer. All e-mail correspondences sent will be permanently deleted at the end of each week. All received e-mail correspondences will be recorded for app usage and then immediately deleted permanently.

What will happen to my information or biospecimens collected for this research after the study is over?

The information collected about the participant for this research will not be used by or distributed to investigators for other research.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?



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It is the participant's choice whether to take part in the research. The participant may choose to take part, not to take part or the participant may change the participant's mind and withdraw from the study at any time.

If the participant do not want to enter the study or decide to stop taking part, the participant's relationship with the research staff and the participant's work or employment status will not change, and the participant may do so without penalty and without loss of benefits to which the participant are otherwise entitled.

The participant may also withdraw the participant's consent for the use of data already collected about the participant, but the participant must do this in writing to co-investigator Ria Lam 65 Bergen Street, 1127, Newark, NJ 07107.

Who can I contact if I have questions?

If the participant has questions about taking part in this study or if the participant feels the participant may have suffered a research related injury, the participant can call the study co-investigator: (Ria Lam, Rutgers School of Nursing, (862) 217-4211.)

If the participant has questions about the participant's rights as a research subject, the participant can call the IRB Director at:
Newark HealthSci (973) 972-3608 or the Rutgers Human Subjects Protection Program at (973) 972-1149 or email us at humansubjects@ored.rutgers.edu.

AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print): _____

Subject Signature: _____ Date: _____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

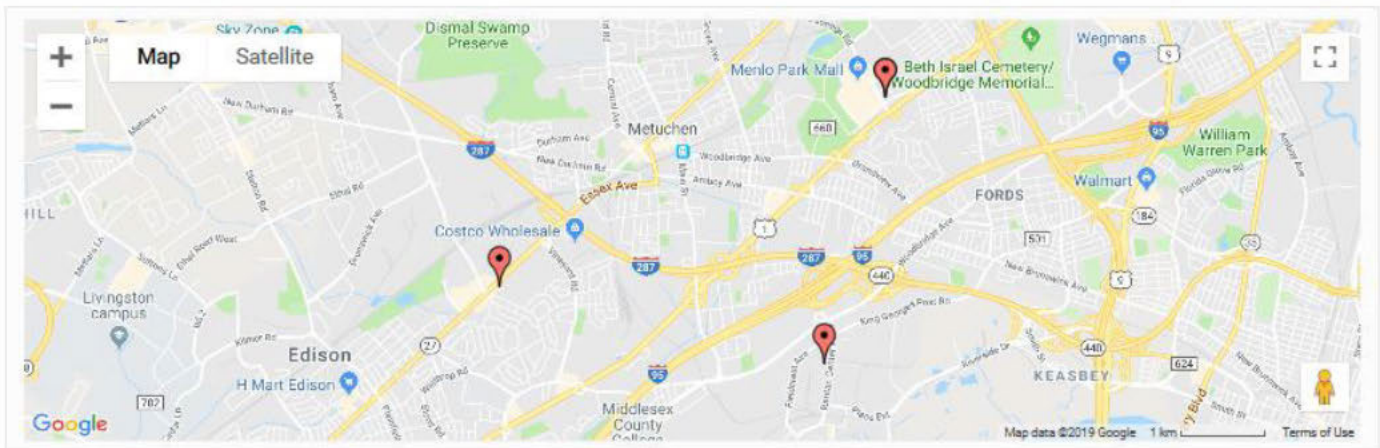
Investigator/Person Obtaining Consent (Print): _____

Signature: _____ Date: _____

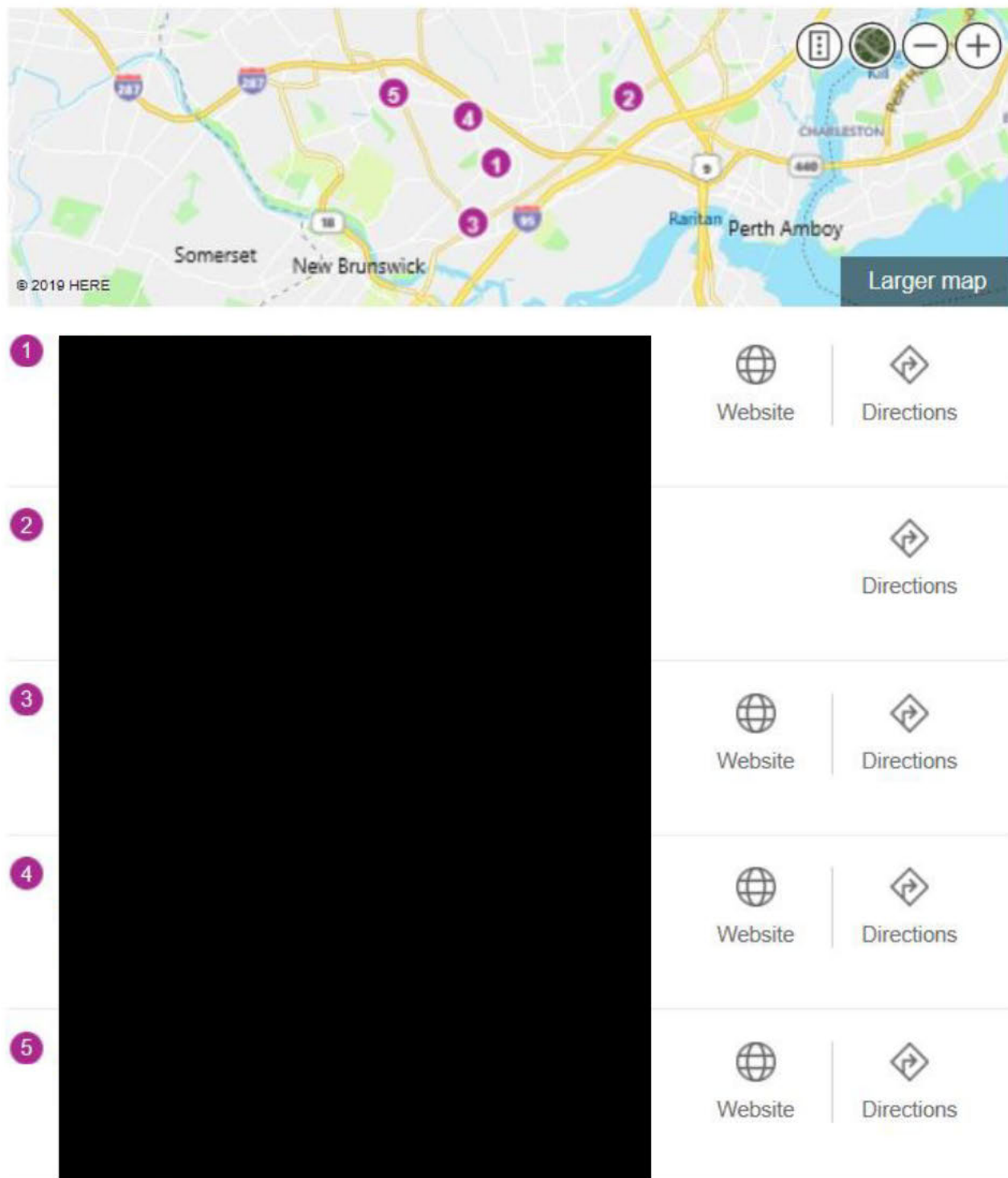
Appendix K

List of Nearby Medical Providers

Urgent Care Centers in Edison, New Jersey

Map of LocationsLocations List

Provider Name	Address	Phone Number	
C			View Details
F			View Details
M			View Details
U			View Details



Appendix L

E-mail Communications

Signature at the end of every e-mail

Regards,
Ria Lam, APN-C (Co-Investigator)
DNP student from Rutgers School of Nursing
65 Bergen St, Newark, NJ 07107

LowBackPainApp@gmail.com

Reminder: Please report back any app-related issues promptly. Remember to consult with your private medical provider prior to engaging in any physical activity. Should you experience any distress or increase in pain, immediately cease any activities and contact your private medical provider. Your participation is voluntary, and you may choose to leave the study at any time.

Introductory e-mail

You are receiving this e-mail because you have consented to be a participant in a research study on self-managing your low back pain with an app.

If you have not yet downloaded the app, use either the link below or a QR code reader to do so.

1. [Low Back Pain App Download Link](#)

Scan QR code



2. or use a QR code reader

This app includes educational modules on low back pain. This includes modules on general information, causes of low back pain, red flag signs to report to your private medical provider promptly, types of providers who treat low back pain, and more. There are links to external sites to home exercises that may help you when performed consistently but be sure to check with your private medical provider if there are any concerns with your participating.

Learning and knowing about your condition will hopefully give you a better understanding and motivate you to be active in your own care.

For the next 4 weeks, please login the app at least 3 times a week. There will be e-mails twice a week reminding you to login to use the app. At the end of each week, you will receive an e-mail requesting you to reply back with the number of days you used the app during the week.

Feel free to contact me with any questions.

Week 1

Welcome to week 1 of the Low Back Pain App Research Study!

Be sure to login to the app 3 times this week. The following are examples of suggested uses of the app for this week:

Day 1:

- Read the module “About Low Back Pain”
- Take a look at some of stretches and exercises you can do at home

Day 2:

- Read the module “Structure of the Lower Back”
- Try one gentle stretch when you wake up

Day 3:

- Read the module “Risk Factors”
- Try one gentle stretch when you wake up and at the end of the day

Feel free to contact me with any questions.

Mid-week 1

Take a look at “About Low Back Pain” and “Structure of the Lower Back” if you have not done so yet.

Remember to take a stretch break!

End of Week 1:

This is your end of the week check-in for Week 1. Reply back with the number of days this week you went into the Low Back Pain App.

For example, if you went into the Low Back Pain App at least once during the day on Monday, Tuesday, and Friday this week, then reply back with the number 3. Your response will be noted, and the e-mail immediately deleted.

Week 2

Welcome to week 2 of the Low Back Pain App Research Study!

Be sure to login to the app 3 times this week. The following are examples of suggested uses of the app for this week:

Day 1:

- Read the module “Causes of Low Back Pain”
- Try 2 gentle stretches when you wake up and at the end of the day

Day 2:

- Read the module “Red Flag Signs”
- Try 2 or 3 gentle stretches when you wake up and at the end of the day on most days

Day 3:

- Read the module “Types of Providers”
- Try 3 or 4 gentle stretches when you wake up and at the end of the day on most days

Feel free to contact me with any questions.

Mid-week 2

Take a look at “Causes of Low Back Pain” and “Red Flag Signs” if you have not done so yet.

Try a stretch break twice a day!

End of Week 2:

This is your end of the week check-in for Week 2. Reply back with the number of days this week you went into the Low Back Pain App.

For example, if you went into the Low Back Pain App at least once during the day on Monday, Tuesday, and Friday this week, then reply back with the number 3. Your response will be noted, and the e-mail immediately deleted.

Week 3:

Welcome to week 3 of the Low Back Pain App Research Study!

Be sure to login to the app 3 times this week. The following are examples of suggested uses of the app for this week:

Day 1:

- Read the module “Types of Providers”
- Continue your stretches and check out the external link to Kaiser Permanente Exercises. Consult with your private medical provider to see which ones are right for you

Day 2:

- Read the module “Diagnostic Testing”
- Continue your stretches and check out the external link to McKenzie Exercises. Consult with your private medical provider to see which ones are right for you

Day 3:

- Read the module “Treatment – General Info”

Continue your stretches and exercises most days of the week

Mid-week 3

Take a look at “Types of Providers” and “Diagnostic Testing” if you have not done so yet.

Remember to take a stretch break!

End of Week 3:

This is your end of the week check-in for Week 3. Reply with the number of days this week you went into the Low Back Pain App.

For example, if you went into the Low Back Pain App at least once during the day on Monday, Tuesday, and Friday this week, then reply back with the number 3. Your response will be noted, and the e-mail immediately deleted.

Week 4

Welcome to the final week 4 of the Low Back Pain App Research Study!

Be sure to login to the app 3 times this week. The following are examples of suggested uses of the app for this week:

Day 1:

- Read the module “Treatment – Non-Medication Treatments”
- Continue your stretches and check out the external link to Mayo Clinic exercises. Consult with your private medical provider to see which ones are right for you.

Day 2:

- Read the module “Treatment – Medication Treatments”

- Continue your stretches and check out the external link to OnHealth Exercises. Consult with your private medical provider to see which ones are right for you.

Day 3:

- Read the module “Treatment – Advanced Treatments”
- Continue your stretches and exercises most days of the week

Feel free to contact me with any questions.

Mid-week 4

Take a look at “Treatment – Non-Pharmacologic” and “Treatment – Pharmacologic” if you have not done so yet.

Remember to take a stretch break!

End of Week 4:

This is your end of the week check-in for Week 4. Reply with the number of days this week you went into the Low Back Pain App.

For example, if you went into the Low Back Pain App at least once during the day on Monday, Tuesday, and Friday this week, then reply back with the number 3. Your response will be noted, and the e-mail immediately deleted.

Final e-mail:

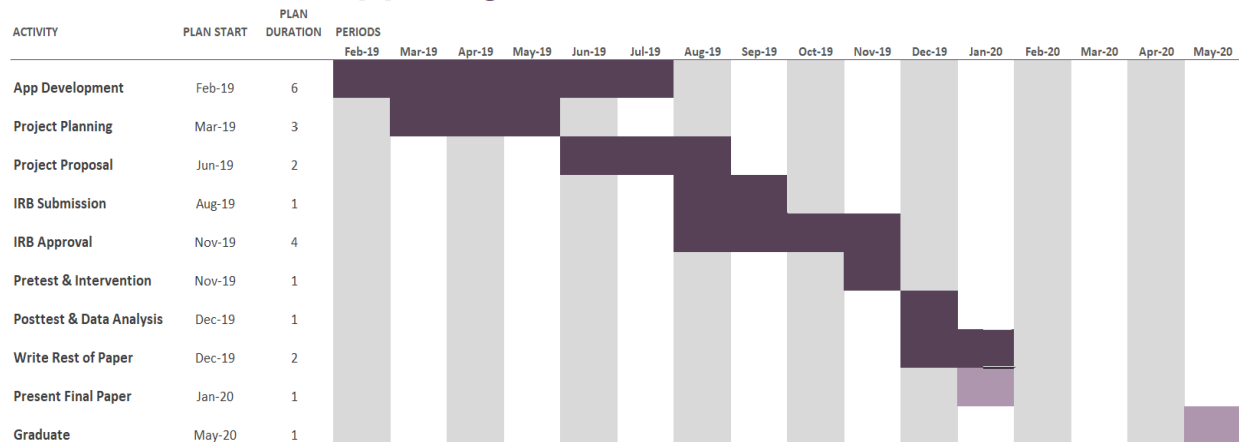
This concludes the four-week research study using the Low Back Pain app. I will have the final questionnaires for you to fill out during my visit at Forevermark Cabinetry on DATE XX/XX/XXXX. The app will continue to be available for your use at your leisure until the end of May 2020.

Thank-you again for your participation.

Appendix M

Project Timeline

Low Back Pain App Project Timeline



Appendix N
Project Budget

Table 2

Project Budget

Expense		Cost		Total Cost
SPSS Software		\$175	\$	175.00
Swiftic App Annual Membership		\$316.61	\$	316.61
Recruitment Flyers		50 x 0.15	\$	7.50
Light Refreshments		\$50 x 2 on-site visits	\$	100.00
Questionnaire Handouts (pre)	0.02/page x 6 pages x 90 copies		\$	10.80
Questionnaire Handouts (post)	0.02/page x 4 pages x 90 copies		\$	7.20
Dissemination Posters		\$75	\$	75.00
Total Budget			\$	692.11