International Journal of Care Scholars 2019;2(2)

A Feasibility Study of the ESCAPE-pain Programme for Patients with Knee Osteoarthritis in the Malaysian Context: Preparation of A Protocol

Muhammad Kamil Che Hasan[1,2], Emma Stanmore[1,3,4], Chris Todd[1,3,4]

[1]*The University of Manchester, School of Health Sciences. Manchester, UK.*

[2]*International Islamic University Malaysia, Kulliyyah of Nursing.*

[3]*Manchester Academic Health Science Centre, Manchester, UK.*

[4]*Manchester University NHS Foundation Trust, Manchester, UK.*

ABSTRACT

Background: In Malaysia, around one in ten older people are diagnosed with osteoarthritis (OA), with the knee being one of the most commonly affected areas. This can lead to functional limitations, impaired activities of daily living and reduced quality-of-life. Thus, a systematic review of the literature concludes that a programme integrating exercise, education and active coping strategies, known as Enabling Self-management and Coping with Arthritic Pain using Exercise (ESCAPE-pain) provides the best evidence for patients with knee OA. **Objective:** Through Thus, this study aims to evaluate the feasibility of a randomised controlled trial to explore the implementation of the ESCAPE-pain programme among patients with knee OA in the Malaysian healthcare context guided by the UK Medical Research Council Framework (2000). **Methods**: This is a pragmatic, feasibility randomised controlled trial (RCT) recruiting patients (n=72) with knee osteoarthritis from two hospitals in Malaysia. Participants were randomised to receive ESCAPE-pain intervention plus usual care (n=36) (intervention group) or usual care only (n=36) (control group). The ESCAPE-pain programme was delivered twice weekly for six weeks by a certified trainer. Outcomes were measured for physical function (TUG), knee injury and osteoarthritis outcome scores (KOOS), mental wellbeing (Short-WEMWBS), exercise health beliefs and self-efficacy and fear of falling (Short-FES-I) at baseline, six-week and after 12-week of intervention. **Results**: This is the first study to evaluate the implementation in the Malaysian healthcare context. **Conclusion**: The findings are hoped to facilitate the practicality of the design of a definitive randomised controlled trial, to support people living with knee osteoarthritis in Malaysia.

KEYWORDS: Feasibility, ESCAPE-pain, Knee Osteoarthritis

INTRODUCTION

It is estimated that 250 million people worldwide suffer from knee OA, of which twice as many are female as male (1,2). In Malaysia, it is estimated by the Arthritis Foundation of Malaysia (AFM) that around one in ten of older people aged 60 and above suffer from OA, the most common being knee OA (3). People with knee OA have difficulties performing activities of daily living, which could lead to severe mental wellbeing, physiological consequences, and at risk of ischaemic heart disease and heart failure (4).

Current management for knee OA is focused on non-pharmacological interventions, where exercise and education are among the top priorities (5). In the Malaysian healthcare context, treatment is mainly offered in hospital settings, which is deemed to be difficult by most patients for various reasons. Many intervention programmes for patients with knee OA are being conducted all over the world. Among them, the ESCAPE-pain programme (6) was believed to be feasible and worth evaluating in the Malaysian healthcare context. It is proven to be cost-effective with long-term benefits (7), accepted by the participants in different contexts (8), the contents are accessible (9) and seem practical for healthcare professional.

The UK Medical Research Council (MRC) Framework (2000) and Guidance (2008) recommend four systematic phases for healthcare researchers (10). This methodology is widely used in improving health (11). Phase One identifies the components of the intervention, aims to understand the possible effects and also looks for areas for refinement. Phase Two consists of feasibility or piloting, which includes testing procedures, estimating recruitment and retention, and determining sample size. This phase uses a combination of qualitative and quantitative methods to test the feasibility by focusing on the acceptability of the intervention. The complex intervention is then evaluated on a larger scale after further refinements in the next phase, evaluation. Phase Three consists of assessing effectiveness, understanding the change process, and assessing cost-effectiveness. The last phase (four), implementation, comprises dissemination, surveillance and monitoring, and long-term follow-up. This phase involves moving the complex intervention into practice by targeting knowledge translation and dissemination. Throughout the process, it may be necessary to revisit the earlier phases in the cycle depending on the results of any specific phase, making this revised MRC guidance (2008) iterative and cyclical rather than linear, as compared to a previous one from the year 2000 (12).

This study protocol focuses on just the first two

***** Corresponding author

Muhammad Kamil Che Hasan
Kulliyyah of Nursing, International Islamic University Malaysia, Kuantan, Malaysia.
Email: mkamil@iium.edu.my
Tel: +60199101731

phases, early development and feasibility, and organised according to the MRC framework (2000) as shown in Table 1. Phase One of this study was a pre-clinical phase: a systematic literature search and discussion of the theoretical rationale for the proposed intervention where the gaps of the study are identified. Synthesis of selected studies was carried out to identify an evidence-based exercise programme, and the components of the chosen programme. Next, primary research was carried out to explore healthcare professionals' and patients' views about the chosen programme. Based on analysis of these views, the chosen programme was modified to accommodate the feedback from the healthcare professionals and patients. Then, in accordance with Phase Two of the MRC guidelines, this feasibility trial was conducted to assess the feasibility and acceptability of the modified intervention programme and investigate relevant parameters for future RCT.

Steps in the MRC framework for developing a complex intervention	Steps that were taken to develop an intervention based programme
Phase 1: (Preclinical) Identifying the evidence base	Conducting a systematic literature search to identify the best evidence about exercise intervention programmes for patients with knee OA.
Phase 1: Qualitative and modelling	Primary research: conducting semi-structured interviews to explore the healthcare professionals' and patients' views on the proposed programme. Modifying / developing and presenting the related contents of the intervention programme.
Phase 2: Feasibility and piloting	Feasibility, acceptability and identifying outcome measures for a larger randomised controlled trial.

Table 1 Evaluating an exercise based programme for patients with knee OA, based on MRC framework (2000)

METHODS AND ANALYSIS

Study objectives

The primary objective of this study was to proposed a feasibility randomised controlled trial of the implementation in the Malaysian healthcare context of the adapted ESCAPE-pain programme for patients with knee OA.

Participants

Participants among patients with knee OA were recruited from orthopaedics outpatients' clinics and rehabilitation units at Hospital Tengku Ampuan Afzan (HTAA) and IIUM Medical Centre (IIUMMC) of the state of Pahang, Malaysia.

Inclusion criteria

- Age 50 years or older diagnosed with OA affecting the knee
- Independently mobile either with or without a walking aid.
- Approved medically fit for exercise by a medical officer.
- Able to communicate in the Malay language.
- Must have the mental capacity to give informed consent.

Exclusion criteria

- Has had knee replacement / lower limb arthroplasty.
- Has had intraarticular injections within the past six months.
- Have any significant musculoskeletal issues (e.g. inflammatory arthritis, connective tissue diseases, fibromyalgia, severe osteoporosis, peripheral neuropathy, or gout).
- Very severe joint pain limiting mobility to less than 50 metres.
- Unstable co-morbidities (such as cardiovascular and respiratory conditions, type 2 diabetes, severe pain in other joints).
- Wheelchair user.
- Severe cognitive impairment assessed by a medical officer.
- Severe auditory or visual impairment assessed by a medical officer.
- Inability to comprehend the ESCAPE-pain procedure.

Recruitment

Patients who fulfilled the inclusion criteria attending the orthopaedics outpatient clinic or rehabilitation unit were recruited from IIUM Medical Centre (IIUMMC) and Hospital Tengku Ampuan Afzan (HTAA). All baseline data were obtained for all participants independently in the clinic before the randomisation process. The ESCAPE-pain programme was delivered at two community centres in Pahang, outside the healthcare facilities to avoid difficulties that identified earlier faced by both healthcare professionals and patients with knee OA. The participants were informed about their right to withdraw from the study at any time without giving any reason even though they had signed the consent form, and that this would not affect the care they receive.

Study design

The adapted ESCAPE-pain programme is designed as a randomised, controlled trial with two parallel groups.

Randomisation

Participants were randomised using an online randomisation service (13) by an independent faculty member. The person involved in randomising participants had no clues about the treatment allocation. The online service would not release the randomisation codes until the patients had been recruited into the trial. Allocation took place after all baseline measurements had been completed.

Interventions

Participants allocated to the usual care group received the usual treatment provided by the hospital. Meanwhile, participants randomised to the intervention group also received the usual treatment provided by the hospital, and in addition the ESCAPE-pain programme

intervention.

Adapted ESCAPE-pain programme

The adaptation to the Malaysian context of the ESCAPE-pain programme was completed by the researcher and refined by expert consensus through interviews with experienced healthcare professionals and people living with knee OA in Malaysia. The adaptation followed guidelines from Barrera and Castro (2006) for the cultural adaptation of evidence-based therapy in a different context as shown in Table 2.

Topic 1: Aims of the programme and circuit information
▫ Walking with a dog is changed to walking only without the dog (cultural difference). ▫ Rocker board. wobble board and wall squat are removed from the list for safety reason.
Topic 2: Joint pain and benefits of exercise
▫ Included among the benefits of performing exercise are supporting spiritual needs (linking faith, belief and health). ▫ Talk about cultural belief and idea of joint pain and the implication of exercise.
Topic 3: Goal setting and action plans
▫ Setting up culturally relevant goals and action plans. ▫ Giving an example of a local context such as walking to the nearby market, neighborhood and places of worships. ▫ Encourage participants to include the strength of their faith to create positive change towards better health. ▫ The inclusion of the words from related scripture if applicable.
Topic 4: Pacing activities
▫ Encourage the participants to practice regular physical activities while performing daily routine including spiritual activities. ▫ Recognize the relationship between the participants' belief and stressful events, their responses based on their beliefs, and any actions taken subsequently (promote skills related to resilient body and mind towards exercise).
Topic 5: Healthy diet
▫ Eatwell guide is adapted to local dietary guidance as provided by the Ministry of Health Malaysia. ▫ Tips for reducing the weekly amount of alcohol are removed from the text (culturally sensitive). ▫ Example of the daily menu is replaced the with local context of breakfast, lunch and dinner.
Topic 6: Ice and heat
▫ Discussion of the use of traditional techniques to reduce the pain and swelling being permitted as long as they do not exacerbate the symptoms or worsen the condition. ▫ Incorporate methods which are culturally appropriate in the community to relieve the symptoms.
Topic 7: Mid-way review and shared experiences
▫ Spouse, family or friends are invited to share their experiences throughout the programme.
Topic 8: Anxiety, mood and pain
▫ Include discussion activity for participants by triggering discussion of their religious and spiritual approaches according to their beliefs.
Topic 9: Relaxation techniques
▫ Additional relaxation approaches are encouraged, which relate to spiritual behaviour or the daily practice of religious belief such as prayers and chanting.
Topic 10: Drug management
▫ Selection of drugs follows the guidelines provided by the Ministry of Health Malaysia based on Clinical Practice Guidelines (CPG) to suit the context. ▫ Traditional remedies are allowed as long as they do not exacerbate the symptoms or worsen the condition, based on a medical doctor's view.
Topic 11: Managing flare-ups
Traditional techniques of management are allowed as long as they do not exacerbate the symptoms or worsen the condition, based on healthcare professionals' view.
Topic 12: Exercising in the long-term
Participants are provided with details of the nearest community centre or organisation that conducts exercise for older people. The contact address of an organisation, Arthritis Foundation of Malaysia, is provided for participants to refer to for any related information.

Table 2 : Adapted ESCAPE-pain programme

The ESCAPE-pain programme is a six-week programme consisting of 12 sessions of group discussion and progressive exercise intervention conducted after the discussion class. Each session takes approximately one hour, consisting of 15-20 minutes of discussion followed by 40-45 minutes of exercise. Each group is considered as a single cohort which begins and ends the programme together, with eight to twelve participants per group.

The progressive exercise intervention is stage-adapted, where each participant is encouraged to perform exercise based on their own capabilities. Participants in the intervention group also received a participants' booklet which included an exercise sheet and printed material related to the whole programme provided by the ESCAPE-pain provider, which had been adapted to Malaysian context. The participants' booklet provided information about the programme schedules and content. It also described many activities either as part of face-to-face sessions or as self-management and reflective activities for the participants to complete at home.

Participants attended two sessions a week for six weeks, based on their availability. Each class started with a themed discussion, followed by a 40 -minute exercise programme. Before any type of exercises, stretching was performed.

The exercise programme began with very simple exercises to increase patients' understanding and confidence that controlled exercise would not hurt them (i.e. sitting to standing from a high chair, quadriceps exercises with a block, step-ups onto a low block, knee bends).

Each exercise was done for a particular amount of time such as 1-2 minutes. Any number of

repetitions during that time could be documented.

The researcher encouraged participants to progress the exercises by improving the quality of the exercise or increasing the number of repetitions. Additionally, the resistance of the theraband or bike could be increased.

The participants were taught all the exercise activities to practise at home. A diary checklist and an illustration of the exercises were provided. Participants were also encouraged to walk safely and freely to attain and retain the health benefits of performing physical activity.

Participants worked with the researcher to set specific, measurable, realistic, and achievable goals to bring a sense of progress. The activities and home exercises could help participants toward achieving these goals.

During the programme, participants were encouraged to think about activities they enjoyed, such as dancing, swimming, walking, tai chi, qigong and so forth. They were given the opportunity to choose their own programme to do physical activities. Participants were also told about local exercise opportunities, community centres and activity groups they might consider joining. After completing the 12 sessions, the participants were encouraged and expected to perform the exercises at home. The exercise intervention was individualised based on the ability of the participants through assessment at the beginning of the programme. The intensity and frequency were determined based on the need of the participants either during the session with the researcher or at home.

Usual care
All participants involved in this study continued their treatment as prescribed by their healthcare professionals. In Malaysia, the treatment of knee OA in the MoH is based on clinical practice guidelines (CPG) for the management of osteoarthritis throughout its care centres including IIUMMC and HTAA. It consists of pharmacological and non-pharmacological treatment other than surgical or complementary therapy. Pharmacological treatment offers intra-articular injection and oral medication. Meanwhile, non-pharmacological treatment offers education, lifestyle modification, physiotherapy, occupational therapy and orthoses. Education of patients is tailored based on individual needs. Meanwhile, lifestyle modification focuses on weight reduction and physical activity. Physiotherapy could offer exercise, transcutaneous electrical nerve stimulation (TENS), thermotherapy and therapeutic ultrasound. Referral to occupational therapy and orthoses are based on the needs of the patients.

Adherence reminder
Participants in the intervention group were allocated to three different classes based on their availability and date of commencement. A participant attending a minimum of 10 out of 12 sessions is considered good adherence to the ESCAPE-pain programme. Adherence reminders for each session were sent using social media applications used by most participants or their family members, such as WhatsApp and short message service (SMS). Participants were reminded at each session to attend the next session as scheduled. They were given the researcher's contact number if they needed further reinforcement or information about the programme. There was a brief discussion of reasons for any missed sessions and plans to enhance adherence.

Blinding
In a clinical research study, 'blinding' is defined as the concealment of group allocation of people involved in the study and is particularly used in randomised controlled trials (RCTs) (15). In health-related rehabilitation, the term 'single-blind' refers to a trial where the data collector is blinded to group assignment, which has a similar advantage to an unblinded study (16). 'Double-blind' is the most commonly used term for a trial in which neither participant nor investigator knows the assignment group. Blinding of participants in this study was not possible due to the nature of this intervention study involving exercise, where the participants knew that they were in the intervention group if they joined the programme, and vice versa. The researcher also interacted with the participants while conducting the exercise and education sessions. However, the participants were asked not to discuss this with other patients in order to maintain concealment of the programme, due to limitation in this feasibility study. In the future full randomised trial, distinct geographical centre is suggested to minimise the risk of contamination. In the event of the patients or provider being impossible to blind, it is suggested to ensure that the groups involved are treated equally in terms of follow-up, co-interventions and management of complications (15), which was planned accordingly for this study.

Outcomes
A range of outcomes was measured based on the factors affecting the quality of life among patients with knee OA including physical function, osteoarthritis outcomes, self-efficacy, mental well-being, the risk of falls and exercise adherence without identifying any a priori as primary or secondary. All outcome measurements were collected after completion of a consent form at baseline measurement. The researcher measured the outcomes six and twelve weeks after the intervention for both groups of participants. A version translated into the Malay language was used throughout the study and the original version was acknowledged.

Physical function
Physical function was assessed using the Timed Up and Go (TUG) test. The TUG test is one of the recommended performance-based tests by Osteoarthritis Research Society International (OARSI) (17). It is complementary to self-report measures in research with OA to support decision-making for clinical practice. The TUG test is a modified version of the Get-up and Go test (18) and was developed by Podsiadlo and Richardson (19). The TUG test has a correlation with severity of knee OA based on radiological findings where the longer the time taken for the TUG test is, the more severe the knee OA is (20). It is widely used to measure physical function in older people, but is not suggested as a single tool to measure fall risk among older people who are at risk of falling (21).

Knee osteoarthritis outcomes score
The outcomes of osteoarthritis in regard to the participants' opinions about their knees and associated problems were assessed using the Knee Injury and Osteoarthritis Outcome Score (KOOS) (22). KOOS is a self-reported outcome measurement instrument that consists of five subscales, namely pain (KOOS-pain), symptoms (KOOS-symptoms), function in daily living (KOOS-ADL), function in

sports and recreation (KOOS-sport/rec), and knee -related quality of life (KOOS-QOL). This KOOS has been modified to maximise its suitability for a range of different languages and cultures. The Malay version of KOOS is a highly reliable and valid assessment tool for pain, symptoms, activity of daily living, sports and recreational activity and quality of life among Malaysian adults with knee OA (23). Cronbach's alpha value ranged from 0.776 to 0.946 while the composite reliability values ranged between 0.819 and 0.921 of each construct, indicating satisfactory to high levels of convergent validity (23).

Health beliefs and self-efficacy for exercise
Self-efficacy is considered an important predictor of adherence to an exercise prescription (24). Thus this study used health beliefs and self-efficacy in exercise questionnaires to reflect the concepts of beliefs about individuals' ability to perform exercise and self-efficacy (25). Many RCTs have used this questionnaire in different contexts with participants with musculoskeletal disease (6,26,27). It consists of twenty items which were: self-efficacy for exercise (four items), barriers to exercise (three items), benefits of exercise (five items), and impact of exercise on arthritis (eight items). Meanwhile, the Malay version was piloted with 30 participants as described in Chapter 6, which revealed self-efficacy for exercise (0.781), barriers to exercise (0.736), the impact of exercise (0.858) and benefits of exercise (0.854). The total score was calculated by adding together the respondents' scores on the self-efficacy subscale and the total for all other subscales. The sum of the items indicates higher scores reflecting greater self-efficacy or firmer believe in exercise.

Mental well-being
Changes were found in physical variables such as quality of life and depression which were most likely caused by exercise (28). In addition, pain sensitivity, as mostly seen in patients with knee OA, also contributed to psychological changes (29). Thus, in this study, the mental well-being of the participants was assessed using the Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS) (30). This scale seems to be sensitive to changes in individual mental wellbeing and is widely used globally (31,32). The Malay version was pilot tested on a sample of 30 and revealed a Cronbach alpha of 0.838.

Risk of falls
Risk of falls is particularly reported among older people and an association with OA is seen among those with joint arthroplasty (33). This study uses Short Falls Efficacy Scale-International (Short FES -I) to measure concern of falling among participants (34). Short FES-I consists of seven items which measure confidence in performing a range of activities of daily living without falling. A 4-point scale is used ranging from no concern (1) about falling to severe concern (4) about falling. The sum of the items ranges from 7 to 28 with cut-off points of low (7-8), medium (9-13), and high (14-28) (35). This scale has recently been modified to maximise its suitability for a range of different languages and cultures (36). In the Malay language (Bahasa Malaysia), the Short FES-I showed good internal consistency (Cronbach alpha = 0.794), test-retest reliability, construct validity, and responsiveness (37).

Adherence to the ESCAPE-pain programme
Adherence to the ESCAPE-pain intervention programme was determined through patients' attendance, consistent with the majority of studies (38). The attendance was recorded by the researcher using an attendance sheet at each of the twelve sessions. All participants were encouraged to complete at least 10 sessions if possible, to experience at least the minimum effectiveness of the programme. If any participants were absent on the day of an intervention, they were followed up to determine the reason.

Exercise adherence
Participants in the intervention group were prescribed home-based exercise by the researcher. Their adherence to the prescribed exercise was measured using a self-reported exercise adherence rating scale (EARS) (39). EARS consists of six items which relate to any exercises or activities that patients have been asked to do as part of their treatment. The Cronbach alpha for EARS is 0.81 (39) while the Malay version was found to be 0.88 in a sample of 30 in pilot testing.

Satisfaction survey
Participants who completed the ESCAPE-pain programme were given a satisfaction survey form to get some feedback on the programme. This method of assessment is widely used to evaluate people's satisfaction with an intervention programme (40,41). The survey form is based on several questions related to the content and delivery of the programme. The participants might want to describe their improvement in the quality of life during this satisfaction survey.

Recruitment and retention rates
The recruitment rate (which represents the willingness of patients to be randomised and the practicality of a home-based programme) was calculated based on the number of agreed participants enrolled in the programme out of the total possible number of patients attending the clinics or rehabilitation units for treatment. Meanwhile, the retention rate (which represents the acceptability of the programme) was calculated after week 12 of the intervention, considering the total number of participants remaining in the programme out of the total number of randomised participants.

Data collection methods
Demographic data were obtained after participants consented to participate in this study. The researcher performed the physical function test himself in front of all the participants to ensure consistency in the procedure. The self-administered questionnaires were answered by the participants with the researcher present to provide clarification if needed. The researcher collected the questionnaires from the participants after completion. If the participants had reading difficulties, either their family or friends assisted them or the researcher read the questions aloud, and got the answers from the participants.

To promote participant retention and follow-up, several strategies were implemented. Firstly, the participants were approached during their regular appointment with their healthcare professionals in the hospital setting. Secondly, an appointment was set to see the participants at the hospital, and, thirdly, the participants were

seen at their nearest community centre if they had difficulties getting to the hospital.

Sample size
The sample size for this feasibility study is based on Browne (1995), as cited by Lancaster, Dodd and Williamson (2004), with his rule of thumb of using a sample size of 30 or greater to estimate a parameter in order to alleviate the under-powered problem. To allow for a 20% drop-out, estimation of 72 participants in both groups (36 each) were recruited from Hospital Tengku Ampuan Afzan (HTAA) and IIUM Medical Centre. A power calculation would be inappropriate in this feasibility study as it is focusing on the practicalities of conducting the intervention programme.

Data management
All outcome measures were checked for completeness immediately after the participants handed over the questionnaires. In the case of any missing answer, the researcher requested the participants to supply it. All data were entered into the Statistical Package for the Social Sciences (SPSS) Version 23 after every session of data collection. All information recorded during the study was handled in the strictest confidence. The laptop and devices used to store the data were encrypted and password protected.

Statistical methods
Data were analysed by using statistical package social science (SPSS) version 23.0 with an alpha level of 0.05. Descriptive statistics were initially performed. Mean difference was compared by using t-test and Mann-Whitney U test. The correlations were measured by using Pearson Correlation and also Spearman's rho test. The analysis was appropriately done by using appropriate descriptive statistics and the outcomes. The calculation rate for recruitment, attrition and protocol adherence were estimated with 95% confidence intervals with the effect size for the difference in means between groups in order to inform the future main trial. The final result was presented in chart, graphs, tables and report with careful interpretation as this feasibility study may not be powered in detecting statistical significance.

Trial status
The official study start date was 21 August 2017. The recruitment to the feasibility trial began on the 28 September 2017 with the first patient enrolled in the study on 29 September 2017.

ETHICS AND DISSEMINATION

This study has been granted ethical approval by the Research Ethics Committee, University of Manchester (ref: 2017-2045-3627), Medical Research Ethics Committee Malaysia (ref: KKM/ NIHSEC/P17-1340) and IIUM Research Ethics Committee (ref: IIUM/504/14/11/2/IREC2017-053).
Trial registration number: ClinicalTrials.gov ID: NCT03379623

Potential benefits to research participants
At the beginning of the trial, research participants were expected to potentially benefit from this programme. Those who participated in the intervention programme were expected to see some physical and mental health benefits. However, these changes were not guaranteed, and one would never be able to guarantee an effect. Potential benefits included:

- decreased pain levels, increased independence and improved functional ability, leading to a better quality of life.
- reduction in hospital visits, health and social care costs.
- improved mental health and increased confidence levels to undertake activities, avoiding the sedentary behaviour. (The researcher is a registered nurse and was trained in mental health throughout the course of the study period.)
- the ESCAPE-pain exercises could increase lower limb strength and power and improve coordination and static and dynamic balance.
- a better understanding of managing knee OA.

The participants in the control group were expected to benefit from the usual care provided by the hospital.

Consent
The potential participants were given the opportunity to ask questions and provided with written information about all aspects of the study. They were then given at least 24 hours to decide whether to participate or not, and up to the intervention itself to give written informed consent, and were informed that they had the right to withdraw from the study without penalty at any time if they wished. They were also briefed about continuous consent, where the researcher reaffirms consent throughout the research process. Only those with the capacity to give consent were included.

Study withdrawal
Participants were informed about their right to withdraw from the study at any time without giving any reason as participation in the research was voluntary, even though they had signed the consent form, and that this would not affect the care they receive. Participants could be withdrawn from the study if the investigator deemed it detrimental or risky for the participants to continue.

Confidentiality
All information was kept confidential; their identity and participation were not revealed to anyone and the result of the data obtained was reported in an anonymised manner with no references to specific individuals. Hence, the data from each individual remained confidential.

Research governance and conduct of the trial
This feasibility study was conducted in full conformance with principles of the "Declaration of Helsinki" and Good Clinical Practice (GCP), and within the laws and regulations of Malaysia.

Adverse events
Should there have been adverse events or evidence that warranted stopping the study prematurely, the researcher and supervisory team would have enforced this decision. The core decision was based on serious adverse events (SAE) protocol.

ACKNOWLEDGEMENT

We thank the Ministry of Education Malaysia for sponsoring the SLAI scholarship of the main author.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

REFERENCES

1. Vos T, Flaxman AD, Naghavi M, Lozano R, Michaud C, Ezzati M, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet (London, England) [Internet]. 2012 Dec 15 [cited 2018 Sep 12];380(9859):2163–96. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23245607
2. Cross M, Smith E, Hoy D, Nolte S, Ackerman I, Fransen M, et al. The global burden of hip and knee osteoarthritis: estimates from the global burden of disease 2010 study. Ann Rheum Dis [Internet]. 2014 Jul 1 [cited 2018 Sep 12];73(7):1323–30. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24553908
3. Arthritis Foundation Malaysia. Osteoarthritis [Internet]. Malaysia; 2011 [cited 2014 Nov 10]. Available from: http://afm.org.my/wp/?p=77
4. Hall AJ, Stubbs B, Mamas MA, Myint PK, Smith TO. Association between osteoarthritis and cardiovascular disease: Systematic review and meta-analysis. 2015.
5. Fransen M, McConnell S, Harmer AR, Van der Esch M, Simic M, Bennell KL. Exercise for osteoarthritis of the knee: a Cochrane systematic review. Br J Sports Med [Internet]. 2015 Dec 1 [cited 2018 Jul 18];49(24):1554–7. Available from: http://www.ncbi.nlm.nih.gov/pubmed/26405113
6. Hurley M V., Walsh NE, Mitchell HL, Pimm TJ, Patel A, Williamson E, et al. Clinical effectiveness of a rehabilitation program integrating exercise, self-management, and active coping strategies for chronic knee pain: A cluster randomized trial. Arthritis Rheum [Internet]. 2007 Oct 15 [cited 2018 Jun 19];57(7):1211–9. Available from: http://doi.wiley.com/10.1002/art.22995
7. Hurley M V., Walsh NE, Mitchell H, Nicholas J, Patel A. Long-term outcomes and costs of an integrated rehabilitation program for chronic knee pain: A pragmatic, cluster randomized, controlled trial. Arthritis Care Res (Hoboken) [Internet]. 2012 Feb 1 [cited 2018 May 23];64(2):238–47. Available from: http://doi.wiley.com/10.1002/acr.20642
8. Hurley M, Dickson K, Hallett R, Grant R, Hauari H, Walsh N, et al. Exercise interventions and patient beliefs for people with hip, knee or hip and knee osteoarthritis: a mixed methods review. Cochrane Database Syst Rev [Internet]. 2018 [cited 2018 Nov 29];(4). Available from: http://doi.wiley.com/10.1002/14651858.CD010842.pub2
9. Hurley M, Carter A, Carter D, Hughes L, Ni Mhuiri A, Walsh N. Delivering Escape-Pain: An Online Guide for Healthcare Professionals. Vol. 54. 2015. p. i100–i100.
10. Campbell M, Fitzpatrick R, Haines A, Kinmonth AL, Sandercock P, Spiegelhalter D, et al. Framework for design and evaluation of complex interventions to improve health. Br Med J. 2000;321(7262):694–6.
11. Corry M, Clarke M, While AE, Lalor J. Developing complex interventions for nursing: a critical review of key guidelines. Vol. 22, Journal of Clinical Nursing. 2013. p. 2366–86.
12. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ Br Med J. 2008;337.
13. Sealed Envelope Ltd. Simple randomisation service [Internet]. 2017 [cited 2017 Nov 15]. Available from: https://www.sealedenvelope.com/simple-randomiser/v1/
14. Barrera M, Castro FG. A Heuristic Framework for the Cultural Adaptation of Interventions. Clin Psychol Sci Pract [Internet]. 2006 Dec 1 [cited 2018 Sep 22];13(4):311–6. Available from: http://doi.wiley.com/10.1111/j.1468-2850.2006.00043.x
15. Karanicolas PJ, Farrokhyar F, Bhandari M. Practical tips for surgical research: blinding: who, what, when, why, how? Can J Surg [Internet]. 2010 Oct [cited 2018 Jun 9];53(5):345–8. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20858381
16. Page SJ, Persch AC. Recruitment, retention, and blinding in clinical trials. Am J Occup Ther [Internet]. 2013 [cited 2018 Jul 11];67(2):154–61. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23433269
17. Dobson F, Hinman RS, Roos EM, Abbott JH, Stratford P, Davis AM, et al. OARSI recommended performance-based tests to assess physical function in people diagnosed with hip or knee osteoarthritis. Osteoarthr Cartil [Internet]. 2013 Aug 1 [cited 2018 Jul 4];21(8):1042–52. Available from: https://www.sciencedirect.com/science/article/pii/S1063458413007905
18. Mathias S, Nayak US, Isaacs B. Balance in elderly patients: the “get-up and go” test. Arch Phys Med Rehabil [Internet]. 1986 Jun [cited 2018 Jul 11];67(6):387–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/3487300
19. Podsiadlo D, Richardson S. The Timed “Up & Go”: A Test of Basic Functional Mobility for Frail Elderly Persons. J Am Geriatr Soc [Internet]. 1991 Feb [cited 2018 Jul 11];39(2):142–8. Available from: http://doi.wiley.com/10.1111/j.1532-5415.1991.tb01616.x
20. Sabirli F, Paker N, Bugdayci D. The relationship between Knee Injury and Osteoarthritis Outcome Score (KOOS) and Timed Up and Go test in patients with symptomatic knee osteoarthritis. Rheumatol Int [Internet]. 2013 Oct 6 [cited 2018 Jul 12];33(10):2691–4. Available from: http://link.springer.com/10.1007/s00296-012-2512-3
21. Barry E, Galvin R, Keogh C, Horgan F, Fahey T. Is the Timed Up and Go test a useful predictor of risk of falls in community dwelling older adults: a

systematic review and meta-analysis. BMC Geriatr [Internet]. 2014 [cited 2018 Jul 11];14:14. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24484314
22. Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee Injury and Osteoarthritis Outcome Score (KOOS)—Development of a Self-Administered Outcome Measure. J Orthop Sport Phys Ther [Internet]. 1998 Aug 1 [cited 2018 Jul 1];28(2):88–96. Available from: http://www.jospt.org/doi/10.2519/jospt.1998.28.2.88
23. Zulkifli MM, Kadir AA, Elias A, Bea KC, Sadagatullah AN. Psychometric Properties of the Malay Language Version of Knee Injury and Osteoarthritis Outcome Score (KOOS) Questionnaire among Knee Osteoarthritis Patients: A Confirmatory Factor Analysis. Malaysian Orthop J [Internet]. 2017 Jul [cited 2018 Jun 6];11(2):7–14. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29021872
24. Dalle Grave R, Calugi S, Centis E, El Ghoch M, Marchesini G. Cognitive-behavioral strategies to increase the adherence to exercise in the management of obesity. J Obes [Internet]. 2011 [cited 2018 Dec 10];2011:348293. Available from: http://www.ncbi.nlm.nih.gov/pubmed/21052533
25. Gecht MR, Connell KJ, Sinacore JM, Prohaska TR. A survey of exercise beliefs and exercise habits among people with arthritis. Arthritis Care Res (Hoboken) [Internet]. 1996 Apr [cited 2018 Jun 30];9(2):82–8. Available from: http://doi.wiley.com/10.1002/1529-0131%28199604%299%3A2%3C82%3A%3AAID-ANR1790090203%3E3.0.CO%3B2-T
26. Haugmark T, Hagen KB, Provan SA, Bærheim E, Zangi HA. Effects of a community-based multicomponent rehabilitation programme for patients with fibromyalgia: protocol for a randomised controlled trial. BMJ Open [Internet]. 2018 Jun 4 [cited 2018 Sep 19];8(6):e021004. Available from: http://www.ncbi.nlm.nih.gov/pubmed/29866731
27. Sweeney S, Taylor G, Calin A. The effect of a home based exercise intervention package on outcome in ankylosing spondylitis: a randomized controlled trial. J Rheumatol Rheumatol [Internet]. 2002 [cited 2018 Sep 19];29(4):763–6. Available from: http://www.jrheum.org/content/29/4/763http://www.jrheum.org/alerts1.SignupforTOCsandotheralertshttp://jrheum.com/faqwww.jrheum.orgwww.jrheum.orgDownloadedfrom
28. Bagnato G, De Andres I, Sorbara S, Verduci E, Corallo G, Ferrera A, et al. Pain threshold and intensity in rheumatic patients: correlations with the Hamilton Depression Rating scale. Clin Rheumatol [Internet]. 2015 Mar 10 [cited 2018 Jun 28];34(3):555–61. Available from: http://link.springer.com/10.1007/s10067-013-2477-y
29. Cruz-Almeida Y, King CD, Goodin BR, Sibille KT, Glover TL, Riley JL, et al. Psychological profiles and pain characteristics of older adults with knee osteoarthritis. Arthritis Care Res (Hoboken) [Internet]. 2013 Nov [cited 2018 Jun 28];65(11):1786–94. Available from: http://www.ncbi.nlm.nih.gov/pubmed/23861288
30. Stewart-Brown S, Tennant A, Tennant R, Platt S, Parkinson J, Weich S. Internal construct validity of the Warwick-Edinburgh Mental Well-being Scale (WEMWBS): a Rasch analysis using data from the Scottish Health Education Population Survey. Health Qual Life Outcomes [Internet]. 2009 Feb 19 [cited 2018 Jul 5];7(1):15. Available from: http://hqlo.biomedcentral.com/articles/10.1186/1477-7525-7-15
31. Ng SSW, Lo AWY, Leung TKS, Chan FSM, Wong ATY, Lam RWT, et al. Translation and validation of the Chinese version of the short Warwick-Edinburgh Mental Well-being Scale for patients with mental illness in Hong Kong. East Asian Arch psychiatry [Internet]. 2014 [cited 2018 Jun 29];24(1):3–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/24676481
32. Vaingankar JA, Abdin E, Chong SA, Sambasivam R, Seow E, Jeyagurunathan A, et al. Psychometric properties of the short Warwick Edinburgh mental well-being scale (SWEMWBS) in service users with schizophrenia, depression and anxiety spectrum disorders. Health Qual Life Outcomes [Internet]. 2017 Aug 1 [cited 2018 Jul 1];15(1):153. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28764770
33. Ng CT, Tan MP. Osteoarthritis and falls in the older person. Age Ageing. 2013 Sep 1;42(5):561–6.
34. Kempen GIJM, Yardley L, Van Haastregt JCM, Zijlstra GAR, Beyer N, Hauer K, et al. The Short FES-I: a shortened version of the falls efficacy scale-international to assess fear of falling. Age Ageing [Internet]. 2007 Oct 11 [cited 2018 Jun 6];37(1):45–50. Available from: https://academic.oup.com/ageing/article-lookup/doi/10.1093/ageing/afm157
35. Delbaere K, Close JCT, Mikolaizak AS, Sachdev PS, Brodaty H, Lord SR. The Falls Efficacy Scale International (FES-I). A comprehensive longitudinal validation study. Age Ageing [Internet]. 2010 Mar 1 [cited 2018 Jun 30];39(2):210–6. Available from: https://academic.oup.com/ageing/article-lookup/doi/10.1093/ageing/afp225
36. Yardley L, Beyer N, Hauer K, Kempen G, Piot-Ziegler C, Todd C. Development and initial validation of the Falls Efficacy Scale -International (FES-I). Age Ageing [Internet]. 2005 [cited 2018 Jun 30];34:614–9.
37. Pin Tan M, Nalathamby N, Mat S, Tan PJ, Kamaruzzaman SB, Morgan K. Reliability and Validity of the Short Falls Efficacy Scale International in English, Mandarin, and Bahasa Malaysia in Malaysia. Int J Aging Hum Dev [Internet]. 2018 [cited 2018 Jun 19];0(0):1–14. Available from: http://journals.sagepub.com/doi/pdf/10.1177/0091415017752942
38. Hawley-Hague H, Horne M, Skelton DA, Todd C. Review of how we should define (and measure) adherence in studies examining older adults' participation in exercise classes. BMJ Open [Internet]. 2016 Jun 23 [cited 2018 Jun 21];6(6):e011560. Available from: http://www.ncbi.nlm.nih.gov/pubmed/27338884
39. Newman-Beinart NA, Norton S, Dowling D,

Gavriloff D, Vari C, Weinman JA, et al. The development and initial psychometric evaluation of a measure assessing adherence to prescribed exercise: the Exercise Adherence Rating Scale (EARS). Physiotherapy. 2016;
40. Nikolian VC, Williams AM, Jacobs BN, Kemp MT, Wilson JK, Mulholland MW, et al. Pilot study to evaluate the safety, feasibility, and financial implications of a postoperative telemedicine program. Ann Surg [Internet]. 2018 [cited 2018 Sep 19];268(4):700–7. Available from: www.annalsofsurgery.com
41. Shawley-Brzoska S, Misra R. Perceived Benefits and Barriers of a Community-Based Diabetes Prevention and Management Program. J Clin Med [Internet]. 2018 Mar 13 [cited 2018 Sep 19];7 (3). Available from: http://www.ncbi.nlm.nih.gov/pubmed/29534005
42. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. J Eval Clin Pract [Internet]. 2004 May [cited 2018 Jun 6];10(2):307–12. Available from: http://doi.wiley.com/10.1111/j..2002.384.doc.x

Flowchart of participants' involvement