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College of Health
and Sport Sciences



Department
of Physiotherapy

The Effectiveness of an Internet-Based Cognitive Behavioural Therapy and Exercise in Chronic Knee Patients with Psychological Distress

A Thesis Submitted in Partial Fulfilment of the Requirements for the Master of
Science Degree in Physiotherapy

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Defence Committee's Approval

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☐ Without making any changes to the thesis.

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Dissertation Deposit Form

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Abstract

Introduction: Internet-based cognitive behavioural therapy (iCBT) and exercises have been used widely to treat chronic musculoskeletal pain. We aimed to examine the effects of a combined iCBT with a standardized exercise program in chronic knee patients with psychological distress.

Methods: This was a 2-arm quasi-randomized controlled trial of eight weeks of intervention involving eight sessions of standardized exercise program and either concomitant iCBT and educational sessions or educational sessions only. Measurements were taken at baseline and eight weeks immediately following the intervention. Primary outcome measures were a numerical pain rating scale, 40-m Fast-Paced Walk Test, Step Test, and 30 seconds Chair Stand Test. Secondary outcome measures were Patient Health Questionnaire, Psychological Distress, Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form, Health-Related Quality of Life-Short Form-12, and Quadriceps Maximum Isometric Muscle Strength.

Results: Thirty-seven participants aged (Mean $\pm$ SD) 55.5 ± 7.9 years with chronic knee pain at a certain level of psychological distress were enrolled. In the intervention group (19 participants), there were significant differences in all the primary and secondary outcome measures post-treatment. Furthermore, there were statistically significant differences between both groups in pain levels (MD = 1.79, [95%CI 0.5 to 3.08], $P = 0.008$), and step test (MD = -1.74, [95%CI -3.38 to -0.9], $P = 0.04$) favouring the intervention group post-treatment. Yet, there were no significant differences between both groups post-treatment in walking speed (MD = -0.07, [95%CI -0.24 to -0.11], $P = 0.449$) nor in 30s CST (MD = -1.86, [95%CI -3.99 to 0.26], $P = 0.084$). Lastly, there was no significant difference between the groups in any secondary outcome measure post-treatment.

Conclusion: A combined iCBT and a standardized exercise program intervention can effectively improve pain, function, patient's reported outcomes and the quadriceps muscle strength in chronic knee patients with psychological distress. However, when compared to a control group, only pain and step test had improved significantly. Future studies should investigate the effects of the combined iCBT and standardized exercise program intervention on a larger number of participants. Additionally, longer term effects of the intervention should be investigated.

Publications

Alaradi, A., Irum, S., Ebrahim, N., Mohamed, F. M. J., Hazeem, F. M. J., & Ashfaq, M. (2021). The mental health impact of COVID-19 pandemic on health care workers and coping strategies: A systematic literature review. *International Journal of Online and Biomedical Engineering (IJOE)*, 17(09), 48–69.
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Dedication

My Master's degree journey has been a very long journey, yet I thank God for blessing me with a supporting and loving family and relatives.

To my parents, for their continuous love and support. Their prayer for me was what sustained me this far.

To my father and mother in-law, to my three brothers and to the whole "Ali Ghanem Alaradi" family for their encouragement and passion.

To my sister in-law "Ameera" who took care of my daughters and their studies while I was in the tornado of my MSc's studies.

To my loving husband who believed in me and guided me all along the way...

To my eldest daughter who taught me that nothing is impossible ...

To my youngest daughter who kept reminding me of enjoying the journey...

To my family: Husain, Noor, and Fatima for bearing all the trouble with me and never stopped supporting me...

To my family, this work is dedicated with love and appreciation.

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List of Abbreviations

AQoL	Assessment of Quality of Life
ASES	Arthritis Self-Efficacy Scale
BMI	Body Mass Index
CBT	Cognitive Behavioural Therapy
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
COVID-19	Coronavirus Disease 2019
CR 10	Category Ratio 10
CSQ	Coping Strategies Questionnaire
DASS-21	Depression Anxiety Stress Scales
FTSST	Five-Times-Sit-to-Stand Test
GAD7	Generalized Anxiety Disorder
GIF	Graphics Interchange Format
HID	Hand Held Dynamometer
iCBT	Internet-based Cognitive Behavioural Therapy
ICC	Intra-class Correlation Coefficients
IKD	Isokinetic Dynamometer
JPEG	Joint Photographic Experts Group
K6	Kessler 6
KOOS- PS	Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form
MCS-12	Mental Component Summary
MCID	Minimal Clinically Important Difference
MD	Mean Difference
MDC	Minimal Detectable Change

MDD	Major Depressive Disease
MINI	Mini-International Neuropsychiatric Interview
MOH	Ministry of Health
MSK	Musculoskeletal
NBB-Arad HC	National Bank of Bahrain-Arad Health Center
Nm/Kg	Newton metre per kilogram
NCD	Non-Communicable Diseases
NDC	Non-Directive Counselling
NRS	Numerical Rating Scale
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
OA	Osteoarthritis
OARSI	Osteoarthritis Research Society International
PCS	Pain Catastrophizing Scale
PCS-12	Physical Component Summary
PCST	Pain Coping Skills Training
PGIP	Patient's Global Impression of Pain
PHQ-2	Patient Health Questionnaire
PROMIS	Patient-Reported Outcomes Measurement Information System
QoL	Quality of Life
RCT	Randomized controlled trials
RPE	Rating of Perceived Exertion
SD	Standard Deviation
SEM	Standard Error of Measurement
SF-12	Short Form-12
SF-36	Short Form 36
ST	Step Test

STS	Sit-To-Stand
SSS-8	Somatic Symptoms Scale
TAU	Treatment As Usual
TUG	Timed Up-and-Go
UOB	University of Bahrain
VAS	Visual Analogue Scale
40-m FPWT	40-m Fast-Paced Walk Test
30s CTS test	30 seconds Chair Stand Test

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Chapter One

Introduction

1.1 Introduction and short background

1.2 Theoretical framework

1.3 Research Problem

1.4 Research Hypotheses

1.5 Research Questions

1.6 Research Aims/ Objectives

1.7 Research Significance

1.8 Definition of Term

1.1 Introduction and short background

1.1.a. The Chronicity of Knee Pain

Knee pain is one of the highly prevalent musculoskeletal conditions (Ibeachu et al., 2019; Nguyen et al., 2011; Vos et al., 2015). It is a condition that can cause prolonged suffering of pain (Ibeachu et al., 2019; Vos et al., 2015). Chronic knee pain is usually associated with a lot of physical disabilities that eventually reduce physical activity levels, thus compromising the quality of life (QoL) in these conditions (Breivik et al., 2006).

1.1.b. Recommendations on Chronic Knee Pain Management

In the current practice, recommendations to adapt biopsychosocial approaches to manage chronic musculoskeletal conditions have been widely spread (Jay et al., 2015; Monticone et al., 2014; Takahashi et al., 2019). Cognitive behavioural therapy (CBT) is one of the approaches that can be delivered efficiently by physiotherapists to address chronic musculoskeletal pains including chronic knee pain (Bryant et al., 2014; Nielsen et al., 2014). Moreover, Internet-based Cognitive Behavioural Therapy (iCBT) has been examined in the literature as a novel method for delivering CBT. Using the internet to deliver CBT has overcome the barriers that might hinder patients' access to this therapy, thus optimizing the management of chronic pain in musculoskeletal conditions (Bennell, Campbell et al., 2016; Dobson et al., 2014; Mecklenburg et al., 2018; Nelligan et al., 2019).

It is well-known that iCBT has positive effects in improving pain, self-efficacy, depression and many other complains in chronic knee pain (Bennell et al., 2018; DiRenzo & Finan, 2019; Mecklenburg et al., 2018;

Nelligan et al., 2019; O'moore et al., 2018; Rini et al., 2015). Despite the growing evidence supporting the use of CBT -regardless of delivery mode- in the management of chronic pain, it is still considered limited and more studies are needed (Briani et al., 2018; Feinmann, 2009; Rice et al., 2019).

1.1.c. Previous Studies and the Formulation of the Research Hypothesis

Previous studies have combined iCBT intervention and exercise for the treatment of knee osteoarthritis (OA) (Bennell, Ahamed et al., 2016; Bennell et al., 2018; Mecklenburg et al., 2018; Rini et al., 2015). Some of these studies have specifically targeted their treatment towards treating knee OA symptoms such as pain and function, yet the outcomes have not been favourable for such intervention (Bennell, Ahamed et al., 2016; Bennell et al., 2018). Meanwhile, a study that has targeted treating depression in knee OA patients, has incurred concomitant improvements in pain and function (O'moore et al., 2018).

It can be implied from the previous evidence that an iCBT intervention might be effective in improving pain and function if targeted towards certain type of patients. A retrospective cohort study found that patients with persistent musculoskeletal problems have certain levels of psychological distress (Lentz et al., 2019). Current studies on iCBT and exercises in knee OA have not investigated the effects of this combined interventions in individuals with psychological distress or depression. Moreover, due to the delivery mode of the intervention in the previous studies (web-based or application-based), most of these studies had a common confinement, in that the outcome measurements were based on subjective-reported outcomes. Systematic reviews of persistent musculoskeletal pain have urged future studies to incorporate objective

measures of physical activity besides the subjective measures (Marley et al., 2017).

Our study aimed to examine the effects of a combined iCBT intervention and exercise program in improving pain and function in patients with chronic knee pain by incorporating subjective and objective outcome measures. To our knowledge, this study was the first to investigate the effects of a combined iCBT intervention and exercise in chronic knee pain patients with psychological distress. We hypothesized that implementing an iCBT intervention and exercise in chronic knee patients with psychological distress will yield a significant difference in pain and function compared to a control group.

1.2 Theoretical framework

Several studies have examined the combined effects of iCBT intervention and exercise on pain and function in chronic knee individuals (Bennell et al., 2017, 2018; O'moore et al., 2018). The results of these studies vary a lot with no definite conclusion. To produce more beneficial effects, appropriate individuals who benefit the most from such programs must be identified and targeted (Rice et al., 2019). Retrospective cohort study by Lentz et al. (2019) have categorized individuals with chronic musculoskeletal pain into three categories, low, medium, and high depending on their levels of health care utilization. It was found that chronic musculoskeletal individuals who are categorized as high health care utilizers have several modifiable factors or variables. Among these variables are depression and psychological distress (Lentz et al., 2019). Administering iCBT intervention in chronic knee pain individuals with depression revealed promising results in terms of pain, function, and depression although the intervention did not include exercises. The study suggested combining iCBT and exercises to explicitly investigate the effects of the combined treatment on knee pain and function (O'moore et al., 2018).

On the other hand, when combined with exercise, iCBT intervention did not always result in the expected outcome. This might be due to not targeting the appropriate individuals that were targeted in the previous study (Bennell, Ahamed et al., 2016; Bennell et al., 2017). The researcher in the present study has included chronic knee OA individuals who have certain levels of depression and psychological distress (based on the study of Lentz et al. (2019)) to answer the study question: does combined iCBT interventions and exercises significantly improve pain and function in

chronic knee pain individuals with psychological distress compared to a control a group?

1.3 Research Problem

There are many studies regarding the use of iCBT and exercise as an intervention for chronic knee pain patients, yet the results of some might not be satisfactory (Bennell, Ahamed et al., 2016; Bennell et al., 2018). This study aimed to study the effects of the combined intervention in chronic knee pain patients who have a certain level of depression and psychological distress. The study has examined if applying such a program in this specific group could yield positive significant results compared to control group. Moreover, the use of objective outcome measures in previous studies is lacking. This study has incorporated subjective and objective outcome measures to investigate the added effect of an iCBT to a standardized exercise program in chronic knee pain patients.

1.4 Research Hypotheses

Primary Hypothesis: Internet-cognitive behavioural therapy interventions combined with a standardized exercise program significantly improves pain and function in chronic knee pain patients who have certain medium depression and psychological distress compared to a control group.

Secondary Hypothesis: Internet-cognitive behavioural therapy interventions combined with a standardized exercise program significantly improves depression, psychological distress, physical function, QoL, and quadriceps muscles strength in chronic knee pain patients who have certain levels of depression and psychological distress compared to a control group.

1.5 Research Questions

1. What are the effects of a combined iCBT and standardized exercise program on pain and function in chronic knee pain patients with psychological distress?
2. What are the effects of a combined iCBT and standardized exercise program on depression, psychological distress, physical function, QoL, and quadriceps muscle strength in chronic knee pain patients with psychological distress?
3. Do a combined iCBT and standardized exercise program significantly improve pain and function in chronic knee pain patients with psychological distress compared to a control group?
4. Do a combined iCBT and standardized exercise program significantly improve depression, psychological distress, physical function, QoL, and quadriceps muscles strength in chronic knee pain patients with psychological distress compared to a control group?

1.6 Research Aim/Objectives

Aim:

To investigate the effects of combining iCBT intervention with a standardized exercise program in chronic knee pain patients with psychological distress compared to a control group.

Objectives:

1. To measure the effect of combined iCBT intervention with a standardized exercise program on pain and function in individuals with chronic knee pain at 8 weeks.
2. To measure the effect of combined iCBT intervention with a standardized exercise program on depression, psychological distress,

physical function, QoL, and quadriceps muscle strength in individuals with chronic knee pain at 8 weeks.

3. To measure the effects of combined iCBT intervention with a standardized exercise program on pain and function in individuals with chronic knee pain compared to a control group at 8 weeks.
4. To measure the effects of combined iCBT intervention with a standardized exercise program on depression, psychological distress, physical function, QoL, and quadriceps muscle strength in individuals with chronic knee pain compared to a control group at 8 weeks.

1.7 Research Significance

Chronic knee pain is a debilitating condition that can affect the physical and mental health of individuals consequently compromising their QoL. It is of great importance to address the intercorrelated physical and mental health consequences of chronic pain as this is reflected in one's wellbeing. General guidelines recommend education and exercises as core treatments (Rice et al., 2018). Furthermore, recommendations to incorporate CBT programs in the management of chronic knee pain are growing. Such programs are time and cost-consuming interventions. Novel methods of CBT delivery have been investigated and done with different methodologies. Previous studies have been done combining exercise with an internet-based CBT. Due to the delivery mode (internet or application-based) of these studies, objective outcome measures were missed, thereby compromising the confidence in the results of these studies. To improve the quality of evidence, it is important to incorporate subjective and objective outcome measures. This study aimed to remedy the shortcoming of missing objective outcome measures through combining a supervised face-to-face exercise program with an iCBT. In turn, this has enhanced the

delivery of comprehensive cost- and time-effective intervention for patients and has ensured patients' availability for objective outcome measures.

Moreover, this study aimed to study the effects of the combined program in patients who have certain levels of depression and psychological distress. Conducting this research has helped in identifying individuals who would benefit the most of such programs and added to reframing the criteria for patients to be included in these programs. The effectiveness of combined iCBT intervention and exercise in this specific group of individuals has not been addressed in the literature. According to previous studies on musculoskeletal pain, greater than one-third of direct health care costs are concentrated among individuals defined as persistent high-cost utilizers. These individuals have a number of modifiable factors, among them are depression and psychological distress. Interventions targeting this specific group of individuals and addressing these modifiable factors would reduce the societal and economical burden they sustain on health care systems (Lentz et al., 2019).

This research has a great impact on individuals' lives and hence on society. From individual's perspective, depression and psychological distress are highly prevalent mental disorder in chronic knee OA patients, yet only few patients access mental health treatment. This study has ensured providing a remotely accessible cognitive behavioural therapy for psychologically distressed chronic knee OA patients. The results of this study would help in providing a comprehensive evidence-based intervention for chronic knee OA patients with psychological distress. Addressing the physical and psychological aspect of knee OA, through combining iCBT intervention and an exercise program, would be reflected positively on patient's wellbeing. Physically, this would improve patients'

pain, physical functions, and muscle strength. Psychologically, it would improve patients' depression, psychological distress, and the QoL.

Additionally, providing a comprehensive non-pharmacological intervention for chronic knee pain has many advantages. First, reducing the chronicity of knee pain would reduce the high utilization of health care services. Second, it would reduce patients' dependency on pharmacological intervention, thus would cut a lot of its costs. Third, it can be incorporated as a program for patients waiting for surgery or even -in selected cases- can work as an alternative for surgical interventions. Fourth, reducing the chronicity of knee pain is reflected positively on individuals' physical function and consequently reducing the burden of physical disability. Improved physical function reduces the risk of diseases where reduced mobility is considered one of its highest risk factors, such as the most common non-communicable diseases (NCD) of hypertension, diabetes, and high cholesterol levels. NCDs are considered a health burden that cost much of the health budget. Reducing the burden of NCD through such programs will reduce its costs that can be utilized in other health areas.

To summarize, this research has provided an improved quality of evidence for the use of iCBT intervention and exercise in the treatment of the chronic musculoskeletal patients with psychological distress who are considered as high health care utilizers individuals. Providing a comprehensive treatment program for these individuals has many benefits both on one's life and on the society. On individual's life, this research has helped its participants' to improve their physical and psychological status. On the societal level, targeting these individuals in the primary health care treatment plans will be reflected positively on the health care costs and value.

1.8 Definition of Terms

Biopsychosocial approaches: The Biopsychosocial model was first conceptualised by George Engel in 1977, suggesting that to consider the biological, psychological and social factors to understand person's medical condition. It consists of three terms: 1. Bio which refers to physiological pathology. 2. Psycho that indicates thoughts emotions and behaviours such as psychological distress, fear/avoidance beliefs, current coping methods and attribution and 3. Social socio-economical, socio-environmental, and cultural factors such as work issues, family circumstances and benefits/economics (Engel, 1977).

Internet-based cognitive behavioural therapy (iCBT): it is a therapy that highlights the contribution of cognitive, emotional, and behavioural factors in the pain experience delivered to patients through the internet (Keefe & Somers, 2010).

Standardized exercise program: an exercise program that is designed to primarily strengthen the knee extensor and hip abductor muscles of the affected limb and have shown, based on research, to be effective in improving knee pain and function (Bennell et al., 2012).

Chronic pain: is pain that has lasted beyond the body's usual healing time. It is often described as pain that has lasted for at least three months. Chronic pain causes many problems, beyond the pain itself, including fatigue, anxiety, depression, and a poor QoL (Geneen et al., 2017).

Chronic knee pain: pain that is felt in the knee joint or region that lasted more than three months (Mayo Clinic, 2021).

Depression: a negative affective state, ranging from unhappiness and discontent to an extreme feeling of sadness, pessimism, and despondency, that interferes with daily life. Various physical, cognitive, and social changes also tend to co-occur, including altered eating or sleeping habits, lack of energy or motivation, difficulty concentrating or making decisions, and withdrawal from social activities. It is symptomatic of a number of mental health disorders (*APA Dictionary of Psychology*, 2013).

Patient Health Questionnaire (PHQ-2): it is a two-item depression scale that is a useful tool in screening for depression in primary care (Kroenke, 2012).

Psychological distress: a set of painful mental and physical symptoms that are associated with normal fluctuations of mood in most people. In some cases, however, psychological distress may indicate the beginning of major depressive disorder, anxiety disorder, schizophrenia, somatization disorder, or a variety of other clinical conditions. It is thought to be what is assessed by many putative self-report measures of depression and anxiety (*APA Dictionary of Psychology*, 2013).

Kessler 6: the Kessler (K6) measure is a 6-item self-report questionnaire intended to yield a global measure of ‘psychological distress’ based on questions about the level of anxiety and depressive symptoms in the patient’s most recent 4-week period (Kessler et al., 2002).

The single-item numerical rating scale (NRS): a measure of pain intensity that is recommended as a core outcome measure in clinical trials of chronic pain treatments. Patients are asked to rate their pain on a scale from 0 to 10, with 0 meaning ‘No pain’ and ‘10’ meaning ‘Pain as bad as you can imagine’(Dworkin et al., 2005).

40-m Fast-Paced Walk Test (40-m FPWT): it is a test for walking in patients with OA. A patient is asked to walk as quickly but as safely as possible to a mark 10 m away, return, and repeat for a total distance of 40 m (Dobson et al., 2013).

Step Test (ST): This test is performed to study the patient’s ability to balance on one limb. The count of the number of times the participant could step the foot up and return it to the floor over a 15-s interval is recorded (Hatfield et al., 2016; Hinman et al., 2002).

30 seconds Chair Stand Test (30s CTS test): it is a test of sit-to-stand activity for OA patients. From the sitting position, the patient will stand completely up, then sit completely back down, repeatedly for 30 seconds (Dobson et al., 2013).

Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS- PS): it is a 7-item measure of physical function derived from the items of the Function, daily living and Function, sports, and recreational activity subscales of the KOOS. It is intended to elicit people’s opinions about the difficulties they experience with activity due to problems with their knee (Torad et al., 2015).

Health-related quality of life-Short Form-12: the SF-12 is a health-related quality-of-life questionnaire consisting of twelve questions that measure eight health domains to assess physical and mental health (Huo et al., 2018).

Maximum isometric muscle strength (Nm/kg): the maximal force generated by a muscle and is measured with different methods including manual resistance or hand-held dynamometer (Hébert et al., 2011).

Chapter Two

Literature Review

2.1. Evidence-Based Practice in Treating Chronic Knee Pain Conditions

2.1.a. Exercises

2.1.b. Cognitive Behavioural Therapy (CBT)

2.2. RCTs Combining CBT and Exercises for Chronic Knee Pain Conditions

2.3. Outcome Measures

2.3.a Primary Outcome Measures

2.3.b. Secondary Outcome Measures

2.1. Evidence-Based Practice in Treating Chronic Knee Pain Conditions

2.1.a. Exercises

Several systematic reviews, guidelines, and recommendations have been published to better address the chronicity in knee pain (Bannuru et al., 2019; Brosseau et al., 2017; Kolasinski et al., 2020; Wu et al., 2022). In a systematic review with meta-analysis of the interventions that can improve QoL or psychosocial factors in individuals with knee OA, Briani et al. (2018) searched the following database: Medline, Embase, SPORTDiscus, the Cumulative Index to Nursing and Allied Health Literature (CINAHL) and Web of Science from database inception to November 2017. Randomized controlled trials (RCT) investigating the effect of conservative interventions on QoL or psychological factors that considered them as the primary outcomes in individuals with knee OA were included. The review found supporting evidence for the use of exercise in improving health-related or knee-related QoL (Briani et al., 2018).

The supporting evidence for exercise intervention is similarly reported in an overview of Cochrane reviews (Geneen et al., 2017). It was suggested that exercise as an intervention could improve pain severity, physical function, and consequent QoL in adults with chronic pain (Geneen et al., 2017). Moreover, the updated 2019 osteoarthritis research society international (OARSI) guidelines included education and structured land-based exercise programs with or without dietary weight management as core non-surgical treatment for knee OA (Bannuru et al., 2019).

The type of exercises that are most beneficial for chronic knee pain cases was also investigated in the literature (Croke, 2014; de Rooij et al.,

2017; Fransen et al., 2015). High-quality evidence from Cochrane systematic review indicated that land-based therapeutic exercise provided short-term benefits that are sustained for at least two to six months after cessation of formal treatment in terms of reduced knee pain, and moderate-quality evidence showed improvement in physical function among people with knee OA (Fransen et al., 2015). Moreover, the Ottawa panel clinical practice guidelines for the management of knee osteoarthritis (Part two: strengthening exercise programs) recommended the use of strengthening exercises as it showed significant improvement for pain relief and physical functions (grade A evidence). The QoL measures has also shown significant improvement after strengthening exercises program (grade B evidence) (Brosseau et al., 2017).

The previous literature can be summarized as follows: First, evidence supports the use of exercise for improving health-related or knee-related QoL. Second, specifically speaking, land-based strengthening exercise program has proved its effectiveness in improving pain, function, and other outcome measures.

The exercise program used in our study was adopted from Bennell et al. (2017) study. It has proved its effectiveness in improving pain and function in chronic knee pain patients (Bennell et al., 2017).

2.1.b. Cognitive Behavioural Therapy (CBT)

Charlotte Feinmann (2009) conducted a systematic review with meta-analysis of the following database: The Cochrane Central Register of Controlled Trials, MEDLINE, EMBASE, and Psychlit from database inception to August 2008. The review concluded that there is limited evidence to support psychological therapies for adults with chronic pain (Feinmann, 2009). The systematic review of Briani et al. (2018) reported

that evidence supports the use of CBT for improving psychosocial factors such as self-efficacy, depression, and psychological distress in individuals with knee OA, yet this evidence is limited (Briani et al., 2018). It is noteworthy that despite the 10 years difference between the two systematic reviews, the conclusion of the limited evidence to support CBT use did not change. This is said, in spite of the fact that the modes of CBT delivery have evolved drastically (Bennell et al., 2012; Dobson et al., 2014; Mecklenburg et al., 2018; Nelligan et al., 2019).

Rice et al (2019) in a recent review on the best evidence rehabilitation for chronic OA pain has discussed CBT interventions as one of the rehabilitation options. It was found that there is low to moderate quality evidence which reported that CBT has small effects on OA pain and fatigue, and moderate to large positive effects on self-efficacy and pain coping. The authors recommended considering CBT in the treatment of OA patients who have co-existing psychosocial comorbidities (e.g. depression) or when there are psychological barriers to physical function such as fear of movement and pain catastrophizing. Thus, they recommended the use of CBT in appropriate individuals for it to yield positive effects (Rice et al., 2019). The results of Rice et al. (2019) could explain, to some extent, the limited evidence to support CBT intervention found in the systematic reviews of Briani et al. (2018) and Feinmann (2008). So, it would be appropriately concluded that CBT interventions are recommended in a certain group of participants.

2.2. RCTs Combining CBT and Exercises for Chronic Knee Pain Conditions

The Ottawa panel clinical practice guidelines for the management of knee osteoarthritis (part two: strengthening exercise programs) urged the

need to develop combined behavioural and muscle-strengthening strategies to improve long-term maintenance of regular strengthening exercise programs (Brosseau et al., 2017). Numerous studies have been published before and after that recommendation studying the combined effect of CBT and exercises in CKP patients. These studies were done with varying study designs and novel methods of delivering the intended intervention.

Bennell, Ahamed et al (2016) have conducted a 12-week study that investigated the effects of combining pain coping skills training (PCST) to a tailored exercise program. This was an assessor-blinded, 3-arm RCT in 222 people at the age of 50 yr. or above with knee OA fulfilling the American College of Rheumatology criteria (pain on most days in the past month and radiographic changes), knee pain for 3 months or more, average pain during the previous week more than or equal to 40 on 100-mm visual analog scale (VAS), and at least moderate difficulty with daily activities (WOMAC physical function subscale more than or equal to 25 of 68 units). Participants were randomized into one of the following groups: 73 PCST/exercise, 75 exercises, and 74 PCST.

All participants received 10 treatments over 12 weeks plus a home program. PCST included pain education and training in cognitive and behavioural pain coping skills, exercise comprised strengthening exercises (for quadriceps, hamstrings, and hip abductors), and PCST/exercise integrated both. Primary outcomes were self-reported average knee pain (VAS, range 0–100 mm) and physical function (WOMAC, range 0–68) at week 12. Secondary outcomes included other pain measures, global change, physical performance, psychological health, physical activity, QoL, and cost-effectiveness. Outcome measures were taken at 12, 32, and 52 weeks. Data were analysed by intent-to-treat methodology with multiple imputations for missing data. There was no significant between-group difference in pain comparing PCST/exercise versus exercise (MD 5.8 mm,

95% CIs: -1.4—13.0) and PCST/exercise versus PCST (MD 6.7 mm, 95% CIs: -0.6—14.1) at 12 weeks. Significantly greater improvements in function were found for PCST/exercise versus exercise (MD 3.7 units, 95% CIs: 0.4—7.0) and PCST/exercise versus PCST (MD 7.9 units, 95% CIs: 4.7—11.2). These differences persisted at weeks 32 (both) and 52 (PCST). Benefits favouring PCST/exercise were seen on several secondary outcomes. The study concluded that an exercise intervention can be augmented for a better functional outcome if it was combined with pain coping skills training mainly on the long term effects (Bennell, Ahamed et al., 2016).

The previous face-to-face PCST program was translated to an internet-based program and was implemented to evaluate the effectiveness of Internet-delivered, physiotherapist-prescribed home exercise and pain-coping skills training. This was an RCT that recruited 148 participants aged 50 years or older with chronic knee pain. Participants were assigned to either group without blinding. The intervention was delivered via the Internet and included educational material, 7 videoconferencing sessions with a physiotherapist for home exercise, and a PCST program over 3 months. The PCST program was provided through 8 highly interactive automated training sessions that were provided using the PainCOACH program which translated key therapeutic components of face-to-face PCST. The program consisted of eight 35 to 45 minutes modules designed to be completed weekly, each provided interactive training in a cognitive or behavioural pain coping skill. On the other side, the control group received the Internet-based educational material only. Primary outcomes included pain during walking (11-point numerical rating scale) and physical function (WOMAC Index) at 3 months. Secondary outcomes were knee pain, QoL, global change (overall, pain, and functional status),

arthritis self-efficacy, coping, and pain catastrophizing. Outcomes were also measured at 9 months. It was found that the intervention group reported significantly more improvement in pain (Mean Difference (MD) 1.6 units, 95% CIs: 0.9—2.3) and physical function (MD 9.3 units, 95% CIs: 5.9—12.7) than the control group at 3 months, and improvements were sustained at 9 months (MD, 1.1 units 95% CIs: 0.4—1.8 and 7.0 units CIs: 3.4—10.5, respectively). Intervention participants showed significantly more improvement in most secondary outcomes than control participants. Considering the only limitation of the study, unblinded participants, the authors concluded that an Internet-delivered, physiotherapist-prescribed exercise and PCST can provide clinically meaningful improvements in pain and function for individuals with chronic knee pain. The intervention effects can be sustained for at least 6 months (Bennell et al., 2017).

Bennell et al (2018) have used the same PCST program in an RCT to study its immediate effect on pain and function. The study concluded that although iCBT improved pain coping and function immediately, it did not confer additional benefits to a subsequent exercise program, despite sustained pain-coping improvements. Bennell et al. (2018) investigated the effects of adding an internet-based PCST protocol to a standardized education and exercise program for people with persistent hip pain. To be eligible, a participant must be 50 years of age or above, reported hip pain for more than 3 months, and for most days in the previous months with an intensity of 4 out of 10 on an 11-point numeric rating scale. A participant has to have access to a computer with the internet and can read and understand English to be included in the study. Participants were excluded from the study if they had a hip joint replacement, were planning hip or knee surgery within the next 12 months and or were using corticosteroids in the previous 3 months. Based on these criteria, one hundred forty-four

people were randomised to either the PCST group or the control group. In the first 8 weeks, the comparison group received online education only that covered information on arthritis, OA, managing pain, saving energy, healthy eating, physical activity, emotions, and tips for hip OA. Participants were instructed to access one fact sheet per week. Whereas the intervention group received 8 sessions of the PainCOACH program. From weeks 8 to 24, both groups visited a physiotherapist 5 times for home exercise prescription. This 30-minutes face-to-face session focused on developing an individualized home exercise program designed to strengthen lower limb muscles and increase hip joint range of motion. The Program contained 3 mandatory exercises: quadriceps muscle strengthening, hip abductor strengthening, hip stretch/flexibility exercises, and 2 or 3 other exercises chosen at the physical therapists' discretion based on their assessment of the patient.

Assessments were performed at baseline, 8, 24, and 52 weeks. Primary outcomes were hip pain on walking (11-point numerical rating scale) and physical function measured with the WOMAC index at 24 weeks. Secondary outcomes were: (1) participant-perceived response to treatment measured on a 7-point scale; (2) hip pain measured with the WOMAC pain subscale; (3) health-related QoL measured with the Assessment of Quality of Life (AQoL); (4) use of coping skills to manage pain using the scale of the coping attempt of the Coping Strategies Questionnaire (CSQ); (5) self-efficacy for pain and function measured with the Arthritis Self-Efficacy Scale (ASES); (6) pain catastrophizing using the Pain Catastrophizing Scale (PCS); and (7) emotional states of depression, anxiety, and stress using the 21-item version of the Depression Anxiety Stress Scales (DASS-21) questionnaire. At week 8, the PCST group had greater improvements in function, pain coping, and global improvement than comparison. Greater pain-coping improvements persisted at 24 and 52

weeks. Yet, there were no significant between-group differences in primary outcomes at week 24 (change in walking pain MD 0.5 units; 95% CIs: -0.3—1.3) and function (MD -0.9 units; 95% CIs: -4.8—2.9), with both groups showing clinically relevant improvements (Bennell et al., 2018).

O'moore et al., (2018) have a contrary results to the previous study. An RCT about the effects of iCBT for depression in knee OA individuals brought a surprising result. Although not targeting Knee OA symptoms, the intervention exerted significant improvements in arthritis-related self-efficacy, pain, stiffness, and physical function in this group. The results of the study were achieved by randomizing eligible participants into two groups: iCBT group or control group. Participants were included if they were 50 years of age or above, had symptomatic knee OA based on symptoms and radiographs, and were diagnosed with major depressive disease (MDD) based on the clinician-administered Mini-International Neuropsychiatric Interview (MINI). Participants were excluded if: (1) criteria for bipolar, psychotic, or substance dependence disorders was met, (2) taking antipsychotics or benzodiazepines, (3) were not on a stable dose of antidepressant medication for at least 2 months, (4) currently suicidal based on both self-report and diagnostic interview or (5) currently receiving CBT for depression.

Simple randomization into either: OA treatment as usual (TAU) and iCBT for MDD (iCBT group) or the TAU control group who received the standard OA treatment was done. The iCBT group received the iCBT sadness program that consisted of 6 online sessions of the CBT best practice. Primary outcomes were depression symptoms (9-Item Patient Health Questionnaire [PHQ-9]) and psychological distress (Kessler-10[K-10]). Secondary outcomes included ASES, OA pain, stiffness, physical function (Western Ontario and McMaster Universities Osteoarthritis Index

[WOMAC]), and physical and mental health (Short Form 12-Item health survey physical component and mental component summaries). Depression status was assessed by blinded diagnostic interview (the Mini-International Neuropsychiatric Interview) at baseline and follow-up. Between-group analyses indicated superiority of iCBT over TAU on the primary outcomes (PHQ-9: Hedges $g = 1.01$, 95% CIs: 0.47—1.54; K-10: Hedges $g = 0.75$, 95% CIs: 0.23—1.28), and on secondary OA-specific measures (ASES: Hedges $g = -0.81$, 95% CIs: -0.29—-1.33; WOMAC: Hedges $g = 0.56$ – 0.65 , 95% CIs: 0.04—1.18) at the 3-month follow-up. Eighty-four percent of iCBT participants no longer met diagnostic criteria for MDD at a 3-month follow-up. The study concluded that an iCBT intervention for older adults is acceptable and efficacious in reducing depression as well as musculoskeletal symptoms related to knee OA. One of the study's limitations was that the intervention was not tailored to knee OA management. Moreover, the authors recommended that future studies should develop a program that targets both depression and OA-related pain and functions (O'moore et al., 2018).

There are two points to be discussed in relation to the results of the previous four studies. First, to compare the results of the three studies that combined CBT and exercises for intervention (Bennell, Ahamed et al., 2016; Bennell et al., 2017, 2018). There was a concerning limitation in the study of Bennell et al. (2018) in that there was no blinding to the study participants. Participants knowledge about their assignment group could be a reason for biased results. When blinding was done in almost similar circumstances, significant between groups difference was not achieved (Bennell, Ahamad et al., 2016; Bennell et al., 2017).

Second point to be discussed, is to compare the results of the studies that targeted the treatment of knee OA symptoms with the studies that

targeted the treatment of depression in knee OA (Bennell, Ahamad et al., 2016; Bennell et al., 2018; O'moore et al., 2018). It is of surprise that CBT (whether delivered online or face to face) and tailored exercise did not bring suspected results, while on the other hand, an iCBT aimed at depression improved pain and physical function despite it not being intended for OA symptoms. To justify the results of the previous three studies, the findings of a retrospective United States cohort study must be considered. This was a study of the factors associated with persistently high-cost health care utilization for musculoskeletal pain. It was found that individuals with persistent musculoskeletal (MSK) pain, who are considered high utilizers of the health care services, have specific variables associated with their expenditure classification group. Some of these variables are modifiable and others are not. Among the modifiable variables were lower perceived physical and mental health status, higher levels of psychological distress and depression, and higher pain interference (Lentz et al., 2019). To break the chain of persistently high-cost utilization, an intervention must target individuals with these specific variables so that it will avail positive effects compared to a control group. This was clearly proven in O'moore et al. (2018) study where specialized iCBT for depression was introduced to subjects who had a certain level of depression. The effects of iCBT in this study have extended beyond depression levels reduction to include a reduction in OA symptoms like pain, stiffness, and physical function, although treatment did not directly target these symptoms (O'moore et al., 2018). A physical therapist delivered CBT did not show any significant difference for pain or function when a comparison between the three groups was done (PCST/ PCST and exercise/ Exercise only) (Bennell, Ahmad et al., 2016).

The same CBT program was translated into an internet version of CBT (iCBT) and was applied before a standardized exercise program in

hip OA persistent pain patients. Similarly, it was concluded that adding an iCBT program did not confer any additional improvements in pain or function except for the sustained pain-coping improvements (Bennell et al., 2018). This is justified in both studies in that the individuals with the modifiable factors were not targeted, and if they were targeted -as in the iCBT depression study- positive results and significant differences between the groups might be incurred. Target individuals are those with lower perceived physical and mental health status, higher levels of psychological distress and depression, and higher pain interference as what was found in Lentz et al. (2019) study. This is in accordance with Rice et al. (2109) review of the best evidence for chronic knee pain rehabilitation that recommended the use of CBT in appropriate individuals for it to yield positive effects. Appropriate individuals are OA patients who have co-existing psychosocial comorbidities (e.g. depression) or those with psychological barriers to physical function such as fear of movement and pain catastrophizing (Rice et al., 2019). CBT interventions for pain have proved effectiveness for reducing anxiety, depression, and stress as well and could be administered in cases of knee OA with co-existing psychosocial comorbidities (Bennell, Ahamed et al., 2016; Bennell et al., 2017).

The results, recommendations, and limitations of the previous studies were all incorporated to formulate the hypothesis of this study that is: an iCBT combined with a standardized exercise program significantly improves pain and function in chronic knee pain patients who have certain levels of depression and psychological distress compared to a control group (Fig. 2.1).

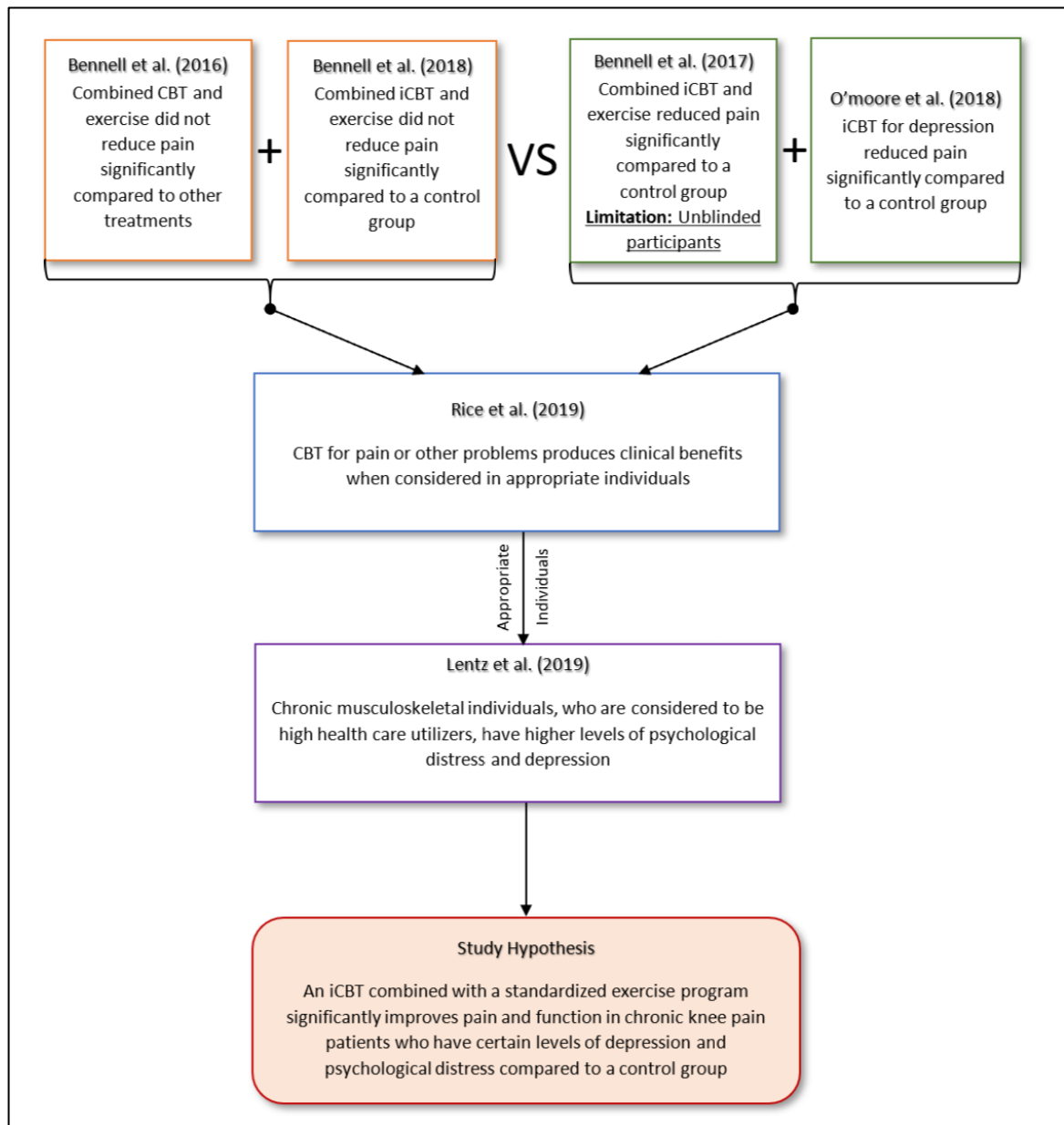


Fig. 2.1: Studies summary and formulation of the study hypothesis

2.3. Outcome Measures

2.3.a. Primary Outcome Measures

- The Single-Item Numerical Rating Scale (NRS)

NRS was recommended by the Veterans health administration work group as one of the core outcome measures for chronic musculoskeletal conditions (Kroenke et al., 2019). For several reasons, the authors recommend the NRS as a minimum core measure to assess pain intensity. First, rating scales with numeric rather than verbal response options have a somewhat longer track record of use in clinical trials and other research studies. Second, the cut-points for differing levels of pain on 0–10 NRS have been extensively studied (Cleeland et al., 2003). For example, one common cut-point range (1–3 representing mild pain, 4–6 moderate pain, and 7–10 severe pain) has been used in major Veterans health administration quality improvement initiatives. Third, the responsiveness of the NRS equals or exceeds that of the most-studied verbal response scales (Patient-Reported Outcomes Measurement Information System (PROMIS) and Short Form 36 (SF-36)).

The minimal clinically important difference (MCID) in changes of chronic musculoskeletal pain intensity was determined by a prospective cohort study by Salaffi et al. (2004). Patients' pain intensity was assessed by NRS and compared to the validated patient's global impression of pain (PGIP). It was found that on average, a reduction of one point or a reduction of 15.0% in the NRS represented a MCID for the patient. An NRS change score of -2.0 and a percent change score of -33.0% were best associated with the concept of "much better" improvement. For this reason, these values can be considered as appropriate cut-off points for this measure.

Chuang et al., 2015, found that NRS is a reliable and valid tool for pain measurement by Spearman Rank $r=0.85$, IC95%.

-Functional Performance Tests (40-m Fast-Paced Walk Test (40mFPWT)/ Step Test (ST)/ 30 seconds Chair Stand Test (30s CST test))

The OARSI has recommended a set of performance-based measures of physical function representing typical activities relevant to individuals diagnosed with hip or knee OA. These tests were the 30-s chair-stand test, 40 m fast-paced walk test, a stair-climb test, timed up-and-go test and 6-min walk test. The first three were recommended as the minimal core set of performance-based tests for hip or knee OA (Dobson et al., 2013).

The reliability and the measurement error of the 40mFPWT and 30s CST were investigated in another study by Dobson et al. (2017). This was a prospective study with repeated measures between independent raters within a session and within-rater over a week interval. Relative reliability was estimated for 51 people with hip and/or knee OA (mean age 64.5 years, standard deviation (SD) 6.21 years; 47% females; 36 (70%) primary knee OA) on the two tests using intra-class correlation coefficients (ICC). Absolute reliability was calculated using standard error of measurement (SEM) and minimal detectable change (MDC). Measurement error was acceptable ($SEM < 10\%$) for both tests. Between-rater reliability was optimal ($ICC > 0.9$, lower 1-sided 95% CI > 0.7) for the 40mFPWT and sufficient ($ICC > 0.8$, lower 1-sided 95% CI > 0.7) for 30sCST. Within-rater reliability was optimal for 40mFPWT and sufficient for 30sCST. It was concluded that both tests have demonstrated, at minimum, acceptable levels of both between and within-rater reliability and measurement error. As both tests demonstrated sufficiently small measurement error, this

indicates that both are adequate for measuring change over time in individuals with knee/hip OA.

Reliability and validity for the Step Test have not been reported for people with knee OA (Hatfield et al., 2016). Yet, this specific test was selected as the resources required were available in the health center setting, where the study took place.

Nonetheless, there were 2 studies that have compared step test results for knee OA participants with health controls. One of the studies, published point estimates for data between participants with knee OA and healthy controls where performance was 12 and 17 steps, respectively (a large Standardized Mean Difference (SMD) of -3.29; 95% CIs: -4.08—-2.50) (Mohammadi et al., 2008).

The other study comparing data for people with knee OA and healthy controls also showed that healthy controls were able to complete 5 more steps in the 15 seconds than the knee OA group. The healthy controls completed an average of 17.1 steps in 15 seconds, and the knee OA group completed an average of 12.1 steps, a large SMD of -1.54 (95% CIs: -2.09—-0.98) (Hinman et al., 2002).

2.3.b. Secondary Outcome Measures

-Patient Health Questionnaire (PHQ-2)

The internal consistency and concurrent validity of the PHQ-2 were investigated in a study that recruited 400 Iranian university students (Ghazisaeedi et al., 2021). Among participants, 206 (51.5%) were male, and 194 (48.5%) were female, and the mean age was 23.67 ± 5.37 years, with a range between 18 and 47 years. The study aimed to investigate the validity, reliability, and optimal cut-off points for the PHQ-2, PHQ-9, and Well-being Index (WHO-5) to screen mild depression among Iranian

students who completed these tools and Beck Depression Inventory (BDI-13). Further, a psychiatrist diagnosed the depression by using the “Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders.” The internal consistency value of PHQ-2 was 0.88. The PHQ-2 was significantly associated with the BDI-13 ($r = 0.53$; $P < 0.001$). The PHQ-2 had optimal cut-off points of 2 with an area under the curve (AUC) of 0.809.

Elhadi et al. (2021) undertook cross-cultural adaptation of the PHQ-2 in the Arabic language. The English version of the PHQ-2 was translated into the Arabic language by two independent Libyan translators, and Arabic is the official language of the Libyan population. The questionnaires were then back-translated into English to determine the internal consistency of the English versions. Any discrepancy in the translations was resolved by a third person until a consensus was reached. A pilot study involving 30 respondents to ensure a high level of internal consistency, as determined by a Cronbach's alpha value of above 0.7. The reported internal consistency of the PHQ-2 was determined by a Cronbach's alpha value of 0.828 (Elhadi et al., 2021).

In our study, a minimum depression level of 2 out of 6 was determined as an inclusion criterion. A score of 2 was identified as the most optimal cut-off for detecting depression (Arroll et al., 2010; Ghazisaeedi et al., 2021; Lentz et al., 2019; Sedeeq et al., 2022).

-Psychological Distress (Kessler 6)

The Kessler psychological distress scale was translated from English to Arabic by an experienced language expert (Easton et al., 2017). The translated version was then tested for reliability and validity in a sample of 243 Palestinian social workers. Reliability was tested by measuring internal consistency using Cronbach's alpha coefficient. Scale reliability analysis showed satisfactory results on both K6 and K10 versions

(Cronbach's $\alpha = 0.81$ (K6) and 0.88 (K10)). Next, factor structure was assessed using variance-covariance matrix with maximum likelihood estimation. Confirmatory factor analysis was performed to examine three competing models: unidimensional K10 model, unidimensional K6 model, and two-factor K6 model. Fit indices and parameter estimates were reported. Last, convergent validity was examined by assessing correlations with GAD-7 and Somatic Symptoms Scale (SSS-8). Among three competing models, the two-factor K6 scale demonstrated the best model fit with high factorial correlations ($r = 0.60$, $P < 0.001$). Moreover, the K6 has high convergent validity with GAD-7 ($r = 0.66$, $P < 0.001$) and SSS-8 ($r = 0.61$, $P < 0.001$). Study results indicated that the translated version of the two-factor K6 scale is a valid and reliable measurement of psychological distress.

A minimum level of 7 out of 24 psychological distress was set as an inclusion for this study. This was based on the mean levels of psychological distress in chronic musculoskeletal patients (Lentz et al., 2019).

- Arabic Version Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS- PS)

Torad et al. (2015) assessed the reliability and validity of the Arabic version of KOOS-PS. Sixty-nine patients with knee osteoarthritis were recruited. Three expert panels (each consists of ten experts) participated in this study for forward translation, development of preliminary initially translated version, backward translation, development of the pre-final version, and testing of pre-final version. The final version was tested on patients. Clarity index, expert proportion of clearance, index of content validity, expert proportion of relevance, descriptive statistics, missed item index, Cronbach's alpha, and Spearman's rank correlation coefficient were used for statistical analysis. The study showed that scale index of clarity

equals 100%, scale - level clarity index universal agreement equals 100%, scale index of content validity equals 97.14%, scale - level content validity index universal agreement equals 71%, the scale items were filled by 99.4% in all sheets, the scale needed less than five minutes to answer in about 99% all sheets, Cronbach's alpha equals 0.848 (95% CIs: 0.789–0.896) and all Spearman's correlations between test and retest results were statistically significant. The study concluded that the Arabic language version of the KOOS-PS is valid and reliable enough to measure the physical function in knee OA patients (Torad et al., 2015).

-Health-Related Quality of Life-Short Form-12 (SF-12)

SF-12 is a briefer alternative for SF-36 for measuring the QoL in general and specific populations. Haddad et al. (2021) has studied the reliability and validity of the Arabic version of this questionnaire. This was a cross-sectional study performed between July and November 2019 that recruited 269 participants of Lebanese adults. Cronbach's alpha was used to assess the reliability of the SF-12 questionnaire, and a factor analysis using the principal component analysis was performed to confirm its construct validity.

The mean score for the “physical component summary (PCS-12)” was 50.27 ± 8.94 (95 % CIs: 49.18–51.36) and for the “Mental component summary (MCS-12)” was 44.95 ± 12.17 (95 % CIs: 43.47—46.43). A satisfactory Cronbach's alpha was found for the two components: MCS ($\alpha = 0.707$) and PCS ($\alpha = 0.743$). The principal component analysis converged over a two-factor solution (physical and mental), explaining a total variance of 55.75 %. Correlations between the SF-12 scales and single items were significant, showing a good construct validity. There was high association between “physical functioning”, “role physical”, “bodily pain”,

“general health” subscales and “PCS-12”, while the “vitality”, “social functioning”, “role emotional”, and “mental health” subscales were more associated with MCS-12. The study concluded that the Arabic version of the SF-12 is a reliable, easy-to-use, and valid tool to measure health-related QoL in the general population (Haddad et al., 2021).

-Maximum Isometric Muscle Strength

Luc-Harkey et al. (2018) found that greater quadriceps and hamstrings muscle strength was associated with less pain, less difficulty completing activities of daily living, and better mobility in individuals aged 45 years and above with knee OA and meniscal tear (Luc-Harkey et al., 2018).

Hand-held dynamometer (HHD) can be used to evaluate strength when gold-standard isokinetic dynamometer (IKD) is not feasible (Katoh et al., 2011; Lesnak et al., 2019; Mentiplay et al., 2015). Chopp-Hurley et al. (2019) have examined the test-retest reliability and validity of the hand-held dynamometer in older women with knee OA. A total of 28 older women with knee OA completed knee extension and flexion exertions measured using hand-held dynamometer and isokinetic dynamometer. High test–retest reliability between trials, as exhibited by low SEM%, low MDC, and high ICCs, was demonstrated for both knee extension and flexion with both the isokinetic dynamometer and the hand-held dynamometer. The results of the SEM%, MDC, and ICC using the IKD for knee extension were 6.4%, 15.9, and 0.96 (99% CIs: 0.91–0.98), respectively. The results of the SEM%, MDC, and ICC using the HHD for knee extension were 6.8%, 14, 0.95 (99% CIs: 0.90–0.98), respectively. Criterion validity between IKD and HHD was in the range considered good. The ICC between IKD and HHD was 0.76; however, wide CIs were elicited (-0.02–0.96). It was concluded that the hand-held dynamometer is

a reliable tool for capturing knee extension and flexion in individuals with OA (Chopp-Hurley et al., 2019).

Chapter Three

Research Methods and Procedures

3.1. Study Design

3.2. Participants

3.3. Study Procedure

3.4. Interventions

3.5 Outcome Measures

3.6. Data Collection

3.7. Ethical Considerations

3.8. Data Analysis

3.1. Study Design

This is a 2-arm randomized controlled trial of 8 weeks of intervention involving 8 sessions of standardized exercise program of either concomitant iCBT and educational sessions or educational sessions only. Measurements were taken at baseline and 8 weeks immediately following the intervention. The study has been conducted at the physiotherapy department at National Bank of Bahrain-Arad Health Center (NBB-Arad HC), Kingdom of Bahrain. The study flow is summarized in Fig. 3.1.

3.2. Participants

Participants were recruited from NBB-Arad HC who were referred to the physiotherapy department for knee pain. Participants' enrolment took place from July to October 2021.

- **Inclusion criteria:**

1. Age $\geq$ 45 years
2. Depression level of at least 2 out of 6 on the PHQ-2 questionnaire and/or psychological distress level (K-6) of at least 7 out of 24
3. Knee pain for more than 3 months and for most days of the previous month
4. A minimum average knee pain intensity of 4 on an 11-point numeric rating scale in the previous week
5. Mild to moderate difficulty with physical activities on KOOS-PS questionnaire, at least 6 out of 24
6. Has a smartphone with internet access.

- **Exclusion criteria:**

1. Knee surgery including arthroscopy within the past 6 months

2. Awaiting or planning any back or lower limb surgery within the next 12 months
3. Current or past (within 3 months) oral or intra-articular corticosteroid use
4. Current long-term use of analgesics or drugs that cause analgesic effects such as the drugs used for epilepsy and bipolar disorders
5. Systemic arthritic conditions such as rheumatoid arthritis
6. Physiotherapy, chiropractic or acupuncture treatment or exercises specifically for the knee within the past 6 months
7. Walking >30 min continuously daily or participating in a regular (more than twice a week) exercise program
8. Past participation in a CBT program
9. Inability to walk unaided as this is necessary for some of the physical testing
10. Grade IV on Kellgren and Lawrence grading system for Osteoarthritis classification
11. Medical condition precluding safe exercise such as uncontrolled hypertension or heart condition
12. Major joint pain (e.g., back, hip or ankle) to a greater extent than the knee pain that could limit the ability to exercise
13. Self-reported psychiatric history such as schizophrenia, epilepsy, and bipolar disorders
14. Self-reported diagnosis of current clinical depression
15. Neurological condition such as Parkinson's disease, Multiple sclerosis, or stroke
16. Inadequate written and spoken Arabic
17. Unable to comply with the protocol such as the inability to attend therapy sessions or attend assessment appointments at the health center.

- **Sample Size**

Convenient sampling has been used for this study based on the time and resources limit for this study. A number of twenty participants were assigned in each group.

3.3. Study Procedure

All participants have provided electronic informed consent prior to their enrolment (Appendices 8 and 9). Eligible patients were randomly allocated to either the study group or the control group (1:1). Participants were blinded to their group assignment.

Initial assessments by self-reported questionnaires were done at baseline. Initial assessment of knee joint as well as the objective outcome measures were taken. This included: Isometric muscle strength of quadriceps using a hand-held dynamometer, functional tests (40mFPWT/ 30s CST/ ST). Knee strengthening exercises was then prescribed to the participant under the supervision of the researcher. Participants were asked to follow the exercises at home for 3 times per week. Depending on the participant's allocation, a link to access either online material of pre-recorded sessions of CBT or educational material was given. Educational material included information about knee pain, healthy diet, and other general information. In addition to their access to iCBT sessions, the study group were given access to the same educational material that was accessed by the control group. On the 2nd -8th session, the researcher followed up on the exercises and progressed as needed. The researcher has discussed the disease-specific and general health benefits of increased levels of general physical activity, including both incidental physical and whole-body exercise. The researcher has responded to any questions or doubts the participant has regarding the online sessions.

In the 8th session, self-reported questionnaires were undertaken again as well as the objective outcome measures. All self-reported questionnaires were completed through a survey administration application (Google and Microsoft forms).

Due to Coronavirus Disease 2019 (COVID-19) pandemic, the following safety precautions have been considered:

- The researcher and the participant have had to wear mask (and gloves if required).
- All equipment used were cleaned and disinfected after each participant use.
- Participants were seen individually whether for examination or exercises sessions.
- Social distancing was maintained whenever possible.

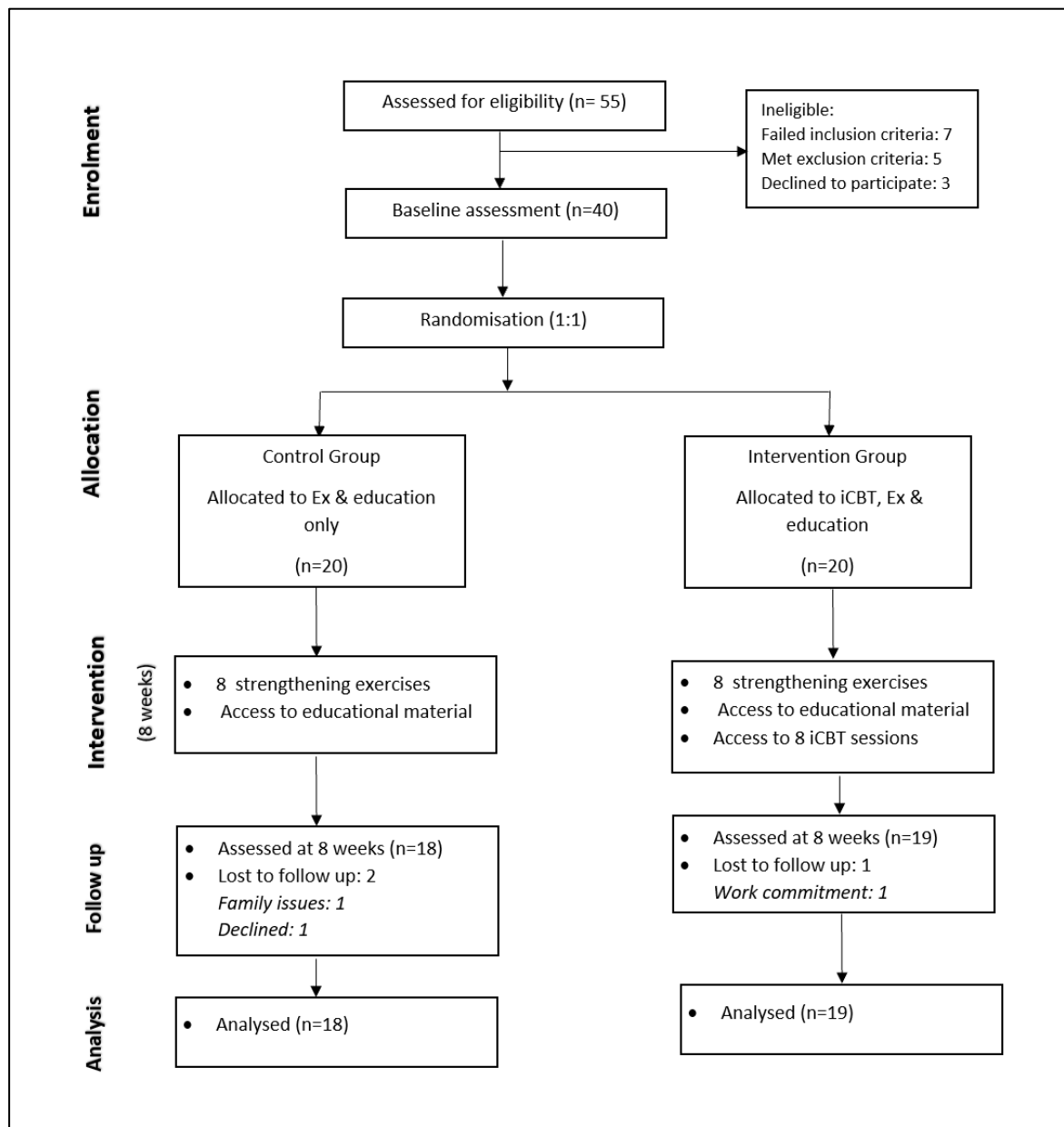


Fig. 3.1: Study flow diagram

3.4. Interventions

1. Standardized Exercise Program (common to both groups)

Participants were asked to attend to the department for 8 supervised physiotherapy sessions designed to strengthen lower limb muscles. Eight sessions were chosen as this number should be able to achieve improvements in pain and function (Fransen et al., 2015). Standardized exercises sessions were held once weekly in the health center and were supervised by the researcher. In addition, participants were requested to perform the prescribed exercises 3 times per week at home, with 1-2 days rest interval between the exercise's sessions.

The exercise program was adopted from a previous RCT study that has proved the effectiveness of an internet-delivered exercises and pain coping skills in improving pain and function in chronic knee patients (Bennell et al., 2017). The program is comprised of a minimum of 4 and a maximum of 6 individualized lower limb exercises to be performed 4 times per week (once in the health center and 3 times at home). All exercise programs have included at least 2 knee extensor strengthening exercises, 1 hip abductor strengthening exercise, 1 hamstring strengthening exercise, 1 calf strengthening exercise, and 1 other exercise chosen based on assessment findings. Exercises were selected from a pre-determined list (Table (3.1)). The remaining optional 1 exercise was chosen from other exercises on the list or any exercise of the researcher's choice, in order to address an impairment or functional deficit related to the participant's knee problem. Examples included deep squats, deep lunges, and bridging. The researcher selected exercises and prescribed dosages for each exercise based on the assessment findings, including muscle strength, the participant's pain, and their perceived level of effort during the performance of the exercise. Moreover, participants were asked to have elastic bands and/or ankle cuff weights for the execution of the exercises if

required. Participants were asked to follow exercises at home 3 times/week. Examples of the exercises given to participants in the clinic are shown in Fig. 3.2.



a. Standing knee flexion



b. Wall squats



c. Forward Touchdowns from a step



d. Standing hip abduction



a. Deep lunges

Fig. 3.2: Examples of the exercises given to participants at the clinic

Table (3.1): Pre-determined List of Exercises Program (Bennell et al., 2017)

Maximum of 6 exercises (with progression as appropriate)			
		2 knee extensor strengthening exercises	
		1 hip abductor strengthening exercise	
		1 hamstring strengthening exercise	
		1 calf strengthening exercise	
		1 other exercise chosen based on assessment findings	
1. Quads strengthening (each program must include 2 exercises)			
Knee extension	Non weight-bearing	A. Seated knee extension (with resistance) with 5 second hold	Indications: suggested as an initial exercise Progression: Increase cuff weight or theraband resistance – red through to black Simplification: eliminate weight or see 1B
	Non weight-bearing	B. Inner range quads over roll (with resistance) with 5 second hold	Indications: Usually only required when any flare ups with seated knee extension (1A) Progression: Use appropriate level of ankle cuff weight Simplification: eliminate weight if flare up
Sit-to-stand	Weight-bearing	C. Sit to stand without using hands	Indications: suggested as an initial exercise Progression: lower chair height, hover above the seat without touching down, more weight on affected leg, slit leg position (affected leg closer to seat) Simplification: use hands
Steps	Weight-bearing	D. Step-ups	Indications: suitable progression from sit to stand (1C) Progression: Increase step height, hold extra weight (in hands or backpack) Simplification: sit to stand (1C)
	Weight-bearing	E. Forward touchdowns from a step	Indications: suitable progression from step-ups (1D) Progression: Increase step height, hold extra weight (in hands or backpack), don't touch down Simplification: step-ups (1D)
Partial squats	Weight-bearing	F. Partial wall squats	Indications: suitable progression from sit to stand (1C) Progression: Increase to 5 sec hold, more weight on study side Simplification: if find flare/problematic step back to sit to stand (1C)
2. Hip abductor strengthening (1 exercise)			
Standing hip abduction	Non weight-bearing	A. Side leg raises in standing	Indications: suggested as an initial exercise Progression: Increase cuff weight or theraband resistance – red through to black Simplification: eliminate weight
Side stepping	Weight-bearing	B. Crab walk with resistance band	Indications: good progression from standing leg side raises (2A) Progression: Increase theraband resistance – red through to black Simplification: side leg raises in standing (2A)
Standing hip abduction	Weight bearing	C. Wall push standing on study leg	Indications: good progression from crab walking (2B) and for variety at final session Progression: Increase step height. Hold extra weight (in hands or backpack) Simplification: If unable to tolerate static standing on joint then avoid and use 2B or 2A. Precaution in those with increased varus.
3. Hamstring strengthening (1 exercise)			
Standing knee flexion	Non weight-bearing	Standing over bench knee curls with weight	Progression: Increase cuff weight or theraband resistance – red through to black Simplification: eliminate weight
4. Calf strengthening (1 exercise)			
Standing plantar-flexion	Weight-bearing	Double heel raises	Progression: single heel raises, raises from the edge of a step
5. Others (1 exercise if appropriate)			
Knee ROM	Weight bearing	A. Deep squats holding onto a bench/chair	Progression: increase squat depth
Hip ROM	Weight bearing	B. Deep lunges holding onto back of chair/bench	Progression: increase lunge depth
Hip extensors	Weight-bearing	C. Bridging	Progression: split leg bridge, single bridge with a hold, bridging one leg

A brief assessment was performed by the researcher at each physiotherapy session to ascertain any adverse effects (if any) that may have occurred with home exercises and to check the quality and form of exercise performance. Progression of exercises was an essential component of the program and the findings from the assessment helped guide the researcher's decisions regarding progression. Progression was provided by varying the exercises including the type of exercise as well as the number of repetitions, load, or degree of difficulty within an exercise. In order to gain strength, the level of effort experienced during each strengthening exercise was self-rated as at least 5 out of 10 (hard) on a modified Borg Rating of Perceived Exertion (RPE) CR10 scale designed specifically for strengthening exercise (Appendix 1) (Day et al., 2004). In addition, the resistance prescribed aimed to approximate a 10-repetition maximum level. Exercises were sent to participants via WhatsApp either in GIF format or JPEG format to follow up at home (Figure 3.3 a - e). A track of exercises performance was kept by the researcher. In the weekly session, the researcher asked the participant about the frequency of the exercises done in the past week and kept a track of it in a separate Excel Sheet.



b. Bridge



a. Double heel raises



c. Sit to stand



d. Seated knee extension



e. Resisted Hip Abduction



f. Squats

Fig. 3.3: Examples of WhatsApp GIF exercises that were sent to participants to follow as home program

To view the GIF format of the images, click on the link:

<https://drive.google.com/drive/folders/1ZPCulH9K1m33Y3v1PloQkt-QLTj-p6dI?usp=sharing>

Risk Factor

Some discomfort is expected during the strengthening exercise sessions and whole-body physical activity however, the pain should subside to usual levels by the next day with no increase in swelling following the exercise session. Participants were taught how to determine whether pain levels during and for a short time after the exercises are acceptable. If a specific exercise was aggravating the participant's pain, then the researcher had to reduce the resistance, dosage and/or level of challenge within the exercise until the pain flare settled. Progression was partially based on the absence of significant pain (2-3 out of 10, Fig. 3.4) during exercises (Crossley et al., 2019).

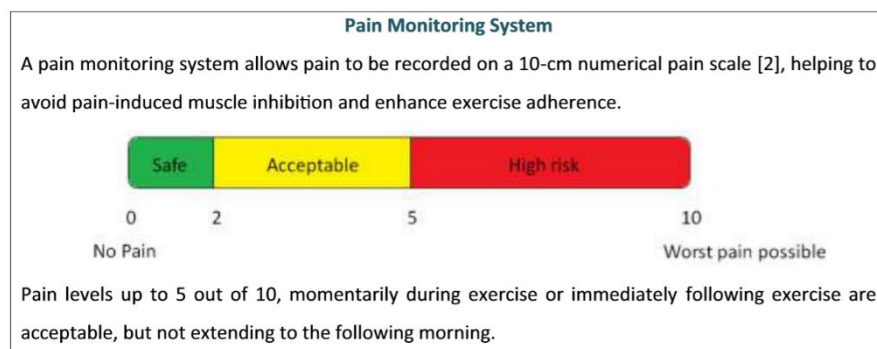


Fig. 3.4: Pain Monitoring System (Crossley et al., 2019)

2. Educational Material (common to both groups)

All participants received a link to access online educational material about chronic knee pain. This was a YouTube link that consisted of 5 sessions, with each lasting for 5-7 minutes, and was comprised of general information about the following: healthy eating, OA and X-Ray, physical

activity, the full pain experience, and proper footwear. Participants were encouraged to access the educational material at their own leisure and pace. Snapshots of each of the five educational sessions are shown in Figure 3.5.

Educational sessions YouTube Link:

https://www.youtube.com/channel/UCY-b9jHKDI_va6kXarbzycA



Fig. 3.5: Snapshots of each of the five educational sessions

3. Internet-Based Cognitive Behavioural Therapy (intervention group only)

In addition to their access to the educational material, participants in this group have received a link to access pre-recorded online sessions of CBT. The content of sessions was adopted from the painTRAINER program. The painTRAINER was originally based on the painCOACH program that was effectively used in an RCT for the effects of adding and iCBT to an exercise program in persistent hip pain patients (Table (3.2)) (Bennell et al., 2015). The iCBT translated key therapeutic components of face-to-face PCST (Rini et al., 2014). The program proved its effectiveness in improving pain and function in patients with arthritis (Bennell et al., 2018; Rini et al., 2015).

Table (3.2): Summary of the PainCOACH Content and the Recommended Home Practice Schedule for Each Pain Coping Skill as described by Bennell et al 2016

Module Number	Coping Skill	Content	Recommended Home Practice
1	Progressive relaxation	Teach gate control theory (how thoughts, feelings, and actions affect and are affected by pain); introduce and demonstrate progressive relaxation with animation; walk user through use of the technique and active practice; help user identify/address circumstances that might impede relaxation and choose strategies to overcome obstacles; plan regular practice times; set practice goals	2 times per day
2	Mini-practices	Review prior session content and practices; introduce and demonstrate “mini-practices” (brief relaxation) with animation; walk user through use of the technique and active practice, gather/evaluate preactivity and postactivity pain; help user identify/address circumstances that might impede relaxation and choose strategies to overcome obstacles; discuss benefits and reminders for practicing; plan regular practice times; set and review practice goals	Start at 5–10 times per day, working up to 10 times per day
3	Activity/rest cycling	Review prior session content and practices; introduce concept of activity/rest cycling; identify activities user tends to overdo; vicarious learning exercise—demonstrate how to change overdone activities; create personal plan to fit daily routine and personal goals; review how other skills help with use of this skill; plan regular practice times; set and review practice goals	Use for any activity that you tend to overdo
4	Pleasant activity scheduling and identify negative automatic thoughts	Review prior session content and practices; introduce concept of pleasant activity scheduling; lead user through exercise for adding pleasant activities to his or her life; mini-practice of 10-min pleasant activity to be done immediately (gather/evaluate pre-activity and post-activity pain); schedule 3 pleasant activities for week; problem solve barriers with interactive vicarious learning exercise; introduce concept of negative automatic thoughts; describe connections between thoughts, emotions, behaviors, and pain; walk user through a thoughts exercise; plan regular practices; set and review practice goals	Plan a few pleasant activities each week
5	Identify/change negative automatic thoughts and coping thoughts	Review prior session content and practices; continue and advance prior session's activities related to automatic thoughts and introduce coping thoughts; practice identifying negative thoughts and accompanying emotional and physical reactions of virtual patients, then self; exercise to teach generation of alternative thoughts, then practice and record accompanying sensations; focus on teaching generation of alternative thoughts; practice generating calming self-statements; practice skills and get feedback; identify and address circumstances that impede use of these skills and strategies to overcome obstacles; mini-practices for specific circumstances; plan regular practices; set and review practice goals	Use whenever you have unhelpful thoughts
6	Pleasant imagery and distraction techniques	Review prior session content and practices; introduce pleasant imagery and auditory and focal point distraction techniques; complete exercises with audio instructions; plan regular practices; set and review practice goals	Practice a few times a week
7	Problem solving	Review prior session content and practices; introduce concept of problem solving and describe steps; demonstrate problem solving with character stories; generate list of challenging situations; exercise to help users select skills for each situation, with personalized plan for overcoming barriers; plan regular practices; set and review practice goals	Whenever a challenging thought arises
8	Monitoring for maintenance	Review all session content; evaluate skill frequency, helpfulness, and comparison with other users; exercises to develop plan for maintenance of skills; motivate further practice and skill development; remind participant how skills facilitate personal goals; review practice goals	
	Booster sessions	Review module 8 and revisit any useful/meaningful sessions	

The iCBT link contained eight 35- to 45-minute sessions, designed to be completed weekly, each provided an explanation of a cognitive or behavioural pain coping skill. Session 1 provided an overview, including a therapeutic rationale of CBT, followed by training in progressive muscle relaxation. Sessions 2 through 7 taught brief relaxation skills, activity-rest cycling, pleasant activity scheduling, cognitive restructuring, pleasant imagery, and problem-solving. Session 8 consolidated the learnt and taught strategies for long-term skill use (Fig. 3.6). Each session has to be completed within the same week where the physiotherapy session was given. Participants were asked to practice and actively use each new skill they learn. Skills practices were reviewed in subsequent sessions. The researcher has developed a website that contained all the CBT materials (Fig. 3.7).

Link: <https://toalaradi.wixsite.com/website>



Fig. 3.6: iCBT website developed by the researcher

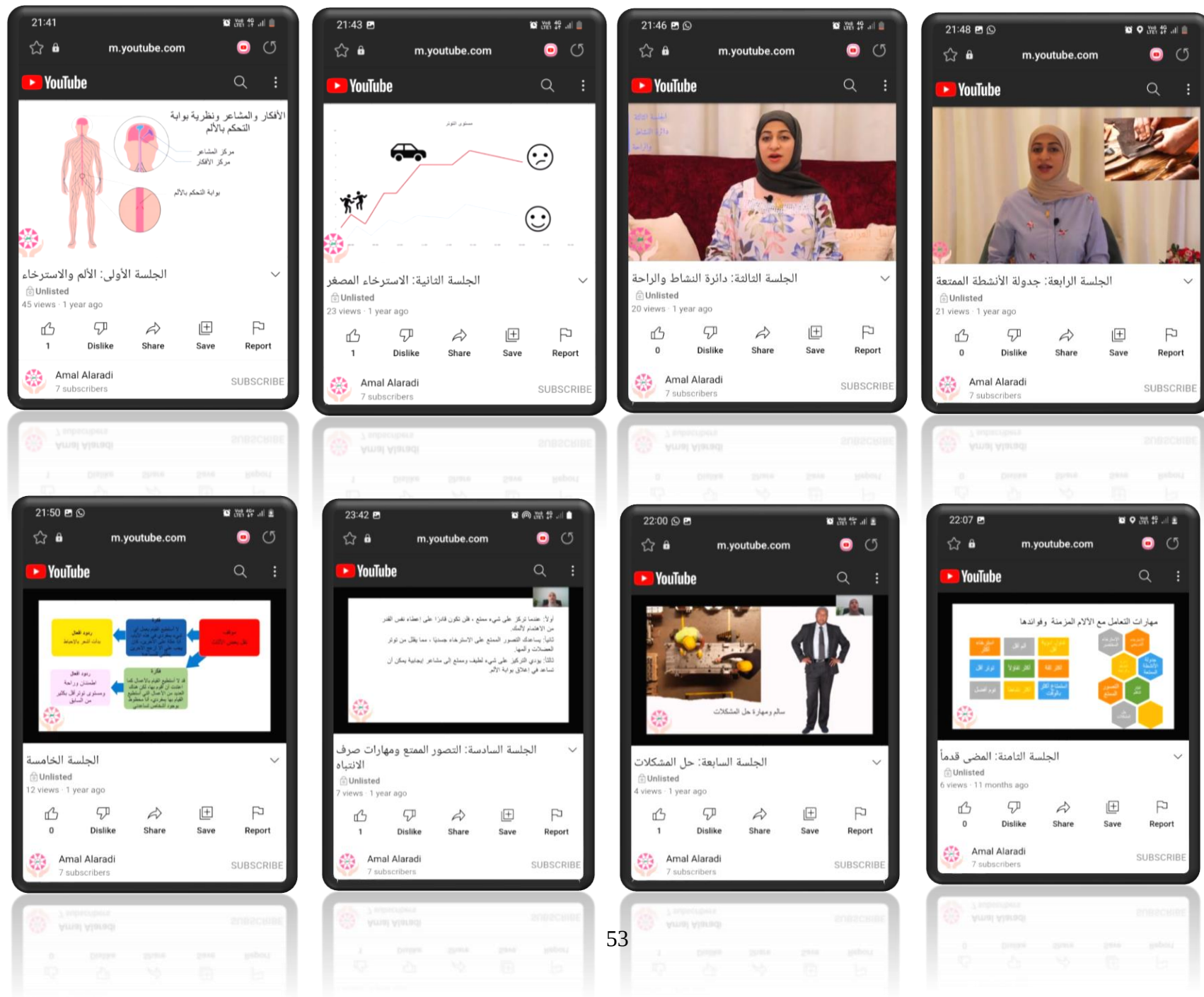


Fig. 3.7: Snapshots of the eight iCBT sessions

Participants have had the opportunity to ask questions about the iCBT session they've completed when attending the physiotherapy exercise session. In addition, a companion iCBT workbook was provided, that included some notes, summaries, and questions of each iCBT session (Fig. 3.8).

Workbook Link:

<https://drive.google.com/file/d/1DuOJBPSaOO9Ai5BSIP0o8yD1Ax2EcjPc/view?usp=sharing>

Participants were encouraged to write their own notes and answer the questions available on the workbook for each session (Fig. 3.9)

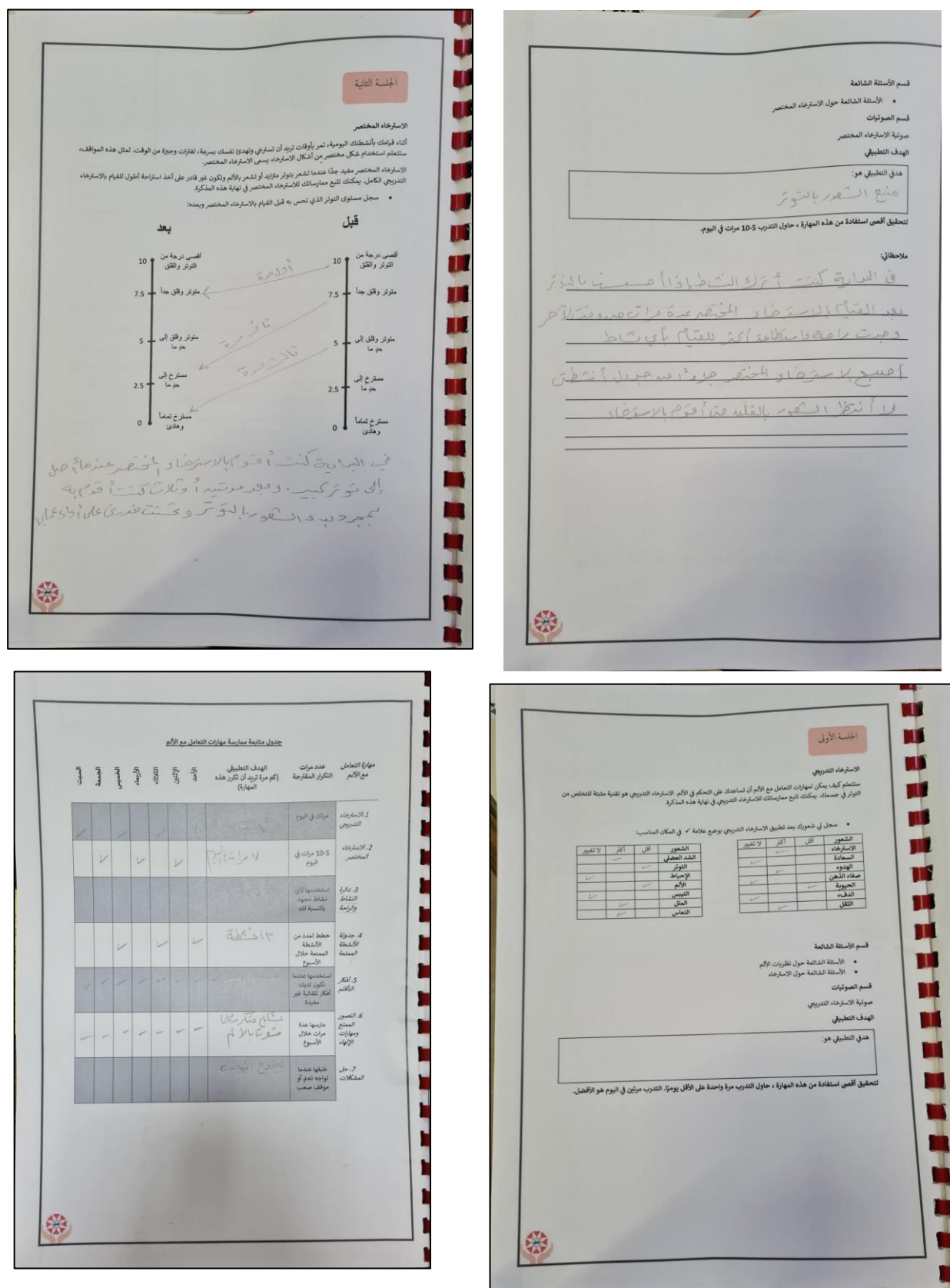


Fig. 3.9: Examples of the iCBT worksheets solved by a participant

Retention and Adherence Plan

To maintain a high retention rate, participants who miss their appointments were contacted and another suitable appointment was arranged for them. To improve program adherence, participants were encouraged to follow on their home exercises as instructed in all the eight sessions. In addition, participants in the intervention group were encouraged, in each of their weekly sessions, to complete their iCBT session and to practice the skills they learn weekly.

3.5. Outcome Measures

1. Primary Outcome Measures

- The Single-Item Numerical Rating Scale (NRS)

Participants were asked to rate their average knee pain in the past week on a scale from 0 to 10, with '0' meaning 'No pain' and '10' meaning 'Pain as bad as you can imagine' (Dworkin et al., 2005). This is a reliable tool that was recommended by the Veterans health administration workgroup as one of the core outcome measures for chronic musculoskeletal conditions (Kroenke et al., 2019). This was recorded via online form (Appendix 2)

- 40-m Fast-Paced Walk Test (40-m FPWT)

A participant was instructed to walk as quickly but as safely as possible to a mark 10 m away, return, and repeat for a total distance of 40 m (Fig. 3.10). Time of one trial, with turn time excluded, is recorded and expressed as speed m/s by dividing distance (40 m) by time (s) (Dobson et al., 2013).



Fig. 3.10: 40-m Fast-Paced Walk Test (40-m FPWT)

- **Step Test (ST)**

This test was performed while the participant maintained balance on the study limb, then the contralateral foot was stepped on and off a 15-cm step as many times as possible within 15 seconds. The count of the number of times the participant could step the foot up and return it to the floor over a 15-s interval was recorded. The test was performed with no hand support allowed (Hatfield et al., 2016; Hinman et al., 2002). For participants with unilateral knee OA, the test was performed while standing on the affected side. For participants with bilateral knee OA, the most symptomatic limb was considered the osteoarthritic limb for the purpose of this study (Fig. 3.11).



Fig. 3.11: Step Test

- **30 seconds Chair Stand Test (30s CTS test)**

From the sitting position in the middle of seat with feet shoulder-width apart, flat on the floor, arms crossed at chest, a participant was asked to stand completely up, then sit completely back down, repeatedly for 30s. The chair was against a wall. Count the total number of complete chair stands (up and down represents one stand) of one trial. If a full stand was

completed at 30s then this was counted in the total (Fig. 3.12). The same chair was used for re-testing (Dobson et al., 2013).



Fig. 3.12: 30 seconds Chair Stand Test (30s CTS test)

2. Secondary Outcome Measures

- Patient Health Questionnaire (PHQ-2)

This is a 2-item scale for depression screening in primary care (Kroenke, 2012). Its Arabic version is a valid and reliable tool to screen for depression (AlHadi et al., 2017). This questionnaire was administered via online forms (Appendix 3).

- Psychological Distress (Kessler 6)

This is a 6-item self-report questionnaire that measures psychological distress based on anxiety and depressive symptoms in the patient's most recent 4-week period (Kessler et al., 2002). The translated version of the K6 scale is a valid and reliable measurement of psychological distress

(Easton et al., 2017). This questionnaire was administered via online forms (Appendix 4).

- **Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS- PS)**

This is a 7-item measure of physical function derived from the items of the Function, daily living and Function, sports, and recreational activity subscales of the KOOS. The Arabic language version of the KOOS-PS was found to be valid and reliable enough to measure the physical function in knee OA patients (Torad et al., 2015). It was administered through an online survey (Appendix 5).

- **Health-Related Quality of Life-Short Form-12 (SF-12)**

This is a questionnaire consisting of twelve questions that measure eight health domains to assess physical and mental health-related QoL (Huo et al., 2018). The Arabic version of this questionnaire was found to be a reliable and valid tool to measure health-related QoL in the general population (Haddad et al., 2021). It was administered through an online survey (Appendix 6).

- **Participant-perceived response to treatment measured on 8-point scales**

Participants rated their perceived change in a) pain, b) physical function and c) overall condition on an eight-point ordinal scale (0-no change to 7-much better). This scale was used as an external criterion for comparison with changes in scores of other outcomes (Bennell, Ahmad et al., 2016; Bennell et al., 2017). Measuring participant-perceived change using a rating of change scale is a reliable and clinically relevant method of identifying improvements that are truly meaningful from the individual

perspective (ten Klooster et al., 2006). Participants who report that they were moderately better and above were classified as improved (Appendix 7).

- **Maximum Isometric Muscle Strength**

Assessing quadriceps muscle strength can indicate the individual's mobility and pain and hence it was assessed in this study (Luc-Harkey et al., 2018). Maximal voluntary isometric quadriceps muscle strength was assessed using a hand-held dynamometer as described by Luc-Harkey et al (2018) (Fig. 3.13). To do the test, a participant was seated on an examination table with their knees flexed to 60° and their feet off the ground. The hand-held dynamometer was positioned on the anterior aspect of the distal tibia, just superior to the malleoli. The participant grasped the examination table with his/her hands for stabilization, and the participant was instructed to extend his/her knee “as hard as possible” into the hand-held dynamometer. The participant continued to exert force into the hand-held dynamometer for 4 s, and the maximum force across the trial was recorded. Three testing trials were completed, and the average force (Newtons [N]) across the three trials were normalized to body mass (N/kg) (Luc-Harkey et al., 2018).



Fig. 3.13: Quadriceps muscle strength assessment

3. Other Measures

- Treatment Benefit Expectation

Participants were asked to rate their expectations of the treatment effects on their knee pain using a 5-point ordinal scale ranging from “no effect” to “complete recovery”.

3.6. Data Collection

Data collection points are summarized in table (3.3). In addition to the outcome measures, descriptive data were collected at baseline by an online questionnaire. Descriptive data collected were age, gender, employment status, marital status, body mass index (BMI), duration of knee symptoms, previous treatments, medical history, and medications.

Table (3.3): Summary of Measures that were Collected

Primary Outcome Measures	Data Collection Instrument	Collection Points
Average pain in the past week	11-point NRS	0 and 8 weeks
Functional performance	40-m Fast-Paced Walk Test	0 and 8 weeks
	30s Chair Stand Test	0 and 8 weeks
	Nine Step Stair Test	0 and 8 weeks
Secondary Outcome Measures		
Muscle strength	Isometric quadriceps muscle strength using a hand held dynamometer	0 and 8 weeks
Depression	Patient Health Questionnaire (PHQ-9)	0 and 8 weeks
Psychological distress	Kessler 6 (K-6)	0 and 8 weeks
Physical function	Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS- PS)	0 and 8 weeks
Health-related quality of life	SF-12	0 and 8 weeks
Perceived change overall	7-point ordinal scale	8 weeks
Perceived change in pain	7-point ordinal scale	8 weeks
Perceived change in function	7-point ordinal scale	8 weeks
Other Measures		
Descriptive data	Online questionnaire	0 week
Adherence to intervention	Therapist treatment records	During intervention
	Educational material access	During intervention
	Weekly home exercise log books	During intervention
	iCBT sessions completion	During intervention
	iCBT skills practice log books	During intervention
Adverse events and harms	Log sheets during exercise intervention	During intervention
Medications and co-interventions	Online questionnaire	0 and 8 weeks
Treatment benefit expectations	5- point likert scale	0 week
Treatment satisfaction	Online questionnaire	8 weeks

3.7. Ethical Considerations

- Ethical Approval

The ethical approvals to start the study was obtained from the Deanship of Graduate Studies and Scientific Research at the University of Bahrain (UOB) and the undersecretary of primary health care services at the Ministry of Health (MOH) in the Kingdom of Bahrain.

- Human Participants

Participants took part in the study voluntarily after receiving sufficient information and after signing a consent sheet (Appendices 8 and 9). Moreover, participants had the right to withdraw from the study at any stage if they wish to do so without prejudice.

- Personal Data

Personal information of participants was dealt with confidentiality and was not shared with anyone. Research information was kept safely in a USB flash drive. Only research personnel had access to the files. After completion of this study, the personal and contact details of participants were erased. The data was confidential and for current research purpose only and was not used for any other or future research.

- Anonymity of Participants

The anonymity of participants was ensured by assigning each participant a code number to enter and to analyse the primary data collected from questionnaires or physical assessments. Participant's identity was not revealed if photographs or video recordings were taken.

- Conflict of Interest

The researcher declares that she has no conflict of interest.

3.8. Data Analysis

Demographic characteristics, as well as baseline scores on primary and secondary outcome measures, were inspected to assess baseline comparability of treatment groups. Descriptive statistics were presented for each group as the mean change (SD, 95% CIs) in the outcomes from pre-treatment to post-treatment. Paired samples tests were done to measure within group differences. Independent sample t-tests were done to measure between group differences.

Chapter Four

Results, Discussion, and conclusion

4.1. Results

4.1.a. Baseline Characteristics

4.1.b. Retention, Adherence, Adverse Events, Medications, and Co-interventions

4.1.c. Treatment Satisfaction and Treatment Outcome

4.1.d. Primary Outcome Measures

- Within Group Analysis
- Between Group Analysis

4.1.e. Secondary Outcome Measures

- Within Group Analysis
- Between Group Analysis
- Participant-Perceived Response to Treatment

4.2. Discussion

- Strengths
- Limitations

4.3. Conclusion

4.1. Results

4.1.a. Baseline Characteristics

We enrolled 40 participants attending for physiotherapy treatment at NBB-Arad Health center in the kingdom of Bahrain, with 20 participants in each group. Two participants in the control group were lost to follow up (One participant had family issues and another declined to continue). One participant in the intervention group was lost due to work commitment. The remaining 18 and 19 participants in the control and intervention group, respectively were analysed. The mean age of the sample was 55.5 years (range 45-70 years). The majority were female in both the control and intervention group (72.2% and 73.7%, respectively). There were no significant differences among the two groups in physical parameters at the baseline: age ($P = 0.590$), height ($P = 0.165$), weight ($P = 0.203$) and BMI ($P = 0.781$).

In the control group, there were 17 (94.4%) married participants, compared to 13 (68.4%) in the intervention group. The educational level in both groups was almost similar. There were 9 (50%) participants in the control group who had secondary school degree and 7 (38.9%) had university degree. In the intervention group there were 9 (47.4%) participants who had secondary school degree and similar number had university degree. Both groups were almost similar in their employment status. In the control group there were 9 (50%) retired participants and 6 (33.3%) unemployed. In the intervention group the number of retired and unemployed participants were 7 (36.8%) participants each.

There were 8 participants in the control group who had multiple coexisting diseases, among them were 5 participants who had osteoporosis/osteopenia related diseases. In the intervention group, there were 5 participants with multiple coexisting diseases, among them only 1 who had

osteoporosis/ osteopenia related diseases. There were 7 (38.9%) participants in the control group who had no coexisting musculoskeletal pain compared to 5 (26.3%) in the intervention group. Neck and/or upper extremity pain were present in 5 (27.8%) and (52.6%) in the control and intervention group, respectively.

Half of the participants in the control group had unilateral knee symptoms while the other half had bilateral symptoms. In the intervention group there were 11 (57.9%) participants with unilateral symptoms and 8 (42.1%) participants had bilateral symptoms. More than half of the sample in each group had their symptoms 3-6 months back. There were 7 participants (38.9%) in the control group who had previous knee treatment. This treatment included: hydrotherapy, physiotherapy, and knee supplementation injection. All the previous treatments were done 6 months or more prior to enrolling to current study. In the intervention group there were 7 participants who had previous knee pain treatment, 6 of them had physiotherapy one year back or more and 1 had knee supplementation injection more than 6 months prior to enrolling to the study. There were 5 participants in each group who were taking non-steroidal anti-inflammatory drugs (NSAIDs). There was 1 (5%) participant in the intervention group who were taking oral corticosteroids and 1 (5%) other taking Glucosamine/Chondroitin products. There were 8 (44%) participants in the control group who were using topical NSAIDs compared to only 4 (21%) participants in the intervention group.

There was no significant difference between groups in their treatment outcome expectation ($P = 0.355$). Yet, higher expectations of complete recovery were scored in the intervention group than the control group, 9 (47.4%) and 5 (27.8%) participants, respectively.

The majority of the sample have been using the internet 5 years or more (77.8% in the control group and 94.7% in the intervention group).

Daily internet use was scored by the majority of the sample as well (88.9% in the control group and 94.7% in the intervention group). Self-rated ability to use the internet varied widely among the two groups. There were 9 participants in the control group compared to 1 participant in the intervention group who rated their ability as fair (50% and 5.3%, respectively). Good ability to use the internet was scored higher by the intervention group than the control group, with 14 (73.7%) participants compared to 3 (16.7%) participants, respectively in each group (Table (4.1)).

4.1.b. Retention, Adherence, Adverse Events, Medications, and Co-interventions

There was high participants retention rate. The percentage of participants retention was 90% and 95% in the control and intervention group, respectively.

Both groups have accessed the educational material, 55.6% and 47.4% in the control and intervention group have accessed all the 5 sessions, respectively (Appendix 10). There was no significant difference between both groups in accessing the educational material ($P = 0.787$).

There were no significant differences between both groups in the frequency of following home exercises ($P = 0.574$). in the control group, there were 14 (77.8%) participants who followed their home exercises 3 times per week. Similarly, there were 14 (73.7%) participants in the intervention group who followed their home exercises 3 times per week. There were 4 (22.2%) participants in the control group and 5 (26.3%) participants in the intervention group who followed their home exercises 1-2 times per week.

Of the 19 participants in the intervention group, 16 (84.2%) participants completed all the 8 iCBT sessions, 2 (10.5%) participants completed 7 sessions and 1 (5.3%) participant completed 5 sessions only.

There were no major adverse events during treatment, except for 1 (5.6%) participant in the control group who had increased transient knee pain, and another 1 (5.3%) participant in the intervention group who had increased knee clicking.

Medications' intake and co-interventions used during the treatment period varied among both groups. The most used medications in the control group were analgesia and topical NSAID. Each of them has been used by 4 (22.2%) participants. While in the intervention group the most used co-intervention was tape followed analgesia that have been used in 3 (15.8%) participants and 2 (10.5%) participants, respectively.

4.1.c. Treatment Satisfaction and Treatment Outcome

Treatment satisfaction rates varied among the two groups. More participants in the intervention group (78.9%) were completely satisfied compared to the control group (44.4%). There was significant difference in the treatment satisfaction rate between the two groups ($P = 0.019$).

Treatment outcome also varied among both groups. There were 13 (68.4%) participants in the intervention group who reported large improvement compared to 9 (50%) participants in the control group. Complete recovery was reported by 3 (15.8%) participants in the intervention group while only 1 (5.6%) participant in the control group reported the same (Appendix 10). Yet, there was no significant difference between the groups in the treatment outcome rating ($P = 0.059$).

Table (4.1): Baseline Descriptive Characteristics

Characteristic	Control (n = 18)	Intervention (n = 19)
Mean Age (SD), y	56 (7.5)	55 (8.3)
Gender, n (%)		
Male	5 (27.8)	5 (26.3)
Female	13 (72.2)	14 (73.7)
Mean height (SD), cm	161.3 (9.9)	161.9 (7.1)
Mean weight (SD), kg	78.7 (9.6)	72.9 (12.4)
Mean body mass index (SD), Kg/m²	30 (3.5)	27.9 (3.3)
Marital status, n (%)		
Married	17 (94.4)	13 (68.4)
Divorced	0 (0)	1 (5.3)
Widowed	1 (5.6)	3 (15.8)
Single	0 (0)	2 (10.5)
Level of education, n (%)		
Below Secondary	2 (11.1)	0 (0)
Secondary	9 (50)	9 (47.4)
University	7 (38.9)	9 (47.4)
Postgraduate	0 (0)	1 (5.3)
Employment status, n (%)		
Employed	3 (16.7)	5 (26.3)
Retired	9 (50)	7 (36.8)
Unemployed	6 (33.3)	7 (36.8)
Coexisting disease, n (%)		
Cardiovascular	4 (22.2)	3 (15.8)
Endocrine	2 (11.1)	4 (21.1)
Gastrointestinal	0 (0)	0 (0)
Osteoporosis	0 (0)	0 (0)
Other	1 (5.6)	0 (0)
None	3 (16.7)	7 (36.8)
Multiple coexisting diseases	8 (44.4)	5 (26.3)
Coexisting musculoskeletal pain (other than knee pain), n (%)		
Neck and/or upper extremity	5 (27.8)	10 (52.6)
Back and or lower extremity	6 (33.3)	4 (21.1)
None	7 (38.9)	5 (26.3)
Affected side, n (%)		
Unilateral	9 (50)	11 (57.9)
Bilateral	9 (50)	8 (42.1)
Symptom duration, n (%)		
3-6 months	10 (55.6)	12 (63.2)
7-12 months	3 (16.7)	2 (10.5)
13-24 months	1 (5.6)	0 (0)
>24 months	4 (22.2)	5 (26.3)
Previous knee pain treatment, n (%)		
Yes	7 (38.9)	7 (36.8)
No	11 (61.1)	12 (63.2)

Current drug/supplement use, n (%)		
Analgesia	5 (28)	8 (42)
NSAIDs	5 (28)	5 (26)
Topical NSAIDs	8 (44)	4 (21)
Opioids	0 (0)	0 (0)
Glucosamine/Chondroitin products	0 (0)	1 (5)
Oral Corticosteroids	0 (0)	1 (5)
Treatment Benefit Expectations, n (%)		
No effect	0 (0)	0 (0)
Minimal improvement	0 (0)	1 (5.3)
Moderate improvement	6 (33.3)	3 (15.8)
Large improvement	7 (38.9)	6 (31.6)
Complete recovery	5 (27.8)	9 (47.4)
Years using the internet, n (%)		
<1	1 (5.6)	0 (0)
1-4	3 (16.7)	1 (5.3)
5 or more	14 (77.8)	18 (94.7)
Internet use, n (%)		
Never	0 (0)	0 (0)
Once per month or less	0 (0)	0 (0)
Once per week	1 (5.6)	0 (0)
Several times per week	1 (5.6)	1 (5.3)
Daily	16 (88.9)	18 (94.7)
Self-rated ability to use the internet, n (%)		
Poor	0 (0)	0 (0)
Fair	9 (50)	1 (5.3)
Good	3 (16.7)	14 (73.7)
Excellent	6 (33.3)	4 (21.1)

4.1.d. Primary Outcome Measures

- Within Group Analysis

Pre-treatment and post-treatment results analysis for the control group showed significant improvement in all the primary outcome measures except for the 40-m FPWT. NRS scores for the control group pre-treatment and post-treatment (mean $\pm$ SD) were 7.28 ± 1.99 and 4 ± 2.33 , respectively. Paired sample t-test showed significant difference in pain post-treatment levels (MD = 3.28, [95% CIs: 2.14—4.42], $P < 0.001$).

The speed results of the 40-m FPWT for the control group pre-treatment and post-treatment were 1.13 ± 0.28 and 1.18 ± 0.27 , respectively. There was no significant improvement in speed post-treatment (MD = -0.05, [95% CIs: -0.11—0.01], $P = 0.095$).

The scores of the step test for the control group pre-treatment and post-treatment were 9.72 ± 2.59 and 11 ± 2.11 , respectively. There was significant improvement in speed post-treatment (MD = -1.28, [95% CIs: -2.09—-0.46], $P = 0.004$).

The results of the 30s CTS test pre-treatment and post-treatment for the control group were 9.06 ± 3.19 and 11.61 ± 3.47 , respectively. Post-treatment 30s CTS scores have improved significantly for the control group compared to pre-treatment scores (MD = -2.56, [95% CIs: -3.54—-1.57], $P < 0.001$).

In the intervention group, pre-treatment and post-treatment results analysis showed significant improvement in all the primary outcome measures. Scores of the NRS pre-treatment and post-treatment in the intervention group were 6.74 ± 1.82 and 2.21 ± 1.48 . There was significant

reduction in pain levels post-treatment (MD = 4.53, [95% CIs: 3.72—5.34], $P < 0.001$).

Pre-treatment and post-treatment speed results of the 40-m FPWT for the intervention group were 1.13 ± 0.22 and 1.24 ± 0.26 , respectively. Walking speed has improved significantly post-treatment in the intervention group (MD = -0.12, [95% CIs: -0.16—-0.08], $P < 0.001$).

Step test results of the intervention group pre-treatment and post-treatment were 9.21 ± 2.35 and 12.74 ± 2.77 , respectively. There was significant improvement in speed post-treatment (MD = -3.53, [95% CIs: -4.83—-2.23], $P < 0.001$).

The results of the 30s CTS test pre-treatment and post-treatment for the intervention group were 10.42 ± 3.02 and 13.47 ± 2.89 , respectively. Post-treatment 30s CTS scores have improved significantly for the intervention group compared to pre-treatment scores (MD = -3.05, [95% CIs: -3.95—-2.15], $P < 0.001$).

- Between Group Analysis

Pre-treatment independent sample t-tests results showed no significant difference between both groups neither in pain levels nor in functional levels. Pain levels in the control and intervention groups were 7.28 ± 1.99 and 6.74 ± 1.82 , respectively. There was no significant difference between both groups in pain levels pre-treatment (MD = 0.54, [95% CIs: -0.81—1.89], $P = 0.885$).

Walking speed in the control and intervention group were 1.13 ± 0.29 and 1.13 ± 0.22 , respectively. There was no significant difference between both groups in walking speed pre-treatment (MD = 0.00, [95%

CI: -0.17—0.17], $P = 0.159$). Step test scores in the control and intervention group were 9.72 ± 2.59 and 9.21 ± 2.35 , respectively. There was no significant difference between both groups scores pre-treatment (MD = 0.51, [95% CI: -1.14—2.16], $P = 0.733$). The 30s CST results for the control and intervention group were 9.06 ± 3.19 and 10.42 ± 3.02 , respectively. Results of the 30s CST showed no significant difference between both groups (MD = -1.37, [95% CI: -3.44—0.71], $P = 0.915$).

Post treatment independent sample t-tests results showed significant difference between both groups in pain levels and step test favouring the intervention group. Yet, there was no significant difference between both groups in walking speed nor in 30s CST post-treatment.

Pain levels in the control and intervention groups were 4.00 ± 2.33 and 2.21 ± 1.48 , respectively. Pain levels have improved significantly in the intervention group compared to the control group post-treatment (MD = 1.79, [95% CI: 0.5—3.08], $P = 0.008$).

Post-treatment walking speed in the control and intervention group were 1.18 ± 0.27 and 1.24 ± 0.26 , respectively. There was no significant difference between both groups in walking speed post-treatment (MD = -0.07, [95% CI: -0.24—0.11], $P = 0.449$). Step test scores in the control and intervention group were 11 ± 2.11 and 12.74 ± 2.77 , respectively. Step test scores post-treatment has improved significantly in the intervention group compared to the control group (MD = -1.73, [95% CI: -3.39—0.09], $P = 0.04$). The 30s CST results for the control and intervention group were 11.61 ± 3.47 and 13.47 ± 2.89 , respectively. Results of the 30s CST showed

no significant difference between both groups (MD = -1.86, [95% CIs: -3.99—0.26], $P = 0.084$).

Table (4.2): Within Group Analysis

Outcome	Control		P-value	Significance	Intervention		P-value	Significance
	Pre-treatment Mean $\pm$ SD	Post-treatment Mean $\pm$ SD			Pre-treatment Mean $\pm$ SD	Post-treatment Mean $\pm$ SD		
Primary								
1. Pain \$	7.28 $\pm$ 1.99	4.00 $\pm$ 2.33	0.000	*	6.74 $\pm$ 1.82	2.21 $\pm$ 1.48	0.000	*
2. Function:								
a. 30s CST ‡	9.06 $\pm$ 3.19	11.61 $\pm$ 3.47	0.000	*	10.42 $\pm$ 3.02	13.47 $\pm$ 2.89	0.000	*
b. Step Test ‡	9.72 $\pm$ 2.59	11.00 $\pm$ 2.11	0.004	*	9.21 $\pm$ 2.35	12.74 $\pm$ 2.77	0.000	*
c. 40-mFPWT ‡	1.13 $\pm$ 0.29	1.18 $\pm$ 0.27	0.095		1.13 $\pm$ 0.22	1.24 $\pm$ 0.26	0.000	*
Secondary								
1.PHQ-2 §	2.83 $\pm$ 1.25	1.44 $\pm$ 1.29	0.000	*	2.37 $\pm$ 1.50	0.89 $\pm$ 0.88	0.000	*
2. K-6 ¶	8.06 $\pm$ 4.18	5.50 $\pm$ 3.88	0.002	*	9.05 $\pm$ 4.22	4.00 $\pm$ 2.40	0.000	*
3. SF-12 £	32.56 $\pm$ 6.27	37.67 $\pm$ 5.06	0.000	*	34.84 $\pm$ 6.35	40.11 $\pm$ 4.93	0.000	*
4. KOOS-PS ¥	12.00 $\pm$ 5.31	7.83 $\pm$ 4.93	0.000	*	10.58 $\pm$ 3.93	5.68 $\pm$ 2.96	0.000	*
5. Quads Muscle Strength ‡	1.55 $\pm$ 0.47	1.67 $\pm$ 0.46	0.102		1.65 $\pm$ 0.44	1.82 $\pm$ 0.43	0.005	*

30sCST: 30 seconds chair stand test, 40-m FPWT: 40 meter Fast Paced Walk Test, PHQ-2: Patient Health Questionnaire, K-6: Kessler-6, SF-12: Health-Related Quality of Life-Short Form-12, KOOS-PS: Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form.

\$ Ranges from 0-10: lower scores indicate less pain

‡ Higher scores: better

§ Ranges from 0-6: lower scores indicate less depression

¶ Ranges from 0-24: lower scores indicate less psychological distress

£ Ranges from 1-42: higher scores indicate better quality of life

¥ Ranges from: higher scores indicate better functional level

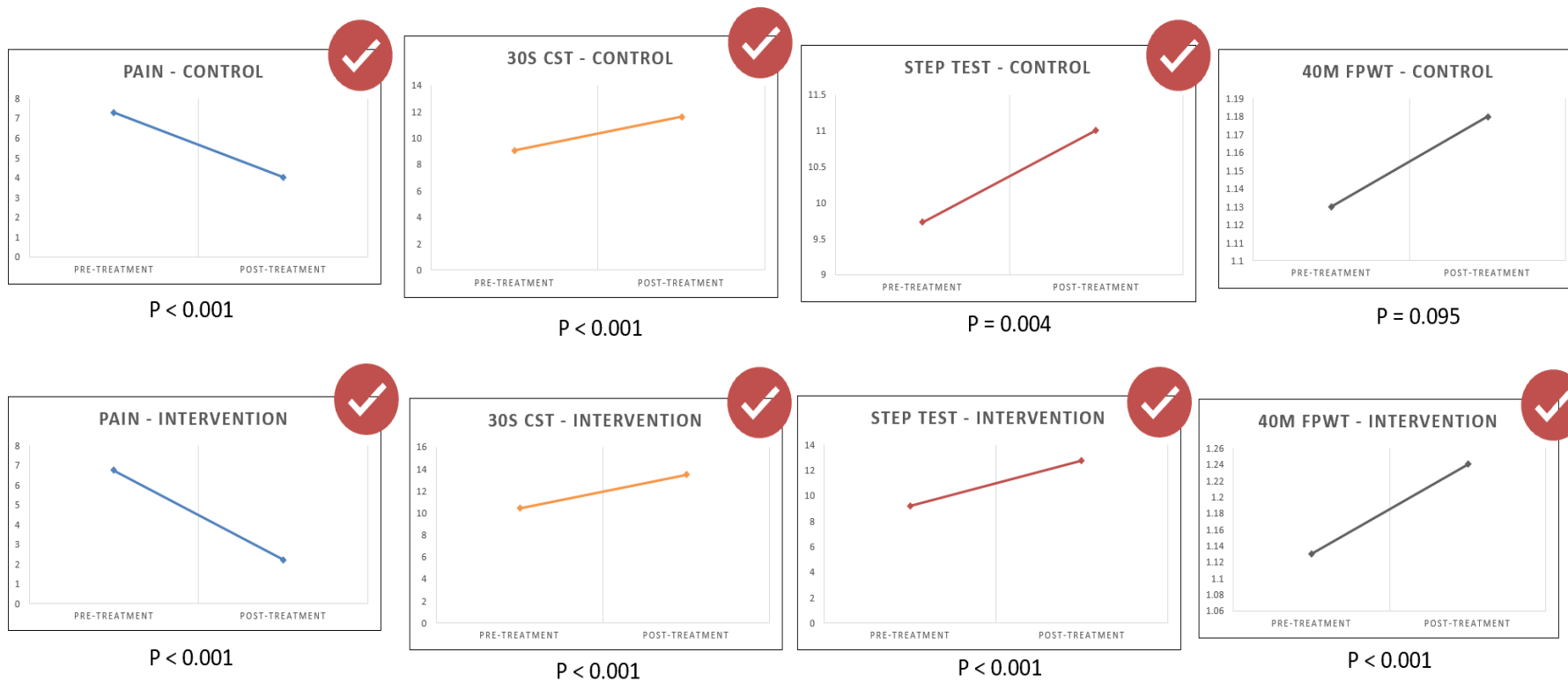


Fig. 4.1: Within Group Analysis – Primary Outcome Measures

 indicates a significant difference

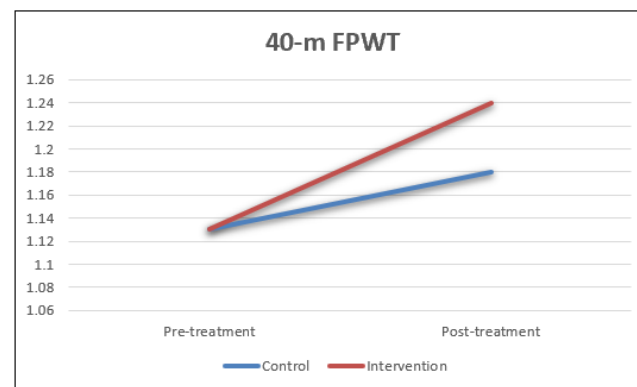
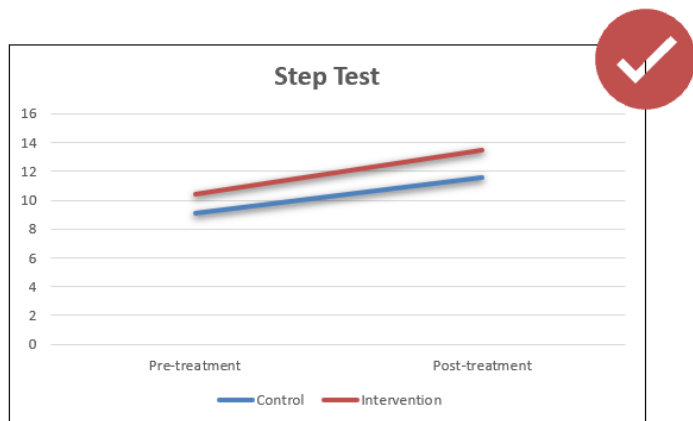
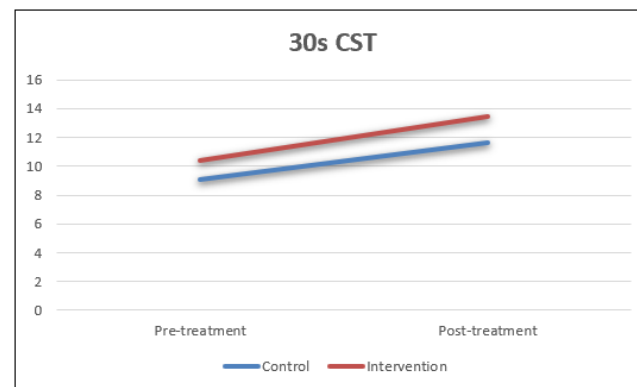
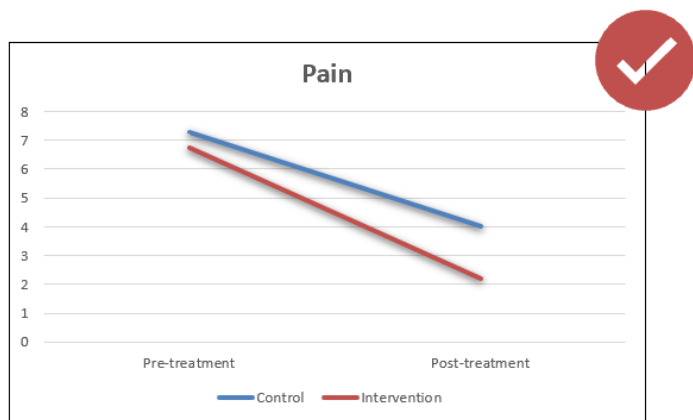


Fig. 4.2: Between Group Analysis – Primary Outcome Measures

 indicates a significant difference

4.1.e. Secondary Outcome Measures

- Within Group Analysis

Pre-treatment and post-treatment results analysis for the control group showed significant improvement in all the secondary outcome measures except for the quadriceps isometric muscle strength. Depression screening scale (PHQ-2) for the control group pre-treatment and post-treatment were 2.83 ± 1.25 and 1.44 ± 1.29 , respectively. Paired sample t-test showed significant reduction in depression levels post-treatment (MD = 1.39, [95% CIs: 0.87—1.91], $P < 0.001$).

The psychological distress levels (K-6) for the control group pre-treatment and post-treatment were 8.06 ± 4.18 and 5.50 ± 3.89 , respectively. There was significant improvement in the distress levels post-treatment (MD = 2.56, [95% CIs: 1.08—4.04], $P = 0.002$).

Physical function scores (KOOS- PS) of the control group pre-treatment and post-treatment were 12.00 ± 5.31 and 7.83 ± 4.93 , respectively. Physical function level has improved significantly post-treatment in the control group (MD = 4.17, [95% CIs: 2.31—6.02], $P < 0.001$).

Quality of life scores (SF-12) pre-treatment and post-treatment for the control group were 32.56 ± 6.27 and 37.67 ± 5.06 , respectively. There was significant improvement in QoL scores post-treatment in the control group (MD = -5.11, [95% CIs: -7.23—-2.99], $P < 0.001$).

Quadriceps isometric muscle strength scores for the control group pre-treatment and post-treatment were 1.55 ± 0.47 and 1.67 ± 0.46 , respectively. There was no significant difference in the quadriceps muscle

strength in the control group pre-treatment and post-treatment (MD = -0.12, [95% CIs: -0.27—0.02], P = 0.102).

In the intervention group, pre-treatment and post-treatment results analysis showed significant improvement in all the secondary outcome measures. Scores of the depression screening scale (PHQ-2) pre-treatment and post-treatment in the intervention group were 2.37 ± 1.5 and 0.89 ± 0.88 . There was significant reduction in depression levels post-treatment (MD = 1.47, [95% CIs: 0.84—2.10, P < 0.001).

Pre-treatment and post-treatment psychological distress results of the K-6 scale for the intervention group were 9.05 ± 4.22 and 4 ± 2.40 , respectively. Psychological distress levels have reduced significantly post-treatment in the intervention group (MD = 5.05, [95% CIs: 3.42—6.69], P < 0.001).

Physical function results (KOOS- PS) of the intervention group were 10.58 ± 3.93 and 5.68 ± 2.96 pre-treatment and post-treatment, respectively. There was significant improvement in the physical function levels post-treatment (MD = 4.90, [95% CIs: 3.19—6.60], P < 0.001).

Quality of life scores (SF-12) pre-treatment and post-treatment for the intervention group were 34.84 ± 6.35 and 40.11 ± 4.93 , respectively. There was significant improvement in QoL scores post-treatment in the intervention group (MD = -5.26, [95% CIs: -7.75—-2.78], P < 0.001).

Quadriceps isometric muscle strength scores for the intervention group pre-treatment and post-treatment were 1.65 ± 0.44 and 1.82 ± 0.43 , respectively. Quadriceps muscle strength has improved significantly in the intervention group post treatment (MD = -0.17, [95% CIs: -0.28—-0.06], P = 0.005).

- **Between Group Analysis**

Pre-treatment independent sample t-tests results showed no significant difference between both groups in all the secondary measurements. Depression screening scores (PHQ-2) for the control and intervention group were 2.83 ± 1.25 and 2.37 ± 1.5 , respectively. There was no significant difference between the groups in depression levels (MD = 0.465, [95% CIs: -0.458—1.39], $P = 0.429$).

Psychological distress levels (K-6) pre-treatment were 8.06 ± 4.18 and 9.05 ± 4.22 in the control and intervention groups, respectively. There was no significant difference between groups in the distress levels (MD = -0.997, [95% CIs: -3.80—1.81], $P = 0.974$).

Physical function levels (KOOS-PS) were lower in the control group compared to the intervention group 12 ± 5.31 and 10.58 ± 3.93 , yet there was no significant difference pre-treatment between the groups in the physical function levels (MD = 1.42, [95% CIs: -1.69—4.53], $P = 0.261$).

Quality of life scores (SF-12) were lower in the control group than in the intervention group (32.56 ± 6.27 and 34.84 ± 6.35 , respectively). Pre-treatment, there was no significant difference between the groups in the QoL scores (MD = -2.29, [95% CIs: -6.50—1.93], $P = 0.798$).

Pre-treatment isometric muscle strength of the quadriceps were 1.55 ± 0.47 and 1.65 ± 0.44 , respectively in the control and intervention group. Quadriceps muscle strength did not differ significantly between the groups (MD = -0.10, [95% CIs: -0.40—0.20], $P = 0.902$).

There was no significant difference between the groups in all secondary outcome measures post-treatment. Although depression scores (PHQ-2) post-treatment for the control group were higher than the

intervention group (1.44 ± 1.29 and 0.89 ± 0.88 , respectively), there was no significant difference between the groups in depression levels (MD = 0.55, [95% CIs: -0.18—1.28], $P = 0.137$).

Psychological distress levels (K-6) in the control group and intervention group were 5.5 ± 3.88 and 4.00 ± 2.40 , respectively. There was no significant difference between the groups post-treatment in psychological distress levels (MD = 1.50, [95% CIs: -0.64—3.64], $P = 0.164$).

Physical function levels (KOOS-PS) in the control group and intervention group were 7.83 ± 4.93 and 5.68 ± 2.96 , respectively. There was no significant difference post-treatment in the physical function levels (MD = 2.15, [95% CIs: -0.55—4.85], $P = 0.115$).

Quality of life scores (SF-12) were lower in the control group than in the intervention group (37.67 ± 5.06 and 40.11 ± 4.93 , respectively). Post-treatment, there was no significant difference between the groups in the QoL scores (MD = -2.44, [95% CIs: -5.78—0.90], $P = 0.147$).

Post-treatment isometric muscle strength of the quadriceps were 1.67 ± 0.46 and 1.82 ± 0.43 , respectively in the control and intervention group. Quadriceps muscle strength did not differ significantly between the groups (MD = -0.15, [95% CIs: -0.45—0.15], $P = 0.307$).

Table (4.3): Between Group Analysis

Outcome	Pre-treatment				Post-treatment			
	Control	Intervention	P-value	Significance	Control	Intervention	P-value	Significance
Primary								
1. Pain \$	7.28 ± 1.99	6.74± 1.82	0.885		4.00 ± 2.33	2.21 ± 1.48	0.008	*
2. Function								
a. 30sCST ‡	9.06 ± 3.19	10.42 ± 3.02	0.915		11.61 ± 3.47	13.47 ± 2.89	0.084	
b. Step Test ‡	9.72 ± 2.59	9.21 ± 2.35	0.733		11.00 ± 2.11	12.74 ± 2.77	0.04	*
c. 40mFPWT ‡	1.13 ± 0.29	1.13 ± 0.22	0.159		1.18 ± 0.27	1.24± 0.26	0.449	
Secondary								
1. PHQ-2 §	2.83 ± 1.25	2.37 ± 1.50	0.429		1.44 ± 1.29	0.89 ± 0.88	0.137	
2. K-6 ¶	8.06 ± 4.18	9.05 ± 4.22	0.974		5.50 ± 3.88	4.00 ± 2.40	0.164	
3. SF-12 ¯	32.56 ± 6.27	34.84 ± 6.35	0.798		37.67 ± 5.06	40.11± 4.93	0.147	
4. KOOS-PS ¥	12.00 ± 5.31	10.58 ± 3.93	0.261		7.83 ± 4.93	5.68 ± 2.96	0.115	
5. Quads Muscle strength ‡	1.55 ± 0.47	1.65 ± 0.44	0.902		1.67 ± 0.46	1.82 ± 0.43	0.307	

30sCST: 30 seconds chair stand test, 40-m FPWT: 40 meter Fast Paced Walk Test, PHQ-2: Patient Health Questionnaire, K-6: Kessler-6, SF-12: Health-Related Quality of Life-Short Form-12, KOOS-PS: Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form.

\$ Ranges from 0-10: lower scores indicate less pain

‡ Higher scores: better

§ Ranges from 0-6: lower scores indicate less depression

¶ Ranges from 0-24: lower scores indicate less psychological distress

¯ Ranges from 1-42: higher scores indicate better quality of life

¥ Ranges from: higher scores indicate better functional level

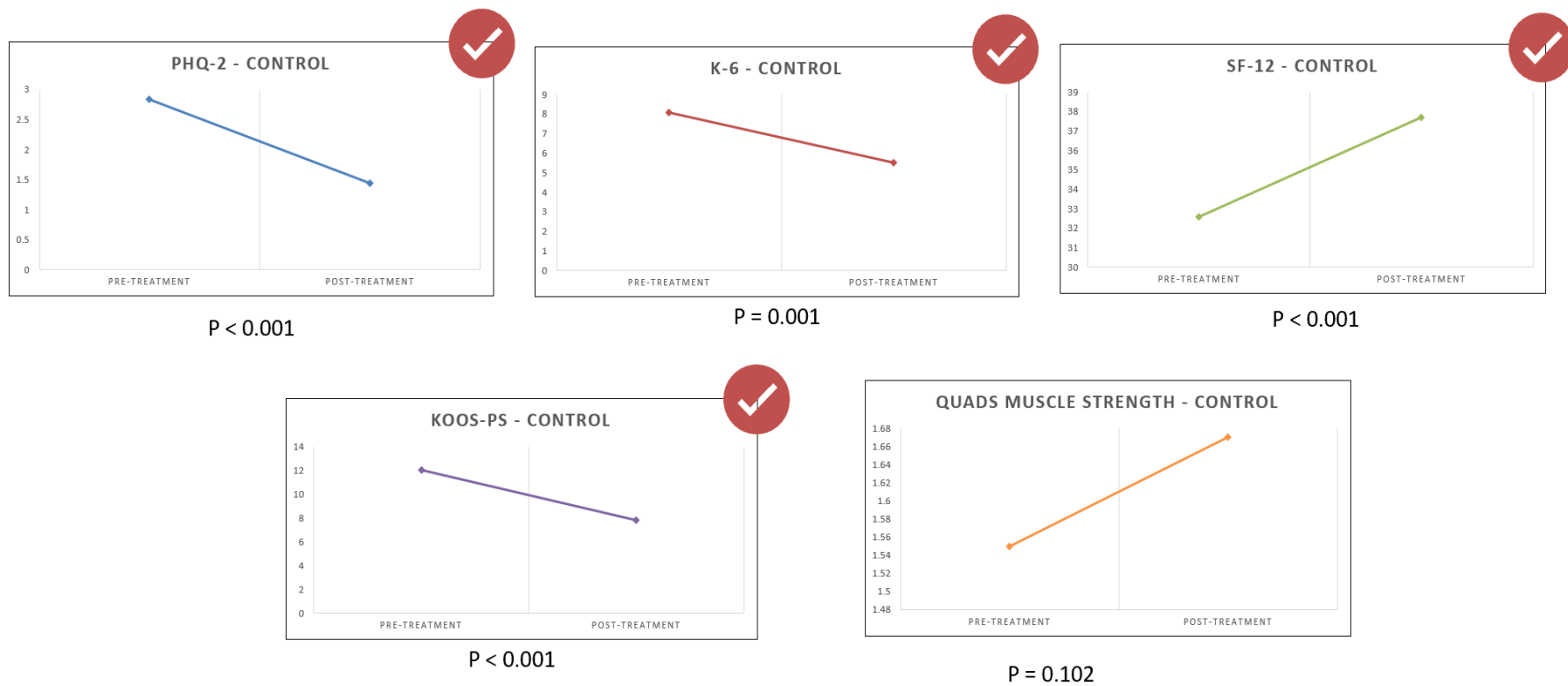


Fig. 4.3.a: Within Group Analysis (Control Group) – Secondary Outcome Measures

 indicates a significant difference

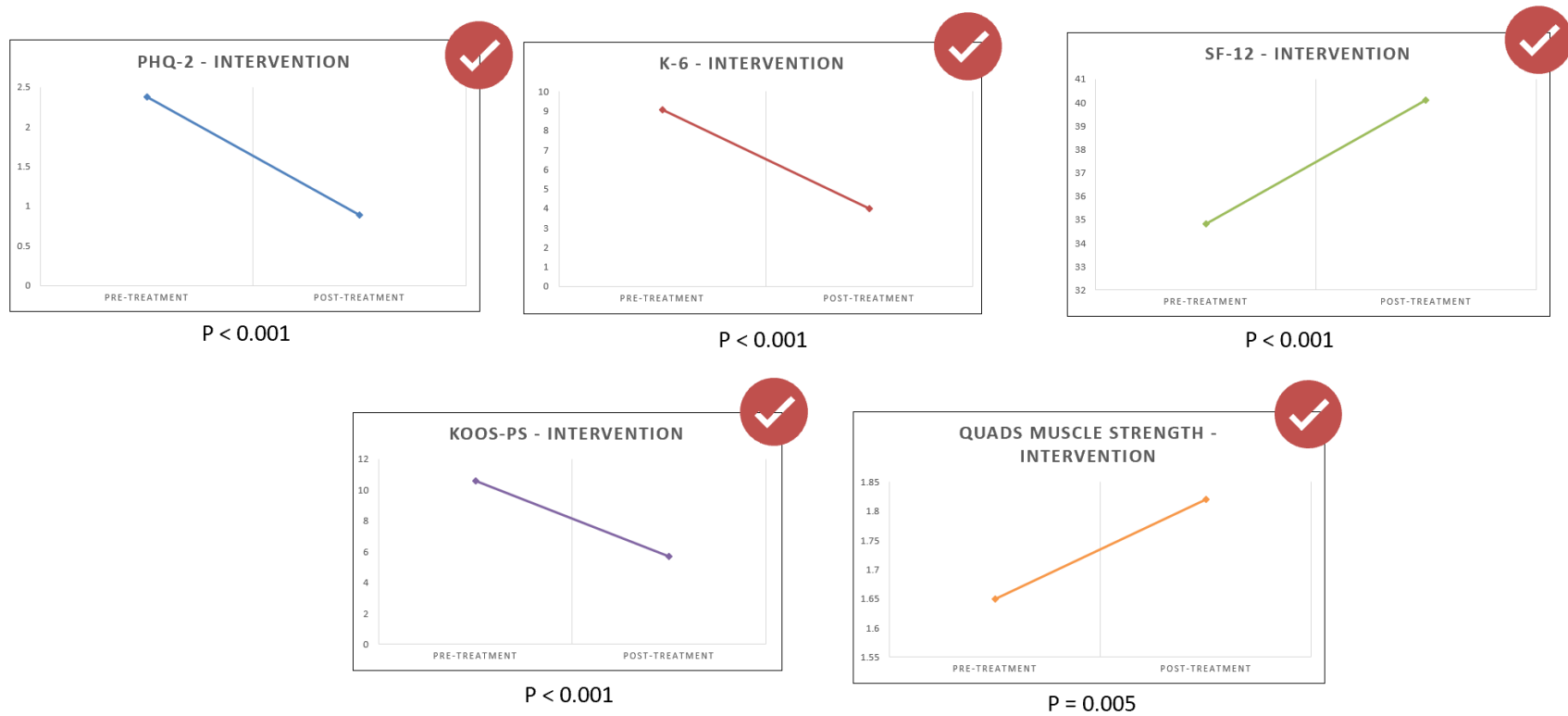


Fig. 4.3.b: Within Group Analysis (Intervention Group) – Secondary Outcome Measures

✓ indicates a significant difference

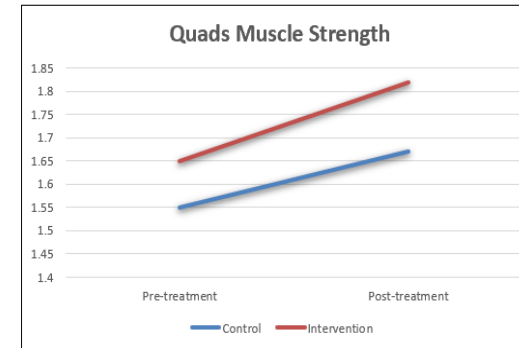
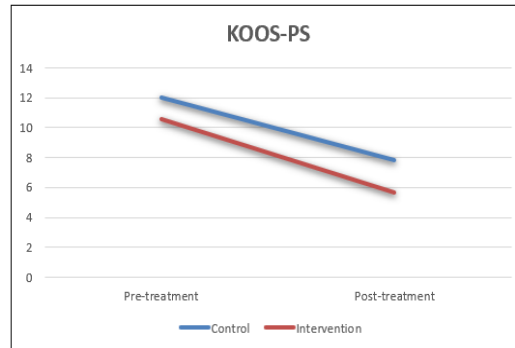
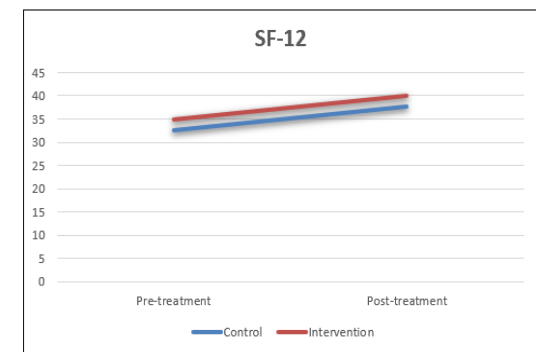
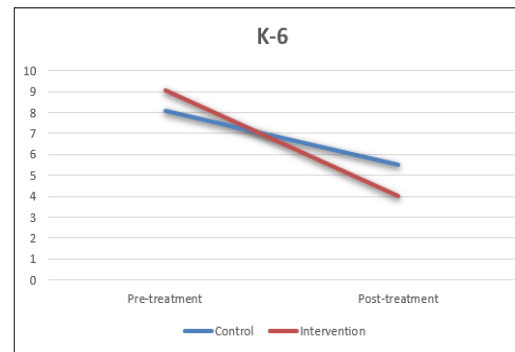
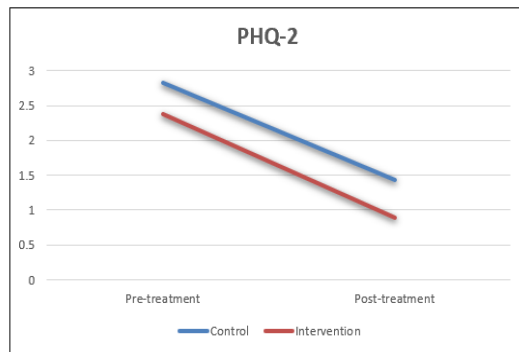


Fig. 4.4: Between Group Analysis – Secondary Outcome Measures

- Participant-Perceived Response to Treatment (Appendix 12)

-Perceived Change Overall

In the control group, around 90% of the participants were classified as improved as they rated their overall change 5 out of 7 or above. There were 4 (22.2%), 5 (27.7%), 4 (22.2%), 3 (16.7%), 1 (5.6%) and 1 (5.6%) participants who rated their overall change as 7, 6, 5, 4, 3, and 2 on an eight-point ordinal scale, respectively.

Around 95% of the participants in the study group were classified as improved as they rated their overall change 5 out of 7 or above. There were 6 (31.6%), 7 (36.8%), 5 (26.3%), and 1 (5.6%) participants who rated their overall change as 7, 6, 5, and 3 on an eight-point ordinal scale, respectively.

-Perceived Change in Pain

Around 90% of the participants in the control group were considered improved in terms of pain, as they rated their change in pain 5 out of 7 or above. There were 4 (22.2%), 4 (22.2%), 3 (16.7%), 5 (26.3%) and 2 (11.2%) participants who rated their change in pain as 7, 6, 5, 4 and 2 on an eight-point ordinal scale, respectively.

All the participants in the study group were considered improved in terms of pain, as they rated their change in pain 5 out of 7 or above. There were 6 (31.6%), 5 (26.3%), and 8 (42.1%) participants who rated their overall change as 7, 6, and 5 on an eight-point ordinal scale, respectively.

- Perceived Change in Function

There were around 70% participants in the control group who were classified as improved, as they rated their change in function 5 out of 7 or above. Those gave the scores of 7, 6, 5, and 4 out of 7 and were 5 (27.7%), 4 (22.2%), 3 (16.7%), and 1 (5.6%), respectively. While there were 3

(16.7%), 1 (5.6%), and 1 (5.6%) participants who gave the scores of 3, 1, and 0 on an eight-point ordinal scale, respectively.

In the study group, around 90% of the participants were classified as improved in terms of function, as they rated their change in function 5 out of 7 or above. There were 7 (36.8%), 5 (26.3%), 5 (26.3%), and 2 (10.6%) participants who rated their change in function as 7, 6, 5, and 4 on an eight-point ordinal scale, respectively.

4.2. Discussion

4.2.a. Primary Outcome Measures

It is evident from our study that the interventions given to both groups were effective in improving pain and function in knee OA patients with psychological distress.

- Pain

Our results showed that both groups have improved significantly in terms of pain. Moreover, it showed that iCBT combined with exercise intervention was significantly more effective in improving pain in knee OA patients with psychological distress. Our study was based on the hypothesis that targeting chronic knee patients who have certain levels of psychological distress with a combined iCBT and exercise, would significantly improve pain and function in this specific group compared to regular intervention. The results of pain measures support our hypothesis. As we have targeted patients who have certain levels of psychological distress, we have found that adding iCBT to an exercise program has resulted in significant pain reduction than the education and exercise only in this specific group of patients ($P = 0.008$, [95% CI 0.5—3.08]).

Several previous studies on CBT and chronic knees pain have resulted in significant improvement in pain. A significant improvement in pain was found in an RCT that has delivered the intervention, which included exercises and CBT, via the internet (Bennell et al., 2017). An iCBT intervention alone that was delivered to knee OA patients with depression, has proved to be effective in reducing pain compared to a control group (O'moore et al., 2018). Patients with knee or hip OA who

received iCBT intervention reported significantly lower pain than those in the control group (Rini et al., 2015). The way by which iCBT program can reduce pain is explained in a study done to investigate the effect of iCBT on empathy in chronic pain patients. It was found that iCBT program has the ability to reduce pain and distress by modifying physical sensations, catastrophic thinking, and maladaptive behaviors (Lim et al., 2018).

Meanwhile, there are other studies where the iCBT intervention combined with exercises did not result in significant pain reduction (Bennell, Ahamed et al., 2016; Bennell et al., 2018). This might have occurred as CBT intervention provide patients with strategies to better accept and tolerate pain, thereby giving them the confidence to exercise and increase their functional ability despite no additional pain effect.

To summarize, our results of pain suggest that a combined iCBT and exercise intervention can significantly improve pain when applied to chronic knee patient with psychological distress than education and exercise intervention only.

- Functional Performance Tests

It is evident from our study that iCBT and exercise intervention was effective in improving the functional performance in knee OA patients with psychological distress. The education and exercise intervention was also effective in improving the functional performance except the walking speed. Contrary to our hypothesis, our results of functional performance tests did not improve significantly in the iCBT and exercise group compared to the control group.

- Walking Speed

In our study, the results of significant improvement in the walking speed in the intervention group is unexplainable by the baseline

characteristics that could affect walking speed, and these include: BMI, coexistence of back or lower extremity problem or adherence to the treatment program (Bindawas, 2016; Rahimi et al., 2020; Rini et al., 2015).

There is one factor that could explain the results of walking speed between both groups, that is the difference in pain levels post-treatment. The pain levels in the control group have not improved significantly compared to the intervention group and this could be the reason for the insignificant difference in walking speed. Although, the pain levels measured in our study using NRS was not specific to pain during walking, it can still be a suspect for the difference in walking speed. A study was done on the effects of Kinesio Tape applications on pain and gait speed in knee OA patients. Pain was measured using NRS and gait speed with 10meter walk test. It was found that as pain reduced significantly after the intervention, the gait speed increased significantly (Tani et al., 2018). Moreover, the results from a cross-sectional study support our rationale about the difference in walking speed in both groups and pain. The study has included 190 participants aged 50 years or more with advanced OA and chronic pain to evaluate correlates of gait speed in this group. Gait speed was measured using 4-meter walk test and pain was measured using WOMAC knee pain in addition to other variables that were included. Using the univariate analysis, it was found that the gait speed was negatively associated with knee pain (regression coefficient = -0.23 ; $P = 0.002$) (Marcum et al., 2014).

In our study, there was no significant improvement in walking speed between both groups. Similarly, Hunt et al. (2013) found that walking speed does not differ significantly between a group of exercise + PCST and a group of exercise + NDC.

- 30s CTS test

There was significant improvement in the results of the 30s CST in both groups. This result is an expected outcome of the standardized exercise program that was given to both groups. An RCT that have examined the effects of an internet-based exercise program compared to routine self-management on pain and function, has found that the intervention group had better improvements in the 30-second sit-to-stand test compared to the control group (Gohir et al., 2021). Another RCT has studied the effects of a home-based exercise intervention on elderly patients with knee osteoarthritis compared to health education. Results revealed significantly better sit-to-stand results in the intervention group (Chen et al., 2019).

- Step test

There was significant improvement in step test results post-treatment in both groups. This is again attributed to the exercise program that was administered in our study to both groups. A study that has compared an exercise group with a non-exercise group, concluded that adding exercise to other non-invasive methods that routinely are used for knee OA have boosting effect in relieving pain and improving knee function (Nejati et al., 2015).

There is a correlation between step test and the standing balance in knee OA patients. There are two studies that have compared the standing balance in knee OA patients with controls using the specific step test used in our study. One of the studies has compared symptomatic knee OA individuals with matched controls using clinical tests that included the step test. It was observed that OA group had poorer dynamic standing balance as evidenced by the step test ($P < 0.0001$) (Hinman et al., 2002). Another study has similarly compared proprioception, dynamic balance, and maximal quadriceps strength in females with knee OA and normal control

subjects. It was also found that subjects with knee OA had poorer dynamic balance than non-symptomatic ones ($P < 0.001$) (Mohammadi et al., 2008).

It can be implied from the results of the previous studies that the dynamic balance in knee OA individuals is affected when tested with the step test. Hence, exercise intervention must target treatment of this deficit as well. Our study has included exercises that could improve the dynamic balance of participants, and these include step up, step down and unilateral toes standing. This was reflected on the results of our study, as there was significant improvement in the results of step test post-treatment in both groups. A pilot study has investigated the effectiveness of an exercise program on dynamic balance in patients with medial knee OA, with similar exercise program to ours. Fourteen participants were included, and dynamic balance was measured using the Star Excursion Balance test (SEBT). It was found that after six weeks of the designed exercise program, the dynamic balance on the affected side demonstrated significant improvements in the anterior and medial directions ($P = 0.02$ and $P = 0.01$, respectively) (Al-Khlaifat et al., 2016).

Furthermore, there was also significant improvement in this test between both groups favouring the intervention group. The significant improvement in step test between both groups can be explained again by the difference in pain levels favouring the intervention group. As explained earlier in the walking speed results, there were no significant differences in the baseline characteristics that could explain the difference in walking speed between both groups. Similarly in the step test results, the significant difference in pain levels led to significant improvement in the step test.

To summarize, our results suggest that a combined iCBT and exercise intervention did not significantly improve the walking speed and the sit-to-stand results when applied to chronic knee patients with psychological distress than education and exercise intervention only.

4.2.b. Secondary Outcome Measures

- Patient's Reported Outcomes

Our patient's reported outcome results showed significant improvement in all the outcomes in the control and intervention groups. Nevertheless, the results do not support our secondary hypothesis, that is, a combined iCBT and standardized exercise program does not significantly improve depression, psychological distress, physical function, QoL, and quadriceps muscles strength in chronic knee pain patients with psychological distress compared to a control group. This result may seem somewhat paradoxical, given that iCBT involved training in pain coping, relaxation techniques, distraction techniques and thoughts challenging. These skills were expected to confer significantly greater improvement in the secondary outcome measures in the intervention group compared to the control. It is possible that the measurements were collected earlier than the iCBT took an effect (Ismail et al., 2017; Eccleston et al., 2014).

Our theory was based on the recommendation of the review on the best evidence for OA rehabilitation. It was recommended that CBT interventions, whether directed at pain or at other problems, such as depression or sleep, can produce clinical benefits and should be considered in appropriate individuals (Rice et al., 2019). In our study, we have included individuals that we hypothesized would benefit the most from the intervention. Although, the secondary outcomes have improved significantly in the iCBT group, the results did not differ significantly from those in the control group. In other words, we could say that we could not prove additional benefits for adding iCBT intervention in terms of our secondary outcomes compared to control.

An RCT on the effects of internet-based pain coping skills training before home exercise for individuals with hip OA, had sustained similar results in terms of secondary outcomes to ours. In that specific RCT, one hundred forty-four people were randomised to either the PCST group or the comparator group. Secondary outcomes were quality-of-life, global change, self-efficacy, pain coping, pain catastrophizing, depression, anxiety, stress, physical activity, and adverse events. At week 8, the PCST group had greater improvements in function, pain coping, and global improvement than comparison. There were no improvements in other secondary outcome measures (Bennell et al., 2018).

On the other hand, there were studies on iCBT and the treatment of knee OA that have proved the effectiveness of iCBT in improving the psychosocial status of participants compared to controls, despite not accounting for the psychological distress levels pre-enrolment. An RCT was done to examine the effects of an internet-delivered exercise and PCST in chronic knee pain individuals. Participants were randomised to PCST and exercise or internet based educational material. Secondary outcome measures included: WOMAC knee pain, QoL, self-efficacy, pain catastrophizing and coping attempts. Results showed significant between-group differences at 3 months except for coping attempts (Bennell et al., 2017). Another RCT was done to investigate the effects of a 12-week PCST skills and exercise in chronic knee OA individuals. Participants were randomized to 3 groups: PCST and exercise, exercise alone or PCST alone. Secondary outcomes included: VAS walking pain, WOMAC pain and function, self-efficacy, pain coping, catastrophising, anxiety, depression, stress, QoL and quadriceps strength. PCST and exercise group showed significantly greater improvements in WOMAC function, walking pain, self-efficacy, coping strategies, depression, anxiety, stress, and QoL (Bennell, Ahmad et al., 2016).

A potential explanation for the significant improvement in most of the secondary outcome results in the control group, could be related to the mode of delivering the exercise program. In our study, standardized exercise program was delivered to participants in the clinic, and thus that interaction with the therapist could result in the significant improvement in participants' psychological distress, depression, physical function, and QoL. A qualitative study on the inpatient rehabilitation experience, have interviewed 19 adults undergoing inpatient rehabilitation for neurological and musculoskeletal impairments. It was concluded that the patient-therapist interaction was more important to the patient than the amount or content of their physiotherapy (Peiris et al., 2012). Furthermore, a systematic review was done to investigate the influence of the therapist-patient relationship on treatment outcome in physical rehabilitation. The included studies recruited patients with a mix of diagnoses. Six of the 14 studies included patients with musculoskeletal pain conditions who were undergoing physical therapy or physical conditioning programs. Various outcomes were measured, including pain, disability, QoL, depression, adherence, and satisfaction with treatment. The alliance was most commonly measured with the Working Alliance Inventory, which was rated by both patient and therapist during the third or fourth treatment session. These studies showed a consistent pattern of positive correlations between alliance and outcomes of pain, disability, physical and mental health, and satisfaction with treatment (Hall et al., 2010).

The previously narrated studies augment our justification about the significant improvement in secondary outcome measures in the control group, despite not introducing any therapy that could improve those outcome measures, except for the exercise and educational program. Similar results were attained by Bennell et al. (2016), where all the groups (PCST and exercise, PCST only, and exercise only) showed large and

clinically important improvements in most secondary outcomes after attending 10 individual treatment sessions. On the other hand, Bennell et al. (2017) study has delivered all the intervention via the internet. It was found that the control group -who had access to educational material only- showed no significant improvement in the secondary outcome results. Moreover, Bennell et al. (2018) has found that administering 8 weeks of online education followed by 5 visits to the physiotherapist for home exercise prescription to the control group were not enough to sustain positive effects in the secondary outcomes that included: QoL, depression, stress, physical activity, and anxiety.

It is noteworthy, that all of the previously discussed studies were done prior to COVID-19 pandemic. Patients' acceptance and perceptions to internet-based interventions have been limited at that time (Bennell, Campbell et al., 2016; Kairy et al., 2013). This could be a suspectable factor for the insignificant secondary outcome results in the previous studies. In 2020, the COVID-19 pandemic had a dramatic impact on healthcare delivery worldwide, with many physiotherapy services rapidly transitioning to telehealth. This rapid transition consequently led to radical change in patients beliefs and interventions about this service (Bennell et al., 2021).

Our study was executed in a time where the Kingdom of Bahrain was in the Green Alert Level from 16th of July to 19th of December 2021 (except for first half of July and the full month of August where the alert level was yellow) in accordance with the COVID-19 Alert Level Traffic Light System. This came after periods of closure of some health services and confining it to certain defined conditions. Therefore, initiating such a study and having a personal interaction with participants in that particular period, regardless of the intervention given, could be the reason for

sustaining a positive result on the secondary outcome measures of the control group.

To summarize, our results showed significant improvement in all the patient's reported outcomes in both groups. Nevertheless, the results did not show significant improvement in depression, psychological distress, physical function, and QoL in the intervention group compared to the control group.

- **Maximum Isometric Muscle Strength**

Quadriceps muscle strength had a contrasting result compared to other secondary outcome measures. The isometric quadriceps muscle strength has not differed significantly in the control group, despite administering the same exercise program to that in the intervention group.

Similar results were attained in a pilot study that has examined the effects of a physiotherapist-delivered combined exercise and pain coping skills training intervention for individuals with knee OA. Participants were randomized to receive either 10 weeks of physiotherapist supervised exercises (lower limb strengthening and walking) combined with non-directive counselling (NDC) or the same exercise program delivered concurrently with PCST. Among the secondary outcome measures was the quadriceps muscle strength. Both groups experienced improvement in muscle strength, yet this improvement is non-significant. Moreover, there was no between-group difference in this measure. The results were justified by the author, that the exercise resistance were not aggressive enough for participants to change the outcome post-treatment (Hunt et al., 2013).

Bennell et al. (2016) RCT study on the physical therapist-delivered pain coping skills training and exercise for knee OA, had different results

than our study and Hunt et al. (2013) study. It was found that at 12 weeks of either PCST alone, PCST and exercises or exercises alone brought a significant improvement in the quadriceps muscle strength in all the groups. On top of that, exercise group had more significant improvement than PCST group, and the PCST and exercises group had significantly greater improvement than PCST group in that specific outcome measure.

It is possible that increases in exercise resistance were not aggressive enough for the participants in the control group, hence exercises incurred improvements in this group yet not statistically significant as similarly found by other researchers (Hunt et al., 2013).

- Participants Retention and Adherence

There were high participants retention rate in our study. This could be due to the retention plan adapted (Abshire et al., 2017). Another reason could be short study period (Catherine et al., 2020).

Adherence rate to the iCBT sessions was high with 84.2% participants who completed all the 8 sessions. On the other hand, the educational material was accessed by about 50% only of the participants in each group. In our study, more than 70% of participants in each group followed their home exercise 3 times per week (as instructed).

Adherence rate to study interventions varies among studies related to the same subject (Bennell, Ahamed et al., 2016; Bennell et al., 2017). There are several patient-, intervention-, and environment-related factors that are considered determinants of adherence to the online programs (Bossen et al., 2013; de Vries et al., 2017; Kelders et al., 2012). These determinants include, but are not limited to, the following: Internet skills, self-discipline, OA symptoms duration, website usability, persuasive design, time required, participants recruitment strategy (Bossen et al., 2013; de Vries et

al., 2017; Kelders et al., 2012). In our study, higher rates of completing the iCBT sessions and lower rates for accessing the educational material, could be due to the method of the researcher encouragement in accessing each material (Bossen et al., 2013; de Vries et al., 2017). Unlike the iCBT sessions, where participants were encouraged to access the sessions on weekly basis, participants were encouraged to access the educational material on their own pace.

4.3.a. Rethinking the Study Hypothesis

Our hypothesis was based on Lentz et al (2019) study that high healthcare utilization individuals have certain modifiable variables that are associated with this high utilization. Among these variables were psychological distress and depression, and we have specifically chosen these variables in our study as we found supporting literature on the effectiveness of iCBT in managing individuals with psychological distress and depression (O'moore et al., 2018; Wang & Ni, 2022). Nonetheless, after conducting the study and extracting the results, we found that our results did not support all of our hypotheses and that we could not prove significant improvement between the groups neither in function nor in secondary outcome results. This demanded revisiting correlated literature regarding factors associated with healthcare utilization.

Speaking about healthcare utilization, Budtz et al. (2020) investigated the socio-demographic, clinical and psychological predictors of healthcare utilization among patients with musculoskeletal disorders. It was found that clinical factors and sickness leave seem to be the main predictors of primary care physiotherapy utilization and not psychological factors. However, it was found also that patients with less physiotherapy utilization showed greater improvements in psychological wellbeing and fear avoidance compared to those with high utilization. The authors explained

that this could imply that high utilization individuals were treated based on the biomedical approach while the biopsychosocial approach is integrated in those with low utilization (Budtz et al., 2020). Another cohort study by Emilson et al. (2020) investigated the association between health care utilization and musculoskeletal pain. It was found that the presence of chronic pain predicted high health care utilization. Moreover, their results also indicated an association between low health-related QoL and high health care utilization in the long-term (Emilson et al., 2020).

Besides the previously mentioned studies, another congruent cohort by Mose et al. (2021) reported that participants with high number of MSK healthcare contacts reported significantly higher pain intensity score, higher BMI, higher depression score, higher degree of participation restriction due to pain, had more comorbidity, more musculoskeletal healthcare contacts before baseline and were less often working or student and did more often receive social health-related benefit compared to participants in other groups of the study (Mose et al., 2021).

To sum up the results of the previous studies, it would be appropriately implied that high healthcare utilization is dependent on several factors. The factor that has been repeatedly explored in literature and that is highly associated with high healthcare association was pain (Budtz et al., 2020; Emilson et al., 2020; Mose et al., 2021). In fact, among the factors associated with high healthcare utilization that were investigated by Lentz et al. (2019) was greater pain interference as well. Depression and mental health status were also investigated in the previously mentioned studies (and some associations were proved), yet it was not agreed by all the studies that it could predict healthcare utilization. Afterall, it might not be the choice of individuals variables, rather it could be the determination of the minimum levels of psychological distress and depression. Those levels might not be high enough to incur a significant

improvement in these individuals. Moreover, higher levels of depression and psychological distress may require further psychological intervention that are beyond this research scope.

Strengths

To date, this is the first study on the effects of iCBT and exercise in knee OA individuals that have specified the individuals enrolled based on certain psychological levels. This filled the gap and came in line with the recommendations of implementing such treatment interventions in this specific group of individuals.

Major strengths of our study were a sufficient level of pain and physical dysfunction to allow scope for improvement, comparable groups at baseline, and good participant retention and adherence. Additionally, outcome measures covering a range of domains, both subjective and objective, many were recommended for OA clinical trials.

Limitations

Our study has limitations. First, it was executed all together by one researcher, so there was a risk of researcher bias. According to the rules and regulations of the UOB; thesis research is supposed to be done by the researcher him/herself and no research assistant is allowed to be recruited. That is why, full blinding in the research was not possible. Yet, the risk of bias was minimized by blinding the baseline outcome measures to the researcher and blinding the participants to their group assignment. Second, due to the resources- and time-limits of the thesis, a small sample size of participants was chosen. This reduced the generalizability of our results. Third, this study had only one time point measurement (at 8 weeks). It is

usually advised in biopsychosocial interventions to measure the effects over longer follow-up periods.

Future studies should examine implementing the same intervention to a larger sample size. Further, participants should be followed on a longer follow-up period. Moreover, individuals with more severe psychological distress and depression levels should be included in future studies to examine the effect of such interventions on that specific group. Researchers could also design a study where the same intervention is administered to participants with certain psychological distress and depression levels and those without any distress or depression.

4.3. Conclusion

We have conducted a 2-arm quasi-randomized controlled trial to investigate the effectiveness of an iCBT and exercise in chronic knee patients with psychological distress compared to a control group. Our results suggest that a combined iCBT and exercise can effectively improve pain and function in chronic knee patients with psychological distress. Furthermore, when compared to a control group, pain and step tests have improved significantly in the intervention group. Additionally, our results showed significant improvement in all the patients-reported outcomes as well as the quadriceps muscle strength in the intervention group. However, when compared to a control group, the patients-reported outcomes and quadriceps muscle strength did not appear to be improving significantly in the intervention group compared to controls.

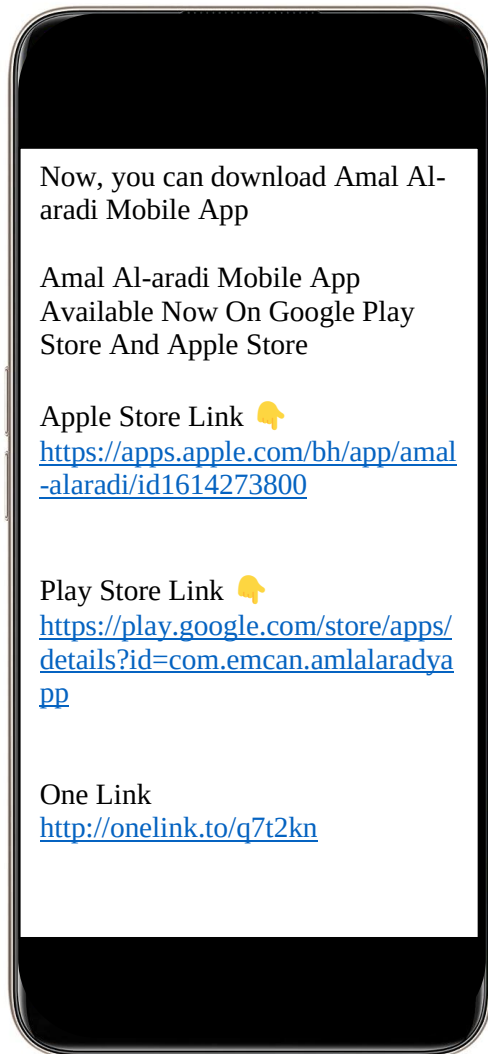
Future research is recommended to study the effects of the combined iCBT and exercise on a larger population so that the results could be generalized. The aim of combining iCBT and exercise in the treatment of chronic knee patients with psychological distress is to reduce the burden of the chronicity of knee pain, that is why studying the long-term effects of the intervention is highly recommended in future studies. Moreover, it is recommended that future studies investigate the effects of the educational material in a separate control group.

Thesis Collateral Project
Amal Alaradi Mobile Application

Amal Alaradi Mobile Application

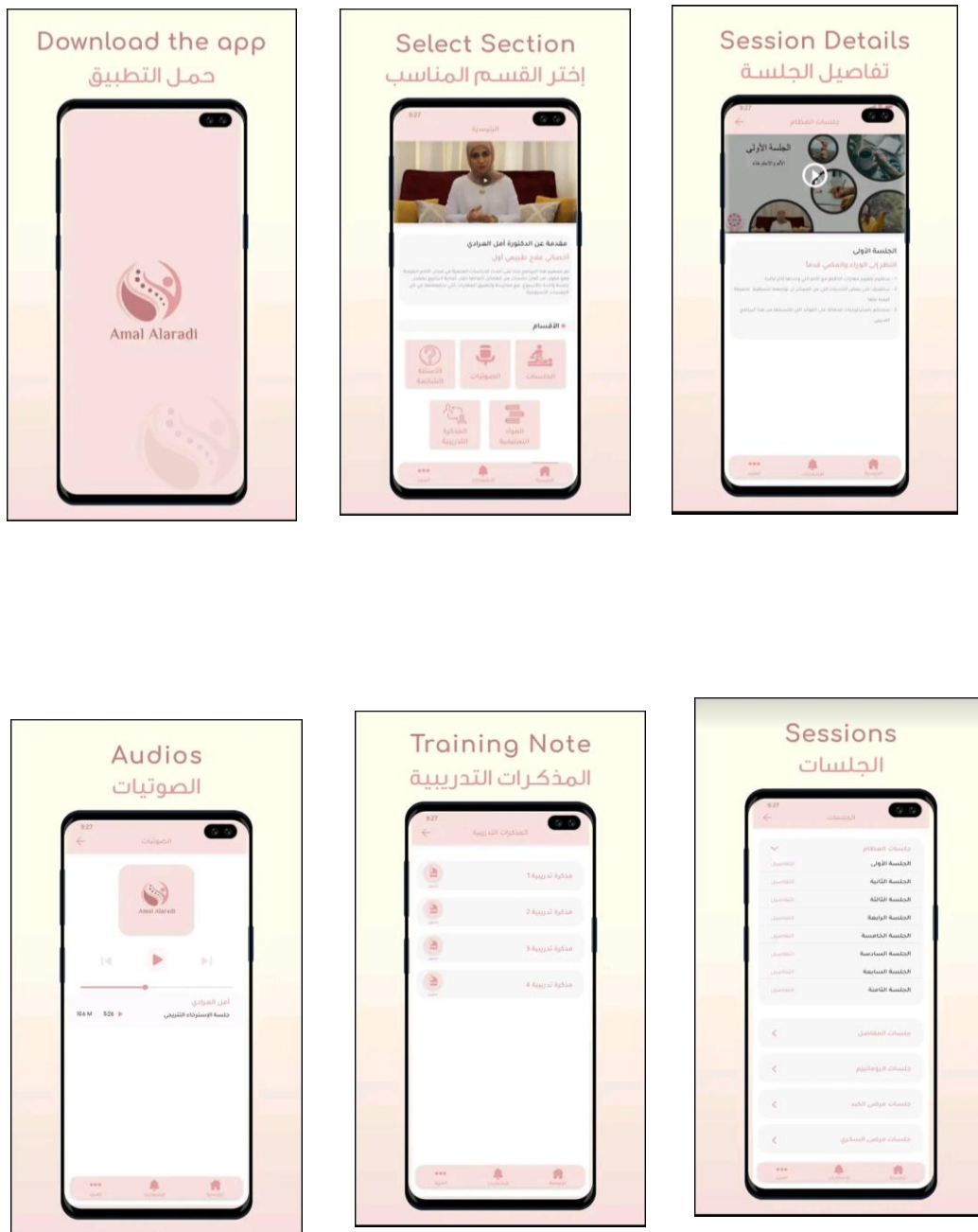
As a result of this research, a mobile application “Amal Alaradi Mobile Application” was developed by the researcher that included all the iCBT content delivered during the intervention, it is available for download from the apple store or play store. The application will serve all individuals with chronic musculoskeletal pain who need iCBT intervention. Specifically speaking, the application will be offered for chronic musculoskeletal patients with psychological distress who attend at the primary care. We have already proved the effectiveness of combining iCBT intervention with exercise in improving pain and function in chronic knee patients with psychological distress. As Chronic musculoskeletal individuals are considered high-cost utilizers, providing an effective treatment for them will reduce the societal and economical burden they sustain on health care systems.

The application can be downloaded from the play store or the app store:



It can also be downloaded through scanning the following QR Code:





Amal Alaradi Application Contents

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Appendices

Appendix (1): The modified Borg Rating of Perceived Exertion (RPE) CR10 scale

Rating	Descriptor
0	Rest
1	Very easy
2	Easy
3	Moderate
4	Somewhat hard
5	Hard
6	
7	Very hard
8	
9	
10	Maximal

Appendix (2): The Single-Item Numerical Rating Scale (NRS)

مقياس شدة الألم

...

* Required

1. الرقم الشخصي *

Enter your answer

2. هل تعاني من ألم في الركبة لأكثر من 3 أشهر وفي أغلب أيام الشهر الماضي؟ *

نعم

3. قيم متوسط ألم الركبة لديك في الأسبوع الماضي على مقياس من 0 إلى 10 *

0	1	2	3	4	5	6	7	8	9	10
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لا يوجد ألم أسوأ ألم ممكن

Submit

Appendix (3): Patient Health Questionnaire (PHQ-2)

2 (PHQ-2) استبيان صحة المرضى -

...

* Required

* الرقم الشخصي 1.

Enter your answer

* خلال الأسبوعين الماضيين، كم مرة عانيت من أي من المشاكل التالية؟ 2.

ولا مرة (0)

عدة أيام (1)

أكثر من نصف الأيام (2)

تقريباً كل يوم (3)

1. قلة الاهتمام أو قلة
الاستمتاع بممارسة أي
عمل

☐☐☐☐

2. الشعور بالحزن أو ضيق
الصدر أو اليأس

☐☐☐☐

Submit

Appendix (4): Psychological Distress (Kessler 6)

(K-6) استبيان الصحة النفسية والعقلية

الأسئلة التالية تهدف إلى معرفة شعورك خلال الأيام الثلاثين الماضية. يرجى اختيار الخيار الذي يصف بالشكل الأفضل كم غالباً أحسست بهذه المشاعر

...

* Required

* الرقم الشخصي 1.

Enter your answer

* ...خلال الأيام الثلاثين الماضية، كم غالباً كنت تشعر بأنك 2.

	أبداً (0)	نادراً (1)	قليلاً (2)	غالباً (3)	دائماً (4)
1. متوتر	☐	☐	☐	☐	☐
2. يائس	☐	☐	☐	☐	☐
3. متململ	☐	☐	☐	☐	☐
4. شديد الاكتئاب لدرجة أنه لم يعد أي شيء يفرحك	☐	☐	☐	☐	☐
5. تتطلب مجهوداً للقيام بأي شيء	☐	☐	☐	☐	☐
6. لا قيمة لك	☐	☐	☐	☐	☐

Appendix (5): Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS- PS)

استبانة الإلتهاب المفصلي العظمي وإصابات الركبة (KOOS-PS)

الإرشادات: تتضمن هذه الاستبانة أسئلة حول وجهة نظرك عن ركبتيك، وهذه المعلومات سوف تساعدنا على تتبع مدى قدرتك على أداء الأنشطة المختلفة. أجب على كل سؤال عن طريق اختيار المربع المناسب، إذا كنت غير متأكد من كيفية الإجابة على السؤال، يرجى إعطاء أفضل إجابة ممكنة حتى تتمكن من الإجابة على جميع الأسئلة.

...

* Required

1. الرقم الشخصي *

Enter your answer

2. الأسئلة التالية تتعلق بمستوى قدرتك على أداء الأنشطة اليومية المعتادة والأنشطة ذات المستوى الأعلى. لكل من الأنشطة التالية، يرجى الإشارة إلى درجة الصعوبة التي واجهتها في الأسبوع الماضي بسبب مشكلة ركبتيك: *

	شديدة جداً (4)	شديدة (3)	متوسطة (2)	خفيفة (1)	لا يوجد صعوبة (0)
التنهوض من الفراش	☐	☐	☐	☐	☐
ليس الجوارب	☐	☐	☐	☐	☐
القيام من وضع الجلوس	☐	☐	☐	☐	☐
الإنحناء لإلتقاط شيء من الأرض	☐	☐	☐	☐	☐
الدوران أو اللف على ركبتيك المصابة	☐	☐	☐	☐	☐
وضعية القرفصاء (الجلوس على المرحاض العربي)	☐	☐	☐	☐	☐

Submit

Appendix (6): Health related quality of life-Short Form-12

(SF-12) جودة الحياة المرتبطة بالصحة

يدور هذا المسح حول عدد من الأسئلة والاستفسارات حول صحتك وتساعدك هذه المعلومات التالية في متابعة حالتك الصحية ومدى قدرتك على القيام بأنشطتك العادية. الرجاء الإجابة على كل سؤال وذلك من خلال اختيار الإجابة المناسبة، وإذا لم تكن متأكدًا حول إجابة سؤال ما، فالرجاء إعطاء الإجابة الأقرب للصحيح ما أمكن ذلك.

...

* Required

1. الرقم الشخصي *

Enter your answer

2. بصفة عامة يمكنك القول بأن صحتك (حالتك الصحية) *

- ☐ ممتازة (5)
- ☐ جيدة جداً (4)
- ☐ جيدة (3)
- ☐ حسنة (لا بأس بها) (2)
- ☐ ضعيفة (1)

3. الأسئلة التالية تدور حول الأنشطة التي يمكنك القيام بعملها في يومك العادي، هل تجد حالتك الصحية الآن من هذه الأنشطة؟ *

	نعم (محدودة) كثيراً (1)	نعم تحدها قليلاً (2)	لا تحدها مطلقاً (3)
الأنشطة المعتدلة مثل تحريك طاولة، دفع مكينة كهربائية، لعب الكرة	☐	☐	☐
صعود عدة عتبات من الدرج	☐	☐	☐

4. خلال الأربع أسابيع الماضية هل واجهت أي من المشاكل التالية في عملك أو في أي من نشاطاتك اليومية. المنتظمة الأخرى نتيجة لحالتك الصحية *

	نعم (1)	لا (2)
أنجزت في عملك أو نشاطاتك أقل مما كنت تصبو إليه (أو تريده)	☐	☐
كانت محدودة في نوعية العمل أو أنشطة أخرى	☐	☐

5. خلال الأربع أسابيع الماضية، هل واجهت أي من المشاكل التالية في عملك أو أنشطتك اليومية المعتادة. الأخرى نتيجة لأي مشاكل نفسية (أو مشاكل عاطفية مؤثرة) مثل (الشعور بالانكباب أو القلق) *

	نعم (1)	لا (2)
أنجزت أقل مما كنت تصبو إليه (أو تريده)	☐	☐
لم أقم بالعمل أو أنشطة أخرى بدقة كالمعتاد	☐	☐

Appendix (6 continued): Health related quality of life-Short Form-12

6. خلال الأربع أسابيع الماضية، إلى أي مدى أثر ما تشعر به من ألم في عملك اليومي (بما في ذلك عملك خارج * وداخل المنزل)

- ☐ لا البتة (5)
- ☐ قليلاً جداً (4)
- ☐ بصورة متوسطة (3)
- ☐ كثيراً ما (2)
- ☐ بشدة (1)

7. الأسئلة التالية تتعلق بشعورك وكيف كانت تبدو لك الأشياء خلال الأربع أسابيع الأخيرة، الرجاء إعطاء الإجابة:
الأقرب لما كنت تشعر به
*: كم هي المدة الزمنية خلال الأربع أسابيع الماضية التي

	لا شيء من الوقت (1)	قليلاً من الوقت (2)	بعض الوقت (3)	كثيراً من الوقت (4)	معظم الوقت (5)	كل الوقت (6)
التي شعرت فيها بالهدوء والأمن	☐	☐	☐	☐	☐	☐
كان لديك كثيراً من الطاقة	☐	☐	☐	☐	☐	☐
هل شعرت بأي إحباط وانكسار	☐	☐	☐	☐	☐	☐

8. خلال الأربع أسابيع الأخيرة، إلى أي مدى أثرت حالتك الصحية أو النفسية في أي أنشطتك الاجتماعية (مثل * زيارة الأقارب والأصدقاء)

- ☐ كل الوقت (1)
- ☐ معظم الوقت (2)
- ☐ بعض الوقت (3)
- ☐ قليلاً من الوقت (4)
- ☐ لا شيء من الوقت (5)

Submit

Appendix (7): Participant-perceived response to treatment measured on 8-point scales

استبيان تأثير العلاج

يهدف هذا الاستبيان لمعرفة تأثير العلاج على حالتك الصحية وجوانب أخرى

 to.alaradi@gmail.com (not shared) [Switch accounts](#) 

*Required

* الرقم الشخصي

Your answer

* بشكل عام، ما هو مقدار التغيير الملحوظ في حالتك بعد العلاج؟

0	1	2	3	4	5	6	7	
لا تغيير	☐	☐	☐	☐	☐	☐	☐	تغيير كبير جداً

* ما هو مقدار التغيير الملحوظ في الألم لديك بعد العلاج؟

0	1	2	3	4	5	6	7	
لا تغيير	☐	☐	☐	☐	☐	☐	☐	تغيير كبير جداً

* ما هو مقدار التغيير الملحوظ في وظائفك اليومية بعد العلاج؟

0	1	2	3	4	5	6	7	
لا تغيير	☐	☐	☐	☐	☐	☐	☐	تغيير كبير جداً

Submit

Clear form

Appendix (8): Information Sheet



Information Sheet

Study: The Effectiveness of an Internet-Based Cognitive Behavioural Therapy and Exercise in Chronic Knee Patients with Psychological Distress

Overview

Knee pain can be a debilitating problem that can affect the quality of life of individuals. Several treatments are offered to reduce the burden of this problem. This study aims to investigate the effects of a combined program, designed on the latest evidence-based practices for the treatment of chronic knee pain. The program consists of 8 sessions of standardized exercise program and a supporting online educational material.

What is a standardized exercise program?

This will consist of a certain set of exercises designed specifically to strengthen lower limb musculature (mainly knee and hip musculature). The exercise program will be individualized for each participant's tolerance and will be progressed accordingly. The weekly session of exercises will be held at the physiotherapy department at Halat Bu Maher Health Center.

What is internet-based cognitive behavioural therapy (iCBT)?

It is a therapy that highlights the contribution of cognitive, emotional, and behavioural factors in the pain experience delivered to patients through the internet.

Who is eligible to participate?

To be eligible for taking part, a participant must be 45 years old or above, has knee pain for more than 3 months, and for most days of the previous month and has a smartphone with internet access. Also, to be eligible, a participant has to fill a few questionnaires regarding knee pain and psychological health and ensure that he/she gets a certain score in each questionnaire.

What will happen after agreeing on participation?

A participant will sign a consent form, general assessment for the participant condition, and more specifically for knee joint will be done. Then the therapist will prescribe a certain set of exercises for the participant to do at the department and to follow at home 3 times/week. The participant will have to attend 8 weekly sessions of exercises under the supervision of the therapist. Each participant will receive a link to access online sessions that include information about knee pain, emotions, and cognition. Different measurements will be taken at the start of the study and at the end to test the effect of the treatment on participants.

What are the possible benefits of participating in the study?

The participant will have strengthening exercises for lower limbs prescribed by an experienced therapist. The participant will have the latest evidenced-based education regarding knee pain.

What are the possible risks of participating in the study?

As in any exercise program, a participant might have soreness in the muscles of lower limbs that should not exceed 2 days. A hot or cold pack application (upon participant's preference) should reduce the soreness. Participants will be taught how to determine whether pain levels during and for a short time after the exercises are acceptable. If a specific exercise is aggravating the participant's pain, or if pain exceeded 2 days the participant must inform the researcher.

How is the confidentiality and anonymity of participants will be maintained?

All personal information will be dealt with confidentiality and will not be shared with anyone. Participants' names and personal details will not be mentioned by any means in the research. After completion of this study, the personal and contact details of participants will be erased while the dataset will be retained and might be used for further researches done by the University of Bahrain. Participant's face or identity will not be revealed if photographs or video recordings were taken.

Appendix 8 (continued): Information Sheet

What if a participant does not want to continue participating in the study?

A participant has the right to withdraw from the study at any stage without prejudice.

Thank you for your interest in participating in this study.

For further details about the research, please contact any of the researchers below:

Principal researcher:

Amal Abdulmahdi Alaradi, MSc candidate in Physiotherapy

Mobile: 36366300

E-mail: to.alaradi@gmail.com

NBB-Arad Health Center- Physiotherapy Department.

Academic supervisor:

Dr Yusuf Sayed Sharaf

Assistant Professor of Physiotherapy

Phone: 1743 5882 / 5826

Email: Ymohsen@uob.edu.bh

Appendix (9): Informed Consent Form

Informed Consent Sheet



Name: _____

I hereby give my consent to participate in the research project titled: The Effects of an Internet-Based Cognitive Behavioural Therapy and Exercise in Chronic Knee Patients with Certain Levels of Depression and Psychological Distress.

Researcher's name: Amal Alaradi

Student Number: 20040640

Course Title: Applied Research Project

I, the undersigned, confirm that (please circle as appropriate):

• I have read and understood the information about the project and the full description of the project procedures were explained to me.	Yes	No
• I understood the benefits of participating.	Yes	No
• I understand that there might be some adverse effects of participating in exercises program and that the possible risks were well-explained to me.	Yes	No
• I agree to participate in all stages of the study as outlined in the information sheet.	Yes	No
• I have been allowed to ask questions about the project and my participation.	Yes	No
• The procedures regarding my confidentiality have been clearly explained to me.	Yes	No
• I understand that my participation in the research is voluntary and I can withdraw my involvement at any stage without prejudice.	Yes	No
• I agree to have photographs or video recordings taken for me without revealing my identity.	Yes	No
• I understand that my participation in this study might be withdrawn at any stage of the study if I did not follow the instructions given to me by the researcher.	Yes	No
• I understand that once measurement/questionnaires have been completed, the information gained as a result of it may be used as part of an anonymised dataset by the researcher for completion of a master's thesis, publications, and future research projects. The anonymised dataset might be used in future researches done by the University of Bahrain.	Yes	No
• I, along with the researcher, agree to sign and date this informed consent form.	Yes	No

Participant Signature:

Signature

Date

Researcher Signature:

Signature

Date

Appendix (10): Adherence, adverse events, medications, and co-interventions

	Control	Intervention
Adherence		
1. Educational material		
access	1 (5.6)	1 (5.3)
0	1 (5.6)	0 (0)
1	3 (16.7)	3 (15.8)
2	0 (0)	5 (26.3)
3	3 (16.7)	1 (5.3)
4	10 (55.6)	9 (47.4)
5		
2. Frequency of home		
exercises	0 (0)	0 (0)
None	4 (22.2)	5 (26.3)
1-2 times	14 (77.8)	14 (73.7)
3 times		
3. iCBT sessions		
completions	--	1 (5.3)
5 sessions	--	2 (10.5)
7 sessions	--	16 (84.2)
8 sessions		
Adverse events during treatment		
None	17 (94.4)	18 (94.7)
Increased knee pain	1 (5.6)	0 (0)
Increased knee clicking	0 (0)	1 (5.3)
Medications and co-interventions		
	4 (22.2)	2 (10.5)
Analgesia	1 (5.6)	1 (5.3)
NSAIDs	4 (22.2)	1 (5.3)
Topical NSAIDs	1 (5.6)	0 (0)
Glucosamine/Chondroitin	1 (5.6)	0 (0)
products	1 (5.6)	3 (15.8)
Heat/cold modality		
Tape		
Treatment satisfaction		
Completely unsatisfied	0 (0)	0 (0)
Slightly satisfied	2 (11.1)	0 (0)
Moderately satisfied	3 (16.7)	1 (5.3)
Very satisfied	5 (27.8)	3 (15.8)
Completely satisfied	8 (44.4)	15 (78.9)
Treatment outcome		
No effect	0 (0)	0 (0)
Minimal improvement	3 (16.7)	1 (5.3)
Moderate improvement	5 (27.8)	2 (10.5)
	9 (50)	13 (68.4)

<i>Large improvement</i>	1 (5.6)	3 (15.8)
<i>Complete recovery</i>		

Appendix (11): Participant-Perceived Response to Treatment

	Control	Intervention
<i>Perceived Change Overall</i>	90% Improved	95% Improved
0	0 (0%)	0 (0%)
1	0 (0%)	0 (0%)
2	1 (5.6%)	0 (0%)
3	1 (5.6%)	1 (5.6%)
4	3 (16.7%)	0 (0%)
5	4 (22.2%)	5 (26.3%)
6	5 (27.7%)	7 (36.8%)
7	4 (22.2%)	6 (31.6%)
<i>Perceived Change in Pain</i>	90% Improved	100% Improved
0	0 (0%)	0 (0%)
1	0 (0%)	0 (0%)
2	2 (11.2%)	0 (0%)
3	0 (0%)	0 (0%)
4	5 (26.3%)	0 (0%)
5	3 (16.7%)	8 (42.1%)
6	4 (22.2%)	5 (26.3%)
7	4 (22.2%)	6 (31.6%)
<i>Perceived Change in Function</i>	70% Improved	90% Improved
0	1 (5.6%)	0 (0%)
1	1 (5.6%)	0 (0%)
2	3 (16.7%)	0 (0%)
3	0 (0%)	0 (0%)
4	1 (5.6%)	2 (10.6%)
5	3 (16.7%)	5 (26.3%)
6	4 (22.2%)	5 (26.3%)
7	5 (27.7%)	7 (36.8%)

Appendix (12): Barcodes of the Research Links



Examples of WhatsApp GIF exercises that were sent to participants to follow as home program



YouTube Educational sessions



iCBT website developed by the researcher



iCBT workbook



Amal Alaradi Mobile Application

الملخص

المقدمة: تم استخدام العلاج السلوكي المعرفي الإلكتروني (iCBT) والتمارين على نطاق واسع لعلاج آلام العضلات والعظام المزمنة. لقد هدفنا في هذه الدراسة إلى فحص تأثير برنامج علاجي مكون من العلاج السلوكي المعرفي الإلكتروني وبرنامج تمارين موحدة لعلاج مرضى آلام الركبة المقترنة بالتوتر النفسي.

خطة البحث: كانت هذه تجربة شبه عشوائية لمدة ثمانية أسابيع تضمنت ثماني جلسات من برنامج تمارين موحدة وإما علاج سلوكي معرفي إلكتروني (iCBT) مصاحب لجلسات تعليمية أو جلسات تعليمية فقط. تم أخذ القياسات قبل البدء بالبحث وثمانية أسابيع بعد البحث مباشرة. كانت مقاييس النتائج الأولية عبارة عن مقياس تقييم رقمي للألم ، واختبار المشي السريع الخطى 40 مترًا ، واختبار الخطوة ، واختبار وقوف الكرسي لمدة 30 ثانية. كانت مقاييس النتائج الثانوية هي استبيان صحة المرضى ، واستبيان الصحة النفسية والعقلية ، واستبانة الالتهاب المفصلي العظمي وإصابات الركبة، واستبانة جودة الحياة المرتبطة بالصحة ، والقوة العضلية القصوى لعضلة الفخذ الأمامية رباعية الرؤوس.

النتائج: بلغ عدد المشاركين في البحث 37 مشاركًا تتراوح أعمارهم بين (متوسط $\pm$ الانحراف المعياري) 55.5 ± 7.9 عامًا ممن يعانون من آلام الركبة المزمنة والتوتر النفسي. في مجموعة البحث (19 مشاركًا) ، كانت هناك فروق ذات دلالة إحصائية في جميع مقاييس النتائج الأولية والثانوية بعد العلاج. علاوة على ذلك ، كانت هناك فروق ذات دلالة إحصائية بين المجموعتين في مستويات الألم ($MD = 1.79$, [95%CI 0.5 to 3.08], $P = 0.008$) ، واختبار الخطوة ($MD = -1.74$, [95%CI -3.38 to -0.9], $P = 0.04$) ، واختبار المشي ($MD = -0.07$, [95%CI -0.24 to -0.11], $P = 0.449$) ، ولا في اختبار وقوف الكرسي لمدة 30 ثانية ($MD = -1.86$, [95%CI -3.99 to 0.26], $P = 0.084$) . أخيرًا ، لم يكن هناك فرق كبير بين المجموعتين في أي من المقاييس الثانوية ما بعد العلاج.

الخلاصة: يمكن أن يؤدي الجمع بين برنامج العلاج السلوكي المعرفي الإلكتروني (iCBT) وبرنامج التمارين الموحد إلى تحسين الألم والوظيفة واختبارات القياس الذاتية وقوة عضلات الفخذ الأمامية الرباعية في مرضى آلام الركبة المزمنة المقترنة بالتوتر النفسي. ومع ذلك ، عند مقارنتها بمجموعة مراقبة ، لم يتحسن سوى اختبار الألم واختبار الخطوة بشكل ملحوظ. يجب أن تدرس الدراسات المستقبلية تأثير برنامج العلاج السلوكي المعرفي الإلكتروني (iCBT) وبرنامج التمارين الموحد على شريحة أكبر من المشاركين. بالإضافة إلى ذلك ، يجب دراسة تأثير ذلك العلاج على المشاركين على المدى الطويل.

جامعة البحرين

قسم العلاج الطبيعي



كلية العلوم الصحية
والرياضية

(فعالية برنامج العلاج السلوكي المعرفي الإلكتروني والتمارين في علاج حالات آلام الركبة المقتربة بالتوتر النفسي)

أطروحة مقدمة كجزء من متطلبات الحصول على درجة الماجستير في العلاج الطبيعي

إعداد

(أمل عبدالمهدي علي العرادي)

(٢٠٠٤٠٦٤٠)

إشراف

(د. يوسف سيد شرف)

(أستاذ مساعد)

جامعة البحرين

مملكة البحرين

سبتمبر ٢٠٢٢