Evaluation of the Construct Validity of the Questionnaire to Identify Knee Symptoms Among Individuals Across Canada with Chronic Knee Pain

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Abstract

The primary purpose of this study was to evaluate the construct validity of the Questionnaire to Identify Knee Symptoms (QuIKS) measurement scale among individuals with chronic knee symptoms consistent with osteoarthritis. Construct validity was assessed using tests of convergent and discriminative validity on 15 pre-specified hypotheses. The secondary objective was to determine the internal consistency reliability of the QuIKS. One hundred and five individuals recruited in select physiotherapy clinics from across Canada were mailed the QuIKS and five other health questionnaires. Fifty-five individuals completed the questionnaire package. While none of the pre-specified construct validity hypotheses were met, nine of the validity analyses supported the construct validity of the QuIKS. The results also supported the internal consistency reliability of the QuIKS, as Cronbach’s alpha for the scale was 0.81. Overall, the QuIKS appears to be a valid tool to quantify illness behaviour in individuals with chronic knee symptoms.

Keywords: Knee osteoarthritis, questionnaire, psychometrics, screening
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Chapter 1

1 Introduction

Knee osteoarthritis (OA) affects all the tissues of the synovial joint, including the cartilage, bone, meniscus, ligament, tendon, and synovium (Lane et al., 2011). It is estimated that 13% of Canadians and over 300 million people worldwide have OA (Bombardier, Hawker, & Mosher, 2011; Vos et al., 2017). OA is also a major contributor to disability, as it is ranked as the 10th leading cause of disability in Canada and 12th worldwide (Vos et al., 2017). Additionally, the number of individuals with OA, and the disability attributed to this condition, is increasing (Hay et al., 2017).

Knee OA has various modifiable and non-modifiable risk factors. Modifiable risk factors, such as obesity and muscle dysfunction, can be influenced through conservative interventions, and thus are targets for the management of knee OA. While total joint replacement is reserved for individuals with advanced disease or severe pain and functional limitations (Nelson et al., 2014), most knee OA should be managed with education and self-management, weight management, exercise, and corticosteroid injections (McAlindon et al., 2014). However, due to the inability of current diagnostic methods to detect early-stage disease, these treatment strategies have not been comprehensively evaluated in early-stage knee OA, where they are likely to be most effective at preventing disability.

The diagnostic criteria for OA are widely debated, but there has been a recent shift away from imaging-based diagnoses. OA is now considered a clinical diagnosis and imaging is only to be utilized to exclude competing differential diagnoses (Wenham, Grainger & Conaghan, 2014). Major guidelines now support the diagnosis of knee OA based solely on clinical symptoms and examination findings (Altman et al., 1986; National Institute for Health and Care Excellence, 2008; Zhang et al., 2010).

Despite imaging no longer being required to diagnose knee OA, screening attempts have been largely ineffective. Current diagnostic methods are designed to identify
late-stage disease (Jordan, Luta, Renner, Dragomir, Hochberg & Fryer, 1997; O’Reilly, Muir & Doherty, 1996), and thus are not ideal for screening. Patient self-report of symptoms is a cost-efficient method of screening for disease and previous attempts have been made to create screening instruments for knee OA (LaValley et al., 2001; Quintana et al., 2007; Roux et al., 2008; Marra et al., 2007). However, these instruments were developed from current diagnostic criteria and therefore unable to identify the early-onset of disease. An effective screening test should be sensitive to early stages of a disease, when the subsequent course of the disease may still be altered (Fletcher, Fletcher & Fletcher, 2014). Therefore, a new screening instrument that does not rely on late-stage disease criteria would be of benefit.

A new screening tool, the Questionnaire to Identify Knee Symptoms (QuIKS) has been developed to identify individuals with knee OA (Clark, Chesworth, Speechley, Petrella, & Maly, 2014). The QuIKS attempts to quantify illness behaviours of an individual with chronic knee pain (Hamilton, Wong, Gignac, Davis, & Chesworth, 2017). The QuIKS has undergone psychometric evaluation, including reliability and validity testing (Clark, Chesworth, Speechley, Petrella, & Maly, 2014, Hamilton et al., 2015). However, further psychometric testing of the QuIKS has been recommended (Hamilton, Wong, Gignac, Davis, & Chesworth, 2017), including evaluation of construct validity and reliability.

The QuIKS was developed as a discriminative measure to distinguish individuals along a continuum of illness behaviour. As the QuIKS was designed to measure the hypothetical construct of illness behaviour (Hamilton, Wong, Gignac, Davis, & Chesworth, 2017), it is important to understand the psychometric properties of this measure. While the QuIKS instrument has undergone preliminary testing of internal consistency reliability and construct validity in the same sample used to develop the measure, the developers recommended further evaluation in an independent sample of individuals with chronic knee symptoms (Clark, Chesworth, Speechley, Petrella, & Maly, 2014; Hamilton et al., 2015; Hamilton, Wong, Gignac, Davis, & Chesworth, 2017).
Construct validation determines if the measurement tool is an adequate measure of an unobservable construct (Cronbach & Meehl, 1955). A process of specific, a priori hypothesis testing is recommended to evaluate construct validity (Smith, 2005; Terwee et al., 2007). Convergent and discriminative validity tests are two commonly used construct validation methods (Cronbach & Meehl, 1955; Streiner, Norman, & Cairney, 2015). Convergent validation attempts to hypothesize and quantify how closely a measurement scale of the theoretical construct is related to other constructs and measures, and typically utilizes a correlation analysis undertaken at a single time-point (Streiner, Norman, & Cairney, 2015). Discriminative validation is used to distinguish between predictably different individuals or groups and requires the formulation of a hypothesis about which known-groups of people will have higher or lower amounts of the construct under investigation, observed via scores on the measurement index (Streiner, Norman, & Cairney, 2015). In addition to validity, a measurement scale should demonstrate reliability (Carmines & Zeller, 1979). One type of reliability is evaluated using Cronbach’s alpha, a measure of internal consistency reliability (Cronbach, 1951).

The QuIKS could potentially be used as a screening tool to identify individuals with early-stage knee OA. However, the psychometric properties of the QuIKS must first be established. The QuIKS, if proven to have adequate validity and reliability, could be further evaluated as a diagnostic tool. The ability to identify the onset of knee OA could improve implementation of effective interventions in the early stages of disease, potentially slowing the progression of disease and preventing chronic disability.
1.1 Objectives

The overall objective of this study was to assess the psychometric properties of a self-administered questionnaire designed to identify the degree of illness behaviour in individuals with knee symptoms consistent with knee OA, and thus, aid in the validation of a tool for use in the clinical and research environment.

Specific objectives to achieve this goal were as follows:

*Objective 1:* The primary objective was to evaluate the construct validity of the QuIKS measure in a sample of adults with knee symptoms consistent with knee OA.

  *Objective 1A:* To evaluate the convergent validity of the QuIKS measure.

  *Objective 1B:* To evaluate the discriminative validity of the QuIKS measure.

*Objective 2:* The secondary objective was to assess the internal consistency reliability of the QuIKS measure in the same sample of individuals.
Chapter 2

2 Background Literature Review

Osteoarthritis (OA) is a highly prevalent disease and a leading cause of disability in Canada and worldwide (Vos et al., 2017). Early diagnosis of knee OA could result in less disability attributed to this disease (Burstein, 2009), but current diagnostic methods are only able to identify individuals with late-stage knee OA (Jordan, Luta, Renner, Dragomir, Hochberg & Fryer, 1997; O’Reilly, Muir & Doherty, 1996). This literature review will highlight the epidemiology, diagnosis, and management of knee OA, as well as the potential use of patient self-report questionnaires as screening tools. More specifically, a recap of the development of the Questionnaire to Identify Knee Symptoms will be presented along with a review of psychometric properties, namely construct validity and internal consistency reliability.

2.1 Osteoarthritis

2.1.1 Definition

OA is a complex disease that is difficult to define (Symmons, Mathers & Pfleger, 2006). OA was originally defined as a collection of disorders affecting the articular cartilage and subchondral bone of synovial joints (Altman et al., 1986). Newer conceptualizations of the disease acknowledge the heterogeneous presentations of OA, including the role of inflammation in disease pathogenesis (Kraus, Blanco, Englund, Karsdal & Lohmander, 2015; National Institute for Health and Care Excellence, 2014). There is increasing acceptance that OA does not represent a single joint disorder, but rather is a disease spectrum with multiple subsets leading to similar clinical and pathological findings (Hart & Spector, 1995). There has been a recent shift towards viewing OA as a syndrome with multiple phenotypes (Bruyere et al., 2015). Clinical, laboratory, imaging, and etiologic phenotypes have been proposed for knee OA (Deveza, Melo, Yamato, Mills, Ravi & Hunter, 2017). As such, knee OA is likely best defined as a disease of the whole-joint organ, affecting all the tissues of the
synovial joint, including the cartilage, bone, menisci, ligament, tendon, and synovium (Lane et al., 2011).

2.1.2 Epidemiology

It is estimated that over 300 million individuals worldwide have OA (Vos et al., 2017). OA has been shown to have a high prevalence wherever such statistics are available (Reginster, 2002), but estimates will vary depending on the case definition of OA utilized (Zhang & Jordan, 2010; Felson, Naimark, Anderson, Kazis, Castelli, & Mennan, 1987; Jordan et al., 2007; Lawrence et al., 2008; Quintana, Arostegui, Escobar, Azkarate, Goenaga, & Lafuente, 2008). Canadian prevalence estimates also differ based on the choice of OA definition (Kopec et al., 2007). The prevalence of OA was 10.8% in 2001 in the British Columbian population (Kopec et al., 2007), while another study found roughly 1 in 8 Canadians, or 13% of the population, had osteoarthritis in 2010 (Bombardier, Hawker, & Mosher, 2011).

OA is the most common joint disorder in the United States (Felson et al., 2000) with the knee being the most commonly affected (Newman et al., 2003). American prevalence estimates range from 10-19%, depending on the study sample and case definition used (Felson et al., 1988; Jordan, Linder, Renner, & Fryer, 1995; Jordan et al., 2007; Jordan, Linder, Renner, & Fryer, 1995; Jordan et al., 2007). These American figures are comparable to European and Asian estimates (Arden & Nevitt, 2006; Tang et al., 2016; Park et al., 2017). One global review found the knee OA prevalence to be 24% worldwide, but also provided individual estimates of self-reported, radiographic, and symptomatic knee OA (Pereira, Peleteiro, Araujo, Branco, Santos, & Ramos, 2011).

There is limited OA incidence data currently available (Zhang & Jordan, 2010). Data from the Framingham Osteoarthritis Study suggests that approximately 8% of women and 4% of men develop symptomatic knee OA per year (Felson et al., 1995). The estimated lifetime risk of developing knee OA has been reported in the range of 14-44%, depending on the case definition, study sample, and methodology utilized (Murphy et al., 2008; Losina et al., 2013).
The prevalence of OA is rising worldwide, as a 30% increase in the number of prevalent cases was observed between 2006 and 2016 (Vos et al., 2017). This trend has also been observed in Canada. One study found that prevalence of all forms of arthritis has increased from 13.4% to 17.6% between 1994 and 2002, an increase of roughly 50% of the percentage of Canadians reporting arthritis (Perruccio, Power, & Badley, 2006). It is expected the prevalence of arthritis in Canada will continue to rise with estimates between 21% and 26% by 2021 (Perruccio, Power, & Badley, 2006). Another projection found a 47% increase in the prevalence of self-reported arthritis is likely by 2031 (Badley, Rothman, & Wang, 1998). Based on a simulation model used in the 2011 report from the Arthritis Alliance of Canada, the projected prevalence of specifically OA is 25% of the population by 2040, or over 10 million Canadians (Bombardier, Hawker, & Mosher, 2011).

Kopec et al., (2008) found that incidence rates of OA increased in both British Columbian men and women between 1996-97 and 2003-04. The Arthritis Alliance of Canada used these findings in a 2011 report to predict future incidence rates of OA in the entire Canadian population (Bombardier, Hawker, & Mosher, 2011). Compared to 37,342 new diagnoses of OA in 2010, 469,467 new diagnoses of OA are predicted for 2040, which equates to a new OA diagnosis every 60 seconds. All available prevalence and incidence estimates suggest that OA will affect a large number of Canadians in the near future.

2.1.3 Burden

Knee OA has placed a large burden on health care systems worldwide. In the 2016 Global Burden of Disease Study, OA was the 12th leading cause of years lived with disability in the world (Vos et al., 2017). OA is one of the most common musculoskeletal disorders and ranks highly as a cause of morbidity and use of health services (American College of Rheumatology, 2000; Reginster, 2002; Picavet & Hazes, 2003). A report from the Centre for Disease Control and Prevention found that arthritis is the most common cause of disability in the American population, affecting approximately 8.6 million individuals (Centre for Disease Control and Prevention,
Over 350,000 total joint replacements are performed annually in the United States for knee and hip OA (Arden & Nevitt, 2006). This problem is compounded by population projections that show a drastic increase in the future population of persons over the age of 60 years (United Nations Department of Economic and Social Affairs, Population Division, 2017). This is likely to further increase the number of individuals with knee OA and overall economic burden (Woolf & Pfleger, 2003; Sun, Wu, & Kalunian, 2007). One study projected that by 2030, 25% of the total US population and 33% of the working adult population will have arthritis (Hootman & Helmick, 2006), of which a large proportion will have OA, causing significant impact throughout the entire economy.

In Canada, arthritis of all forms is the leading cause of disability and health care utilization (Health Canada, 2003), with annual cost estimates of $4.4 billion (Health Canada, 2002). OA in particular is the 10th leading cause of years lived with disability in Canada (Vos et al., 2017). An individual with OA typically costs the Canadian health care system around $5700 USD per annum (Maetzel, Li, Pencharz, Tomlinson, & Bombardier, 2004), which would rise by roughly $8600 if undergoing joint replacement (Hawker et al., 2009).

Knee OA also causes employed adults to reduce working hours and/or miss work altogether (Gignac, Cao, Lacaille, Anis, & Badley, 2008), which contributes to the overall economic burden through lost productivity. A 2010 estimate of the total economic burden of $27.5 billion was attributed to roughly 4.5 million cases of knee and hip OA (Bombardier, Hawker, & Mosher, 2011). However, Canada too is expected to see a rise in the incidence of new OA cases, equating to a staggering total economic burden of approximately $1.5 trillion by 2040 (Bombardier, Hawker, & Mosher, 2011). A large portion of this is due to the projection that about 30% of the Canadian workforce will have difficulty working due to OA (Bombardier, Hawker, & Mosher 2011). There is a clear need for a better understanding of OA to help reduce this potentially crippling financial burden.
2.2 Risk Factors for Knee Osteoarthritis

Knee OA is a complex condition that has many differing and potentially interacting risk factors. Several risk factors for the development and progression of this multifactorial condition have been identified in the literature. Some risk factors, such as sex, age, previous trauma, and knee alignment, cannot be altered through conservative interventions, and are thus considered non-modifiable risk factors. Modifiable risk factors, such as obesity and muscle dysfunction, can be influenced through conservative interventions. Non-modifiable risk factors may provide an opportunity to identify individuals at increased risk of developing knee OA, while modifiable factors may provide unique intervention targets to limit onset and progression of disease and provide symptomatic management for patients.

2.2.1 Non-Modifiable Risk Factors

*Sex*

The prevalence and incidence of knee OA is significantly greater in women than men (Oliveria, Felson, Reed, Cirillo, & Walker, 1995). Females are two times more likely than men to have OA and typically exhibit higher levels of disability (Statistics Canada, 2007). Females are also more likely to have more severe knee OA (Srikanth, Fryer, Zhai, Winzenberg, Hosmer, & Jones, 2005). However, sex does not seem to affect the progression of knee OA (Felson et al., 1995; Schouten, van den Ouweland, & Valkenburg, 1992). Higher disease rates and severity in females may be caused by the role of estrogen (Zhang & Jordan, 2010) or due to sex differences in bone strength, alignment, neuromuscular strength, pregnancy, and ligament laxity (Johnson & Hunter, 2014).

*Age*

Age is a strong risk factor for knee OA (Felson et al., 2000; Lawrence et al., 2008). The prevalence of knee OA significantly increases with age (Issa & Sharma, 2006). Prevalence and incidence rates of both radiographic and symptomatic OA in general
increase in the aging population (Arden & Nevitt, 2006). As individuals age, it is likely joints become more vulnerable to biomechanical insult and have a decreased reparative capacity (Arden & Nevitt, 2006). Moreover, age-related reductions in physical activity, muscle weakness, and knee joint laxity may also contribute to increased rates of knee OA in the elderly (Loeser & Shakoor, 2003; Rudloph, Schmitt, & Lewek, 2007). However, the exact mechanism(s) by which increasing age affects knee OA is not currently understood (Johnson & Hunter, 2014).

**Trauma**

Knee injury is one of the strongest risk factors for OA (Zhang & Jordan, 2010) and individuals who suffer a knee injury are at an increased risk of early-onset disease (Johnson & Hunter, 2014). Ruptures of the anterior cruciate ligament, meniscal tears and articular cartilage injuries are strongly linked to the development of knee OA (Roos, Ostenberg, Roos, Ekdahl, & Lohmander, 2001; Lohmander, Ostenberg, Englund, & Roos, 2004; Lohmander, Englund, Dahl, & Roos, 2007). Anterior cruciate ligament tears appear to be the most likely to result in knee OA, but the exact mechanism leading to this increased risk is poorly understood (Slauterbeck, Kousa, & Clifton, 2009). It is possible that OA develops as a result of the tissue damage during the initial injury (Buckwalter, 2002; Friel & Chu, 2013) or as a result of altered loading patterns that develop secondary to the knee injury (Chaudari, Briant, Bevill, Koo, & Andriacchi, 2008). Knee OA prevalence rates of up to 70% post-injury are commonly reported in the literature (Johnson & Hunter, 2014), but recent evidence suggests these figures may be overestimated. One study found a 13% prevalence of knee OA after an isolated anterior cruciate ligament rupture, but a higher prevalence of 21-40% if a meniscal injury occurred in combination (Oiestad, Engebretsen, & Storheim, 2009).

**Alignment**

Knee malalignment, or varus and valgus alignment, is a risk factor for the progression of knee OA. It is theorized that malalignment leads to abnormal mechanical forces through the knee joint (Johnson & Hunter, 2014). Varus alignment, or being bow-
legged, is typical in patients with medial compartment knee OA (Hunter, Sharma, & Skaife, 2009). Abnormal alignment has been shown to be strongly associated with increased structural damage in the compartment under greatest mechanical stress (Sharma, Song, Felson, Cahue, Shamiyeh, & Dunlop, 2001). For example, individuals with varus malalignment were four times more likely to experience progression of medial compartment knee OA, while individuals with valgus malalignment were five times more likely to undergo lateral compartment progression (Cerejo, Dunlop, Cahue, Channin, Song, & Sharma, 2002).

The role of knee alignment in the development of knee OA is less understood than its role in disease progression (Johnson & Hunter, 2014; Zhang & Jordan, 2010). There is biomechanical rationale that suggests knee alignment deformities could contribute to the development of knee OA, but this has not been well studied (Arden & Nevitt, 2006). The Rotterdam study found an increased risk of incident knee OA in varus and valgus aligned knees (Brouwer et al., 2007), while no increased risk of knee OA was found with knee alignment in the Framingham cohort (Hunter et al., 2007). This may indicate that malalignment is only a risk factor for disease progression and not for incident knee OA (Hunter et al., 2007). It is also possible the degree of malalignment may affect the incidence and/or progression of knee OA by influencing the impact of other risk factors, such as muscle dysfunction or obesity, thereby altering the load profile placed on the knee joint (Hunter, Sharma, & Skaife, 2009).

2.2.2 Modifiable Risk Factors

Obesity

Obesity, as measured by body mass index (BMI), is one of the strongest and most established risk factors for knee OA (Felson et al., 2000; Jiang et al., 2012). The association between obesity and knee OA is thought to be a result of both joint damage caused by excess joint loads and metabolic factors associated with obesity (Arden & Nevitt, 2006). Nearly two million individuals were followed for 4 years, and the incidence of knee OA was 19.5 per 1000 person-years for obese BMI individuals, but only 3.7 per 1000 person-years for normal BMI individuals (Reyes,
Leyland, Peat, Cooper, Arden, & Prieto Alhambra, 2016). It has been shown that for every 5-unit increase in BMI, there is a 35% increased risk of developing knee OA (Jiang et al., 2012), while a 5 kg reduction in body weight decreases the risk by 50% (Felson, Zhang, Anthony, Naimark, & Anderson, 1992; Christensen, Bartels, Astrup, & Bliddal, 2007).

The progression of knee OA is also affected by obesity (Felson et al, 2000). Increased weight has been shown to accelerate the structural deterioration of knee OA (Cooper et al., 2000). The risk of total knee arthroplasty is 41% greater in overweight BMI individuals and at least 97% greater in obese BMI individuals compared to normal weight individuals (Leyland et al, 2016). As obesity is an established risk factor for knee OA development and is increasing in prevalence, it is likely that a greater number of individuals will develop knee OA in the future (Johnson & Hunter, 2014).

Muscle Weakness

Deficits in muscle strength and activation are a risk factor and common in patients with knee OA (Johnson & Hunter, 2014). It is thought that muscle weakness and atrophy may be a product of disuse due to pain-avoidance by an individual with knee OA (Zhang & Jordan, 2010). Evidence exists that muscle weakness may influence the onset and progression of knee OA (Bennell, Wrigly, Hunt, Lim, & Hinman, 2013). The quadriceps femoris muscle is primarily implicated in the genesis of knee OA. It is hypothesized that quadriceps weakness leads to increased loads at the knee joint (Slemenda et al., 1998). Increasing muscle strength has been shown to be an effective treatment for improving pain and function in knee OA (Bennell, Wrigly, Hunt, Lim, & Hinman, 2013) as well as reducing the likelihood of developing knee OA (Slemenda et al., 1998). However, whether muscle strength can attenuate the progression of knee OA may depend on the influence of other risk factors, such as joint alignment (Arden & Nevitt, 2006). Currently, the relationship between muscle weakness and knee OA is not fully understood (Zhang & Jordan, 2010).
2.3 Management of Knee Osteoarthritis

The management of knee OA is targeted at the modifiable risk factors of the disease. Many guidelines for the management of knee OA have been published and are generally consistent in their recommendations (McAlindon et al., 2014; Fernandes et al., 2013; Hochberg et al., 2012; Nelson, Allen, Golightly, Goode, & Jordan, 2014). Patient management should be individualized based on patient expectations, risk factors, and pain and disability levels (Fernandes et al., 2013). One internationally developed guideline recommends that education and self-management, weight management, exercise, and corticosteroid injections are appropriate for all individuals with knee OA (McAlindon et al., 2014). Individuals with knee OA may also undergo surgical intervention if non-surgical interventions fail to adequately manage the disease. While arthroscopic procedures are no longer supported, high tibial osteotomies may be of value, and total joint replacement is recommended for individuals with end-stage disease or severe pain and functional limitations (Nelson et al., 2014; Richmond et al., 2010).

2.3.1 Education and Self-management

Education and self-management strategies are recommended as core treatments for all individuals with knee OA (McAlindon et al., 2014; Fernandes et al., 2013). Self-management strategies are defined as complex behavioural interventions targeted at patient education and behaviour modification, which encourage people with chronic disease to take an active role in the management of their own condition (Kroon, van der Burg, Buchbinder, Osborne, Johnston, & Pitt, 2014). In 2014, the Cochrane Library published a review of 29 randomized controlled trials assessing the effectiveness of self-management education programs (Kroon et al., 2014). Compared to usual care for individuals with OA, these interventions may improve self-management skills, pain, function, and symptoms, but only low to moderate quality evidence exists (Kroon et al., 2014). However, these interventions are unlikely to cause harm and thus should be implemented for all patients with knee OA (Kroon et al., 2014).
2.3.2 Weight Management

Weight management, defined as addressing weight loss if overweight or obese, is considered standard management for knee OA (McAlindon et al., 2014; Fernandes et al., 2013). Weight management encompasses a range of strategies, including dietary interventions, increasing physical activity, and eating behaviour education (Fernandes et al., 2013). While weight loss shows only small and likely insignificant improvements in pain levels, it has been shown to have a greater impact on disability (Christensen, Bartels, Astrup, & Bliddal, 2007). A 5% reduction in total body weight over a 20-week period is likely the cut-point to provide significant improvements in disability (Christensen et al., 2007). This improvement appears to be accomplished through dietary modification, exercise intervention, or both, which allows patient preference to be incorporated into the shared decision-making process (Christensen et al., 2007).

2.3.3 Exercise

Therapeutic exercise has been widely studied in the management of knee OA. All patients with knee OA should receive an individualized exercise program, which may involve resistance exercise, aerobic exercise, and range of motion or stretching exercises (McAlindon et al., 2014; Fernandes et al., 2013). Patients may also perform these exercises in aquatic settings, when appropriate. A 2015 Cochrane Review concluded there is high-quality evidence that land-based exercises have short-term benefits on knee pain and physical function (Fransen, McConnell, Harmer, Van der Esch, Simic, & Bennell, 2015). While the treatment effects of exercise are considered small, they are comparable to the reported effects of non-steroidal anti-inflammatory drugs (Fransen et al., 2015). A more recent Cochrane Review found that exercise may help improve pain, function and depression, while also providing a wide range of health benefits to people (Hurley et al., 2018).

A recent systematic review of 48 randomized controlled trials found that exercise interventions should focus on a single goal of increasing strength, aerobic capacity, or
proprioception and balance (Juhl, Christensen, Roos, Zhang, & Lund, 2014). A stratified meta-analysis based on type of exercise intervention found that quadriceps-specific exercise, when performed three times a week under supervision, provides the most pain reduction (Juhl et al., 2014). More recently, combination exercise and education interventions have been introduced. One such example is the Good Life with osteoArthritis in Denmark (GLA:D) program. The GLA:D program has been administered to over 9800 participants with OA in Denmark and has been found to have a significant impact on pain, quality of life, physical function and physical activity levels (Skou & Roos, 2017). This program is currently being implemented globally, and preliminary evidence shows meaningful results for people living in Canada with OA (Davis et al., 2017).

2.3.4 Injections

Patients who do not achieve adequate management of their knee OA through education, weight management, and exercise may elect to receive intra-articular injections. Intra-articular injections may include corticosteroid, hyaluronic acid, platelet-rich plasma, or stem cells. Corticosteroid injections are supported for the management of knee OA (McAlindon et al., 2014; Hochberg et al., 2012), although a recent high quality randomized controlled trial suggests these injections are no better than placebo and may have damaging long-term effects to cartilage health (McAlindon et al., 2017). A 2015 Cochrane Review found that corticosteroid injections may provide clinically important benefits, but are generally short-lived (Jüni et al., 2015). Viscosupplementation with hyaluronic acid injections is not currently recommended for the management of knee OA (McAlindon et al., 2014; Hochberg et al., 2012), as insufficient evidence exists to support their use (Bellamy, Campbell, Robinson, Gee, Bourne, & Wells, 2006).

Platelet-rich plasma and stem cell injections have been more recently considered, but are not currently recommended in the management of knee OA. A systematic review on the effectiveness of platelet-rich plasma found superior results compared to placebo and hyaluronic acid, but found that almost all included randomized controlled trials
had a high risk of bias (Laudy, Bakker, Rekers, & Moen, 2015). While some randomized controlled trials have shown stem cell injections to be effective, a second systematic review reported all trials were at a high risk of bias, and as such, stem cell injections could not be recommended for the treatment of knee OA (Pas, Winters, Haisma, Koenis, Tol, & Moen, 2017).

2.3.5 Surgery

If patients do not achieve adequate symptomatic control through non-surgical management, surgical interventions are available for knee OA. Three main types of surgery are used for knee OA: arthroscopic lavage and/or debridement, high tibial osteotomy, and total joint replacement. Arthroscopic surgeries are no longer recommended in surgical guidelines (Nelson et al., 2014; Richmond et al., 2013; Zhang et al., 2010) as many high quality randomized controlled trials have shown them to be ineffective (Moseley et al., 2002; Kirkly et al., 2008; Sihvonen et al., 2013). A review of all available trials on arthroscopic procedures for knee OA found inconsequential benefits and an increased risk of harm (Thorlund, Juhl, Roos, & Lohmander, 2015). As a result, arthroscopic procedures should not be used in the management of knee OA.

A high tibial osteotomy may be used to correct malalignment in knee OA (Richmond et al., 2013; Zhang et al., 2010). However, evidence supporting this procedure is limited and clinicians should use clinical judgment and patient preference when selecting this procedure. In the absence of definitive recommendations for high tibial osteotomies, total joint replacement remains the main surgical intervention. Joint replacement procedures are recommended for appropriate patients with knee OA (Nelson et al., 2014; McAlindon et al., 2014). Joint replacement should only be performed after conservative options have been attempted with limited improvements in symptom control and functional gain (McAlindon et al., 2014).
2.4 Diagnosing Knee Osteoarthritis

The diagnosis of knee OA is a much-debated topic and numerous case definitions have been used throughout the literature. OA is currently considered a clinical diagnosis with imaging reserved for excluding differential diagnoses (Wenham, Grainger & Conaghan, 2014). The American College of Rheumatology, National Institute for Health and Care Excellence and European League Against Rheumatism all support the diagnosis of knee OA based on clinical symptoms and examination findings (Altman, et al., 1986; National Institute for Health and Care Excellence, 2008; Zhang, et al., 2010). The only imaging guidelines for OA recommend that imaging is not required to make the diagnosis in patients with a typical presentation of OA (Sakellariou et al., 2017). These guidelines also note there is a lack of literature suggesting any additional value of imaging over clinical findings in making a diagnosis of OA (Sakellariou et al., 2017). It has also been acknowledged that the diagnosis of knee OA can be made in the presence of specific clinical and examination features, even if radiographs appear normal (Zhang et al., 2010).

2.4.1 Clinical Diagnosis for Knee OA

Table 1 presents the most utilized diagnostic criteria for the diagnosis of knee OA, developed by the American College of Rheumatology (Altman et al., 1986). They include assessment for crepitus, bony swelling, bony tenderness and lack of joint warmth. However, their utility in general practice has been questioned (Cibere, 2006). Consequently, many clinical examination procedures have been developed for the assessment of knee OA. The principle elements of the clinical examination for knee OA include alignment, bony swelling, crepitus, gait, inflammation, instability, muscle strength, tenderness and pain, and knee range of motion, all of which can be reliably assessed (Cibere et al, 2004).
Table 1
American College of Rheumatology Diagnostic Criteria for Knee Osteoarthritis

<table>
<thead>
<tr>
<th>Category of Diagnostic Criteria</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>Knee pain + at least 3 of 6:</td>
</tr>
<tr>
<td></td>
<td>- Age &gt;50 years</td>
</tr>
<tr>
<td></td>
<td>- Stiffness &lt;30 minutes</td>
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<tr>
<td></td>
<td>- Crepitus</td>
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<tr>
<td></td>
<td>- Bony tenderness</td>
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<td></td>
<td>- Bony enlargement</td>
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<tr>
<td></td>
<td>- No palpable warmth</td>
</tr>
<tr>
<td>Clinical and Radiographic</td>
<td>Knee pain + Osteophytes + at least 1 of 3:</td>
</tr>
<tr>
<td></td>
<td>- Age &gt;50 years</td>
</tr>
<tr>
<td></td>
<td>- Stiffness &lt;30 minutes</td>
</tr>
<tr>
<td></td>
<td>- Crepitus</td>
</tr>
<tr>
<td>Clinical and Laboratory</td>
<td>Knee pain + at least 5 of 9:</td>
</tr>
<tr>
<td></td>
<td>- Age &gt;50 years</td>
</tr>
<tr>
<td></td>
<td>- Stiffness &lt;30 minutes</td>
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<tr>
<td></td>
<td>- Crepitus</td>
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<td></td>
<td>- Bony tenderness</td>
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<tr>
<td></td>
<td>- Bony enlargement</td>
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<tr>
<td></td>
<td>- No palpable warmth</td>
</tr>
<tr>
<td></td>
<td>- Erythrocyte sedimentation rate &lt;40mm per hour</td>
</tr>
<tr>
<td></td>
<td>- Rheumatoid factor &lt;1:40</td>
</tr>
<tr>
<td></td>
<td>- Synovial fluid signs of osteoarthritis</td>
</tr>
</tbody>
</table>

*Note. mm = millimeters, Adapted from Altman et al. (1986).*

The European League Against Rheumatism OA Task Force recommends three symptoms: persistent knee pain, limited morning stiffness, and reduced function, and three signs: crepitus, restricted movement, and bony enlargement, as the most useful for diagnosing knee OA. They suggest a diagnosis of knee OA can be made in adults over the age of 40 years with all three symptoms and at least one of the physical
examination signs (Zhang et al., 2010). This diagnosis can be made without radiographs and applies even when radiographs appear normal (Zhang et al., 2010). Further analysis found that adults aged 45 years and older have a 99% probability of having radiographic knee OA when all six symptoms and signs are present (Zhang et al., 2010). These recommendations are echoed in the National Institute for Health and Care Excellence guidelines (National Institute for Health and Care Excellence, 2014). These guidelines state that OA should be diagnosed clinically without investigations when a person is over 45 years of age and has activity-related joint pain with either no morning stiffness or morning stiffness lasting less than 30 minutes. Currently, knee OA should be diagnosed clinically without need for further investigation or imaging in most cases. However, the diagnostic accuracy of any such clinical examination is hindered by the lack of a consensus reference standard.

2.4.2 Diagnostic Imaging for Knee OA

Imaging examinations are commonly used to aid in OA diagnosis (Demehri, Guermazi, & Kwoh, 2016), but should be reserved for when an alternative diagnosis is being considered (Wenham, Grainger, and Conaghan, 2014). Plain film radiographs are the recommended first line imaging modality for OA (Sakellariou et al., 2017) but they are insensitive to the early pathological changes of OA (Hunter & Guermazi, 2012). The lack of correlation between clinical symptoms and structural changes visualized on plain film radiographs is well documented (Bedson & Croft, 2008). Therefore, radiographic images have a limited role in the clinical assessment of OA (Peat, Croft & Hay, 2001). Alternatively, magnetic resonance imaging (MRI) may be a more sensitive tool for the diagnosis of OA (Peterfy, 2002), as it is able to assess all the tissues involved in an osteoarthritic joint (Conaghan, 2006). However, there is a lack of literature validating the use of MRI in the diagnosis of OA (Conaghan, 2006). As such, current imaging guidelines for the diagnosis of OA recommend that no imaging modality of any kind is required to make the diagnosis in patients with the typical presentation of OA (Sakellariou, et al., 2017).
2.4.3 Plain Film Radiography for Knee OA

Plain film radiography is the imaging modality of choice in clinical practice (Demehri, Guermazi & Kwoh, 2016) and has historically been used as the primary technique to obtain a diagnosis of OA (Cibere, 2006; Peterfy, 2002). A number of radiographic grading systems have been developed to diagnose OA. The most commonly used is the Kellgren-Lawrence grading, which uses a global score of 0-4 to grade the joint (Kellgren & Lawrence, 1957). The Kellgren-Lawrence score is primarily based on the presence of osteophytes and joint space narrowing, which are associated with moderate to severe disease (Bedson & Croft, 2008). A score of 2 or greater is the traditional cut-off point for a definitive diagnosis of OA.

The American College of Rheumatology has also developed diagnostic criteria for knee OA that utilize plain film radiographs (Altman, et al., 1986). Table 1 includes the radiographic criteria for knee OA. However, these diagnostic criteria may not be applicable to general clinical practice, as they were developed using cases with more advanced disease than is likely to be encountered in the general population (Cibere, 2006). Moreover, the comparator group was made up of individuals with rheumatoid arthritis, and as a result, these criteria are better suited to differentiate OA from inflammatory joint conditions (Cibere, 2006).

The use of radiography in the diagnosis of OA has a number of limitations. X-rays are insensitive to the earliest pathological changes seen in OA (Hunter & Guermazi, 2012) and can appear normal in symptomatic joints (Guermazi, et al., 2012). This is thought to be due to the fact that articular cartilage changes, which are not visualized on radiographs, are likely altered before bony changes are evident (Hunter et al., 2007; Peterfy, 2002). This is compounded by the limitations of assessing a three-dimensional joint using a two-dimensional radiographic image. Osteophytes that are overlapped by adjacent bony features can remain undetected (Cibere, 2006). One study suggests that plain film radiographs of the knee can only detect 60% of the osteophytes seen on MRI (Chan et al., 1991).
The discordance of clinical symptoms and structural changes visualized on plain film radiographs is well documented (Bedson & Croft, 2008; Chan et al., 1991; Hannan, Felson, & Pincus, 2000; Szebenyi et al., 2006; Toivanen et al., 2007). As such, a review of the literature on radiographic imaging for OA concluded X-ray images have a limited role in the clinical assessment of OA (Peat, Croft & Hay, 2001). Overall, the limited ability of radiography to detect OA features at an early stage of disease questions the utility of plain film radiographs as a diagnostic tool (Cibere, 2006). As such, a reliance on plain film radiographs to diagnose OA is not recommended.

2.4.4 Magnetic Resonance Imaging for Knee OA

While only bone can be visualized on plain film radiographs, advanced imaging techniques, such as MRI have the ability to image all the tissues involved in an osteoarthritic joint (Conaghan, 2006). While MRI has an unparalleled ability to evaluate articular cartilage (Eckstein, Cicuttini, Raynauld, Waterton & Peterfy, 2006), it can also visualize ligaments, synovium, menisci and subchondral bone (Conaghan, 2006). As such, MRI is uniquely suited to assess the joint as a whole organ and may be a more sensitive tool for the diagnosis of OA (Peterfy, 2002).

It has been shown that MRI is better able to detect osteophyte formation than plain films (Chan et al., 1991). However, the potential utility of MRI in the diagnosis of OA may stem from whole-organ evaluation. MRI has the ability to visualize bone marrow edema, which has been shown to be associated with painful knees (Conaghan, 2006). One study found in a sample of 400 individuals with radiographic knee OA that bone marrow edema was present in 78% of the painful knees but only in 30% of knees in the non-painful group (Felson et al., 2001). It is also possible that OA symptomology may be attributed to synovitis, joint effusions, and meniscal and ligamentous pathology, but considerably less research exists evaluating these structures (Conaghan, Felson, Gold, Lohmander, Totterman & Altman, 2006).

MRI-based metrics for whole-joint evaluation have gained attention in recent years (Hafezi-Nejad, Demehri, Guermazi & Carrino, 2018). MRI-based quantitative and semi-quantitative scoring systems have been shown to provide reliable metrics for
evaluating structural morphology and damage (Hunter et al., 2011). However, MRI does not currently have a place in routine clinical practice for diagnosing OA (Conaghan, 2006). This is reflected in international imaging guidelines for OA, which state that should imaging be needed to exclude differential diagnoses, conventional radiography should be used before other modalities (Sakellariou et al., 2017). This may be in part due to the fact that MRI abnormalities can be frequent even in those with normal knee radiographs (Taouli et al., 2002) and those without knee pain (Guermazi et al., 2012). Additionally, MRI was shown to be of no benefit in diagnosing OA if clinical features were present prior to imaging (Petron et al., 2010).

While MRI technologies have great potential to play a role in the diagnosis of OA, the current body of literature suggesting MRI may be useful for routine practice is limited (Conaghan, 2006). This relative lack of literature is likely related to the limited ability to modify the OA disease process, and thus limited application of advanced imaging techniques in the diagnosis of OA (Peterfy, 2002). However, more studies are currently underway and further developments in MRI technology and image analysis tools hold promise for future disease evaluation (Conaghan, 2006; Conaghan, Felson, Gold, Lohmander, Totterman & Altman, 2006; Eckstein, Cicuttini, Raynauld, Waterton & Peterfy, 2006).

2.4.5 Biomarkers for Knee OA

Biochemical markers of osteoarthritic disease may facilitate earlier detection of knee OA (Abramson & Krasnokutsky, 2006, Bauer et al., 2006, Cibere et al., 2009). The World Health Organization defines a biomarker as “any substance, structure, or process that can be measured in the body… and influences or predicts the incidence or outcome of disease” (Strimbu & Tavel, 2010). Biomarkers can be indicators of pathogenic processes (De Grutolla et al., 2001) and are typically molecules or molecular fragments that are released as a result of joint tissue metabolism (Bauer et al., 2006). Biomarkers for OA may come from multiple joint tissues, including synovial fluid, blood, urine, or connective tissue samples (Mobasher & Henrotin, 2015). Identification of molecular abnormalities within joint tissues that precede
structural changes could allow for earlier detection of knee OA (Brandt, Doherty & Lohmander, 1998).

Increased levels of various biomarkers have been found in individuals with OA (Cibere et al., 2009, Hunter et al., 2007). In 2012, the OA Biomarkers Consortium selected twelve serum and/or urine biochemical markers to investigate (Hunter et al., 2014). Since that time, several novel biomarkers have been discovered (Watt, 2018). However, many of these biomarkers have not undergone the rigorous testing required to be considered diagnostic markers. This is complicated by the lack of a gold standard definition for early OA that limits the ability of biomarkers to be evaluated in diagnostic studies (Watt, 2018). Moreover, recent high quality studies have shown that biomarkers may lack the specificity needed to be of clinical utility (Watt, 2018). OA biomarkers are not localized to a specific joint and concentration levels can be influenced by age, sex, body composition, diet, various comorbidities, and drug interactions (Kraus, 2006). While biomarkers are likely to play a role in the diagnosis of knee OA in the future, too little is currently understood to provide any meaningful contribution to the clinical or research setting at this time.

2.5 Screening for Knee Osteoarthritis

Screening for disease implies finding disease (Morrison, 1998) or risk factors (Fletcher, Fletcher & Fletcher, 2014) in asymptomatic individuals. An effective screening test should be sensitive to early stages of a disease, when the subsequent course of the disease may still be altered (Fletcher, Fletcher & Fletcher, 2014). The American College of Rheumatology criteria (Altman et al., 1986) were designed for advanced-stage knee OA and were not developed as epidemiological tools, although they are often used as such (Roux et al., 2008). Many of the current methods for diagnosing knee OA are designed to identify late-stage disease (Jordan, Luta, Renner, Dragomir, Hochberg, & Fryer, 1997; O’Reilly, Muir, & Doherty, 1996), and thus are not ideal for screening. It is well known that there are issues with case identification in the study of knee OA epidemiology (Spector & Hochberg, 1994). Historically, radiographs have been used to screen for knee OA, but they are expensive and expose
patients to potentially harmful radiation (LaValley, McAlindon, Evans, Chaisson, & Felson, 2001). Staged-screening approaches, such as patient self-report of symptoms followed by radiography or physical examination, have been suggested (Cooper, McAlindon, Coggon, Egger & Dieppe, 1994; O’Reilly, Muir & Doherty, 1998; Hopman-Rock, Odding, Hofman, Kraaimaat & Bijlsma, 1997; March, Schwarz, Carfrae & Bagge, 1998; Oliveria, Felson, Klein, Reed & Walker, 1996), but still require costly radiographs and/or clinical evaluation.

Patient self-report of symptoms may be a cheaper alternative to more costly screening strategies. Various symptom questions to predict the presence of knee OA have been studied, but these focus on individual questions rather than on development of a screening instrument (March, Schwarz, Carfrae & Bagge, 1998; O’Reilly, Muir & Doherty, 1996). However, it has been argued that no single symptom can identify patients with knee OA (Corti & Rigon, 2003). Moreover, it remains unknown if multi-item questionnaires can predict symptomatic knee OA without need for additional, more costly evaluations (LaValley et al., 2001).

The goal of a screening questionnaire is to select a group of people in whom further investigations will yield a high rate of OA diagnoses, known as high specificity, without missing a substantial number of patients with OA, known as high sensitivity (Roux, et al. 2008). Previous attempts have been made to create screening instruments for knee OA (LaValley et al., 2001; Quintana et al., 2007; Roux et al., 2008; Marra et al., 2007). However, these instruments were largely based on current diagnostic criteria and their diagnostic testing is limited.

Three screening instruments created by LaValley and colleagues were developed through analysis of questionnaire responses from 1921 participants in the Framingham OA Study (LaValley et al., 2001). Their intent was first to create an instrument that maximized sensitivity, then a second instrument that maximized specificity, and finally a third instrument to provide a balance of both sensitivity and specificity. However, when each instrument was tested against the reference standard of clinical examination and knee radiographs in a validation sample, none of the instruments
displayed adequate diagnostic test performance. As such, they concluded that all three instruments resulted in too much misclassification to be used as a single-step screening process (LaValley et al., 2001).

The next attempt at developing a screening tool for knee OA was undertaken in Spain in 2007 (Quintana et al., 2007). Quintana and colleagues developed the Knee and Hip Osteoarthritis Screening Questionnaire that used questions specific to knee OA, questions specific to hip OA, and shared questions for both hip and knee OA (Quintana et al., 2007). When compared to the reference standard of examination by an orthopedic surgeon, including knee radiographs, the knee questionnaire was found to have a sensitivity of 94.5%, but a poor specificity of only 43.2%. Moreover, only 44% of individuals identified by the questionnaire underwent the reference standard examination, raising questions about the validity of the results. In addition, only individuals over the age of 60 were sampled, which may limit the ability of the knee questionnaire to detect disease in younger individuals at an earlier stage. As a result, the authors suggest that screening for knee OA in the general population still requires individuals to self-report knee symptoms and then be followed up with a clinical examination (Quintana et al., 2007).

In 2008, a questionnaire to identify knee OA was developed in France to be administered over the telephone (Roux et al., 2008). When tested against the reference standard of clinical evaluation and radiographic evidence, the instrument displayed high sensitivity and specificity. The validation sample also included individuals as young as 45 years, which means this instrument may have utility in populations of individuals with early disease. However, less than 23% of the 479 participants who were identified by the questionnaire underwent reference standard testing, questioning the internal validity of the study results. Therefore, the authors concluded that telephone administration of screening instruments is feasible (Roux et al., 2008), but the low participation rate limited any conclusions regarding the effectiveness of the questionnaire utilized.
A Canadian study evaluated the effectiveness of a screening questionnaire for knee OA administered by pharmacists (Marra et al., 2007). Pharmacists administered the questionnaire to 411 participants, of which 274 screened positively. Only 70% of these individuals received the reference standard of clinical examination and radiographs and it was found that the questionnaire could correctly identify over 80% of individuals with undiagnosed knee OA, but considerable bias may exist. The authors concluded that pharmacists could play an important role in the identification of undiagnosed knee OA and that much of this OA is in the early stages and likely most amenable to intervention (Marra et al., 2007). However, only participants who screened positively on the questionnaire received the reference testing, and thus, no calculation of sensitivity or specificity was possible. This is problematic, as it is not known how many subjects excluded by the questionnaire truly had knee OA, known as false negatives. At minimum, this questionnaire requires further testing in a more rigorous diagnostic study before it can be used as a screening instrument for knee OA.

These previous attempts at developing a multi-item questionnaire to screen for knee OA (LaValley et al., 2001; Quintana et al., 2007; Roux et al., 2008; Marra et al., 2007) illustrate the potential of this relatively inexpensive strategy. Unfortunately, the previously developed tools may not be sensitive to early stage knee OA, as they were developed using current diagnostic criteria and were not adequately tested in patient samples likely to suffer from early disease. Furthermore, several methodological flaws, such as lack of patient perspective in questionnaire item generation, low participation rates in validation procedures, and weak diagnostic study design limit our understanding of the utility of these screening instruments. Most notably, not one study included a “period of time for follow-up” in which the disease may be allowed to develop in individuals who initially tested negative (Fletcher, Fletcher & Fletcher, 2014).

However, the diagnostic performance of the previously created instruments suggests there is potential that a screening questionnaire could be developed that will adequately classify individuals as having knee OA or not. As such, a new screening instrument that does not rely on late-stage disease criteria should be developed and
tested in rigorous diagnostic studies. With proper identification of early-stage knee OA, treatments that can alter the disease course, such as exercise and weight-loss programs can be tested and implemented earlier in the disease process. There is a clear need to develop a single-step screening instrument that is able to detect early-stage knee OA.

2.6 Illness Behaviour

Knee OA is a chronic disease where individuals often adapt their behaviours to manage symptoms and disability (Gignac, Cott, & Badley, 2002). Through interviews with 248 individuals with OA, it was found that almost all people make at least one adaptation and that most make multiple adaptations (Gignac, Cott, & Badley, 2002). Analysis revealed that these adaptations were largely motivated by real and perceived changes or losses in function, providing evidence that patient perceptions may play a more significant role in mediating behavioural changes than presumed (Gignac, Cott, & Badley, 2002). There is a psychosocial context in which individuals with chronic knee pain/OA make decisions about their health and need for care. Further knowledge of this process may result in earlier identification of knee OA and better care for these individuals.

Many theoretical models have been developed in the behavioural and social sciences of how individuals appraise and respond to health conditions (Baltes & Baltes, 1990; Diefenbach & Leventhal, 1996; Mechanic, 1986). Three main models of illness contribute to our understanding of illness perception and behaviour in individuals with chronic knee pain/OA. The first is the model of selective optimization with compensation, which describes general adaptation processes across a spectrum of illnesses (Baltes & Baltes, 1990). It has three components describing adaptation: selection or restriction of certain activities, optimization of functional capacity, and compensation or modifying behaviours to perform certain activities (Baltes & Baltes, 1990).

Gignac et al., (2002) used the model of selective optimization with compensation to conceptualize the adaptation process to disability for individuals with OA. Of 248
participants interviewed, most reported using all three types of adaptation from the model. However, it is difficult to differentiate between selection, optimization, and compensation, as these components were found to be interrelated (Gignac, Cott, & Badley, 2002). The findings of this work provide evidence that an individual’s perceptions play a role in facilitating the adaptation behaviours to disability from OA, but this model does not explain the cognitive processes that drive behaviour (Gignac, Cott, & Badley, 2002).

Second is the common-sense model of illness representation, or Leventhal’s self-regulatory model of illness behaviour (Diefenbach & Leventhal, 1996; Leventhal, Meyer, & Nerenz, 1980). This theoretical framework attends to both internal and external sources of information to create illness representations (Diefenbach & Leventhal, 1996). This model positions the individual as an active problem solver based on both cognitive and emotional psychological processes that are ignored by the biomedical model (Diefenbach & Leventhal, 1996; Leventhal, 1970).

Meta-analysis of studies using the common-sense model of illness representation has shown that an individual’s thoughts about their illness are moderate-to-strongly related to coping behaviours (Orbell & Hagger, 2003). These findings illustrate a consistency in the way in which individuals cognitively represent illness in a range of health conditions (Orbell & Hagger, 2003). There is however, no empirical evidence supporting the validity or utility of the common-sense model in individuals with chronic knee pain/OA.

Third is Mechanic’s model of illness behaviour, which posits that symptoms may be perceived, evaluated, and acted upon differently by individuals (Mechanic, 1986; Mechanic & Volkart, 1960). This model predicts large variability in reactions to symptoms and illness, as it is the necessary link between biomedicine and behavioural science (Mechanic & Volkart, 1960; Mechanic, 1995). The model of illness behaviour represents the interaction of bodily dysfunction with both a psychological and sociocultural context, identifying four domains of illness that explain the decision-making process. The first is monitoring of one’s body and symptoms, followed by
defining and interpreting symptoms. Third is remedial actions taken by the individual, and lastly is utilization of help from various sources (Mechanic, 1986; Mechanic, 1995). These four phases make up the socially defined state, which informs the decision-making process and need not be associated with an altered biological state (Febrega, 1973).

Mechanic argued that this illness behaviour model may be more efficient than the diagnostic disease model in addressing the burden of illness and disability (Mechanic, 1995). The disease model does not take into account variability in behavioural responses among individuals with the same disease (Sirri, Fava, & Sonino, 2013). Sirri et al., (2013) argue that illness behaviour can explain the “major prognostic differences among deceptively similar patients” and thus, may provide an improved alternative to the biomedical disease model for illness recognition and medical care for patients, including those with chronic knee pain/OA.

Sirri et al., (2013) posit that illness behaviour is a unifying construct for perceptions, care-seeking behaviour, treatment adherence, and delay in seeking treatment. Many instruments have been developed in an attempt to operationalize features of the illness behaviour construct. Many of these patient self-rated scales provide measurements of subjective views of their illness behaviour (Sirri, Flava, & Sonino, 2013). Prior and Bond (2013) recommended that any measure of illness behaviour include both covert, such as cognitive and emotional processes, as well as overt or observable behaviours. Pilowsky (1969) operationalized abnormal illness behaviour based on Mechanic’s definition through the creation of the Illness Behaviour Questionnaire. The Illness Behaviour Questionnaire was original developed as a 62-item measure consisting of seven different subscales (Pilowsky, 1969). However, there is much debate over the true number of scales and factor structure of the Illness Behaviour Questionnaire, as subsequent factor analysis supported a three-scale model (Prior & Bond, 2010). Furthermore, little is known about the applicability of this measure outside of the chronic pain and psychiatric populations (Prior & Bond, 2013). Most importantly, Prior and Bond (2013) argue that the Illness Behaviour Questionnaire lacks items that directly tap any overt characteristics of illness behaviour.
There have been many other attempts at the operationalization of components of the illness behaviour construct (Prior & Bond 2013; Hamilton et al., 2017). For example, the Fear Avoidance Beliefs Questionnaire (Waddell, Newton, Henderson, Somerville, & Main, 1993), Coping Strategies Inventory (Carver, Scheier, & Weintraub, 1989), Knee Osteoarthritis Fears and Beliefs Questionnaire (Benhamou et al., 2013), and the Arthritis Self-Efficacy Scale (Lorig, Chastain, Ung, Shoor, & Holman, 1989), among others, have all been created to measure components of illness behaviour. However, all of these measures lack items that tap at least one domain from Mechanic’s model of illness behaviour and/or have not been validated in a population with chronic knee pain/OA (Hamilton et al., 2017). The only measure with some evidence of validity in this population that specifically addresses all domains of Mechanic’s model of illness behaviour is the Questionnaire to Identify Knee Symptoms (Hamilton et al., 2017).

2.7 QuIKS Questionnaire

Stemming from the potential utility of a measure able to quantify illness behaviour in individuals with chronic knee pain consistent with OA, a series of studies were undertaken to develop such a tool. The first study by Maly and Cott (2009) aimed to identify the process individuals use to recognize and address chronic knee problems that could be precursors to knee OA, as they hypothesized that patient experience could provide an ideal method to screen for individuals with pre-diagnostic knee OA (Maly & Cott, 2009). A grounded theory methodology was utilized to identify a theoretical model of this process. Twenty-six individuals at varying stages of experiencing a chronic knee problem were identified, of which ten individuals had a recent knee OA diagnosis and sixteen individuals had no formal diagnosis. A model (Figure 1) was developed from the themes identified through axial coding and constant comparative analysis of the interview transcripts.
The process of recognizing and addressing begins with a stage of becoming aware of chronic knee symptoms. This stage is characterized by the admittance and acceptance of a chronic knee problem by the individual, typically associated with increased frequency and consistency of the knee symptoms. A major determinant of this stage is the acknowledgment of difficulty participating in physical activities due to the impact of the knee symptoms (Maly & Cott, 2009).

Their findings further suggested that after becoming aware of the chronic knee symptoms, the individual enters a cyclical process of interpreting the symptoms and being careful during physical activity. Interpreting refers to attempts made by the individual to understand the meaning and significance of their knee symptoms. Of note, the authors found that these interpretations were influenced by social and
cognitive contextual factors, as many participants reported that interactions with others, such as friends, co-workers, and health care practitioners, along with personal experiences and memories from family members with chronic musculoskeletal symptoms, informed their decision-making process (Maly & Cott, 2009).

The second part of the cyclical process, being careful, was defined by the investigators as the perceptions, intentions, and behaviours of the individual used to avoid potential harms while engaging in physical activities. At this stage, individuals typically have the cognitive perception of diminished physical ability, leading to intentions and behaviours to perform physical activities with greater care. Three main actions were identified that compose being careful: 1) monitoring, where attention is given to factors that trigger knee symptoms; 2) modifying, where numerous strategies are employed to adjust physical activities in response to symptoms and to protect the knee; and 3) planning, where intentions to maintain physical activity despite knee symptoms are formed, through the use of anticipatory strategies to prevent harm, such as exercise. The authors describe the process of being careful during daily activities as a cognitive and behavioural approach to self-management of chronic knee symptoms, even before a formal diagnosis of knee OA is made (Maly & Cott, 2009).

The investigators found that the cyclical process of interpreting and being careful continues until the occurrence of an event that signals the inadequacies of this self-management strategy, termed as the interfering stage in the model. The interviews revealed that this interfering event always involved the inability to carry out a task of significant personal value, such as sport or a leisure activity, which caused the individual to seek more formal care for their knee complaint, termed accessing care. The authors posited that the individual’s interpretation of important daily activities is the key criterion for the signal to access care for chronic knee problems in this study population (Maly & Cott, 2009).

There are many social, cognitive, and behavioural elements to the model proposed by Maly and Cott (2009), sharing many components with Mechanic’s model of illness behaviour (Mechanic, 1986). The authors of this model suggested that aspects of the
model, particularly being careful, could be used as a way of identifying pre-diagnostic knee OA prior to these individuals seeking care and formal diagnosis. While no tool existed to quantify the being careful construct, the Arthritis Self-Efficacy Scale (Lorig, Chastain, Ung, Shoor, & Holman, 1989) may capture elements of being careful, but a specifically designed tool is likely required to detect pre-diagnostic knee OA experiences (Maly & Cott, 2009).

Using the process model identified by Maly and Cott (2009), a multi-phase research project was designed to develop an instrument capable of identifying emerging knee problems, ultimately named the Questionnaire to Identify Knee Symptoms (QuIKS) (Appendix 2) (Clark, Chesworth, Speechley, Petrella, & Maly, 2014). The aim was to develop a self-administered questionnaire for clinical and research settings, as all diagnostic procedures for knee OA available at that time identified advanced disease only.

In the first phase of the project, item development, individual questionnaire items to cover Maly and Cott’s (2009) model of recognizing and addressing emerging knee problems were generated (Clark, Chesworth, Speechley, Petrella, & Maly, 2014). Maly and Cott’s (2009) transcripts of the participant interviews were reviewed to identify a list of experiences for each of the four stages of their model: interpreting knee symptoms, monitoring knee pain, modifying activities in response to knee problems, and planning for the future. Potential questionnaire items were then generated to represent each of these experiences, resulting in a total of 33 potential items (Clark, Chesworth, Speechley, Petrella, & Maly, 2014). A 5-point rating scale was chosen to quantify these experiences and behaviours, where some items assessed agreement using a Likert scale from “strongly disagree” (0) to “strongly agree” (4), while others assessed frequency using an adjectival scale from “never” (0) to “always” (4) (Streiner, Norman, & Cairney, 2015). The developers also chose to frame the questions with a two-week time window, as it has been reported that individuals with knee OA requiring arthroscopic surgery can adequately recall their health status over this time period (Bryant, Norman, Stratford, Marx, Walter, & Guyatt, 2006).
In the second phase of tool development, expert review, a 16-member panel of Canadian OA experts reviewed the 33 generated items and response scales. The review panel included rheumatologists, orthopedic surgeons, family practitioners, physical therapists and health care researchers with expertise in OA and measurement scale development and validation. Recommendations on clinical utility, scaling, ambiguous and inappropriate items, and additional constructs to consider were developed by this panel. The expert recommendations were used to inform the drafting of a 35-item questionnaire, organized into three sections: medications and treatments, activities, and living with knee problems (Clark, Chesworth, Speechley, Petrella, & Maly, 2014). Although not specifically stated by the developers of the measure, this phase provides evidence of content validity of the QuIKS (Streiner, Norman, & Cairney, 2015).

In the third phase of the QuIKS development, item reduction, principal components analysis informed the selection of only items that explain a high proportion of the test score variance for the final questionnaire. Participants were recruited from an Ontario family medicine clinic through medical chart review. Patients with evidence of knee pain lasting longer than two weeks, with no diagnosis of knee OA or any other condition that explained their symptoms were invited to complete the preliminary 35-item QuIKS questionnaire. Data from 105 completed questionnaires was used in the principal component analysis. The final solution resulted in a 13-item questionnaire, composed of four subscales, named: medications, monitoring, interpreting, and modifying (Clark, Chesworth, Speechley, Petrella, & Maly, 2014). These subscales were scored individually, as this best captured each individual respondent (Clark, Chesworth, Speechley, Petrella, & Maly, 2014).

A secondary objective of the project was to assess the internal consistency reliability of the final QuIKS subscales (Clark, Chesworth, Speechley, Petrella, & Maly, 2014). Internal consistency reliability of each subscale was assessed using Cronbach’s alpha (Cronbach, 1951). The medication subscale with three items demonstrated an alpha of 0.82, the monitoring subscale with three items 0.83, the interpreting subscale with four items 0.73, and the modifying subscale with three items 0.87.
Through this three-phase development process, a short, self-administered instrument, named the QuIKS, was created with the aim of identifying individuals at increased risk of developing or in the early stages of knee OA (Clark, Chesworth, Speechley, Petrella, & Maly, 2014). This instrument, while primarily designed as a research tool, may also have utility in the clinical setting with limited burden to patients, an important property emphasized during expert review. Furthermore, evidence was provided through the QuIKS development process of content validity (from the expert panel) and internal consistency reliability from a sample of individuals with early knee symptoms. However, the developers recommend that these results be confirmed in an independent sample, as estimates of these properties tend to be overly optimistic when they are derived from development samples (MacCallum, Wideman, Zhang, & Hong, 1999). Moreover, the authors recommended that future research assess the predictive validity of the QuIKS, but note that this may prove difficult as the lack of criterion standard may limit the design (Clark, Chesworth, Speechley, Petrella, & Maly, 2014).

Hamilton et al., (2017) performed a systematic review of measures capturing components of Mechanic’s model of illness behaviour (Mechanic, 1986). Utilizing a systematic methodological framework for scoping reviews, they found sixteen different measures used in 71 studies demonstrating at least content validity in a sample of individuals with knee pain or OA. Each measure captured at least one component of Mechanic’s definition of illness behaviour, but only one measure, the QuIKS, captured all four components of illness behaviour (Hamilton, Wong, Gignac, Davis, & Chesworth, 2017).

Most of the measures identified captured only one or two of the components of illness behaviour, as they were originally conceptualized to quantify constructs such as coping strategies, self-efficacy, and fear avoidance behaviours (Hamilton, Wong, Gignac, Davis, & Chesworth, 2017). Therefore, the QuIKS is the most comprehensive measure providing complete coverage of illness behaviours experienced by an individual with emergent chronic knee symptoms. While the work by Clark et al. (2014) provides evidence of content validity, other forms of validity, such as construct or criterion validity have not been addressed (Hamilton, Wong, Gignac, Davis,
Chesworth, 2017; Streiner, Norman, & Cairney, 2015). Hamilton and colleagues recommended that the QuIKS undergo further studies of its validity to determine whether its psychometric properties are sound (Hamilton, Wong, Gignac, Davis, & Chesworth, 2017).

Hamilton and colleagues also performed a study to investigate the validity of the QuIKS in individuals with chronic knee problems, such as OA (Hamilton et al., 2015). With no criterion measure available for illness perception and behaviour, criterion validity could not be tested (Clark, Chesworth, Speechley, Petrella, & Maly, 2014; Streiner, Norman, & Cairney, 2015). Therefore, investigations of the validity of the QuIKS need to focus on construct validity (Streiner, Norman, & Cairney, 2015).

Hamilton et al., (2015) used two objectives to evaluate the construct validity of the QuIKS measure. The primary objective was to use Rasch analysis to determine if the QuIKS captures a unidimensional construct, as combining the subscales of the QuIKS into a single measure may reflect the higher-order construct of illness behaviour (Hamilton et al., 2015). Rasch validation has been argued as a form of construct validity in itself (Velozo, Seel, Magasi, Heinemann, & Romero, 2012). The secondary objective was to test the known-groups validity and convergent validity of the Rasch-validated QuIKS (QuIKS-R) (Hamilton et al., 2015).

Fifty-five individuals with healthy knees, 111 individuals with chronic knee pain but no OA diagnosis, and 34 patients with diagnosed knee OA awaiting surgery were enrolled for a total of 200 participants. Rasch analysis of the QuIKS measure revealed an adequate fit to a unidimensional model, providing evidence of construct validity of the QuIKS-R (Appendix 2). Analysis also required the response structure to be altered to conform with the Rasch model, such that the original 5-point scale (scored 0 to 4) be converted to a 0 to 2 scale with the original middle three response categories (1, 2, and 3) all scored as 1. As such, the QuIKS-R (the Rasch version of the QuIKS) can be used to provide interval-level scoring for the unidimensional construct of illness behaviour.
As per the secondary objective, mean QuIKS-R scores from each of the three enrolled groups were used to compare the three known-groups to determine whether there was evidence of construct validity. The a priori hypothesis was the distribution of QuIKS-R scores should vary by group with the highest scores in the pre-surgical group and lowest scores in the subjects with healthy knees. Total scores on the QuIKS-R were found to be significantly different between all three known-groups in the hypothesized directions, with moderate effect sizes. As hypothesized a priori, the healthy knee group exhibited significantly less illness perceptions and behaviours than the chronic knee pain group, who in turn exhibited significantly less illness perceptions and behaviours than the pre-surgical group. These findings support the construct validity of the QuIKS-R in a sample of individuals with chronic knee symptoms.

To complete the secondary objective, the total QuIKS-R scores were correlated with the five subscales (pain, symptoms, function in daily living, function in sport and recreation, and knee-related quality of life) of the Knee injury and Osteoarthritis Outcome Score (KOOS) to evaluate the convergent validity. As predicted, total QuIKS-R scores had significant moderate correlations with scores on the KOOS subscales. Spearman correlation coefficients ranged from 0.45 to 0.77, supporting the construct validity of the QuIKS-R in a population of individuals with chronic knee symptoms.

While evidence of construct validity for the QuIKS-R was shown through its measurement of a unidimensional construct, as well as through its hypothesized ability to discriminate between known-groups and correlations with other measures of related constructs, the results must be viewed with hesitation. These tests involved participant data used to develop the QuIKS-R measure, and therefore, may represent an overly optimistic picture of its construct validity (MacCallum, Wideman, Zhang, & Hong, 1999). It has been recommended that the QuIKS-R undergo investigation of construct validity using a larger sample that is independent from the development sample (Hamilton et al., 2015).
2.8 Construct Validity

Construct validity, originally described by Cronbach and Meehl (1955), is a framework used to interpret a measure of a latent trait that is not directly observable or measurable. This framework is utilized when no criterion standard is accepted as entirely adequate to measure the quality (Cronbach & Meehl, 1955). Measures of unobservable psychological phenomena, which can be valuable to explaining human behaviour, can be validated using these principles (Smith, 2005). The validation of these phenomena, or constructs, is demonstrated through predictable relationships derived from theoretical hypotheses between a measure of a particular construct and other measures of similar constructs (Kirshner & Guyatt, 1985; Cronbach & Meehl, 1955; Nunnally, 1978; Carmines & Zeller, 1979).

Smith (2005) has proposed a model for construct validation. The first requirement for construct validation is the specification of the construct in question. This requires explicit definition of the construct under investigation. Once defined, the construct must undergo translation into informative hypotheses that can be tested. Based on the hypothesis generated, specification of the appropriate research design can be made. Following data collection, an explanation of how the observations pertain to predictions must be formulated. Based on the relationship between the observations and predicted outcomes, revision of theory and construct can be performed. It is through this framework that a construct can be evaluated and shown to have validity.

The key feature of the model prosed by Smith (2005) is the focus on testing of specified hypotheses. Subscribing to the notion that construct validity can be assessed through a number of potential hypotheses (Lawshe, 1985; Landy, 1985; Streiner, Norman, & Cairney, 2015), the researcher is able to generate different methods and validation analyses. The notion of validation as a framework of hypothesis testing and analysis dictates that no one research design or statistic defines construct validity (Streiner, Norman, & Cairney, 2015), and as such, various types of analysis can be used to demonstrate construct validity (Lawshe, 1985).
Two commonly utilized construct validation methods are convergent validation and discriminative validation (Cronbach & Meehl, 1955; Campbell & Fiske, 1959; Streiner, Norman, & Cairney, 2015). Convergent validation attempts to hypothesize and quantify how closely a measurement scale of the theoretical construct is related to other constructs and measures (Cronbach & Meehl, 1955; Kirshner & Guyatt, 1985; Streiner, Norman, & Cairney, 2015). Simply stated, two measures of similar constructs should be hypothesized to show similar scores. Conversely, two measures of unrelated constructs should show less similar scores. As such, convergent validation typically utilizes a correlation analysis of data collected at a single time-point (Kirshner & Guyatt, 1985; Streiner, Norman, & Cairney, 2015). The correlation statistic selected depends on the nature and properties of the measurement scales under investigation (Bonett & Wright, 2000; Streiner, Norman, & Cairney, 2015).

While there is no specific correlation value at which a measure can be said to exhibit convergent validity, it has been suggested that a moderate Pearson coefficient value of 0.5 or greater is supportive (Guyatt, Norman, Juniper, & Griffith, 2002). However, a correlation value between two measurement scales that is too high (greater than 0.9) suggests that both scales are measuring the same construct, and thus, are redundant and unneeded (Streiner, Norman, & Cairney, 2015). Therefore, moderate to strong correlational values observed in convergent validation designs can be considered to support construct validity.

The second commonly utilized test of construct validity is known as discriminative validation. Discriminative validation is used to distinguish between predictably different individuals or groups (Streiner, Norman, & Cairney, 2015). This methodology requires the formulation of a hypothesis about which known-groups of people will have higher or lower amounts of the construct under investigation, observed via scores on the measurement index (Cronbach & Meehl, 1955; Kirshner & Guyatt, 1985; Streiner, Norman, & Cairney, 2015). For example, a group of individuals with severe knee OA may be hypothesized to have higher pain level scores than individuals known to have mild knee OA.
As discriminative validation involves testing the predicted differences between known-groups of individuals, statistical analysis typically involves tests of the mean difference. A between groups t-test or ANOVA can be considered for discriminative validation analyses. While no specific magnitude of mean difference, or effect size, is required to show discriminative validity, one would expect differences of at least moderate effect size between observably-distinct groups (Cohen, 1988).

The validation procedures of a construct and measurement scale must be designed and conducted using rigorous scientific methods. Quality criteria have been proposed to ensure the internal validity of the inferences made from these study designs (Terwee et al., 2007, Mokkink et al., 2010). A convergent validation design requires that expected correlational magnitude and direction be hypothesized prior to data collection and analysis (Terwee et al., 2007). Similarly, a discriminative validation design requires that the predicted magnitude and direction of the differences between known-groups be stated a priori (Terwee et al., 2007). Tools such as the Consensus-based Standards for the selection of health status Measurement Instruments (COSMIN) Checklist can be used to ensure the methodological quality when designing a construct validity study (Mokkink et al., 2010). However, these quality criteria were derived from expert opinion, as there is no empirical evidence to suggest that certain correlational or mean difference values must be attained to support construct validity (Terwee et al., 2007). Even Cronbach and Meehl (1955), predicted that a single “construct validity coefficient” was unlikely to be developed, due to the approximate nature of the validation process.

2.9 Internal Consistency Reliability

In addition to validity, a measurement scale should demonstrate reliability (Carmines & Zeller, 1979). Reliability of a scale is “the extent to which measurements are repeatable and that any random influence which make measurements different from occasion to occasion is a source of measurement error” (Nunnally, 1967). Simply stated, reliability is the ratio of the variance of true scores (or subject variability) to the variance of total scores (or total variability) (Streiner, 2003; Streiner, Norman,
The total variability of a scale can be broken down into the variability attributed to the items, subjects, and raters (Cortina, 1993).

One of the most widely utilized estimates of reliability is coefficient alpha (Cortina, 1993; Streiner, 2003). Coefficient alpha, or Cronbach’s alpha or $\alpha$, is a measure of the internal consistency of a scale and is mathematically equivalent to the mean of all split-half correlations (Cronbach, 1951). This method for estimating reliability has the practical advantage of requiring only a single administration of the measurement scale, as compared to other methods, which require multiple test administrations or multiple raters (Streiner, 2003; Streiner, Norman, & Cairney, 2015).

Coefficient alpha was originally touted as an estimate of the lower limit of reliability, as it was thought that test-retest or interrater reliability would produce higher values (Lord & Novick, 1968; Cortina, 1993). However, coefficient alpha may actually be an estimate of the upper bound of reliability, depending on the properties of the measurement scale. Simply stated, if a measurement scale is comprised of items that all measure one construct and use the same number of response options, the scale can be said to be tau-equivalent or parallel (Streiner, Norman, & Cairney, 2015). Under these circumstances, coefficient alpha is an estimate of the upper limit of reliability (Falk & Savalei, 2011).

Assuming that the internal consistency of a tau-equivalent or parallel scale is under investigation, one must determine an acceptable coefficient alpha value. There are many published recommendations for acceptable values (Ponerotto & Ruckdeschel, 2007). Nunnally (1967) originally recommended a value of 0.50 to 0.60 for scales in the early stages of research, but later revised these values to 0.70 (Nunnally, 1978; Nunnally & Bernstein, 1994). A value of 0.80 for basic research tools and 0.90 for clinical tools was also recommended (Nunnally, 1967). Carmines and Zeller (1979) also supported the use of 0.80 for research tools. However, Streiner (2003) argues that a coefficient value over 0.90 likely indicates redundancy in the items, and thus should be viewed as the upper limit for measurement scales.
It is important to note that the internal consistency of a scale, as measured by coefficient alpha, is highly sensitive to changes in the number of items in the measure (Cortina, 1993; Streiner, 2003). The coefficient alpha will increase simply as a function of the increasing number of items, so long as the additional items are equally good measures of the construct. As such, some authors argue that the acceptable coefficient value is dependent on the number of items in the scale and the study sample size. For example, Ponterotto and Ruckdeschel (2007) state that for measurement scales with 12 or more items, tested on less than 100 subjects, requires an internal consistency coefficient of 0.70 to be considered fair and 0.85 to be considered excellent.

In general, a coefficient alpha value of 0.80 can be considered an adequate estimate of the lower bound of reliability for measurement scales used in basic research (Nunnally & Bernstein, 1994; Streiner, 2003). The original four-subscale version of the QuIKS measure was shown to have internal consistency reliabilities from 0.73 to 0.87 (Clark, Chesworth, Speechley, Petrella, & Maly, 2014). However, these coefficient values were calculated in the same sample of individuals used to create the scale and since that time, the QuIKS has been revised into a unidimensional measure (Hamilton et al., 2015). Therefore, the latest version of the QuIKS requires evaluation of the internal consistency reliability in an independent test sample.
Chapter 3

3 Methods

3.1 Design

This was a cross-sectional study where participants recruited from physical therapy clinics across Canada completed a package of self-report health questionnaires at a single point in time. The questionnaire package also contained a detailed letter of information (Appendix 3) and consent form (Appendix 4), as well as a participant characteristics form to collect demographic and illness-related data on each participant. Participant eligibility was further verified with a self-report inclusion and exclusion criteria checklist.

Included in the questionnaire package were six self-report health questionnaires: 1) Brief Pain Inventory – Short Form (BPI), 2) Questionnaire to Identify Knee Symptoms (QuIKS), 3) European Quality of Life 5 Dimensions (EQ-5D-5L), 4) Medical Outcomes Study Short Form 12 Survey - version 2(SF-12v2), 5) Physical Activity Scale for the Elderly (PASE), and 6) Knee Osteoarthritis and Injury Outcome Score Physical Function Short Form (KOOS-PS).

Ethics approval was granted by Western University’s Health Sciences Research Ethics Board (#106206) (Appendix 5). Each participant provided written informed consent.

3.2 Participants

Participants were recruited from select physical therapy clinics across Canada according to study eligibility criteria. Physical therapist collaborators from selected clinics identified potential participants for eligibility and provided initial information about the study and a postcard to send to the investigators indicating their interest in participating. The study coordinator mailed interested participants a questionnaire package at the time of receipt of the postcard requesting further information. Data were collected from April 2016 to June 2018.
To qualify for the study, participants must have fulfilled the following inclusion criteria: 1) fluency in the English language, 2) between the ages of 40-79 years, 3) have had pain, aching, or discomfort in or around the knee during the past 12 months, and 4) have had knee pain on most days of the month at any time in the past.

Participants with any of the following criteria were excluded: 1) diagnosed with a neurological problem, 2) diagnosed with chronic obstructive pulmonary disease, 3) diagnosed with rheumatoid arthritis or ankylosing spondylitis, 4) diagnosed with fibromyalgia, 5) diagnosed with lupus, 6) diagnosed with gout, 7) have had chronic back, hip, or foot pain, 8) have a history of acute knee injury within the last 6 months, 9) have had or are scheduled for a total knee replacement, 10) have had a high tibial osteotomy, 11) have a terminal condition, or 12) are missing a leg. These inclusion and exclusion criteria helped to ensure that the knee pain and illness perceptions and behaviours of the subjects would be consistent with knee OA.

3.3 Measures

Sample descriptive data included sex, age, height and weight to calculate body mass index, as well as data regarding the affected knee (unilateral or bilateral), history of previous knee injury, history of formal diagnosis of knee OA, and time period of knee symptoms.

QuIKS

The QuIKS was designed to be a discriminative measure to quantify illness behaviour in knee pain consistent with knee OA (Clark, Chesworth, Speechley, Petrella, & Maly, 2014; Hamilton et al., 2015). It is the only measure shown to capture all components of illness behaviour identified in people with knee pain and knee OA (Hamilton, Wong, Gignac, Davis, & Chesworth, 2017).

The QuIKS is a 13-item self-administered questionnaire, with each item having a 5-point rating scale. The monitoring, interpreting, and modifying portions of the QuIKS use Likert responses from strongly disagree (0) to strongly agree (2), while the 3-item
medication portion use adjectival responses from never (0) to always (2). When the total raw score is converted to the final score, scores of the QuIKS range from 0 to 100 (worst to best state).

The original version of the QuIKS has been shown to have adequate measurement reliability (Clark, Chesworth, Speechley, Petrella, & Maly, 2014), while the Rasch validated version of the QuIKS was shown to be unidimensional and have interval-level measurement properties (Hamilton et al., 2015). Preliminary evidence of construct validity of the 13-item Rasch-validated QuIKS was also found across a range of individuals with knee symptoms consistent with knee OA that provided the data used to develop the QuIKS (Hamilton et al., 2015).

**KOOS-PS**

The Knee injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS) is a 7-item self-administered questionnaire, used to assess an individual’s difficulty with physical function due to problems with their knee (Perruccio et al., 2008). The KOOS-PS has interval-level measurement properties with scores ranging from 0 to 100 (no difficulty to extreme difficulty) (Perruccio et al., 2008). The KOOS-PS has strong internal consistency reliability and construct validity in knee OA populations (Perruccio et al., 2008; Davis et al., 2009; Collins, Prinsen, Christensen, Bartels, Terwee, & Roos, 2016). Moreover, the KOOS-PS instrument is recommended as a measure of knee function for patients with osteoarthritis (Rolfson et al., 2016).

**BPI**

The Brief Pain Inventory (BPI) is a 9-item self-administered questionnaire, used to assess pain in a number of chronic pain conditions (Poquet & Lin, 2016). The BPI has two subscales: Pain Severity and Pain Interference. The pain severity score consists of the sum of 4 items about pain intensity, with cumulative scores ranging from 0 to 40 (no pain to worst pain). The pain interference scale is the total of 7 sub-items, with scores ranging from 0 to 70 (no interference to complete interference) (Poquet & Lin,
The BPI has ordinal-level measurement properties. The BPI has been shown to be a reliable instrument for assessing chronic pain, with good test-retest reliability and internal consistency (Pelayo-Alvarez, Perez-Hoyos, & Agra-Varela, 2013; Wu, Beaton, Smith, & Hagan, 2010; Tittle, McMillan, & Hagan, 2003). The BPI has also been shown to have good construct and criterion validity (Gjeilo, Stenseth, Wahba, Lydersen, & Klepstad, 2007; Tan, Jensen, Thornby, & Shanti, 2004).

**SF-12v2**

The Medical Outcomes Study Short Form 12 Survey - version 2 (SF-12v2) is a subset scale of the SF-36 health related quality of life measure. It is a 12-item measure with two component scores, the Physical Component Summary Score (PCS) and the Mental Component Summary Score (MCS) (Ware, Kosinski, Turner-Bowker, & Gandek, 2002). These component scores represent the underlying construct of perceived physical and mental health, respectively. Both the PCS and MCS have scores that range from 0 (worst health) to 100 (best health). The SF-12v2 has been shown to have adequate reliability and validity in a number of musculoskeletal conditions, including rheumatoid arthritis, spinal disorders, and other health-related conditions (Linde et al., 2009; Lee, Browell, & Jones, 2008; Sutton & Raines, 2010; Sloan, Sawada, Martin, Church, & Blair, 2009). The SF-12 instrument is recommended as a measure of health-related quality of life for patients with knee OA (Rolfson et al., 2016).

**EQ-5D VAS**

The EuroQOL Five Dimensions questionnaire (EQ-5D) is a measure of health status developed by the EuroQol Group (EuroQol Group, 1990). The EQ-5D instrument is recommended as a measure of health-related quality of life for patients with knee OA (Rolfson et al., 2016). The EQ-5D has two sections. First is a descriptive section measuring mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The second is the EQ Visual Analogue Scale (EQ-5D VAS), which measures an individual’s self-rated health from 0 (worst imaginable health state) to 100 (best imaginable health state). The most recent version, used in this study, includes 5 response levels for each dimension of the descriptive section, and is
thus called the EQ-5D-5L (Herdman et al., 2011). The introduction of 5 response levels to the EQ-5D has been shown to increase reliability and validity (Brooks, 1996). However, the response levels have no arithmetic properties and only provide a descriptive code for the individual (van Reenen & Janssen, 2015). As such, only data from the EQ-5D VAS was used in this study.

**PASE**

The Physical Activity Scale for the Elderly (PASE) is designed to measure self-reported physical activity levels in older adults (Washburn, Smith, Jette, & Janney, 1993). The PASE includes questions on household, leisure time, and work-related activities, which are assigned a value corresponding to light, moderate, or strenuous levels of intensity. The frequencies of these activities are also recorded as never (0 days/week), seldom (1-2 days/week), sometimes (3-4 days/week), or often (5-7 days/week). The frequency of each activity is multiplied by its intensity to determine an overall physical activity level score. The PASE has been shown to be a valid and reliable measure of physical activity in the community-dwelling elderly and in sedentary older adult populations (Washburn, Smith, Jette, & Janney, 1993; Washburn, McAuley, Katula, Mihalko, & Boileau, 1999).

### 3.4 Data Analysis

#### 3.4.1 Sample Characteristics

Descriptive characteristics were summarized for the entire sample. All data analyses were performed with SPSS version 24.0 (SPSS Inc, Chicago, Illinois).

#### 3.4.2 Objective 1: Construct Validation

**Objective 1A. Convergent Validation**

The QuIKS measure was assessed for convergent validity with each of the self-report measures completed by the study participants. Statistical analysis utilized a correlation procedure, dependent on the measurement properties of the scale being correlated to
the QuIKS measure, as well as the satisfaction of the underlying assumptions of the specified statistical procedure. Confidence intervals for correlation coefficients, $r$ and $r_s$, were constructed using Fisher’s z transformation: 

$$z = \frac{1}{2} \log_e \frac{1+r}{1-r}$$

with standard error, $SE_z = \frac{1}{\sqrt{N-3}}$. A 95% confidence limit was constructed using $z \pm 1.96 \times SE_z$. These confidence limits were then back transformed to provide intervals for the correlation coefficients (Norman & Streiner, 2008). Seven a priori hypotheses were made, each specifying the expected direction and magnitude of the correlation. The seven hypotheses are presented in order from strongest to weakest anticipated correlation. Final decisions on the evidence from each test to support the convergent validity were based on the satisfaction of the a priori hypotheses, taking into account both the magnitude and direction of the relationship. A moderate correlation of at least 0.5 was considered to be supportive of convergent validity (Guyatt, Norman, Juniper, & Griffith, 2002). Any questionnaires with missing values were excluded from the analysis.

**QuIKS & KOOS-PS**

It was hypothesized that a strong negative correlation would be observed between scores on the QuIKS and KOOS-PS. This hypothesis was based on the reasoning that a measure of people’s opinions about the difficulties they experience with activity due to problems with their knee should be substantially related to a measure that quantifies an individual’s knee illness perception and behaviour. As a lower QuIKS score indicates increased illness perception and behaviour, while a higher KOOS-PS score indicates increased difficulty with physical function, a negative correlation was expected. Pearson’s product-moment correlation coefficient ($r$) was used to quantify this relationship, as both scales have interval-level properties. This analysis required an estimated sample size of 49 subjects, calculated using an $r$ of -0.7 (95% CI = -0.85, -0.55) at an alpha value of 0.05 (Bonett & Wright, 2000).
**QuIKS & BPI Pain Interference**

It was hypothesized that a strong negative correlation would be observed between scores on the QuIKS and Pain Interference subscale of the BPI. This hypothesis was based on the reasoning that a measure of pain interference during an individual’s daily life should be substantially related to a measure that quantifies an individual’s knee illness perception and behaviour. As a lower QuIKS score indicates increased illness perception and behaviour, while a higher BPI Pain Interference score indicates increased pain interference, a negative correlation was expected. Spearman’s rank correlation coefficient ($r_s$) was used to quantify this relationship, as the BPI Pain Interference scale has ordinal-level properties. This analysis required an estimated sample size of 60 subjects, calculated using an $r_s$ of -0.7 (95% CI = -0.85, -0.55) at an alpha value of 0.05 (Bonett & Wright, 2000).

**QuIKS & BPI Pain Severity**

It was hypothesized that a moderate negative correlation would be observed between scores on the QuIKS and Pain Severity subscale of the BPI. This hypothesis was based on the reasoning that a measure of an individual’s knee pain severity should be substantially related to a measure that quantifies an individual’s knee illness perception and behaviour. As a lower QuIKS score indicates increased illness perception and behaviour, while a higher BPI Pain Severity score indicates increased pain levels, a negative correlation was expected. Spearman’s rank correlation coefficient ($r_s$) was used to quantify this relationship, as the BPI Pain Severity scale has ordinal-level properties. This analysis required an estimated sample size of 86 subjects, calculated using an $r_s$ of -0.6 (95% CI = -0.75, -0.45) at an alpha value of 0.05 (Bonett & Wright, 2000).

**QuIKS & SF-12v2 PCS**

It was hypothesized that a moderate positive correlation would be observed between scores on the QuIKS and the Physical Component Summary (PCS) of the SF-12v2. This hypothesis was based on the reasoning that a measure of an individual’s physical
health should be substantially related to a measure that quantifies an individual’s knee illness perception and behaviour. As a higher QuIKS score indicates decreased illness perception and behaviour, while a higher PCS score indicates a higher level of physical health, a positive correlation was expected. Pearson’s product-moment correlation coefficient \( r \) was used to quantify this relationship. This analysis required an estimated sample size of 74 subjects, calculated using an \( r \) of 0.6 (95% CI = 0.45, 0.75) at an alpha value of 0.05 (Bonett & Wright, 2000).

**QuIKS & EQ-5D VAS**

It was hypothesized that a moderate positive correlation would be observed between scores on the QuIKS and EQ VAS. This hypothesis was based on the reasoning that a measure of an individual’s health status should be substantially related to a measure that quantifies an individual’s knee illness perception and behaviour. As a higher QuIKS score indicates decreased illness perception and behaviour, while a higher EQ VAS score indicates better health status, a positive correlation was expected. Pearson’s product-moment correlation coefficient \( r \) was used to quantify this relationship, as both scales have interval-level properties. This analysis required an estimated sample size of 74 subjects, calculated using an \( r \) of 0.6 (95% CI = 0.45, 0.75) at an alpha value of 0.05 (Bonett & Wright, 2000).

**QuIKS & PASE**

It was hypothesized that a moderate positive correlation would be observed between scores on the QuIKS and PASE. This hypothesis was based on the reasoning that a measure of an individual’s physical activity should be substantially related to a measure that quantifies an individual’s knee illness perception and behaviour. As a higher QuIKS score indicates decreased illness perception and behaviour, while a higher PASE score indicates greater physical activity levels, a positive correlation was expected. Spearman’s rank correlation coefficient \( r_s \) was used to quantify this relationship, as the PASE scale has ordinal-level properties. This analysis required an estimated sample size of 111 subjects, calculated using an \( r_s \) of 0.5 (95% CI = 0.35, 0.65) at an alpha value of 0.05 (Bonett & Wright, 2000).
QuIKS & SF-12v2 MCS

It was hypothesized that a moderate positive correlation would be observed between scores on the QuIKS and the Mental Component Summary (MCS) of the SF-12v2. This hypothesis was based on the reasoning that a measure of an individual’s mental health should be substantially related to a measure that quantifies an individual’s knee illness perception and behaviour. As a higher QuIKS score indicates decreased illness perception and behaviour, while a higher MCS score indicates a higher level of mental health, a positive correlation is expected. Pearson’s product-moment correlation coefficient ($r$) was used to quantify this relationship. This analysis required an estimated sample size of 99 subjects, calculated using an $r$ of 0.5 (95% CI = 0.35, 0.65) at an alpha value of 0.05 (Bonett & Wright, 2000).

Objective 1B. Discriminative Validation

The QuIKS measure was assessed for discriminative validity by identifying known-groups from the collected demographic characteristics, as well as the self-report health questionnaires. Statistical analyses compared group mean QuIKS scores, dependent on the number of groups being compared and the satisfaction of the underlying assumptions of the specified statistical procedure. Any questionnaires with missing values were excluded from the analysis. Eight a priori hypotheses were made, each specifying the expected magnitude of the difference between the known-groups. Final decisions on the evidence from each test to support the discriminative validity were based on the satisfaction of the a priori hypotheses, taking into account both the magnitude of the effect size between groups and the direction of mean differences between the known-groups. The eight a priori hypotheses are presented in order of strongest to weakest hypothesized effect size.

Previous Diagnosis of Knee OA vs. No Diagnosis of Knee OA

It was hypothesized that the total scores from the QuIKS would be significantly higher for the known-group with no diagnosis than for the known-group with a previous knee OA diagnosis, with at least a moderate effect size. This hypothesis was based on the
premise that individuals with a formal diagnosis of knee OA are likely to have more advanced disease and therefore exhibit greater levels of illness perception and behaviour. An independent samples t-test was used to compare the mean QuIKS scores between the groups. A Cohen’s $d$ of 0.8 is considered a large effect size (Cohen, 1988). To detect the anticipated effect size (Cohen’s $d = 0.8$), the required sample size would be 27 subjects per group with an alpha value of 0.05 and a power of 0.80 (Kastenbaum, Hoel, & Bowman, 1970).

**Groups of High, Medium, and Low Physical Function**

Distribution-based cut points were used to form three tertiles in the KOOS-PS data, resulting in three groups of high, medium, and low physical function. It was hypothesized that the total scores from the QuIKS would be significantly higher for the high physical function group versus the medium physical function group, and higher for the medium physical function group versus the low physical function group, with a large effect size. It was expected that individuals with lower KOOS-PS scores, and therefore higher physical function, would display less illness perception and behaviour, and thus higher QuIKS scores. One-way analysis of variance was used. A Cohen’s $f$ of 0.8 is considered a large effect size (Cohen, 1988). To detect the anticipated effect size (Cohen’s $f = 0.8$), the required sample size would be 30 subjects per group at an alpha value of 0.05 and a power of 0.8 (Kastenbaum, Hoel, & Bowman, 1970).

**Groups of High, Medium, and Low Pain Interference**

Distribution-based cut points were used to form three tertiles in the BPI Pain Interference data, resulting in three groups of high, medium, and low pain interference. It was hypothesized that the total scores from the QuIKS would be significantly higher for the low pain interference group versus the medium pain interference group, and higher for the medium pain interference group versus the high pain interference group, with a strong effect size. It was expected that individuals with increasing levels of pain interference in their daily activities, thus higher BPI Pain Interference scores, would exhibit greater illness perception and behaviour and therefore lower QuIKS
scores. One-way analysis of variance was used. A Cohen’s $f$ of 0.8 is considered a large effect size (Cohen, 1988). To detect the anticipated effect size ($Cohen’s f = 0.8$), the required sample size would be 30 subjects per group at an alpha value of 0.05 and a power of 0.8 (Kastenbaum, Hoel, & Bowman, 1970).

*Groups of High, Medium, and Low Pain Severity*

Distribution-based cut points were used to form three tertiles in the BPI Pain Severity data, resulting in three groups of high, medium, and low pain severity. It was hypothesized that the total scores from the QuIKS would be significantly higher for the low pain severity group versus the medium pain severity group, and higher for the medium pain severity group versus the high pain severity group, with a moderate effect size. It was expected that individuals with increasing levels of pain severity in their lives, thus higher BPI Pain Severity scores, would exhibit greater illness perception and behaviour and therefore lower QuIKS scores. One-way analysis of variance was used. A Cohen’s $f$ of 0.7 is considered a moderate effect size (Cohen, 1988). To detect the anticipated effect size ($Cohen’s f = 0.7$), the required sample size would be 40 subjects per group at an alpha value of 0.05 and a power of 0.8 (Kastenbaum, Hoel, & Bowman, 1970).

*Groups of High, Medium, and Low Physical Health*

Distribution-based cut points were used to form three tertiles in the SF-12v2 PCS data, resulting in three groups of high, medium, and low physical health. It was hypothesized that the total scores from the QuIKS would be significantly higher for the high physical health group versus the medium physical health group, and higher for the medium physical health group versus the low physical health group, with a moderate effect size. It was expected that individuals with increasing levels of physical health, thus higher PCS scores, would display less illness perception and behaviour and therefore higher QuIKS scores. The nonparametric equivalent of the one-way analysis of variance (Kruskall-Wallis test) was used. A Cohen’s $f$ of 0.7 is considered a moderate effect size (Cohen, 1988). To detect the anticipated effect size
(Cohen’s $f = 0.7$), the required sample size would be 40 subjects per group at an alpha value of 0.05 and a power of 0.8 (Kastenbaum, Hoel, & Bowman, 1970).

**Groups of High, Medium, and Low Health Status**

Distribution-based cut points were used to form three tertiles in the EQ-5D VAS data, resulting in three groups of high, medium, and low health status. It was hypothesized that the total scores from the QuIKS would be significantly higher for the high health status group versus the medium health status group, and higher for the medium health status group versus the low health status group, with a moderate effect size. It was expected that individuals with increasing health status, thus higher EQ VAS scores, would display less illness perception and behaviour and therefore higher QuIKS scores. One-way analysis of variance was used. A Cohen’s $f$ of 0.7 is considered a moderate effect size (Cohen, 1988). To detect the anticipated effect size (Cohen’s $f = 0.7$), the required sample size would be 40 subjects per group at an alpha value of 0.05 and a power of 0.8 (Kastenbaum, Hoel, & Bowman, 1970).

**Groups of High, Medium, and Low Physical Activity**

Distribution-based cut points were used to form three tertiles in the PASE data, resulting in three groups of high, medium, and low physical activity. It was hypothesized that the total scores from the QuIKS would be significantly higher for the high physical activity group versus the medium physical activity group, and higher for the medium physical activity group versus the low physical activity group, with a moderate effect size. It was expected that individuals with increasing levels of physical activity, thus higher PASE scores, would display less illness perception and behaviour and therefore higher QuIKS scores. One-way analysis of variance was used. A Cohen’s $f$ of 0.6 is considered a moderate effect size (Cohen, 1988). To detect the anticipated effect size (Cohen’s $f = 0.6$), the required sample size would be 50 subjects per group at an alpha value of 0.05 and a power of 0.8 (Kastenbaum, Hoel, & Bowman, 1970).
Groups of High, Medium, and Low Mental Health

Distribution-based cut points were used to form three tertiles in the SF-12v2 MCS data, resulting in three groups of high, medium, and low mental health. It was hypothesized that the total scores from the QuIKS would be significantly higher for the high mental health group versus the medium mental health group, and higher for the medium mental health group versus the low mental health group, with a moderate effect size. It was expected that individuals with increasing levels of mental health, thus higher MCS scores, would display less illness perception and behaviour and therefore higher QuIKS scores. One-way analysis of variance was used. A Cohen’s $f$ of 0.6 is considered a moderate effect size (Cohen, 1988). To detect the anticipated effect size (Cohen’s $f = 0.6$), the required sample size would be 50 subjects per group at an alpha value of 0.05 and a power of 0.8 (Kastenbaum, Hoel, & Bowman, 1970).

3.4.3 Objective 2: Internal Consistency Reliability

The QuIKS measure was assessed for internal consistency reliability using Cronbach’s alpha (Cronbach, 1951). A high value of alpha implies that the QuIKS is measuring a single construct (Carmines & Zeller, 1979). An alpha value $\geq 0.8$ is adequate to provide evidence for instrument reliability for basic research tools (Nunnally & Bernstein, 1994; Streiner, 2003). The estimated required sample size was 80 subjects for the 13-item QuIKS measure, to achieve a 95% confidence interval of width 0.2 for Cronbach’s alpha of 0.8 (95% CI = 0.7, 0.9) (Bonett, 2002).

3.4.4 Sample Size Requirement

A total sample of 150 subjects with knee pain and symptoms consistent with knee OA was calculated to be required to adequately assess all construct validity and internal consistency reliability hypotheses.
Chapter 4

4 Results

4.1 Response Rate

The collaborating physiotherapists identified 105 potentially eligible participants and mailed a postcard to the research team, indicating their interest in taking part in the study. Flow diagram of participant enrollment in the study is shown in Figure 2. Of the 105 questionnaire packages mailed by the research team, 23 (21.9%) of the participants were deemed ineligible due to eligibility criteria. Fifty-five of the potential 82 participants consented to participate and returned the questionnaire package. With 82 eligible participants as the denominator and 55 completed questionnaires, the response rate was calculated to be 67.1%. Of the 55 returned questionnaires, four individuals did not complete the QuIKS measure, excluding them from the final analysis.
Figure 2. Flow diagram of participant enrollment in study.
4.2 Sample Characteristics

Table 2 presents the demographic characteristics of the 51 respondents with useable data. Fifty-three percent of respondents were women and the average age of the sample was 60.3 ± 10.0 years. The average BMI for the sample was 27.7 ± 6.8 kg/m², indicating participants in the study on average, were overweight. Forty-seven percent of the respondents reported suffering from unilateral knee symptoms and 51% reported suffering from bilateral knee symptoms, while one individual did not indicate whether they had unilateral or bilateral knee complaints. Over 37% of the respondents reported a previous knee injury and over 41% reported having received a formal knee OA diagnosis.

Table 2
Sample Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean</th>
<th>Standard deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>60.3</td>
<td>10.0</td>
</tr>
<tr>
<td>BMI, kg/m²</td>
<td>27.7</td>
<td>6.8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex, Female</td>
<td>27</td>
<td>52.9</td>
</tr>
<tr>
<td>Affected Knee(s)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unilateral</td>
<td>24</td>
<td>47.0</td>
</tr>
<tr>
<td>Bilateral</td>
<td>26</td>
<td>51.0</td>
</tr>
<tr>
<td>Missing</td>
<td>1</td>
<td>2.0</td>
</tr>
<tr>
<td>History of Knee Injury, Yes</td>
<td>19</td>
<td>37.3</td>
</tr>
<tr>
<td>Previous Knee OA Diagnosis, Yes</td>
<td>21</td>
<td>41.2</td>
</tr>
</tbody>
</table>

*Note: BMI = Body mass index.*
4.3 Objective 1: Construct Validation

Objective 1A. Convergent Validation

The a priori hypothesized correlation coefficient magnitudes were not observed for relationships between the QuIKS and hypothesized related constructs of the KOOS-PS, BPI pain interference, BPI pain severity, and SF-12v2 PCS measures, although for each of these, statistically significant moderate correlations of magnitudes from 0.4 to 0.6 were found. The a priori hypothesized correlation magnitudes were not observed on comparisons of QuIKS scores with EQ-5D VAS, PASE, and SF-12v2 MCS scores. A statistically significant, but weak correlation was found with the EQ-5D VAS. No significant correlations were observed with the PASE and SF-12v2 MCS scores. Correlation values and 95% confidence intervals are listed in Table 3 and scatter plots for each comparison can be found in Figure 3.

Table 3
Convergent Validity Results

<table>
<thead>
<tr>
<th>Comparator Measure</th>
<th>Comparator Hypothesis</th>
<th>Correlation Statistic</th>
<th>95% Confidence Interval</th>
<th>n</th>
<th>Match Hypothesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>KOOS-PS</td>
<td>$r = -0.70$</td>
<td>$r = -0.46$</td>
<td>-0.66, -0.20</td>
<td>48</td>
<td>No</td>
</tr>
<tr>
<td>BPI Pain Interference</td>
<td>$r_s = -0.70$</td>
<td>$r_s = -0.57$</td>
<td>-0.74, -0.34</td>
<td>46</td>
<td>No</td>
</tr>
<tr>
<td>BPI Pain Severity</td>
<td>$r_s = -0.60$</td>
<td>$r_s = -0.44$</td>
<td>-0.65, -0.17</td>
<td>46</td>
<td>No</td>
</tr>
<tr>
<td>SF-12v2 PCS</td>
<td>$r = 0.60$</td>
<td>$r = 0.56$</td>
<td>0.33, 0.73</td>
<td>49</td>
<td>No</td>
</tr>
<tr>
<td>EQ-5D VAS</td>
<td>$r = 0.60$</td>
<td>$r = 0.30$</td>
<td>0.02, 0.53</td>
<td>50</td>
<td>No</td>
</tr>
<tr>
<td>PASE</td>
<td>$r_s = -0.50$</td>
<td>$r_s = -0.13$</td>
<td>-0.41, 0.17</td>
<td>44</td>
<td>No</td>
</tr>
<tr>
<td>SF-12v2 MCS</td>
<td>$r = 0.50$</td>
<td>$r = -0.04$</td>
<td>-0.32, 0.24</td>
<td>49</td>
<td>No</td>
</tr>
</tbody>
</table>

Note. KOOS-PS= Knee injury and Osteoarthritis Outcome Score Physical Function Short Form, BPI= Brief Pain Inventory, SF-12v2 PCS= Medical Outcomes Study Short Form 12 Survey - version 2 Physical Component Summary, EQ-5D VAS= EuroQOL Five Dimensions Visual Analogue Scale, PASE= Physical Activity Scale for the Elderly, SF-12v2 MCS= Medical Outcomes Study Short Form 12 Survey - version 2 Mental Component Summary, $r$= Pearson correlation coefficient, $r_s$= Spearman correlation coefficient.
Figure 3. Scatter plot of Questionnaire to Identify Knee Symptoms total score and other health measures score (one for each test of convergent validity). QuIKS= Questionnaire to Identify Knee Symptoms, KOOS-PS= Knee injury and Osteoarthritis Outcome Score Physical Function Short Form, BPI= Brief Pain Inventory, SF-12v2 PCS= Medical Outcomes Study Short Form 12 Survey - version 2 Physical Component Score, EQ-5D VAS= EuroQOL Five Dimensions Visual Analogue Scale, PASE= Physical Activity Scale for the Elderly, SF-12v2 MCS= Medical Outcomes Study Short Form 12 Survey - version 2 Mental Component Summary.
**Figure 3 continued.** Scatter plots of Questionnaire to Identify Knee Symptoms total score and other health measures score (one for each test of convergent validity). QuIKS= Questionnaire to Identify Knee Symptoms, KOOS-PS= Knee injury and Osteoarthritis Outcome Score Physical Function Short Form, BPI= Brief Pain Inventory, SF-12v2 PCS= Medical Outcomes Study Short Form 12 Survey - version 2 Physical Component Score, EQ-5D VAS= EuroQOL Five Dimensions Visual Analogue Scale, PASE= Physical Activity Scale for the Elderly, SF-12v2 MCS= Medical Outcomes Study Short Form 12 Survey - version 2 Mental Component Score.

**Objective 1B. Discriminative Validation**

The independent samples t-test revealed that the total scores on the QuIKS were significantly different among individuals with a previous diagnosis of knee OA when compared to those without a previous diagnosis. The one-way ANOVA (or Kruskal-Wallis H test) revealed that a priori hypotheses were not met for the QuIKS ability to discriminate between known-groups of physical function, pain interference, pain severity, and physical health, as measured by the KOOS-PS, BPI pain interference, BPI pain severity, and SF-12v2 PCS measures. However, moderate effect sizes were observed in the hypothesized direction. Statistically significant mean differences were found between at least two of the groups in these analyses. This relationship is evident in the corresponding box plots (Figure 4) where the gradient in distribution between groups is in the anticipated direction. Non-significant group differences indicated that the QuIKS was unable to discriminate between known-groups of health status, physical activity, and mental health, as defined by the EQ-5D VAS, PASE, and SF-12v2 MCS, respectively. This finding is illustrated in the corresponding box plot (Figure 4), where no gradient between groups is visualized. Effect sizes can be found in Table 4 and box plots for each analysis in Figure 4.
Table 4

**Discriminative Validity Results**

<table>
<thead>
<tr>
<th>Known-group (Measure)</th>
<th>Hypothesized Effect Size</th>
<th>Hypothesized Effect Size</th>
<th>n</th>
<th>Test Statistic</th>
<th>p</th>
<th>Match Hypothesis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diagnosed Knee OA</td>
<td>$d = 0.80$</td>
<td>$d = 0.70$</td>
<td>50</td>
<td>$t = 2.45$</td>
<td>0.02</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Physical Function (KOOS-PS)</td>
<td>$f = 0.80$</td>
<td>$f = 0.62$</td>
<td>48</td>
<td>$F = 10.27$</td>
<td>&lt;0.001</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Pain Interference (BPI)</td>
<td>$f = 0.80$</td>
<td>$f = 0.69$</td>
<td>46</td>
<td>$F = 11.29$</td>
<td>&lt;0.001</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Pain Severity (BPI)</td>
<td>$f = 0.70$</td>
<td>$f = 0.46$</td>
<td>46</td>
<td>$F = 5.31$</td>
<td>0.009</td>
<td>No</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Physical Health (SF-12v2 PCS)</td>
<td>$f = 0.70$</td>
<td>$f = 0.63$</td>
<td>49</td>
<td>$H = 13.31$</td>
<td>0.001</td>
<td>No</td>
</tr>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Health Status (EQ-5D VAS)</td>
<td>$f = 0.70$</td>
<td>$f = 0.09$</td>
<td>50</td>
<td>$F = 0.26$</td>
<td>0.77</td>
<td>No</td>
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<td>No</td>
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<tr>
<td>Physical Activity (PASE)</td>
<td>$f = 0.60$</td>
<td>$f = 0.16$</td>
<td>44</td>
<td>$F = 0.42$</td>
<td>0.66</td>
<td>No</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Mental Health (SF-12v2 MCS)</td>
<td>$f = 0.60$</td>
<td>$f = 0.19$</td>
<td>49</td>
<td>$F = 0.89$</td>
<td>0.42</td>
<td>No</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>No</td>
</tr>
</tbody>
</table>

_Note._ OA= osteoarthritis, KOOS-PS= Knee injury and Osteoarthritis Outcome Score Physical Function Short Form, BPI= Brief Pain Inventory, SF-12v2 PCS= Medical Outcomes Study Short Form 12 Survey - version 2 Physical Component Summary, EQ-5D VAS= EuroQOL Five Dimensions Visual Analogue Scale, PASE= Physical Activity Scale for the Elderly, SF-12v2 MCS= Medical Outcomes Study Short Form 12 Survey - version 2 Mental Component Summary, $d=$ Cohen’s $d$, $f=$ Cohen’s $f$, $t=$ independent samples $t$-test statistic, $F=$ one way analysis of variance test statistic, $H=$ Kruskal-Wallis test statistic.
Figure 4. Box plots of mean Questionnaire to Identify Knee Symptoms scores for each known group (one for each test of discriminative validity). QuIKS = Questionnaire to Identify Knee Symptoms, OA = osteoarthritis.
4.4 Objective 2: Internal Consistency Reliability

The second objective was to assess the internal consistency reliability of the QuIKS. The internal consistency reliability was found to be 0.81, which meets the minimum value for acceptable reliability (Streiner, Norman, & Cairney, 2015). No items were missing in the calculation of the internal consistency reliability.
Chapter 5

5 Discussion

5.1 Overview of Results

The primary objective of this study was to evaluate the construct validity of the QuIKS measurement tool in a sample of individuals with chronic knee symptoms consistent with OA. This was the first evaluation of the construct validity of the QuIKS in an independent sample. The construct validity of the QuIKS was evaluated using tests of both convergent and discriminative validity. In total, 15 a priori hypotheses were tested. However, none of the pre-specified hypotheses were met. Despite the findings not affirming the a priori hypotheses, the majority of data does appear to support the construct validity of the QuIKS, as many of the findings met the recommended thresholds for construct validity (Guyatt, Norman, Juniper, & Griffith, 2002; Terwee et al., 2007). The secondary objective was to evaluate the internal consistency reliability in an independent sample. The QuIKS appears to have adequate internal consistency reliability, as the Cronbach’s alpha for the scale was 0.81. Overall, the findings of this study support the construct validity and internal consistency reliability of the QuIKS.

5.2 Convergent Validity

Seven convergent validity hypotheses were generated a priori. The findings of this study indicate that the QuIKS may be a valid measure, as the total scores were moderately correlated with the KOOS-PS, BPI Pain Interference, BPI Pain Severity, and SF-12v2 PCS scales. While these findings did not meet the a priori hypotheses, there were moderate correlations in the hypothesized direction for these comparisons, and moderate correlation values have been suggested to support convergent validity of a measure (Guyatt, Norman, Juniper, & Griffith, 2002). Therefore, illness behaviour appears to be a higher order construct that incorporates an individual’s physical function, pain-related cognitions and behaviours, and perceptions of their physical health. However, only weak associations were found between scores on the QuIKS and the EQ-5D VAS, PASE, and SF-12v2 MCS measures. These results do not support the convergent validity of the QuIKS. Therefore, it is possible that health-related quality of life, physical activity levels, and self-perceived mental health are not captured in the illness behaviour construct.
Prior to this study, the QuIKS has only ever been compared to the Knee injury and Osteoarthritis Outcome Score (KOOS). Clark and colleagues (2014) found statistically significant moderate correlations for each subscale of the original version of the QuIKS with the KOOS-sports and recreation function and the KOOS-quality of life subscales. These correlation values ranged from 0.40 to 0.70 (Clark, Chesworth, Speechley, Petrella, & Maly, 2014), but no correlation analysis was performed using the total QuIKS score. Hamilton et al., (2015) compared total QuIKS scores to all sections of the KOOS, and found the lowest correlation was with the KOOS-other symptoms ($r_s = 0.45$), followed by the KOOS-sports and recreation function ($r_s = 0.65$), the KOOS-activities of daily living ($r_s = 0.70$), the KOOS-pain ($r_s = 0.72$), and the highest correlation was with the KOOS-quality of life ($r_s = 0.77$). Our results, despite finding a correlation of 0.46 with the KOOS-PS, are in line with previous convergent validity studies of the QuIKS.

5.3 Discriminative Validity

Eight discriminative validity hypotheses were created a priori. The data suggests that the QuIKS is a valid measure of illness behaviour in this sample, as it was able to discriminate between most study groups, despite not matching the pre-specified hypotheses for magnitude of effect sizes between groups. Individuals with a previous diagnosis of knee OA scored significantly lower on the QuIKS than those with no formal diagnosis, indicating more illness behaviour in the group with a prior diagnosis of knee OA. The effect size for this difference was $d = 0.70$, which was compared to the hypothesis of $d = 0.80$. Mean QuIKS scores were also significantly different between groups of differing levels of physical function, pain interference, pain severity, and physical health. The effect sizes for these groups were moderate, ranging from 0.46 to 0.69, which did not quite meet the hypothesized effect sizes, but does support the QuIKS ability to discriminate between these known-groups. The ability of the QuIKS measure to discriminate between these groups is evident in the gradients found between groups in the box plots found in Figure 4. Therefore, the discriminative validity results also support illness behaviour as a higher order construct that incorporates an individual’s physical function, pain-related cognitions and behaviours, and perceptions of their physical health.

Conversely, mean QuIKS scores were unable to differentiate between groups of differing levels of health-related quality of life, as measured by the EQ-5D VAS, physical activity levels, as measured by the PASE, and mental health status, as measured by the SF-12v2 MCS. No significant between-group
differences in QuIKS scores were found, indicating that illness behaviour may not capture elements of health-related quality of life, physical activity levels, and mental health status.

Prior to this study, the discriminative validity of the QuIKS has only been evaluated in one other study. Hamilton et al., (2015) tested whether mean QuIKS scores were able to discriminate between known-groups of individuals with differing severity of knee symptomology. A statistically significant moderate effect size was found between individuals with healthy knees and those with knee pain, as well as between those with knee pain and individuals scheduled for surgical intervention. These findings suggest that those with more severe knee disease exhibit more illness behaviour. Our results reflect these findings, as those with a previous formal diagnosis of knee OA, likely indicating more chronic and severe disease, also exhibit significantly more illness behaviour. While the effect sizes in our study are smaller than those found in the work by Hamilton et al., (2015), this is likely a result of the different samples studied. Hamilton et al., (2015) used a spectrum of individuals ranging from healthy knees to those awaiting surgical intervention, where our study used a much more narrow sample. All participants in our study must have had chronic knee symptoms, but not be awaiting surgical intervention. The much more select group enrolled in this study likely decreased the variability between known-groups and therefore, smaller effect sizes are not surprising.

5.4 Overall Construct Validity

Overall, there appears to be some evidence to support the construct validity of the QuIKS, as a majority of the tests of convergent and discriminative validity were supportive, despite not meeting the pre-specified hypotheses. These findings should be considered strong, as this study followed the recommended design and reporting for construct validity studies (Terwee et al., 2007; Mokkink et al., 2010). The research team developed a priori hypotheses that included the direction and magnitude of correlations and expected differences in scores between known-groups. Testing predefined hypotheses prevented retrospective rationalization of why a correlation value or effect size between groups may be low and incorrectly concluding the measure is valid. Furthermore, this study reported the results of all tests of construct validity and not just those that were supportive.

It has been proposed by Terwee et al., (2007) that in order to support the construct validity of a health measurement tool, at least 75% of the results must be in-line with predefined hypotheses, when tested in
at least 50 subjects. None of the a priori hypotheses in our study were met, but the majority of tests had significant moderate correlations or effect sizes in the anticipated direction. Moreover, these quality criteria were derived from expert opinion, as there is no empirical evidence to suggest that certain correlational or mean difference values must be attained to support construct validity (Terwee et al., 2007). Guyatt et al., (2002) also note that no specific correlation value is required for convergent validity, but moderate correlation values should be considered supportive. Therefore, despite not meeting the expert quality criteria proposed by Terwee et al., (2007) the overall findings of this study do support the construct validity of the QuIKS.

The results of both the convergent and discriminative validity tests using health status as measured by the EQ-5D VAS did not support the construct validity of the QuIKS. Health status, or health-related quality of life, measured by the EQ-5D-5L, is a complex construct that is likely to be influenced by other contextual factors. It may be that illness behaviour does not adequately assess these other factors, explaining the poor convergent and discriminative validity results. However, it is possible that the EQ-5D VAS is not a suitable measure of health status in those with knee OA, influencing the results of this study. While the psychometric properties of the original EQ-5D-3L have been evaluated in knee OA populations, the validity of the EQ-5D-5L has not been as well established (Rolfson et al., 2016). Furthermore, visual inspection of the EQ-5D VAS data collected (Figure 3) shows an apparent ceiling effect, as the majority of respondents rated their health status between 80 and 100 on the scale. Thus, the EQ-5D VAS data gathered in this study may not be a valid measure of health status, resulting in weaker than expected tests of convergent and discriminative validity.

Additionally, both hypotheses for the convergent and discriminative validity of the QuIKS that involved physical activity levels measured by the PASE were not supported by the data. While it is possible that illness behaviour may not incorporate physical activity levels as we expected, the findings of this study may also be explained by the limitations of the PASE questionnaire. The PASE questionnaire was originally developed to measure physical activity levels in individuals over the age of 65 years (Washburn, Smith, Jette, & Janney, 1993) and has demonstrated validity in some studies (Washburn, McAuley, Katula, Mihalko, & Boileau, 1999). However, it is only weakly correlated with objective measures of physical activity in community-dwelling older adults (Logan, Gottlieb, Maitland, Meegan, & Spriet, 2013). It is possible that the PASE is unable to accurately measure physical activity levels in
our sample, as we included individuals as young as 40 years of age and the average age of our sample was 60.3 years.

The PASE may also have limited ability to accurately measure physical activity levels in an osteoarthritic population. The PASE was found to have limited reliability and validity in individuals who have undergone total knee and total hip arthroplasty (Bolszak, Casartelli, Impellizzerri, & Maffiuletti, 2014; Casartelli, Bolszack, Impellizzeri, & Maffiuletti, 2015). It has also been shown that the PASE is unable to assess physical activity levels for patients with hip OA (Svege, Kolle, & Risberg, 2012). As such, the PASE is not recommended as part of an international standard set of outcome measures for individuals with knee OA (Rolfson et al., 2016). These studies call into question the ability of the PASE to accurately measure the physical activity levels of the individuals in our sample, and thus, may explain why the results of this study were not in line with the predefined hypotheses.

Along with the EQ-5D VAS and PASE, the results from the convergent and discriminative tests using data from the SF-12v2 MCS did not support the construct validity of the QuIKS. Mental health status may be influenced by a number of factors and may not be related to illness perception and behaviour. While the SF-12 has been recommended as a standard measure for individuals with knee OA (Rolfson et al., 2016), this recommendation appears to be based more so on the measurement properties of the original SF-36 (Kosinksi, Keller, Hatoum, Kong, & Ware, 1999). It is possible the SF-12v2 may have limited measurement capabilities in a knee OA population, as there has been a lack of psychometric studies. The unknown psychometric properties of the SF-12v2 may explain the lack of support for the construct validity of the QuIKS when using this measure in convergent and discriminative validity tests.

5.5 Internal Consistency Reliability

The secondary objective of this study was to estimate the internal consistency reliability of the QuIKS measure. Internal consistency reliability was estimated using Cronbach’s alpha, which was found to be 0.81. Therefore, the QuIKS appears to have good internal consistency reliability, as many sources cite 0.80 as a minimum for a good research tool (Carmines & Zeller, 1979; Nunnally & Bernstein, 1994; Streiner 2003). Moreover, it has been suggested that for measurement scales with 12 or more items, tested on less than 100 subjects, an internal consistency coefficient of 0.70 should be considered fair and 0.85 should be considered excellent (Ponterotto & Ruckdeschel, 2007). Lastly, the quality criteria for
health measurement tools developed by Terwee et al., (2007) suggest that a positive rating can be given for internal consistency reliability when Cronbach’s alpha is between 0.70 and 0.95.

Prior to this study, the reliability of the QuIKS has only been evaluated on one other occasion. Clark et al., (2014) evaluated the internal consistency reliability of each of the original QuIKS subscales individually. All subscales of the original version of the QuIKS were shown to be internally consistent, as Cronbach’s alpha ranged from 0.73 to 0.87. However, no other estimates of the internal consistency reliability are available when scoring all items on the QuIKS as a single scale. No other comparison values of internal consistency are available in the literature, as no other knee OA screening tools have reported reliability estimates (LaValley et al., 2001; Marra et al., 2007; Quintana et al., 2007; Roux et al., 2008). Overall, the findings of this study are in-line with previous literature and support the internal consistency reliability of the QuIKS, as recommended minimum requirements were met while using recommended study methods.

5.6 Limitations

A limitation of this study is that the study participants in the sample did not receive a formal diagnosis of their knee complaint. It is therefore possible that individuals may have knee pathology and symptoms unrelated to knee OA. However, this is unlikely as the strict exclusion criteria were likely to have removed individuals with other causes of knee pain from the study sample. Furthermore, over 40% of the individuals in the sample reported having received a formal diagnosis of knee OA in the past.

The number of participants completing questionnaires yielded a smaller sample size than indicated to test the predefined hypotheses. This is likely due to the stringent eligibility criteria, as almost one-quarter of the individuals who were mailed a questionnaire package were deemed ineligible. This may be a result of many individuals with chronic knee problems also having comorbid low back, hip, foot and ankle pain, or other health conditions making them ineligible to participate. However, we were able to find statistically significant correlation values and effect sizes between known-groups when comparing the QuIKS to these individuals’ levels of physical function, pain interference, pain severity, and physical health status. Furthermore, Terwee et al., (2007) suggest tests of construct validity be performed on groups of 50 or more individuals. Fifty-five individuals completed the questionnaire package in this study. However, due to incomplete questionnaires, sample sizes in this study ranged from 44 to 50.
While not meeting the recommended sample size by Terwee and colleagues (2007), our sample sizes were quite close and the addition of a few more participants to reach the 50 participant threshold is unlikely to significantly alter the findings of this study.

Another limitation of this study is the use of distribution-based cut points to formulate the known-groups in the tests of discriminative validity. Identifying known-groups using the distribution of scores in the sample to form tertiles may not be an accurate indication of the level of trait assumed in each group. For example, when identifying three known-groups of physical function based on scores from the KOOS-PS, it is possible that the differences between the mean KOOS-PS scores in the high, medium and low physical function groups do not represent true differences in these individuals’ physical function level. This is evident in the three known-groups of health status based on scores from the EQ-5D VAS. The ceiling effect in the scores on this measure resulted in three known-groups with roughly equivalent mean EQ-5D VAS scores, meaning these groups have essentially the same level of health status, but have been labeled high, medium, and low health status groups according to the distribution-based cut points.

Ideally, the strongest study design would be to identify known-groups using previously defined and validated scoring-based cut points for these measures. However, we are unaware of any literature that references scoring-based cut points for the measures included in this study. We also included a comparison of known-groups of individuals with and without a formal diagnosis of knee OA, which was based on self-report from the participants and not using a measurement scale or cut points. The inclusion of this comparison between valid known-groups should be viewed as a strength of the discriminative validity analysis in this study.

The findings of this study should be interpreted with caution due to the overall lack of measurement studies on most measures in knee OA populations. As a result, the construct validity of the QuIKS has been established in our study using comparator measures that may have validity and reliability limitations themselves. For example, the KOOS-PS is a relatively well-studied measurement scale and a recommended measure for function in knee OA (Rolfson et al., 2016), but also requires further evaluation of its measurement error, structural validity, cross-cultural validity, and construct validity (Collins, Prinsen, Christensen, Bartels, Terwee, & Roos, 2016). However, we have used six different comparator measures and a known-group of individuals with and without knee OA to evaluate the
construct validity of the QuIKS. The multiple tests of construct validity should reduce the potential bias from any one single comparator measure, enhancing the credibility of our results.

Lastly, the major limitation of this study is that it represents only an initial step in the validation process of the QuIKS measure. This study was the first evaluation of the construct validity of the QuIKS in an independent sample of individuals with chronic knee symptoms consistent with knee OA. The sample of individuals in this study is only representative of those with knee symptoms likely due to OA and therefore requires many more validation steps prior to the implementation of the QuIKS into clinical practice. The sample utilized in this study is not representative of the population for which the QuIKS may be used in the clinical setting. For example, the QuIKS should be evaluated for its ability to discriminate illness behaviour between individuals with knee OA and other causes of knee symptoms, or even other unrelated health conditions. Further evaluation of the QuIKS measurement tool, including diagnostic testing, must be performed prior to concluding the QuIKS is a valid measure of pre-diagnostic knee OA.

5.7 Future Research

While the results of this study support the construct validity of the QuIKS in this sample, this study did not assess the QuIKS ability to identify asymptomatic individuals. These results indicate that the QuIKS is a valid measure of illness behaviour in this sample and should serve as a framework for the future prospective evaluation of the QuIKS as a screening tool for knee OA. The QuIKS could improve early detection of knee OA, as the questionnaire was developed using a cohort of individuals with emerging knee symptoms (Maly & Cott, 2009). It would be of interest to follow a group of participants longitudinally to determine if QuIKS scores can be used to predict individuals who develop identifiable knee OA. Further reliability assessments should also be conducted, including a test-retest assessment of the QuIKS to ensure the construct remains stable over a shorter time period. Lastly, the QuIKS may have potential to be used as an evaluative measure to track response to various interventions, but assessment of the scales responsiveness to change is required.
Chapter 6

6 Conclusion

Knee OA is a highly prevalent condition and leading cause of disability in Canada (Bombardier, Hawker, & Mosher, 2011) and throughout the world (Vos et al., 2017). While there is no gold standard diagnosis for OA, most current diagnostic procedures are designed to identify individuals in the later stages of the disease process (Burstein, 2009). As a result, patient self-report screening measures for knee OA have not been designed to identify early-stage disease. The QuIKS measure quantifies illness perception and behaviour in individuals with chronic knee symptoms indicative of knee OA (Hamilton, Wong, Gignac, Davis, & Chesworth, 2017) with the hope of identifying individuals earlier in the disease process than currently possible (Clark, Chesworth, Speechley, Petrella, & Maly, 2014).

In order to accurately quantify illness behaviours in these individuals, we evaluated the psychometric properties of the QuIKS, namely the construct validity and internal consistency reliability. While the magnitude of the relationships may not have been as large as originally hypothesized, the work in this thesis supports the construct validity and internal consistency reliability of the QuIKS and illness behaviour construct in individuals with chronic knee symptoms. The findings of this study can be used to inform further psychometric evaluation and diagnostic testing of the QuIKS as a potential screening tool for knee OA. A screening tool able to identify individuals earlier in the OA disease process would allow for more optimal patient care and evaluation of interventions that could potentially slow disease progression and prevent the development of long-term disability.
References


Benhamou, M., Baron, G., Dalichampt, M., Boutron, I., Alami, S., Rannou, F., et al. (2013). Development and validation of a questionnaire assessing fears and beliefs of patients with knee osteoarthritis: the Knee Osteoarthritis Fears and Beliefs Questionnaire (KOFBeQ). PloS One, 8(1), e53886.


Kosinski, M., Keller, S., Hatoum, H., Kong, S., & Ware, J. (1999). The SF-36 Health Survey as a generic outcome measure in clinical trials of patients with osteoarthritis and rheumatoid arthritis: tests of data quality, scaling assumptions and score reliability. *Medical Care, 37*(5), MS10-MS22.


APPENDICES

Appendix 1. Copyright agreement for Figure 1 (Maly & Cott, 2009)

| License Number | 4414390839522 |
| License date   | Aug 22, 2018  |
| Licensed Content Publisher | John Wiley and Sons |
| Licensed Content Publication | Arthritis Care and Research |
| Licensed Content Title | Being careful: A grounded theory of emergent chronic knee problems |
| Licensed Content Author | Monica R. Maly, Cheryl A. Cott |
| Licensed Content Date | Jun 29, 2009 |
| Licensed Content Volume | 61 |
| Licensed Content Issue | 7 |
| Licensed Content Pages | 7 |
| Type of use | Dissertation/Thesis |
| Requestor type | University/Academic |
| Format | Print and electronic |
| Portion | Figure/table |
| Number of figures/tables | 1 |
| Original Wiley figure/table number(s) | Figure 1 |
| Will you be translating? | No |
| Title of your thesis / dissertation | Evaluation of the construct validity of the Questionnaire to Identify Knee Symptoms among individuals across Canada with chronic knee pain |
| Expected completion date | Oct 2018 |
| Expected size (number of pages) | 150 |
## Appendix 2. QuIKS and QuIKS-R

*Items and Response Structure of the Questionnaire to Identify Knee Symptoms and the Questionnaire to Identify Knee Symptoms – Rasch Validated*

<table>
<thead>
<tr>
<th>Subsection and Items</th>
<th>Response Structure and Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medications</strong></td>
<td></td>
</tr>
<tr>
<td>Take pills before doing some activities to prevent knee pain</td>
<td>Never (0), Rarely (1), Sometimes (2), Often (3), Always (4)</td>
</tr>
<tr>
<td>Take pills after doing some activities to reduce knee pain</td>
<td></td>
</tr>
<tr>
<td>Carry pills in case knees start to hurt</td>
<td></td>
</tr>
<tr>
<td><strong>Monitoring</strong></td>
<td></td>
</tr>
<tr>
<td>Notice knee pain when kneeling</td>
<td>Strongly Disagree (0), Disagree (1), Neutral (2), Agree (3), Strongly Agree (4)</td>
</tr>
<tr>
<td>Knee(s) feel stiff after sitting or standing</td>
<td></td>
</tr>
<tr>
<td>Knee(s) hurt after sitting or standing</td>
<td></td>
</tr>
</tbody>
</table>
Interpreting

Talk to family and friends about knee problems
Consult doctor about knee problems
Suspect knee problems are result of getting older
Suspect knee problems are arthritis

Modifying

Participate in certain activities less due to knee problems
Considering stopping a favourite activity due to knee problems
Considering changing exercise routine due to knee problems

Note. QuIKS= Questionnaire to Identify Knee Symptoms, QuIKS-R= Questionnaire to Identify Knee Symptoms – Rasch Validated.
Appendix 3. Letter of Information

Study Title: The QuIKS Knee Study, the Questionnaire to Identify Knee Symptoms (QuIKS) validation among physical therapy clients and people in the community

Primary Researcher
Dr. Bert Chesworth, PhD
Associate Professor and Acting Director
School of Physical Therapy
Western University

Study Coordinator &
Graduate Student Researcher
James Young, DC
MSc candidate
Graduate Program in
Health and Rehabilitation Sciences
Western University

Co-Researcher
Dr. Rob Petrella, MD, PhD
Professor of Family Medicine,
Rehabilitation, Kinesiology and
Cardiology
Western University

Co-Researcher
Dr. Dawn Gill, PhD
Allied Scientist
ARGC Research Centre, Lawson Health Research Institute

Dear <<Name of prospective participant>>,

Introduction
We are writing to ask for your help in this study. This study aims to finalize the development of a health questionnaire to be used by clinicians to recognize the early symptoms of chronic knee pain problems in adults. We are contacting you because you sent us your contact information and indicated your interest in learning more about this study. The early recognition of chronic knee pain problems may play an important role in improving treatment of these problems. Early recognition may inform clinicians when providing therapy that should keep individuals with knee pain problems physically active for longer. The purpose of this letter is to provide information for potential participants to make an informed decision as to whether they want to participate in this study.

Background and Purpose
The Questionnaire to Identify Knee Symptoms (QuIKS) was recently developed from work done by health scientists at Western University in London, Ontario. For this questionnaire to provide evidence-informed application in the health care of people with knee pain problems, it should undergo further validation through clinical research. Therefore, the purpose of this research study is to provide further evidence that this health questionnaire can accurately and precisely measure key aspects of people’s experience with knee pain problems.
Study Design
Approximately 200 people from the community in London Ontario and surrounding areas and physical therapy clinics across Canada will take part in this research study. Participants will complete a set of questionnaires about their health.

Inclusion Criteria
You may be eligible to participate in this study if you are aged 40 through 79 years. Also, if you have had knee pain within the last year, and if you speak and understand the English language.

Exclusion Criteria
You are not eligible to participate in this study if your physician or a clinician told you that you have a neurological problem such as stroke, chronic obstructive pulmonary disease (COPD), rheumatoid arthritis, gout, ankylosing spondylitis, fibromyalgia, lupus, chronic back, hip or foot pain lasting six months or longer, an acute injury to the knee within the last six months, or a terminal condition. Also, you are not eligible to participate if you have had a total knee replacement or a high tibial osteotomy.

Procedures
If you agree to participate, you will be asked to respond to questions about your demographic characteristics (such as sex and age) and illness history (such as if you have a history of knee injury). This first questionnaire will take about 5 minutes to complete. If you meet the eligibility criteria of this study based on your history of illnesses, you will be asked to complete the six health questionnaires included with this letter. This one-time participation will take approximately 30 minutes.

Voluntary Participation
Participation is totally voluntary. Your decision to participate, or not to participate, will have no influence on the health care provided to you. You may refuse to participate in this study. If you withdraw your consent after returning your completed questionnaires, you will not be able to withdraw your data from this study once your data have been collected.

Possible Risks and Harms
There are no known or anticipated risks or discomforts associated with participating in this study. However, if you do experience any problems or discomfort, you may discontinue your participation at any time without penalty.

Possible Benefits
You may not directly benefit from participating in this study, but information gathered may provide benefits to society as a whole. However, you may benefit from the knowledge and experience gained when participating in this research, which could improve your understanding of knee pain problems.

Reminders and Responsibilities
Participants are required to complete the set of questionnaires included with this letter. Then, please return the completed questionnaires by mail within two weeks of receipt. We will send you a reminded next week to complete and return your set of questionnaires. If we don’t receive your set of completed questionnaires within three weeks of it being sent to you, we will contact you either by phone, or by mail, to remind you to complete and return your set of questionnaires. If for any reason you choose not
to participant in this study, please let us know by returning the questionnaires using the enclosed pre-stamped envelope.

Name of Sponsor
This research study is not sponsored by any third party organization.

Costs
There is no direct cost to you for your participation in this research study.

Compensation
You will not be compensated for participating in this research study.

Conflict of Interest
The researchers declare that they have no conflict of interest in relation to this study.

Confidentiality and Rights as a Participant
Your confidentiality is important and will be respected. All data collected will remain confidential and accessible only by the researchers in this study. No information that discloses your identity will be released or published at any time. Your identity will be kept anonymous for all the health information we collect from you, using a four digit identification number unique to you. For the purpose of contacting you, your name and contact information will be kept on a master list safely stored on the secure password protected Western University server available to Dr. Chesworth at Elborn College located at Western University in London, Ontario, Canada. Your name, address and telephone number will be removed from the set of questionnaires received from you and the return envelope will be destroyed before we record you anonymized data.

Your information will be kept confidential throughout this study, and at the end of this study, the master list with your name and any information linking you to any data collected will be destroyed. All data collected in this study will be analyzed in aggregate and any future publication or presentations of the results will not reveal your identity. Therefore, no information identifying you will be released or printed. Only group results will be reported and all de-identified hard copy of the information we collected from you will be destroyed 5 years after the project has been completed. When all information that could identify you is removed from the data you provide, an electronic record of the data will be stored indefinitely and used for future clinical research.

Representatives of Western University’s Health Sciences Research Ethics Board may contact you or require access to your study-related records to monitor the conduct of this study.

Questions about the Study
This letter of information is yours to keep. If you require any further information regarding this research study or your participation in this study you may contact the primary researcher, Dr. Bert Chesworth, or the study coordinator, James Young.

If you have any questions about your rights as a research participant or the conduct of this study, you may contact The Office of Research Ethics.
Consent
You may indicate your voluntary agreement to participate by completing the questionnaires and signing the consent form.

Thank you very much for considering to participate in this study.

Sincerely,

Bert Chesworth, PhD
Primary Researcher
Associate Professor and Acting Director
School of Physical Therapy
Western University
London, Ontario
Appendix 4. Consent Form

CONSENT FORM

Study Title: The QuIKS Knee Study, the Questionnaire to Identify Knee Symptoms (QuIKS) validation among physical therapy clients and people in the community

I have read the letter of information, have had the nature of this study explained, and I agree to participate. All questions have been answered to my satisfaction.

____________________________
Name of Participant (please print)

____________________________  ________________
Signature of Participant        Date

____________________________
Name of Person Obtaining Consent (please print)

____________________________  ________________
Signature of Person Obtaining Consent        Date
Appendix 5. Western University Health Science Research Ethics Board Approval Notice

Western University Health Science Research Ethics Board
HSREB Delegated Initial Approval Notice

Principal Investigator: Dr. Hani Chawath
Department & Institution: Schulich School of Medicine and Dentistry Epidemiology & Biostatistics, Western University

HSREB File Number: 156706
Study Title: The QuIKS Knee Study, the Questionnaire to Identify Knee Symptoms (QuIKS) validation among physical therapy clients and people in the community
Sponsor: Canadian Institutes of Health Research

HSREB Initial Approval Date: March 30, 2015
HSREB Expiry Date: March 30, 2016

Documents Approved and/or Received for Information:

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<th>Comments</th>
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</tr>
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<td>Advertisement</td>
<td>Recruitment poster, to be posted in the community of London Ontario and at primary care clinics in London Ontario who gave permission for posting the poster on their notice board.</td>
<td>2014/12/19</td>
</tr>
<tr>
<td>Instruments</td>
<td>The last page of the questionnaire package instruct participants to 'Please use this space, if you would like to tell us anything else about your knee pain problems.'</td>
<td>2014/10/10</td>
</tr>
<tr>
<td>Other</td>
<td>2nd Reminder to complete questionnaires, that will be sent to potential participants at three weeks after the mailing of the questionnaire package if their package was not received by the research team.</td>
<td>2014/11/10</td>
</tr>
<tr>
<td>Advertisement</td>
<td>Newspaper advertisement to be placed in local community newspapers.</td>
<td>2014/12/18</td>
</tr>
<tr>
<td>Advertisement</td>
<td>Recruitment poster, to be posted in physical therapy clinics of physical therapist collaborators.</td>
<td>2014/12/19</td>
</tr>
<tr>
<td>Other</td>
<td>Figure showing study design.</td>
<td>2014/12/19</td>
</tr>
<tr>
<td>Instruments</td>
<td>The EQ-5D is a 6-item generic measure that captures self-reported health-related quality of life in 5 dimensions. (received Dec 22/14)</td>
<td>2014/12/19</td>
</tr>
<tr>
<td>Instruments</td>
<td>The SF-12v2 is a 12-item self-report question of general health-related quality of life during the past four weeks. (received Dec 22/14)</td>
<td>2014/12/19</td>
</tr>
<tr>
<td>Instruments</td>
<td>The QuIKS-R self-report questionnaire will capture key early symptoms of chronic knee pain problems that are consistent with knee osteoarthritis. (received Dec 22/14)</td>
<td>2014/12/19</td>
</tr>
<tr>
<td>Other</td>
<td>Telephone Contact Form, to be used to record telephone contact with potential participants.</td>
<td>2014/11/10</td>
</tr>
<tr>
<td>Other</td>
<td>Post-card to be used by potential participants from specified physical therapy clinics across Canada to provide their contact information. (received Dec 22/14)</td>
<td>2014/11/10</td>
</tr>
<tr>
<td>Western University Protocol</td>
<td>Tracked</td>
<td>2015/03/05</td>
</tr>
</tbody>
</table>
Research Ethics

<table>
<thead>
<tr>
<th>Instruments</th>
<th>Description</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>PASE Questionnaire</td>
<td>(received Mar. 2/15)</td>
<td></td>
</tr>
<tr>
<td>Letter of Information</td>
<td>Updated version of LOI (clean pdf version)</td>
<td>2015/03/02</td>
</tr>
<tr>
<td>Other</td>
<td>Consent form</td>
<td>2015/03/02</td>
</tr>
</tbody>
</table>

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above named study, as of the HSREB Initial Approval Date noted above.

HSREB approval for this study remains valid until the HSREB Expiry Date noted above, conditional to timely submission and acceptance of HSREB Continuing Ethics Review.

The Western University HSREB operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (TCPS2), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Guideline for Good Clinical Practice Practices (ICH E6 R1), the Ontario Personal Health Information Protection Act (PHIPA, 2004), Part 4 of the Natural Health Product Regulations, Health Canada Medical Device Regulations and Part C, Division 5, of the Food and Drug Regulations of Health Canada.

Members of the HSREB who are named as Investigators in research studies do not participate in discussions related to, nor vote on such studies when they are presented to the REB.

The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000990.

Ethics Officer, on behalf of Dr. Marcelo Kremenchutzky, HSREB Vice Chair
Curriculum Vitae

Name: James J. Young

Post Secondary Education and Degrees:
Canadian Memorial Chiropractic College
Toronto, Ontario, Canada
Clinical Sciences Residency
2016 - 2018

Canadian Memorial Chiropractic College
Toronto, Ontario, Canada
Doctor of Chiropractic
2012 – 2016

University of Western Ontario
London, Ontario, Canada
B.A. Kin
2009 - 2012

Honours and Awards:
Ontario Graduate Scholarship
Western University
June 2017 – May 2018

Fellowship Award
Canadian Memorial Chiropractic College
Aug 2016 - July 2018

Publications:
Young JJ. “Conservative management strategies to mitigate the increasing burden of osteoarthritis on the healthcare system”. UWO Medical Journal. 2017;86(2):60-61.