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Original Research Article

Randomised controlled trial of the effects of a self-management patient education program on overall quality of life and knee pain of older people with mild to moderate knee(s) osteoarthritis

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ABSTRACT

Background: Knee osteoarthritis (OA) is the most important chronic rheumatic disease affecting human beings. It is more common among the older population. The objective of OA treatment is to control the symptoms, such as pain, mobility problems and consequently, to improve overall quality of life. Although, self-management patient education programs, such as educational workshops and other learning activities are effective approaches in some chronic diseases, the evidence for arthritis is still inconclusive. The aim of this trial is to compare the effectiveness of an OA of the knee self-management education program with a control group, as determined by improvements in pain and quality of life.
Methods: In this study, a two-group, randomized (1:1 ratio), controlled study with repeated measures will be conducted to examine. the differences between the two groups over time. The research sample will be selected from the patients who are referred to a physiotherapy department with a diagnosed mild to moderate knee(s) OA, aging from 45 to 65 years.
Conclusions: Positive findings of this trial will pave the road for new methods of cooperation between patients and healthcare providers. Also, patient education ensures that patients are well-informed about their own health and they could avoid any deterioration and disability due to bad practices. Finally, an increased understanding helps patients to make informed decisions about their healthcare avenues.

Keywords: Osteoarthritis, Patient education, Physiotherapy, Quality of life

INTRODUCTION

Knee osteoarthritis (OA) is the most important chronic rheumatic disease affecting human beings.[1] Research shows that knee OA is more common among the older population. Since it affects the older population, it is a growing public health issue. In Canada, about 4.4 million people suffer from the chronic condition, and by 2050, about 130 million people are anticipated to suffer from this disabling disease worldwide.[2] The objective of OA treatment is to control the symptoms, such as pain, mobility problems and activity limitations and consequently to improve overall quality of life.[3] Healthcare delivery and policy must not only concentrate on acute conditions, but also it should respond effectively to the wide range of health and public service requirements of people with chronic illness. Strong primary health care policy is an important ground for an effective healthcare delivery and long term management of public health, and is linked to practical outcomes including lower mortality, decreased hospitalization and improved health outcomes.[4]

Although, self-management patient education programs (SMEPs), such as educational workshops, lectures, face-to-face learning, group learning activities, books and

pamphlets are effective approaches in some chronic diseases,[5] the evidence for knee OA is still inconclusive.[6] As a result, these interventions are often poorly accepted and adopted by healthcare professionals and caregivers, and have a limited application in clinical practice.[7-10] SMEPs are a group of interventions that were designed to educate the patient self-management activities that improve and enhance health and management of OA.

The objective of SMEPs is to provide patients with background information about their disease, and the motivation and practical skills they need to decrease pain and reduce the effect of functional limitations on their daily life activities. Also, SMEPs aim to maximize patient adherence to their treatment plan, promote decision making, and minimize psychosocial influences of disease such as anxiety, low self-satisfaction and confidence, depression and disability by combining patient education with behavioral modification and techniques.[3]

The aim of this trial is to compare the effectiveness of an osteoarthritis of the knee self-management education program with a control group, as determined by improvements in pain and quality of life.

METHODS

Research questions

Primary research question

What is the effectiveness of self-management patient education program (SMEP) on overall quality of life of older patients with mild to moderate knee(s) osteoarthritis compared to conventional physiotherapy treatment?

Secondary research question

What is the impact of combination intervention (physiotherapy + SMEP) on knee/s pain of older patients with mild to moderate knee(s) osteoarthritis compared to conventional physiotherapy treatment?

Study design

In this study, a two-group, randomized (1:1 ratio), controlled, and repeated-measures will be performed to examine the differences between the two groups over time. The research sample will be selected from the patients who are referred to a physiotherapy department with a diagnosed mild to moderate knee(s) OA, aging from 45 to 65 years. Independently of the study, all participants will be able to receive standard medical management and/or conventional physiotherapy treatment of knee(s) OA. The patients who accepted to participate and provided a written consent will be randomized and allocated to a focus group (immediate start) or to control group (waiting list). All the clinical examinations and assessments will take place in Misurata Central Hospital by orthopedics, physiotherapists and rheumatologists to ensure their eligibility.

Hypothesis

People with OA of the knee who complete the SMEP will report improved quality of life, and decreased pain compared with those who are managed conventionally by physiotherapy modalities.

Therefore**:**

- **Study hypothesis:** Superiority.
- **H0**: physiotherapy is the same as using combination of physiotherapy and patient self-management educational program. (Mean1=Mean2).
- **H1**: Combination of physiotherapy and patient self-management educational program is different from using physiotherapy alone. (Mean1 ≠ Mean2).

Population (P)

The selection procedure is based on the inclusion and exclusion criteria. The assessment team (Orthopedics, Rheumatologists and Physiotherapists) uses an assessment protocol to evaluate eligibility. The protocol is based on the criteria of the American College of Rheumatology.

Inclusion criteria

All patients who are 45 to 65 years old and are diagnosed with mild to moderate knee OA (based on X-ray or clinical diagnosis) and referred to a physiotherapy department from a specialist are included. Patients should speak the Arabic language fluently, should be residents of Misurata region and should be able to meet program requirements to be included. The patients are included if they have reported crepitation, swelling and stiffness of one or both knee joints.

Exclusion criteria

The patients will be excluded from this study if they have other major health problems (heart disease, renal failure, cancer, mental disorder, or neurologic disease) or any other serious comorbidities (rheumatoid arthritis or other inflammatory disease). Also, they will be excluded if they are on a waiting list for knee replacement within six months. Furthermore, the patients will be excluded from participation if they cannot meet program time-line and/or have learning disabilities.

Intervention (I)

The program consists of 12 weekly educational sessions of 2 hours, with a maximum of 15 participants, this enables participants to incorporate and consolidate information learned from week to week. In each session, 1 hour will be spent on health education in workshop

interactive way. The workshops will provide information on knee osteoarthritis; lifestyle and physical activity; weight control and diet; pain management; coping with activity restriction; and medical concerns. The second hour will be spent on questions and discussions. Health professionals will attend the workshops to facilitate the discussions. Facilitators will include nurses, physio-therapists, and occupational therapists that have the knowledge and skills to present information on disease-specific topics and accurately respond to complex questions. It is necessary that all health professionals who will participate in discussions meet minimum musculoskeletal knowledge requirements. In addition to the weekly sessions, participants will receive a course book, and educational materials relevant to the topics discussed each week. The health education will be delivered by peer educators. Peer education is believed to have a strong influence.[11,12] Participants will continue receiving their regular physiotherapy sessions. The control group will receive regular physiotherapy sessions and will be on a waiting list for the intervention.

The fidelity of the SMEP will be maintained using a facilitator's manual with modules for program delivery each week. To facilitate optimum group dynamics, the target group size will be 15 participants, although this may vary from 15 to 20 depending on recruitment and randomization. The program approach is holistic and will not exclusively focus on one aspect of care. Self-management constructs will be employed to promote behavioral changes that will be aimed at optimizing participants' health status. Goal setting and the development of strategies to achieve these goals long term will be emphasized in the program. Participants will be encouraged to set their own goals related to health areas that they identify as requiring improvement. Topics that will be covered in the weekly sessions include:

- Pain management strategies (cognitive and pharmaceutical)
- Joint protection
- Fitness/exercise
- Correct use of analgesia/medications
- Balance/falls prevention/proprioception
- Cognitive techniques
- Pathophysiology
- Nutrition/weight control
- Self-management skills
- Team approach to health care-SMART goals (**S**pecific, **M**easurable, **A**chievable, **R**ealistic, and **Time**-framed)

Comparison (c)

In this study, pre and post intervention comparisons will be performed for the focus group and the control group (patients in waiting list).

Outcomes (o)

Assessments will be performed at: baseline, 3 months (immediately after the intervention), and at 6 months follow up, whereas the control group will be assessed at baseline and at 3 months. The primary outcome measure will be overall quality of life. The secondary outcome measure will be knee/s pain scores.

Outcome measures

The outcome measures will include both primary and secondary measures. Participants will be evaluated at baseline, at 3 months (immediately after the intervention), and at 6 months follow up.

Primary outcome measures

The primary outcome measure is patients' quality of life (QoL). Quality of life will be measured by the Arthritis Impact Measurement Scale (AIMS2) and the Short Form (SF-36) questionnaires. There is a strong recommendation in literature to use both AIMS2 and SF-36 jointly, as they complement each other.[13,14] Furthermore, use of disease specific instrument (AIMS2) increase the possibility of detecting any clinically significant changes, while the SF-36 questionnaire can differentiate between different levels of self-reported general health conditions and comorbidities. [2]

Secondary outcome measures

Knee/s pain is the secondary outcome which will be measured by self-reported total WOMAC pain score (0–20, with higher scores indicating more pain). Feasibility, validity and reliability of the WOMAC pain score are well established and the questionnaire is sensitive to detect any change in health condition in relation to intervention.[2,6,15]

Randomisation and allocation

A total of 128 patients with established OA of one or both knees will be recruited into the study. As the SMEP is generally provided as a clinical service, participants will be recruited from among people presenting to the physiotherapy department in Misurata Central Hospital. The operational definition for OA knee is diagnosis by a medical practitioner based on either clinical examination or radiological evidence. Inclusion and exclusion criteria were discussed in detail in previous sections (see population section). Participants for the study will be allocated to an intervention group (immediate start) or a control group (waiting list). They will be randomized in blocks to ensure manageable numbers for intervention groups. Once a group of 30 patients are met (both males and females), they will be randomised either to the intervention group or to the control group.

Cards indicating group assignment will be prepared and placed in sealed opaque envelopes and will be drawn as a lottery by a third party for allocation to treatment groups. To ensure optimum group sizes, allocation will not take place until a whole block has been recruited. Blinding the patients is not possible, due to the nature of the intervention; however, the physiotherapists who will do the examination and assessments will not be allowed to participate in the program. In addition, they will be asked not to discuss group allocation with the patients during assessments to maintain blinding. All participants randomized to the control group will be offered the intervention at the completion of the 3-months control period.

Protecting against sources of bias

The reliability of the results of a randomized trial depends on the extent to which potential sources of bias have been avoided. Significant efforts were made in planning meetings and discussions to minimize sources of bias as much as possible for the duration of the trial. All arrangements and agreements for investigators, assessors, patients and any other study-related resources have been determined. The Cochrane Collaboration's tool for assessing risk of bias was used to outline the sources of bias and their practical solutions. A useful classification of biases is divided into selection bias, performance bias, attrition bias, detection bias and reporting bias.

Selection bias

- Randomization (unpredictable allocation).
- Allocation concealment.
- Sequence generation and allocation concealment will be done away from the investigators, assessors and patients as a pre-prepared card will be drawn as a lottery by a third party for allocation to treatment groups.
- Participants will be randomized in blocks to ensure manageable and equal numbers for the intervention group and the control group.

Performance bias

- Blinding of patients is not possible, due to the nature of the intervention; however, the physiotherapists who will do the examination and assessments will not be allowed to participate in the program.
- In addition, they will be asked previously not to discuss group allocation with the patients during assessments to maintain blinding.

Attrition bias

- Assessments will be made for each main outcome (or class of outcomes) whenever possible.
- Description of the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis will be provided.
- Document whether attrition and exclusions were reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.

Detection bias

- Blinding of outcome assessment.
- The physiotherapists who are responsible for the outcome assessment are blinded because they are not allowed to participate in the program.

Reporting bias

- Trial protocol will be published.
- Positive and negative findings will be included in the final trial report.

Assessments and procedures

Assessments will be done one week before the first session and on the week following the final session (week 12) by 2 qualified physiotherapists blinded to group allocation. They (physiotherapists) will have no contact with the participants other than during the assessment sessions and will not participate in facilitation of the program. The same physiotherapists will do evaluations and assessments for all participants whenever possible to ensure consistency and to avoid inter-personal variations and errors. The assessment sessions will include both the intervention group and the control group at baseline, and week 12. All participants will be re-assessed 3 months after randomization.

Self-reported questionnaires (WOMAC, AIMS2, and SF-36) will be mailed to patients who are unable to attend assessment sessions.

Health services research issues

Knee/s osteoarthritis is a chronic condition that has an impact on patient's quality of life. It has a high cost in terms of its effect on patient's functionality and ability to work. Also, it has a high cost in terms of medical care, medications, and knee/s replacements surgeries, cost of rehabilitation / hospitalization / institutionalization and acute medical care. Adding a combination of interventions (Physiotherapy + educational program) will also affect the cost of medication treatment, and it is in our best interests to see whether the cost associated with this intervention is beneficial on a long-term period. Cost-consequence analysis (CCA) will be done using CADTHs' Guidelines for the economic evaluation of health technologies: Canada, 3rd Edition.[16] Another

method to evaluate patients' outcome is to estimate the quality-adjusted life years (QALYs). These will quantify the benefits of a certain interventions by measuring the change in health-related quality of life over time.[17] In this study, the cost effectiveness of a combination intervention (physiotherapy and patient education) will be evaluated and compared with the cost effectiveness of the rehabilitation, medications, and other services including total knee/s replacement procedures.

Sample size calculations

According to PASS (version 14) software, the sample size should be 64 patients in each group.

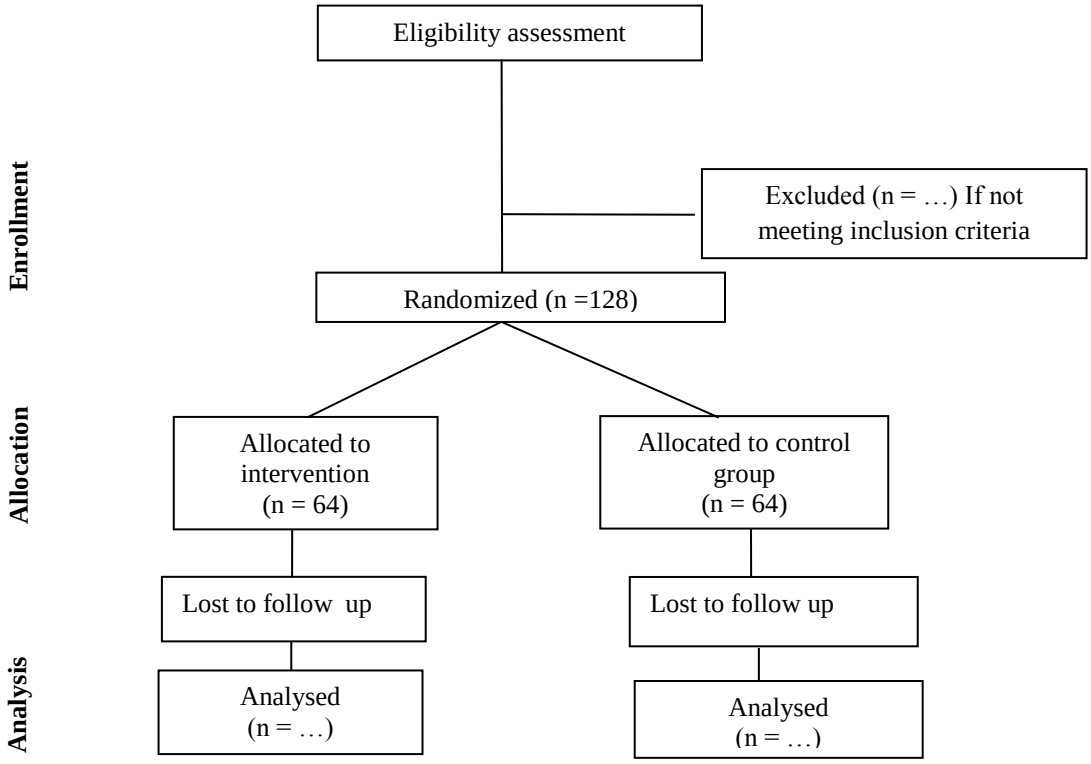

Figure 1: Flow chart summarizing the process of allocation of participants to intervention and control groups.

PASS (V14) summary statement

Group sample sizes of 64 and 64 achieve 80.146% power to reject the null hypothesis of equal means when the population mean difference is 0.3 with a standard deviation for both groups of 0.5 and with a significance level (alpha) of 0.050 using a two-sided two-sample equal-variance t-test.

Data analysis strategy

Descriptive statistics for baseline assessment

Descriptive statistics will be used to all participants to assess the balance between the two groups and to evaluate the background properties for the proposed statistical methods. Group balance between the intervention group and the control group will be evaluated by looking at: Age (mean±SD, y), gender (n, %), duration of the condition (mean±SD, y), and body weight (mean±SD, kg).

Data will be analysed in a blinded manner using two-sided two-sample equal-variance t-test to test for differences between pre-test and post-test scores.

Differences from baseline will be calculated for all primary and secondary outcome variables. Mean differences and 95% confidence intervals (CI) will be calculated for all outcome measures. Statistical testing for primary outcome measures will be an overall quality of life and secondary outcome measures will be restricted to pain scores. All analyses will be performed using SPSS for Windows (SPSS Inc.). Results will not be adjusted for multiple comparisons as all outcomes of interest have been nominated a priori and such adjustment would likely render all findings of interest, despite their clinical importance, nonsignificant.

Primary analysis

Overall patients quality of life (mean difference) will be assessed using t-test.

Secondary analysis

The mean difference between the two groups will be compared in self-reported total WOMAC pain score. T-test to compare the effect of combination intervention (physiotherapy + SMEP) to the conventional physiotherapy treatment arm (control group) will be used. Baseline characteristics differences between groups will be evaluated for statistical significance.

Recruitment and compliance

What recruitment sources have been identified?

As knee OA is common in Misurata region, recruitment of 128 patients will be achievable. To recruit knee OA patients who are transfered to physiotherapy or already having conventional physiotherapy sessions, there are two places to target potential participants: the Misurata Central Hospital, and the Rehabilitation Centre with both in and out patients will be used to recruit participants to this trial. Also, during the recruitment phase, the program will be actively promoted to general practitioners and Rheumatologists through professional societies, and to the general public through advertising and media coverage.

What is the expected rate of recruitment?

According to the literature, average of 2-3 patients per week could be recruited. In similar studies were conducted on the same population showed that recruitment of OA patients is not a challenge. However, one of the inclusion criteria (age of the participant) may be adjusted to meet the target sample size rapidly. Also, there will be a phone number and email address on brochures, posters and will be published in media to recruit other participants.

What is the proposed recruitment process?

Patients' databases maintained at Misurata Central Hospital and the Rehabilitation Centre will be accessed and all patients who have transferred to physiotherapy or are already having physiotherapy sessions will be contacted by their clinician by phone to see if they are interested to participate in this trial.

What is the likely rate of loss to follow-up?

In sample size calculations and data analysis sections, we pointed out that the pilot study SF-36 data showed an average improvement of 10 points across the eight domains measured. Assuming this level of improvement is achieved in the intervention group and there is no change in the control group and allowing for a 10% drop out rate, the number of participants required per group will be 64. In pilot studies, there was a dropout rate of 5% over 3 years, so allowing 10% is a conservative estimate. To reduce loss to follow-up, frequent telephone checks by investigators and assessors will be included to remind patients about appointments and to facilitate their attendance by providing parking spots, bus tickets, and special transportation services if needed. Also food, coffee and refreshments for the participants and a free sports clubs membership for 3 months will be provided to the participants to keep the adherence to the program.

Are there likely problems with compliance?

We hope that our compliance strategies and plans will increase the adherence to the intervention and reduce the level of noncompliance for all measurement visits and follow ups. A phone number for participants will be provided to discuss any questions and concerns with our consultants. Also, phone call checks by the trial coordinator will be included to make sure that all patients are following the workshop materials without any negative influence on their lives.

Trial management

Overall management of this study, communications, financial management, patient recruitment and monitoring will be done at Misurata Central Hospital. An equipped office with all accessories will be provided to the team members. office equipped with all communication needs, internet connection, phone, fax, printer, computers and all other accessories. Meetings will be held every week and there will be a networking facility to communicate between team members and discuss any urgent issues.

Investigator roles and responsibilities

Principal investigator (PI)

Coordinator of the study overall. Responsible for the progress of the trial, protocol development, financial accountability, networking between all team members.

Co-investigators

Not determined yet, but generally, the co-investigators will include Physiotherapists, Rheumatologists, peer educators and professional consultants (e. g., nurses, GPs, formal caregivers) from Misurata Central Hospital and the Rehabilitation Centre with significant experience in clinical practice and research relevant to OA. They will be responsible for patients' recruitment and leading the study in all aspects at their site.

Study committees and responsibilities

Executive committee

(Principal investigator,co-investigators). Responsible for decision-making about urgent issues related to trial operations, documenting and reporting back to the steering committee.

Steering committee

(Principal investigator, co-investigators, statistician, 2 or 3 PTs from the sites). They are responsible for functional operations of the study.

Adjudication committee

(Principal investigator, physiotherapists,rheumatologists, peer educators and statistician). They are responsible for outcomes review and other related issues.

Ethical issues

This trial has been approved by the Research Ethics Committee at Misurata Central Hospital. All participants will be asked to provide a written informed consent showing their acceptance to both the intervention and the waiting list (control group) prior to randomisation. All data will be stored and encrypted for confidentiality, and access will be by trained personnel only. License agreements for measurement tools and surveys (AIMS2 instrument, SF-36 Questionnaire, and WOMAC pain score) will be obtained in advance. Finally, trial registration is planned and will be done to ensure quality and transparency.

Safety

Right now, no obvious safety concerns related to this intervention in particular and to the trial in general. However, we had discussions about the anticipated negative impact of workshops on patients' everyday life. Therefore, participants will be monitored week by week to assist with any questions or concerns they may face. Generally, we cannot predict all safety concerns, that's why we cannot pre-classify them, but can monitor participants for any safety issues identified from the relevant literature.

DISCUSSION

Numerous self-management programs have been developed for different health conditions. There is a considerable body of research evaluating self-management programs. Literature reviews have shown that patient self-management education programs can significantly improve knowledge, compliance behaviors, and health outcomes, however the effectiveness differs between programs and disease states. One systematic review of self-management interventions for a number of chronic diseases, found a trend towards a small benefit from arthritis programs, but the results were not significant. Many of the existing arthritis self-management programs are designed to cater for participants with any form of arthritis. Examples of this approach are the Chronic Diseases and Arthritis Self-Management programs (ASMP) developed at Stanford University. Warsi et al (2004), in their systematic review of self-management interventions for various chronic diseases, found a trend towards a small benefit from arthritis programs, the majority being ASMP or ASMP derivatives, but the results were not significant. We hypothesized that a program designed for a specific diagnostic group may be more effective. We considered a program of this nature would be justified for more prevalent conditions such as osteoarthritis of the knee.[6]

CONCLUSION

Positive findings of this trial will pave the road for a new methods of cooperation between patients and healthcare providers. Also, Patient education ensures that patients are well-informed about their own health and they could avoid any deterioration and disability due to bad practices. Finally, an increased understanding helps patients to make informed decisions about their healthcare avenues.

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