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Effectiveness of routine measurement of health-related quality of life in improving the outcomes of patients with musculoskeletal problems — a cluster randomised controlled trial: protocol paper

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ABSTRACT

Introduction Managing chronic musculoskeletal problems usually focuses on pain control using medications, but outcomes are often unsatisfactory and sometimes harmful. Information on a patient's health-related quality of life (HRQOL) may trigger a doctor to tailor management improving quality of life. The aim of this trial is to find out whether routine measurement and reporting of a patient's EuroQoL 5-Dimension 5-Level (EQ-5D-5L) HRQOL data using an electronic platform can improve HRQOL and pain in patients with chronic knee or back problems in primary care. We will also assess the acceptability of routine electronic measurements and reporting of the EQ-5D-5L in primary care settings.

Methods This is a multicentre, prospective, cluster randomised controlled trial set in six public primary care clinics in Hong Kong. At the intervention clinics, subjects will complete an electronic EQ-5D-5L form at recruitment and at each clinic follow-up over 12 months. A report of the patient's longitudinal EQ-5D-5L data will be provided to the doctor. Subjects in the control clinics will receive care as usual. All subjects will complete the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), a 10-point Pain Rating Scale and a structured questionnaire to collect sociodemographic information and data on morbidity and service utilisation at recruitment at baseline, 3, 6 and 12 months. Primary outcome is the change in WOMAC total score. Secondary outcomes are change in pain, other patient-reported outcome scores and doctor-rated severity of disease. Group differences in the changes in WOMAC and other outcome scores over time will be analysed using generalised estimating equation model with an intention-to-treat principle.

Ethics and dissemination Ethics approval has been obtained from The University of Hong Kong/Hospital Authority Hong Kong West Cluster (IRB reference number: UW 18-270). The results of the trial will be submitted for publication in a peer-reviewed journal.

Trial registration number NCT03609762.

Strengths and limitations of this study

► This is the first study to evaluate the impact of routine measurements of health-related quality of life (HRQOL) in normal clinical practice in a Chinese population.

► It is an effectiveness-implementation hybrid trial that aims to promote more effective and patient-centred care of people with chronic musculoskeletal problems.

► The study aims to overcome implementation barriers by using modern information technology to collect and generate a patient-filled report on the relevant HRQOL data with reference to the general population norm at the point of care in real-world primary care clinics.

► If found to be effective, evidence from this study can support the integration of routine HRQOL data collection into electronic medical record systems.

► As the instruments will be collected using electronic tablets, a certain level of computer literacy is required, and the study may not be able to include participants who are unable to perform such tasks which may introduce selection bias associated with age or educational status.

INTRODUCTION

With ageing of the population and physical inactivity in today's industrialised society, musculoskeletal (MS) problems have become an important disease burden, affecting hundreds of millions of people worldwide.[1] MS problems account for 7% of all the diagnoses presenting to primary care in Hong Kong.[2] Although the spectrum of MS problems is broad, ranging from the common muscle strain, tendinitis and degenerative conditions to the more serious inflammatory joint diseases, they share

the common characteristics of causing pain and disability. Chronic MS problems are the most common cause of severe chronic pain impairing mental and physical well-being.[3] The Global Burden of Disease Study 2013 showed that from 2005 to 2013, the major contributor to the global increase of disability-adjusted life years was MS problems.[3] Four of the top 10 causes of disability in China are MS problems, namely low back pain, neck pain, osteoarthritis and other MS problems.[4] MS problems also significantly affect the psychosocial health of the patients' families and caregivers. Current clinical management of chronic MS problems focuses predominantly on pain control with medications, but the outcomes are often unsatisfactory. There are increasing concerns regarding serious side effects from the use of non-steroidal anti-inflammatory drugs, and the risk of death and dependency from opioids in the treatment of chronic pain.[5] More effective interventions are needed to reduce the suffering, disability and service burden arising from MS problems.

The goal of medical care is to improve or restore health and the patient's perspective needs to be taken into account when assessing the outcomes of care. Patient-reported outcomes (PRO) are defined as 'any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else'.[6] Pain is a commonly used PRO in clinical practice. Health-related quality of life (HRQOL) is becoming a popular PRO measure in clinical trials. HRQOL is a multidimensional concept that measures a person's subjective perceived effect on how health has affected his/her ability to live a fulfilling life, both physically and mentally.[7] A variety of HRQOL instruments are available for different purposes, which can be generic or disease specific.[7] There is a large body of evidence on the psychometrics and clinimetrics of HRQOL measures in assessing the severity of symptoms,[8] monitoring general health and well-being,[9] promoting patient–clinician communication,[10] evaluating treatment/intervention outcomes[11–13] and informing clinical decision-making.[11 12 14 15]

Up until now, HRQOL has rarely been measured in normal clinical practice because it requires a paradigm shift from objective to subjective outcome measurements, and strategies to overcome the implementation barriers of time, workload, cost and patient burden.[12]

The choice of instrument is critical for successful implementation when measuring HRQOL in normal clinical practice. It should be valid, reliable, applicable to most if not all patients, short and easy to use, and meaningful. The EuroQol-5 Dimension (EQ-5D) questionnaire developed by the EuroQol Group is a generic HRQOL measure that satisfies all these criteria.[16] It consists of a descriptive system of five HRQOL dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and a 200 mm visual analogue scale (VAS) for global health rating. It can be completed within a few minutes either by self-completion or by interview administration. The original EQ-5D has three response options to each item (EQ-5D-3L), but was modified to

the EuroQoL 5-Dimension 5-Level (EQ-5D-5L) with five response options to each item to improve responsiveness and sensitivity.[16] The EQ-5D-5L defines a combination of 3125 health states.[16] Each health state can be converted to a composite utility (preference) score from 0 (death) to 1 (perfect health), with a scoring algorithm derived from population-based valuation. The EQ-5D has been adapted in many countries with population-specific scoring algorithms available in the USA, Canada, Europe and China. A Chinese (Hong Kong) version of the EQ-5D-5L has been validated and the Hong Kong population-specific EQ-5D-5L scoring algorithm has been developed from a population-based valuation study.[17 18] The EQ-VAS is a 200 mm vertical scale ranging from 0 to 100, with 0 corresponding to 'the worst imaginable health' and 100 indicating 'the best imaginable health', and the rating scale scores are an easy-to-interpret composite indicator that can be used to monitor the change in HRQOL over time. The EQ-5D-5L has been shown to be valid, reliable and sensitive in patients with MS problems internationally and in Hong Kong.[19]

Aims and hypothesis

The aim of this study is to find out whether the implementation of routine measurement and reporting of the patient's EQ-5D-5L HRQOL data with an electronic platform can improve HRQOL and pain in patients with chronic knee or back problems in primary care. We will also assess the acceptability of the implementation of routine electronic measurement and reporting of the EQ-5D-5L HRQOL data in real-world primary care. We hypothesise that the real-time report on longitudinal HRQOL data will facilitate a more patient-centred care with optimisation of the use of drugs, counselling, rehabilitation service, aids and/or surgery to address the patient's physical, social and psychological needs. Furthermore, the EQ-5D report can make the patient more aware of his/her condition, and will become more motivated and empowered to adhere to medical treatments and lifestyle changes where necessary.

METHODS AND ANALYSIS
Study design

This study is a single-blind cluster randomised controlled trial (RCT) to evaluate the effectiveness of measuring and reporting HRQOL in routine clinical practice in improving the outcomes of patients with chronic knee and/or back problems. Randomisation will be performed at the clinic level. Recruited subjects from the control and intervention clinics will be followed up at 3, 6 and 12 months after enrolment into the trial (figure 1).

Subjects
Recruitment

We will recruit subjects from six primary care clinics, three of which will be randomised as the intervention clinics and three as the control clinics. All adults attending the
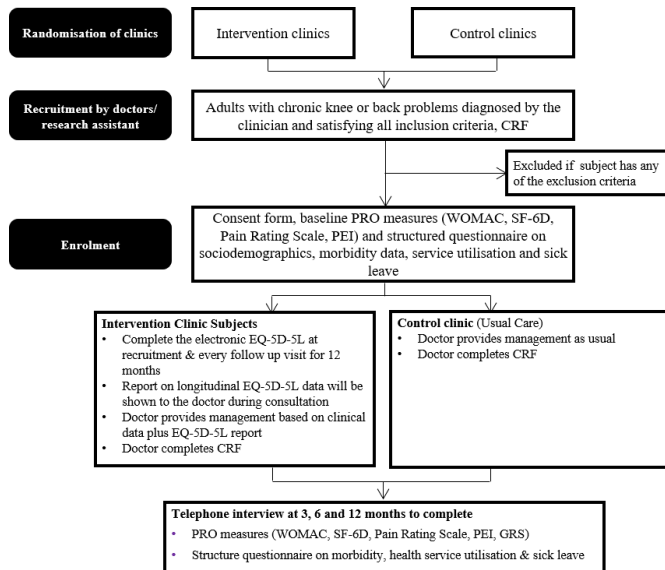
Figure 1 Study flow diagram. CRF, case report form; EQ-5D-5L, EuroQoL 5-Dimension 5-Level; GRS, Global Rating Scale; PEI, Patient Enablement Instrument; PRO, patient-reported outcome; SF-6D, Short-Form Six-Dimension; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

study clinics for symptomatic chronic knee and/or back pain will be assessed by the attending doctors and invited to join the study if they satisfy the following inclusion criteria and do not meet any of the exclusion criteria.

The inclusion criteria are:

A. Adults aged 18 years or above.
B. Has a doctor-diagnosed symptomatic knee and/or back pain problem that is expected to last for 1 month or more.
C. Scheduled for at least one follow-up visit in the clinic within 12 months.
D. Has given written consent to participate in this study.
The exclusion criteria are:
A. Life expectancy less than 12 months (judged by the doctor).
B. Has cancer. (Patients with current cancers undergoing active or palliative treatment will be excluded since they may have impairment of quality of life from cancer and opioids or other pain relief treatments, which

would make an independent evaluation of the outcomes related to the chronic (non-malignant) knee or back pain impossible.)
C. Too ill (both physically or cognitively) to complete a questionnaire.
D. Unable to communicate in Chinese.
E. Does not give consent to participate in the study.

The doctor will complete the clinician-reported baseline clinical case report form (CRF)) for each eligible patient at the end of their consultation. Each subject will sign a written consent form (online supplemental appendix 1) and then complete a structured questionnaire containing items on sociodemographics, service utilisation, pain rating and quality of life. Subjects recruited from the intervention clinics will also complete the electronic EQ-5D-5L on a computer tablet in the clinic after the doctor's consultation. The name and telephone number of each subject will be collected for the follow-up telephone interviews.

To ensure the feasibility and acceptability of the measurement and reporting of the EQ-5D-5L before the doctor consultation in busy outpatient clinics, a pilot study was undertaken in July to December 2018 in two outpatient clinics. All 151 subjects recruited were able to complete the electronic EQ-5D-5L in a mean time of 2 min; 69% of the patients perceived the electronic EQ-5D-5L survey as both easy to use and understand and 95% thought the assessment was useful. Among the EQ-5D reports provided to the doctors involved in the pilot, 88% of the EQ-5D-5L reports were rated as easy to understand and 80% of the EQ-5D-5L results were rated as being useful by the doctors. The electronic EQ-5D-5L platform operated smoothly with a notebook computer or iPad connected to the clinic public Wi-Fi and the report was able to be generated within seconds.

Randomisation

A statistician not involved in subject recruitment or data collection will carry out the randomisation of the clinics into the intervention group (three clinics) and control group (three clinics). The allocation will be blinded to the interviewers (assessors) who administer the telephone surveys on the outcomes, and the research team member who will carry out the data analysis.
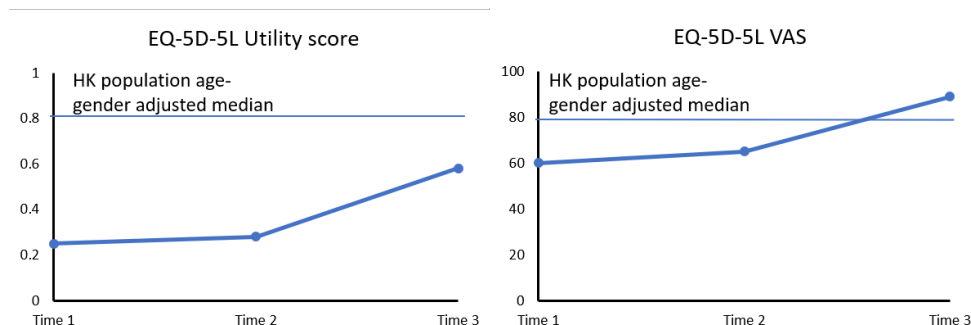

Figure 2 Example of the EuroQoL 5-Dimension 5-Level (EQ-5D-5L) utility score and rating scale score. HK, Hong Kong; VAS, visual analogue scale.

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Table 1 Example of the EuroQoL 5-Dimension 5-Level (EQ-5D-5L) data presented to the doctor

	HK population age-gender adjusted median	Time 1	Time 2	Time 3
Mobility	1	1	2	1
Self-care	1	1	1	1
Usual activities	1	1	1	1
Pain/discomfort	1	2	2	3
Anxiety/depression	2	2	2	2

Present the level of each domain at each time point.
EQ-5D-5L level: 1=no problems, 2=slight problems, 3=moderate problems, 4=severe problems, 5=extreme problems.
EQ-5D-5L, EuroQoL 5-Dimension 5-Level; HK, Hong Kong.

Intervention group (EQ-5D-5L HRQOL results will be available to the attending doctor)

All subjects attending the intervention clinics will complete the electronic EQ-5D-5L before seeing the doctor during each follow-up visit for the MS problem, a printout of the longitudinal EQ-5D-5L data (table 1) since recruitment will be given to the patients to show to the attending doctors during the consultation. The doctors will provide the management based on the usual clinical information and the additional EQ-5D-5L HRQOL results (figure 2). The doctor will complete the clinician-reported follow-up clinical data form (CRF) of each eligible patient at the end of the consultation.

Control group (usual care, EQ-5D-5L HRQOL results will not be available to the attending doctor)

Subjects attending the control clinics will not need to complete the electronic EQ-5D-5L before seeing the doctor during their follow-up visits. The doctor will manage the patient as usual, based on the usual clinical information. The doctor will complete the clinician-reported follow-up clinical data form (CRF) for each subject at the end of the consultation.

Training and consent of clinicians

The investigators (CL, JPYC, CKHW) will provide a training session on the interpretation of the EQ-5D-5L HRQOL profile and VAS scores to all doctors of the intervention clinics. Each participating doctor will complete a consent form (online supplemental appendix 2) to take part in the study.

Outcome measures
Primary outcome

The primary outcome is the change in HRQOL measured by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total score.

Secondary outcomes

1. Change in pain score as measured by the 10-point Pain Scale.
2. Change in PROs: Short-Form Six-Dimension (SF-6D) utility score, global health measured by the Global Rating Scale (GRS), patient enablement measured by the Patient Enablement Instrument (PEI) score.
3. Change in clinician-reported disease severity and progression.

Exploratory outcomes

1. Health service utilisation rates.
2. Drug and other treatment utilisation rates.
3. Patient acceptability of routine measurement of HRQOL by the electronic EQ-5D-5L.

Confounders

Clinical settings, sociodemographics, MS diagnosis, duration and severity, treatment and comorbidity.

Sample size calculation

The sample size calculation was based on the primary outcome of a difference in WOMAC total score between the intervention and control groups. A previous RCT study evaluating a rehabilitation programme integrating exercise, self-management and active coping strategies for patients with chronic knee pain showed that the average change in WOMAC total score at 6 months after baseline for the intervention and control groups was −3.4 (mean: 35; SD: 16 at 6 months) and −8 (mean: 30.4; SD: 17 at 6 months), respectively,[20] indicating an effect size of 0.3. Using this, a minimum of 380 (190 in each group) patients are needed to achieve 80% power at 5% significant level, by two-sample t-test. There were no studies that provided an intracluster correlation (ICC) coefficient for WOMAC scores, but a review showed the ICC coefficient of pain outcome was 0.03[21]; to adjust for the clustering effect from six clinics, a larger sample size of 1098 (549 patients per group, and 183 subjects per clinic) will be required. We plan to recruit 1374 (687 in each group) subjects to allow for a 20% attrition rate.

Study instruments

Chinese (Hong Kong) EQ-5D-5L and the acceptability of routine completion of the electronic EQ-5D-5L:

1. The electronic Chinese EQ-5D-5L comprises a descriptive system of five questions on five HRQOL dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and a 100 mm (adapted from 200mm to fit the Tablet screen) VAS on global health from 0 corresponding to 'the worst imaginable health' to 100 indicating 'the best imaginable health'. Each question has five response options (1=no problems, 2=slight problems, 3=moderate problems, 4=severe problems, 5=extreme problems). The responses to the five questions give an HRQOL profile.[16]
2. The acceptability of routine completion of the electronic EQ-5D-5L will be evaluated by the perceived ease of use and perceived usefulness scales based on

the technology acceptability model, which was translated and validated on a local Chinese population.[22] Their Cronbach's alpha was 0.90 and 0.89, respectively. They had good convergent validity with significant correlation of 0.69.

PROs on:

1. Chinese Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): the WOMAC is a widely used condition-specific HRQOL measure to assess pain, stiffness and physical function (PF) of patients with MS problems. It has been applied to patients with hip and/or knee osteoarthritis, low back pain, rheumatoid arthritis and fibromyalgia.[23] It consists of 24 items on three domains: pain (5 items), stiffness (2 items) and PF (17 items). Each question is rated on a 5-point Likert scale from 0 to 4, with lower scores indicating lower levels of symptoms or impairment. The item scores in each domain subscale are summated to a domain score. The total WOMAC score is calculated by summating the three domain scores. A Chinese version of the WOMAC is available and has been shown to be valid, reliable and sensitive in Chinese patients.[24]

2. Ten-point Pain Scale: the patient will be asked to rate their pain that best represents the intensity of their pain using a scale from 0 to 10, where 0 indicates no pain and 10 indicates the worst pain.

3. Chinese Short-Form Six-Dimension (SF-6D): the SF-6D is a preference-based measure of health, derived from the 36-Item Short Form Health Survey, that generates a utility score. It has six items measuring six HRQOL dimensions of physical functioning, role limitation, social functioning, bodily pain, mental health and vitality. The SF-6D responses have a combination of 18 000 health states. Each health state can be converted to a composite preference (utility) score from 0 indicating death to 1 indicating perfect health. The Chinese SF-6D was validated in the Chinese population in Hong Kong,[25] and a Hong Kong population-based scoring algorithm has been established. The mean SF-6D utility score of the Hong Kong Chinese population is 0.78.[25]

4. Chinese Patient Enablement Index (PEI): the PEI is a six-item questionnaire that measures the patient's perceived change in coping with illness and self-care. Each item is rated on a 3-point (0, 1 and 2) scale. The sum of the item scores gives the final PEI score, with higher scores indicating better enablement. The Chinese version was shown to be a valid, reliable and sensitive outcome measure among Chinese patients in Hong Kong.[26]

5. Global Rating Scale (GRS): the GRS on change in health will be used to assess the patient's self-perception of any change in the overall health condition on a 7-point scale: −3 (much worse), −2 (worse), −1 (a little worse), 0 (no change), 1 (a little better), 2 (better), 3 (much better).[27]

A structured questionnaire (online supplemental appendix 3—baseline and follow-up) on

1. Sociodemographic characteristics including age, sex, education background, marital status, occupation, monthly household income, smoking and drinking status.

2. Comorbidities: the presence of doctor-diagnosed chronic diseases including hypertension, diabetes, stroke, heart disease, pulmonary diseases including asthma and chronic obstructive pulmonary disease, mental illness, renal disease, osteoporosis, cancer and others.

3. Health service utilisation: monthly frequency of outpatient consultations with Western/Chinese medicine practitioners, allied health service visits, accident and emergency department attendance and admissions to hospitals.

4. Days of sick leave in the past 1 month.

5. Medication use in the past 1 month.

Clinician-reported clinical case report form (CRF) (online supplemental appendix 4—baseline and follow-up) on:

1. Disease diagnosis and duration: the diagnosis and duration of the chief MS problem will be reported by the attending doctor.

2. Global rating on disease severity: the attending doctor will rate the patient's disease severity on a 5-point Likert scale: 1=no problem, 2=mild, 3=moderate, 4=severe, 5=very severe.

3. Global rating on disease progression: in each follow-up clinic consultation, the attending doctor will rate the patient's disease progression on a 7-point scale: −3 (much worse), −2 (worse), −1 (a little worse), 0 (no change), 1 (a little better), 2 (better), 3 (much better).

4. Disease management: the management modalities including investigations, drugs (type and dosage), referral to allied health service (types and frequency) and surgery (type and year of the surgery) will be extracted from the medical record.

5. Perceived usefulness of the EQ-5D-5L data in enhancing patient management.

Data collection

A computer program will be developed to administer the electronic version of the Chinese (Hong Kong) EQ-5D-5L on a computer tablet, to calculate the utility score and to generate a report on the longitudinal EQ-5D-5L profile scores, preference scores and VAS scores in a printable form (table 1 and figure 2).

All subjects from the intervention clinics will complete the electronic Chinese (Hong Kong) EQ-5D-5L at recruitment and during every follow-up visit at the clinic before the doctor consultation over the next 12 months.

To control for potential confusing variables and errors, a trained research assistant will assist the subjects in the completion of the electronic EQ-5D-5L. All other patient data will be collected by interviewers who will be trained by the project coordinator to ensure all questions are asked in a standardised manner. We will conduct briefing

meetings with the doctors in charge of all participating clinics and send a written briefing of the study and a guide on the interpretation of the EQ-5D-5L report to each participating doctor.

The doctor will complete the CRF (online supplemental appendix 4) for each study subject after the consultation at recruitment and during every follow-up consultation over the next 12 months for subjects from both the intervention and control clinics.

A survey on sociodemographic, comorbidity, PRO and health service utilisation will be administered to each subject within 2 weeks from recruitment (baseline), and the survey on PRO and health service utilisation will be repeated by telephone at 3, 6 and 12 months (blinded to group allocation) after the baseline survey. The telephone survey will be carried out by the HKU Social Science Research Centre. Data collection at baseline and follow-up for intervention and control groups is shown in table 2.

Data processing and analysis

Data will be analysed by intention to treat, in which all subjects who are randomised and have completed at least one repeat outcome measurement will be included in the analysis. Multiple imputations will be used to substitute missing data. Complete case analysis will also be conducted to confirm the results.

The within-group changes in WOMAC, pain and SF-6D scores will be compared by paired t-test, or Wilcoxon signed-rank test if the outcome data are not normally distributed. Between-group difference of changes in WOMAC, pain and SF-6D scores, and between-group difference in GRS and PEI scores at the end of 12 months will be compared by two-sample t-test, or Mann-Whitney U test if the outcome data are not normally distributed.

The differences between groups in outcomes, including WOMAC, pain, SF-6D, GRS and PEI, will be assessed by the generalised estimating equations (GEE).[28] Specifically, we shall use the identity link to regression on group, baseline value and time, and allow extra-covariance of repeated from the same subject and different subjects from the same cluster by an unstructured working covariance matrix. Between-group differences in clinician-rated disease severity rates of medication use, service utilisation and sick leave will be similarly assessed by GEE but with a Poisson link to cater the different measurement scale of the outcomes. The acceptability of measurement of routine HRQOL measurement by the electronic EQ-5D-5L will be summarised by descriptive statistics on patient and doctor evaluation.

The STATA software V.13 (StataCorp, Texas) will be used for the data analysis. A 5% level of significance will be used in all significance tests.

Data monitoring

An external data monitoring committee was not deemed to be necessary for this trial. Data will be monitored by

Table 2 Data collection at baseline and follow-up for intervention and control groups

	Baseline		Follow-up	
	Intervention	Control	Intervention	Control
1. Patient-reported outcomes				
EQ-5D-5L	×	×	×	×
WOMAC	×	×	×	×
SF-6D	×	×	×	×
PEI			×	×
GRS			×	×
Patient acceptability questionnaire	×	×		
2. Sociodemographic status and lifestyle				
Age	×	×		
Sex	×	×		
Education background	×	×		
Occupation	×	×		
Monthly household income	×	×		
Smoking	×	×		
Drinking	×	×		
3. Burden of illness				
Medical service utilisation	×	×	×	×
Sick leave	×	×	×	×
Use of medication	×	×	×	×
4. Clinician-reported outcomes				
Global rating on disease severity	×	×	×	×
Global rating on disease progression			×	×
Doctor acceptability questionnaire			×	×
5. Clinical data				
Disease diagnosis and duration	×	×		
Drug treatment	×	×	×	×
Comorbidities	×	×	×	×
Investigations/ referrals	×	×	×	×

EQ-5D-5L, EuroQoL 5-Dimension 5-Level; GRS, Global Rating Scale; PEI, Patient Enablement Instrument; SF-6D, Short-Form Six-Dimension; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

the research team which includes clinicians, statisticians and information technology experts. This study is considered to be a low-risk trial where both the intervention and control groups will receive their usual medical care. Rules for early stopping have not been implemented as the clinicians involved in this study are not blinded to intervention allocation.

Collection and assessment of reported adverse events and other unintended effects of the trial interventions or trial conduct will be performed on a continuous basis as such events arise. Queries identified will be resolved promptly by the research team. All unintended effects and adverse events will be reported every 6 months to the Institutional Review Board (IRB) of the University of Hong Kong and Queen Mary Hospital. Interim analyses will be reported to the IRB and funding body every 6 months. The principal author (CL) will be responsible for overseeing the interim analyses and any decisions to stop the trial.

Patient and public involvement

This research is planned to be done without patient involvement. Patients will not be invited to comment on the study design and will not be consulted to develop patient-relevant outcomes or interpret the results. Patients will not be invited to contribute to the writing or editing of the future manuscript for readability or accuracy.

DISCUSSION

Routine measurement of HRQOL in normal clinical practice has been used in selected patient populations, mostly in oncology[29] and specific surgical settings in the UK and Sweden.[14] In the UK, as a government initiative to compare service providers' performance, HRQOL has been routinely measured by the EQ-5D before and after the National Health Service funded elective hip or knee replacement, varicose vein and inguinal hernia surgeries since 2009. This changes the paradigm of evaluation of effectiveness of care from the clinician to the patient's perspective in order to improve accountability.[29] It also enables patients to make an informed choice on service providers.[29] In Sweden, the Swedish Hip Arthroplasty Register has recorded the EQ-5D utility score and a VAS pain score of each patient since 2002, and demonstrated that the overall PRO of total hip replacement surgery is satisfactory, leading to a mean increase of 0.36 in EQ-5D utility score.[14] Data on routine measurement of HRQOL by the EQ-5D or other measures in busy outpatient settings are currently lacking, and we could not find any study on routine measurement of HRQOL in normal clinical practice in Chinese populations.

In preparation for this study, we have developed an electronic platform for the administration, scoring and reporting of EQ-5D-5L data in normal outpatient clinics, which can make the results available to the attending doctors in real time (a mock example is shown in figure 3). If found to be beneficial, routine measurement of HRQOL by an electronic EQ-5D-5L platform may be applied to other outpatient clinics to help improve the care of MS problems and other conditions, and to facilitate more effective and patient-centred care.

DATA MANAGEMENT AND OVERSIGHT

Members of the research team from the University of Hong Kong will take responsibility for the conduct of research staff and study participants to ensure protocol compliance, proper study management and timely completion of study procedures. The Consolidated Standards of Reporting Trials table with the RCT plan is available at online supplemental appendix 5.

PROTOCOL AND REGISTRATION

The trial is registered with the US Clinical Trial Registration at ClinicalTrials.gov; protocol ID HKUCTR-2418.

DATA STORAGE SECURITY AND PATIENT CONFIDENTIALITY

Personal identifiable information will be deidentified and replaced with research identification codes. Data sets will have all personal identifiers removed so that participant identities cannot be determined in case of data security breaches. Cover and consent sheets containing identifiable information will be stored separately from any completed survey instruments and access to master code lists will be limited to the investigation team only. Individual files containing electronic data will be password protected and encrypted and stored on institutional network drives with firewalls and security measures in place. Consent forms and other hard copy records will be stored securely

Figure 3 Example of an electronic platform for measuring and scoring EuroQol-5 Dimension (EQ-5D).

in a locked cabinet in a secure location separate from where the research data are kept. All research staff will be trained in the IRB-approved methods for managing and storing research data.

ETHICS AND DISSEMINATION

Ethics approval hasbeen obtained from Institutional Review Board of The University of Hong Kong/Hong Kong/ Hospital Authority Hong Kong West Cluster (IRB Reference Number: UW18-270) who have reviewed and approved the study procedures, ethics, subjectinformation and consent, and subject safety. The results of the trial will be submitted for publication in a peer-reviewed journal.

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Consent Form (Intervention Group)

Research conducted by
Department of Family Medicine and Primary Care, HKU
Information and Consent Form

Effectiveness of Routine Measurement of Health-Related Quality of Life in Improving the Outcomes of Patients with Musculoskeletal Problems – A Randomized Controlled Trial

Thank you for reading this information and agreeing to consider taking part in this study. Please read this form, and if you have understood the purpose and procedure of the study and kindly agree to take part, please sign and date at the end of this Consent Form.

Study Information

The aim of this research is to determine the effectiveness of routine measurement of health- related quality of life (HRQOL) in improving the clinical outcomes of patients with chronic musculoskeletal problems in primary care. You will be invited to answer a structured questionnaire administered by a research assistant at the time of recruitment. During the 12 months of follow-up, each time when you visit the clinic, you will be invited to complete a short electronic questionnaire on HRQOL. We will also contact you through telephone to collect follow-up information 3, 6 and 12 months later. Each telephone survey will last for about 10 minutes.

Your doctor-in-charge <u>will</u> receive the reports of your HRQOL measured on the day of every follow up consultation during the study period, and he/she will manage your musculoskeletal problem taking into consideration of your clinical and HRQOL conditions. Your doctor-in-charge will also be asked to rate provide information about your disease and management.

All the data collected from you will be kept confidential and no individual identity information will be disclosed in any reports, data record forms or publications.

You can withdraw from the study anytime you want without infringement on any of your rights to treatment in this clinic or other services provided by the Hospital Authority.

For further information please contact:
Prof. Cindy Lam / Dr. Carlos Wong, Department of amily Medicine and Primary Care,The University of Hong Kong, 3/F., Ap Lei Chau Clinic, 161 Main Street, Ap Lei Chau, Hong Kong
Telephone: 25185657; Fax: 2814 7475

Declaration on Protection of Personal Data
   Under the laws of the Hong Kong Special Administrative Region and, in particular, the Personal Data (Privacy) Ordinance, Cap 486, you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study.
   By signing and dating this Consent Form, you agree to allow the collection, custody, retention, management, control, and use your personal data in this study in ways described in the Information Leaflet. For any query, you should consult the Privacy Commissioner for PrivacyData or his office (Tel No. 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

Consent Form (Intervention Group)

Consent Form

The following statements are to check that you understand and consent to the procedures involved in taking part in this research.

---

1. I confirm that I have read and understood (or had someone read and explained) the information for the above study and have been given a copy to keep. I have had the opportunity to ask questions about the project and I understand why the research is being done and any risks involved.

2. I understand that my participation is voluntary.

3. I agree to take part in the study.

4. I agree to complete the electronic EQ-5D health-related of life questionnaire (5 questions) every time I visit the clinic.

5. I agree to finish a baseline questionnaire through face-to-face interview by an interviewer at the clinic.

6. I understand that I need to complete a telephone survey at 3, 6 and 12 months after the baseline questionnaire to monitor my progress, which will take about 10 minutes.

7. I understand that my doctor-in-charge may get my HRQOL report, and provide information on my diagnosis and treatment at every follow up consultations during the 12 months of the study.

8. I understand that all information that I provide to the research team will be kept confidential and only the investigators and their research team will have access to it.

9. I understand how the data will be collected, that giving data for this research is voluntary and that I am free to withdraw the permission to use my data at any time, without giving reason and without my medical treatment or legal rights being affected.

10. I understand that I am free to withdraw from the study at any time, without giving reason and without my medical treatment or legal rights being affected in any way.

11. I understand the investigators have the right to exclude me from the study in the event of inter-current illness, adverse event, protocol violations, or other reasons.

Please sign and date this Consent Form below:

……………………………… …………………………….. …..………………
Name of Subject in BLOCK letters   Signature   Date

……………………………… …………………………….. …..………………
Name of Investigator in BLOCK letters   Signature   Date

Consent Form (Control Group)

Research conducted by
Department of Family Medicine and Primary Care, HKU
Information and Consent Form

Effectiveness of Routine Measurement of Health-Related Quality of Life in Improving the Outcomes of Patients with Musculoskeletal Problems – A Randomized Controlled Trial

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Study Information

The aim of this research is to aim to determine the effectiveness of routine measurement of health-related quality of life (HRQOL) in improving the clinical outcomes of patients with chronic musculoskeletal problems in primary care. You will be invited to answer a structured questionnaire administered by a research assistant at the time of recruitment. Your doctor-in-charge will manage you as usual and then complete a form to provide information on your disease and management at every follow up during the 12-month study period. We will also contact you through telephone to collect follow-up information at 3, 6 and 12 months after the baseline questionnaire survey. Each telephone survey will last about 10 minutes.

All the data collected from you will be kept confidential and no individual identity information will be disclosed in any reports, data record forms or publications.

You can withdraw from the study anytime you want without infringement on any of your rights to treatment in this clinic or other services provided by the Hospital Authority.

For further information please contact:
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　　By signing and dating this Consent Form, you agree to allow the collection, custody, retention, management, control, and use your personal data in this study in ways described in the Information Leaflet. For any query, you should consult the Privacy Commissioner for PrivacyData or his office (Tel No. 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

Consent Form (Control Group)

Consent Form

The following statements are to check that you understand and consent to the procedures involved in taking part in this research.

1. I confirm that I have read and understood (or had someone read and explained) the information for the above study and have been given a copy to keep. I have had the opportunity to ask questions about the project and I understand why the research is being done and any risks involved.
2. I understand that my participation is voluntary.
3. I agree to take part in the study.
4. I agree to complete a baseline questionnaire through face-to-face interview by an interviewer at the clinic.
5. I understand that I need to complete a telephone survey at 3, 6 and 12 months after the baseline questionnaire to monitor my progress, which will take about 10 minutes.
6. I understand that my doctor-in-charge will manage me as usual, and provide information on my disease and treatment at every follow up consultations during the 12 months of the study.
7. I understand that all information that I provide to the research team will be kept confidential and only the investigators and their research team will have access to it.
8. I understand how the data will be collected, that giving data for this research is voluntary and that I am free to withdraw the permission to use my data at any time, without giving reason and without my medical treatment or legal rights being affected.
9. I understand that I am free to withdraw from the study at any time, without giving reason and without my medical treatment or legal rights being affected in any way.
10. I understand the investigators have the right to exclude me from the study in the event of inter-current illness, adverse event, protocol violations, or other reasons.

Please sign and date this Consent Form below:

…………………………… ……………………………….. …..…………………..…

Name of Subject in BLOCK letters   Signature   Date

…………………………… ……………………………….. …..………………………

Name of Investigator in BLOCK letters   Signature   Date

Consent Form (intervention Group)

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香港大學家庭醫學及基層醫療學系之學術研究

參與研究資料及同意書

《隨機對照試驗– 常規臨床實踐中測量健康相關的生活質量

對於改善筋骨健康問題人士健康的成效》

</div>

謝謝您閱讀這項研究的資料和同意考慮參加。請細閱此同意書，如果您同意參與這項研究，請您在這份同意書的末端　簽署和寫上日期來表明您自願參加和明白研究內容及整個研究程序。

研究資料

　　　　這項研究的目的是評估把患者自我評估健康相關的生活質量常規化是否可以幫助改善患有筋骨健康問題人士的健康惟況。如果您同意參加的話, 您會接受調查員的問卷調查，以及在12個月內每次來診所隨訪 時完成一份自我評估健康相關的生活質量的電子問卷5道問題。在完成第一次問卷調查后，我們會在隨後的 3個月，6個月和12個月通過電話聯絡您，完成電話問卷調查，每次電話問卷調查大約持續10分鐘。

　　　　你的主診醫生會在你每次來診所隨訪時收到您自我評估健康相關的生活質量的電子問卷報告，然後作出適當的治理。您的醫生亦會每次隨訪時提供您的疾病狀況和治療的資料。您所提供的資料將會受到研究小組的絕對保密，任何個人資料將不會在研究報告中披露。

　　　　您有權隨時退出這項研究，您的退出不會影響您在該診所的治療或使用其他醫院管理局所提供的醫療服務。

如您對此項研究有疑問，請聯絡：

　　　　鴨脷洲大街 161 號鴨脷洲診所三樓香港大學家庭醫學及基層醫療學系 林露娟醫生/黃競浩博士

　　　　電話：25185657；傳真號碼：2814 7475

個人資料保障權聲明

　　　　依照香港特別行政區的法律，個人資料(私隱)條例(第 486 章)，您享有個人資料保密的保障權，例如有關在此研究中收集、持有、保存、處理、控制，或使用(包括分析或比較)，在香港以內或以外的傳送，不作披露， 刪除和/或使用任何途徑去處理或棄置您的任何個人資料。

　　　　您在此同意書簽署和寫上日期，表示您同意容許我們在此研究中收集、持有、保存、處理、控制，或使用您的個人資料作為在資料小冊子所述目的之用。如您有任何疑問，請諮詢私隱專員公署或其辦公室(電話: 2827 2827) 有關保障您個人資料的適當監管或指導，以確保您完全知道和明白遵守個人資料(私隱)條例的重要。

Consent Form (intervention Group)

同意書

以下句子是為了確定您是否明白及同意參與這項研究的各程序：

1. 我肯定我已閱讀過和明白(或由他人讀出並解釋)有關以上研究的資料，並得到一份副本作保存。我有機會對這研 究計劃提出疑問，並了解進行這研究的原因和所涉及的風險。

2. 我明白我的參與純屬自願。

3. 我同意參與這項研究。

4. 我樂意在每次來診所隨訪都完成一份自我評估健康相關的生活質量的電子問卷 (5道問題）。

5. 我同意接受調查員基線問卷調查。

6. 我明白我需要在第3個月，6個月和12個月後再接受約10分鐘的電話問卷調查來監測我的疾病狀況。

7. 我明白我的主診醫生會在每次我來診所隨訪時得到我自我評估的健康相關的生活質量的報告。我的主診醫生會給我適當的治理及提供有關我的疾病狀況和治療的資料。

8. 我明白所有我自己提供給研究小組的資料將會絕對保密，只有研究人員及他們的研究小組能夠閱看。

9. 我明白這計劃收集資料的方法，並自願地為這研究提供此資料。我有權隨時拒絕提供資料或收回這些資料的使用權，而不用提供任何理由，以及不會影響到我的治療和法律權利。

10. 我明白我有權隨時退出這項研究，而不用提供任何理由，以及不會影響到我的治療和法律權利。

11. 我明白研究人員有權終止我參與此研究，假如出現併發症或不良反應、或未能符合計劃書要求或其他原因。

請在此同意書末端簽署和寫上日期:

參加者姓名 (請用正楷寫上)　　　簽署　　　　　　　日期

研究員姓名 (請用正楷寫上)　　　簽署　　　　　　　日期

Consent Form (Control Group)

香港大學家庭醫學及基層醫療學系之學術研究
參與研究資料及同意書

《隨機對照試驗- 常規臨床實踐中測量健康相關的生活質量 對於改善筋骨健康問題人士健康的成效》

謝謝您閱讀這項研究的資料和同意考慮參加。請細閱此同意書，如果您同意參與這項研究，請您在這份同意書的末端　簽署和寫上日期來表明您自願參加和明白研究內容及整個研究程序。

研究資料

　　這項研究的目的是評估把患者自我評估健康相關的生活質量常規化是否可以幫助改善患有筋骨健康問題人士的健康惼況。如果您同意參加的話, 您會接受調查員的問卷調查。 在完成第一次問卷調查后，我們會在隨後的 3個月，6個月和12個月通過電話聯絡您，完成電話問卷調查，每次電話問卷調查大約持續10分鐘。

　　在12個月內每次來診所隨訪 時您的主診醫生亦會提供您的疾病狀況和治療情況。你的主診醫生會如常給您適當的治理。您所提供的資料將會受到研究小組的絕對保密，任何個人資料將不會在研究報告中披露。您有權隨時退出這項研究，您的退出不會影響您在該診所的治療或使用其他醫院管理局所提供的醫療服務。

如您對此項研究有疑問，請聯絡：

　　鴨脷洲大街 161 號鴨脷洲診所三樓香港大學家庭醫學及基層醫療學系 林露娟醫生/黃競浩博士
　　電話：25185657；傳真號碼：2814 7475

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Consent Form (Control Group)

同意書

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2. 我明白我的參與純屬自願。
3. 我同意參與這項研究。
4. 我同意接受調查員基線問卷調查。
5. 我明白我需要在第3個月，6個月和12個月後再接受約10分鐘的電話問卷調查來監測我的疾病狀況。
6. 我明白我的主診醫生會如常给我適當的治理及提供有關我的疾病狀況和治療的資料。
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請在此同意書末端簽署和寫上日期：

參加者姓名 (請用正楷寫上)	簽署	日期
研究員姓名 (請用正楷寫上)	簽署	日期

Supplemental material

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Clinician Consent Form

A. Information and Consent Form – Clinician version

Research conducted by
Department of Family Medicine and Primary Care, HKU

Effectiveness of Routine Measurement of Health-Related Quality of Life in Improving the Outcomes of Patients with Musculoskeletal Problems – A Randomized Controlled Trial

Thank you for reading this information and agreeing to consider taking part in this study. Please read this form, and if you **have understood the purpose and procedure of the study and kindly agree to take part**, **please sign and date** at the end of this Consent Form.

Study Information
The aim of this research is to determine the effectiveness of routine measurement of health-related quality of life (HRQOL) in improving the clinical outcomes of patients with chronic knee or back problems in primary care. You will be invited to report on the health of the patients you see. During the study period (12 months), you will be asked to rate on the disease severity and progression of the patients whenever you see them.

Your clinic will be RANDOMLY assigned to one of the two study arms: (1) **Intervention group**: subjects *will* complete the electronic EQ-5D-5L and be given a report on their HRQOL to you during the consultation and you will manage the patients based on the HRQOL and clinical information; (2) **Control group**: subjects will not complete the electronic EQ-5D-5L and you will manage the patients as usual..

All the data collected from you will be kept confidential and no individual identity information will be disclosed in any reports, data record forms or publications.

For further information please contact:
Prof. Cindy Lam or Dr. Carlos Wong
Department of Family Medicine and Primary
Care, The University of Hong Kong
3/F., Ap Lei Chau Clinic, 161 Main Street, Ap Lei Chau, Hong Kong
Telephone: 2518 5657; Fax: 2814 7475

Declaration on Protection of Personal Data
Under the laws of the Hong Kong Special Administrative Region and, in particular, the Personal Data (Privacy) Ordinance, Cap 486, you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study.
By signing and dating this Consent Form, you agree to allow the collection, custody, retention, management, control, and use your personal data in this study in ways described in the Information Leaflet. For any query, you should consult the Privacy Commissioner for Privacy Data or his office (Tel No. 2827 2827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

Version No. 1 dated 2020.03.20

Supplemental material

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Clinician Consent Form

A. Information and Consent Form – Clinician version

The following statements are to check that you understand and consent to the procedures involved in taking part in this research.

1. I confirm that I have read and understood (or had someone read and explained) the information for the above study and have been given a copy to keep. I have had the opportunity to ask questions about the project and I understand why the research is being done and any risks involved.
2. I understand that my participation is voluntary.
3. I agree to take part in the study.
4. I agree to complete a questionnaire rating on the patients' disease severity and progression very time I see him/her during the study period.
5. ***I understand that my clinic will be randomly assigned EITHER TO THE INTERVENTION OR CONTROL GRPOUP, that I need to manage the patients based on HRQOL and clinical information or solely on the clinical information depending on the my clinic group allocation***
6. I understand that all information that I provide to the research team will be kept confidential and only the investigators and their research team will have access to it.
7. I understand how the data will be collected, that giving data for this research is voluntary.
8. I understand that I am free to withdraw from the study at any time, without giving reason and without my legal rights being affected in any way.
9. I understand the investigators have the right to exclude me from the study in the event of inter-current illness, adverse event, protocol violations, or other reasons.

Please sign and date this Consent Form below:

....
Name of Clinician in BLOCK letters   Signature   Date

....
Name of Investigator in   Signature   Date
    BLOCK letters

Version No. 1 dated 2020.03.20

Appendix 3: Structured Questionnaire

Effectiveness of Routine Measurement of Health-Related Quality of Life in Improving the Outcomes of Patients with Musculoskeletal Problems – A Randomized Controlled Trial

Baseline Assessment

Number：_____

Date (DD/MM/YYYY)：_____

Checklist

Patient

☐ Part 1. **Morbidity data**

☐ Part 2. **Health service utilization**

☐ Part 3. **Socio-demographics and lifestyle factors**

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EQ-5D RCT

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Appendix 3: Structured Questionnaire

Part 1. Morbidity data

Diagnosis – what is the type of your musculoskeletal disorders diagnosed by **a western doctor?**

Musculoskeletal disorder diagnosis:　①　Knee　　　②　Back　③others _____

Diagnosis year:_____If don't know⓪<1 year　　①　1-5 years ② 5- 10 years ③> 10 years

Treatment – Have you received any treatment for musculoskeletal disorders **over past three months**

Medication	Topical	⓪ No	① Yes, please specify: How many_____, Frequency:_____times/day
	Oral	⓪ No	① Yes, please specify: How many_____, Frequency:_____times/day
	Injection	⓪ No	① Yes, please specify: How many_____, Frequency:_____times/day

Physiotherapy	⓪ No	① Yes	If yes, frequency:_____times/week
Occupational therapy	⓪ No	① Yes	If yes, frequency:_____times/week
Local injection	⓪ No	① Yes	If yes, frequency:_____times/week
Surgery	⓪ No	① Yes	If yes, type:_____; Surgery year: _____
Counselling	⓪ No	① Yes	If yes, frequency:_____times

Co-morbidities – Do you have any of the following disease diagnosed by a western doctor?

Hypertension	⓪ No	① Yes	Diabetes	⓪ No	① Yes
Stroke (or Transient Ischaemic Attack)	⓪ No	① Yes	Heart disease	⓪ No	① Yes
Pulmonary diseases (asthma and COPD)	⓪ No	① Yes	Mental health disease (depression/anxiety)	⓪ No	① Yes
Renal Disease	⓪ No	① Yes	Osteoporosis	⓪ No	① Yes
Cancer	⓪ No	① Yes	Others	⓪ No　① Yes , please specify_____	

Sick leave

During last month, have you taken any sick leave?	⓪ No　　① Yes
a)　For musculoskeletal disorders	⓪ No　　① Yes ,　How many days? _____
b)　For other reasons?	⓪ No　　① Yes ,　How many　days ? _____

EQ-5D RCT

Appendix 3: Structured Questionnaire

Part 2. Health service utilization

1. During past one month, have you ever consulted Western medicine practitioners?	(0) No	(1) Yes
a) For musculoskeletal disorders	(0) No	(1) Yes, How many times? _____
b) For other reasons?	(0) No	(1) Yes, How many times? _____
2. During past one month, have you ever consulted Chinese medicine practitioners?	(0) No	(1) Yes
a) For musculoskeletal disorders	(0) No	(1) Yes, How many times? _____
b) For other reasons?	(0) No	(1) Yes, How many times? _____
3. During past one month, have you ever self-medicated?	(0) No	(1) Yes
c) For musculoskeletal disorders	(0) No	(1) Yes, How many times? _____
d) For other reasons?	(0) No	(1) Yes, How many times? _____
4. During past one month, have you ever visited the emergency room?	(0) No	(1) Yes ,
a) For musculoskeletal disorders	(0) No	(1) Yes, How many times? _____
b) For other reasons?	(0) No	(1) Yes, How many times? _____
5. During past one month, have you ever visited the allied health service?	(0) No	(1) Yes ,
c) For musculoskeletal disorders	(0) No	(1) Yes, How many times? _____
d) For other reasons?	(0) No	(1) Yes, How many times? _____
6. During past three months, have you ever attended and stayed more one or more nights in hospital?	(0) No	(1) Yes ,
a) For musculoskeletal disorders	(0) No	(1) Yes, How many nights? _____
b) For other reasons?	(0) No	(1) Yes, How many nights ? _____

EQ-5D RCT

Appendix 3 – Structured Questionnaire

Part 3: Socio-demographics and lifestyle factors

Age:_____	Date of birth (DD/MM/YYYY)：____ /_____ /_____
Sex: ⓪Female ①Male	

Education	⓪None
	①Primary or below
	②Secondary Level
	③Tertiary level or above

Occupation:	⓪Unemployed
	① Home-maker
	②Retired
	③ Manual
	④Clerical
	⑤Professional or managerial
	⑥ Other：_____

Marital status	⓪Never married	①Married	②Separated	③Divorced	④Widowed

What is your monthly household income, including sources? (in HKD)	⓪No income
	① Less than HK$5,000
	②HK$5,000-9,999
	③HK$10,000-19,999
	④HK$20,000-29,999
	⑤HK$30,000-39,999
	⑥40,000 or above
	⑦ Refuse to answer
	⑧ Don't know

Smoking Status:	⓪ Non-smoker	① Ex-smoker	② Current Smoker	
Drinking Habit:	⓪ Non-drinker	①Ex-drinker	② Drink occasionally	③ Drink often

EQ-5D RCT

Appendix 3 – Structured Questionnaire

Effectiveness of Routine Measurement of Health-Related Quality of Life in Improving the Outcomes of Patients with Musculoskeletal Problems – A Randomized Controlled Trial

Follow-up Assessment

Number：　_____

Date (DD/MM/YYYY)：　_____

Checklist

Patient

☐ Part 1. **Morbidity data**

☐ Part 2. **Health service utilization**

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Appendix 3 – Structured Questionnaire

Part 1. Morbidity data

Disease diagnosis – what is the type of your musculoskeletal disorders diagnosed by **a western doctor?**	

Musculoskeletal disorder diagnosis:　①Knee　　②Back　③others _____

Diagnosis year:_____If don't know ⓪<1 year　①1-5 years　②5- 10 years　③> 10 years

Treatment – Have you received any treatment for musculoskeletal disorders **over past three months**

Medication　Topical　　　⓪No　①Yes, please specify: How many_____, Frequency:_____times/day

　　　　　　　Oral　　　　⓪No　①Yes, please specify: How many_____, Frequency:_____times/day

　　　　　　　Injection　　⓪No　①Yes, please specify: How many_____, Frequency:_____times/day

Home Exercise	⓪No	①Yes	If yes, frequency:_____times/week
Physiotherapy	⓪No	①Yes	If yes, frequency:_____times/week
Occupational therapy	⓪No	①Yes	If yes, frequency:_____times/week
Local injection	⓪No	①Yes	If yes, frequency:_____times/week
Surgery	⓪No	①Yes	If yes, type:_____; Surgery year: _____
Counselling	⓪No	①Yes	If yes, frequency:_____times

Co-morbidities – Do you have any of the following disease diagnosed by a western doctor?

Hypertension	⓪No　①Yes		Diabetes	⓪No　①Yes
Stroke (or Transient Ischaemic Attack)	⓪No　①Yes		Heart disease	⓪No　①Yes
Pulmonary diseases (asthma and COPD)	⓪No　①Yes		Mental health disease (depression/anxiety)	⓪No　①Yes
Renal Disease	⓪No　①Yes		Osteoporosis	⓪No　①Yes
Cancer	⓪No　①Yes		Others	⓪No　①Yes , please specify_____

Sick leave

During the past one month, have you taken any sick leave? 　a)　For　musculoskeletal disorders 　b)　For other reasons?	⓪No　①Yes ⓪No　①Yes ,　How many days? _____ ⓪No　①Yes ,　How many　days ? _____

EQ-5D RCT

Appendix 3 – Structured Questionnaire

Part 2. Health service utilization

1. During past one month, have you ever consulted Western medicine practitioners?	⓪ No	① Yes
c) For musculoskeletal disorders	⓪ No	① Yes, How many times? _____
d) For other reasons?	⓪ No	① Yes, How many times? _____
2. During past one month, have you ever consulted Chinese medicine practitioners?	⓪ No	① Yes
e) For musculoskeletal disorders	⓪ No	① Yes, How many times? _____
f) For other reasons?	⓪ No	① Yes, How many times? _____
3. During past one month, have you ever self-medicated?	⓪ No	① Yes
g) For musculoskeletal disorders	⓪ No	① Yes, How many times? _____
h) For other reasons?	⓪ No	① Yes, How many times? _____
4. During past one month, have you ever visited the emergency room?	⓪ No	① Yes ,
c) For musculoskeletal disorders	⓪ No	① Yes, How many times? _____
d) For other reasons?	⓪ No	① Yes, How many times? _____
5. During past one month, have you ever visited the allied health service?	⓪ No	① Yes ,
e) For musculoskeletal disorders	⓪ No	① Yes, How many times? _____
f) For other reasons?	⓪ No	① Yes, How many times? _____
6. During past three months, have you ever attended and stayed more one or more nights in hospital?	⓪ No	① Yes ,
c) For musculoskeletal disorders	⓪ No	① Yes, How many nights? _
d) For other reasons?	⓪ No	① Yes, How many nights ? _

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Appendix 3 – Structured Questionnaire

《隨機對照試驗- 常規臨床實踐中測量健康相關的生活質量
對於改善筋骨健康問題人士健康的成效》

基線問卷調查

號碼： _____

日期(日/月/年)： _____

<u>評估清單</u>

☐ 第一部分. 健康信息

☐ 第二部分.服務使用

☐ 第三部分. 背景及生活習慣

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Appendix 3 – Structured Questionnaire

第一部分- 健康信息

疾病診斷
您被西醫診斷為哪一種筋骨健康問題？_____ 確診年份: _____ 　　　　　　如忘記年份:　　⓪少於一年　　　　① 一至五年　　② 五至十年 ③

治療措施:　在過去3 個月，您是否因筋骨健康問題**而接受治療？**
藥物治療　藥膏　　　⓪沒有　　① 有，請註明數量:_____天, 次數:_____次/天 　　　　　口服藥　⓪沒有　　　① 有，請註明數量:_____天, 次數:_____次/天 　　　　　　注射用藥　⓪ 沒有　　　　① 有，請註明數量: _____, 次
物理治療　　　⓪沒有　　① 有　如有, 次數:_____次/周 職素治療　　　⓪ 沒有　　① 有　如有, 次數:　　　次/周
局部注射　　　⓪沒有　　① 有　如有, 次數:_____次/周
手術　　　　⓪沒有　　① 有　如有, 種類:_____; 手術年份: _____
心理輔導　　　⓪沒有　　① 有　如有, 次數:_____次

慢性疾病:　您是否被西醫診斷患有以下任何一種疾病？				
心臟病	⓪ 沒有　① 有	高血壓	⓪ 沒有 ① 有	
中風(或短暫性腦缺血)	⓪ 沒有　① 有	糖尿病	⓪ 沒有 ① 有	
肺病（哮喘或慢性阻塞性肺病）	⓪ 沒有　① 有	精神疾病（抑鬱症或焦慮）	⓪ 沒有 ① 有	
腎病	⓪ 沒有　① 有	關節炎	⓪ 沒有 ①有	
癌症	⓪ 沒有　① 有, 請註明:_____	其他疾病	⓪ 沒有　① 有, 請註明:_____	

病假	
在過去一個月, 您有沒有曾經您請病假？ 　　a)　因為筋骨勞損 　　b)　因為其他原因	⓪沒有　① 有,　天數：_____ ⓪沒有　① 有 ,　天數：_____ ⓪沒有　① 有 ,　天數：_____

EQ-5D RCT

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Appendix 3 – Structured Questionnaire

第二部分 –服務使用

1. 在過去一個月, 您有沒有曾經看西醫? 　　a) 因為筋骨健康問題 　　b) 因為其他原因	⓪ 沒有　① 有 ⓪ 沒有　① 有　次數：____ ⓪ 沒有　① 有, 次數：____
2, 在過去一個月, 您有沒有曾經看中醫? 　　a) 因為筋骨健康問題 　　b) 因為其他原因	⓪ 沒有　① 有 ⓪ 沒有　① 有　次數：____ ⓪ 沒有　① 有, 次數：____
3. 在過去一個月, 您有沒有自行用藥? 　　c) 因為筋骨健康問題 　　d) 因為其他原因	⓪ 沒有　① 有 ⓪ 沒有　① 有　次數：____ ⓪ 沒有　① 有, 次數：_
4. 在過去一個月, 您有沒有曾經訪問急診室? 　　a) 因為筋骨健康問題 　　b) 因為其他原因	⓪ 沒有　① 有 ⓪ 沒有　① 有　次數：____ ⓪ 沒有　① 有, 次數：____
5. 在過去一個月, 您有沒有曾經接受專職醫療服務? 　　a) 因為筋骨健康問題 　　b) 因為其他原因	⓪ 沒有　① 有 ⓪ 沒有　① 有　次數：____ ⓪ 沒有　① 有, 次數：____
6. 在過去3個月, 您有沒有曾經入院一日或多日? 　　a) 因為筋骨健康問題 　　b) 因為其他原因	⓪ 沒有　① 有　天數:____ ⓪ 沒有　① 有　天數：____ ⓪ 沒有　① 有　天數：____

EQ-5D RCT

Appendix 3 – Structured Questionnaire
第三部分 - 背景和生活習慣

年齡：＿＿＿＿＿＿＿	出生日期 (日/月/年)：＿＿＿＿ / ＿＿＿＿ / ＿＿＿＿		
性別：	☐⓪女　　　☐①男		
教育程度：	☐⓪沒有接受教育　☐①小學程度　☐②中學程度　☐③高等程度或以上		
職業：	☐⓪沒有工作　☐①家庭主理者　☐②已退休　☐③勞動工作 ☐④文職　☐⑤專業或管理人士　☐⑥ 其他：＿＿＿＿＿		
婚姻狀況：	☐⓪從未結婚　☐①已婚　☐②分居　☐③離婚　☐④喪偶		
您的平均**家庭**月收入有多少？（包括所有經濟來源）(港幣)	☐⓪沒有收入　☐① 少於 HK$5,000　☐②HK$5,000-9,999 ☐③HK$4,000-5,999　☐④HK$6,000-7,999　☐⑤HK$8,000-9,999 ☐⑥40,000 以上　☐⑦ 拒絕作答　☐⑧ 不清楚		
吸煙習慣:	☐⓪不吸煙者	☐①戒煙者	☐②吸煙者
飲酒習慣：	☐⓪沒有飲酒習慣	☐①戒酒者	☐②偶爾飲酒　☐③經常飲酒

Appendix 3 – Structured Questionnaire

《隨機對照試驗- 常規臨床實踐中測量健康相關的生活質量
對於改善筋骨健康問題人士健康的成效》

隨訪問卷調查

號碼：　_____

日期(日/月/年)：　_____

評估清單

☐　第一部分. **健康信息**

☐　第二部分.**服務使用**

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Appendix 3 – Structured Questionnaire

第一部分- 健康信息

疾病診斷
您被西醫診斷為哪一種筋骨健康問題？＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿ 確診年份: ＿＿＿＿＿ 　　　　　　如忘記年份:　　　Ⓞ少於一年　　　① 一至五年　　② 五至十年③

治療措施:　在過去3個月，您是否因筋骨健康問題而接受治療？
藥物治療 藥膏　　　Ⓞ沒有　　① 有，請註明數量:＿＿＿＿＿＿天, 次數:＿＿次/天 　　　　　　口服藥　Ⓞ沒有　　　① 有，請註明數量:＿＿＿＿＿天, 次數:＿＿次/天 　　　　　注射用藥　Ⓞ 沒有　　　　① 有，請註明數量: ＿＿＿＿ 次
物理治療　　　Ⓞ沒有　　① 有　如有, 次數:＿＿＿次 職素治療　　　Ⓞ 沒有　　① 有　如有, 次數: ＿＿＿次
局部注射　　　Ⓞ沒有　　① 有　如有, 次數:＿＿＿
手術　　　　　Ⓞ沒有　　① 有　如有, 種類:＿＿＿＿; 手術年份: ＿＿＿＿
心理輔導　　　Ⓞ沒有　　① 有　如有, 次數:＿＿＿＿次

慢性疾病:　您是否被西醫診斷患有以下任何一種疾病？		
心臟病	Ⓞ 沒有 ① 有	高血壓	Ⓞ 沒有 ① 有
中風(或短暫性腦缺血)	Ⓞ 沒有 ① 有	糖尿病	Ⓞ 沒有 ① 有
肺病（哮喘或慢性阻塞性肺病）	Ⓞ 沒有 ① 有	精神疾病（抑鬱症或焦慮症）	Ⓞ 沒有 ① 有
腎病	Ⓞ 沒有 ① 有	關節炎	Ⓞ 沒有 ① 有
癌症	Ⓞ 沒有 ① 有, 請註明:＿＿＿	其他疾病	Ⓞ 沒有 ① 有, 請註明:＿＿＿

病假	
在過去一個月, 您有沒有曾經您請病假？	Ⓞ沒有　① 有,　天數：＿＿＿
a) 因為筋骨勞損	Ⓞ沒有　① 有 ,　天數：＿＿＿
b) 因為其他原因	Ⓞ沒有　① 有 ,　天數：＿＿＿

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Appendix 3 – Structured Questionnaire

第二部分 -服務使用

1. 在過去一個月, 您有沒有曾經看西醫?	⓪ 沒有	① 有
a) 因為筋骨健康問題	⓪ 沒有	① 有　次數：＿＿＿
b) 因為其他原因	⓪ 沒有	① 有,　次數：＿＿＿
2. 在過去一個月, 您有沒有曾經看中醫?	⓪ 沒有	① 有
a) 因為筋骨健康問題	⓪ 沒有	① 有　次數：＿＿＿
b) 因為其他原因	⓪ 沒有	① 有,　次數：＿＿＿
3. 在過去一個月, 您有沒有自行用藥?	⓪ 沒有	① 有
a) 因為筋骨健康問題	⓪ 沒有	① 有　次數：＿＿＿
b) 因為其他原因	⓪ 沒有	① 有,　次數：＿
4. 在過去一個月, 您有沒有曾經訪問急診室?	⓪ 沒有	① 有
a) 因為筋骨健康問題	⓪ 沒有	① 有　次數：＿＿＿
b) 因為其他原因	⓪ 沒有	① 有,　次數：＿＿＿
5. 在過去一個月, 您有沒有曾經接受專職醫療服務?	⓪ 沒有	① 有
a) 因為筋骨健康問題	⓪ 沒有	① 有　次數：＿＿＿
b) 因為其他原因	⓪ 沒有	① 有,　次數：＿＿＿
6. 在過去3個月, 您有沒有曾經入院一日或多日?	⓪ 沒有	① 有　天數:＿＿＿＿
a) 因為筋骨健康問題	⓪ 沒有	① 有　天數：＿
b) 因為其他原因	⓪ 沒有	① 有　天數：＿＿＿

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Appendix 4: Clinician Report Form (CRF)

Effectiveness of Routine Measurement of Health-Related Quality of Life in Improving the Outcomes of Patients with Musculoskeletal Problems – A Randomized Controlled Trial

Baseline

Number： _____

Date (DD/MM/YYYY)： _____

Appendix 4: Clinician Report Form (CRF)

Clinical data

Disease diagnosis –
What is the patient's main musculoskeletal diagnosis (can choose one or more)**?**

⓪ Knee, diagnosis _____   ① Back, diagnosis _____   ② Others: _____

Diagnosis year:_____   If don't know: ⓪ <1 year   ① 1-5 years   ② 5- 10 years   ③ > 10 years

Management –
Have you advised any of the following management for the patient's musculoskeletal disorders **today?**

Investigations ⓪ No   ① Yes, (circle):   X ray   CT   MRI   Others: _____

Topical   ⓪ No   ① Yes (circle): analgesic balm   Others _____

Oral   ⓪ No   ① Yes, (circle): paracetamol NSAID others, _____

Injection   ⓪ No   ① Yes, (circle): NSAID   opioid   others, :_____

Home-care   ⓪ No   ① Yes (circle) Ice pack   Heat pad   brace/splint   home exercise others_____

Physiotherapy   ⓪ No   ① Yes   please specify _____

Occupational Therapy   ⓪ No   ① Yes   please specify _____

Prosthesis & Orthosis   ⓪ No   ① Yes, please specify _____

Local injection   ⓪ No   ① Yes, please specify frequency: _____   times

Referral   ⓪ No   ① Yes (circle): Orthopedics, Surgery Chiropractor Others _____

Others   ⓪ No   ① Yes please specify:_____

Global Rating on Disease Severity

How would you rate the patient's disease severity today?

⓪ No problem   ① Mild   ② Moderate   ③ Severe   ④ Very severe

Appendix 4: Clinician Report Form (CRF)

Effectiveness of Routine Measurement of Health-Related Quality of Life in Improving the Outcomes of Patients with Musculoskeletal Problems – A Randomized Controlled Trial

Follow-up

Number：_____

Date (DD/MM/YYYY)：_____ _____

Appendix 4: Clinician Report Form (CRF)

Clinical data

Disease diagnosis –
What is the patient's main musculoskeletal diagnosis (can choose one or more)**?**

⓪ Knee, diagnosis _____ ① Back, diagnosis _____ ② Others: _____

Diagnosis year:_____ If don't know: ⓪ <1 year ① 1-5 years ② 5- 10 years ③ > 10 years

Management –
Have you advised any of the following management for the patient's musculoskeletal disorders **today?**

Investigations ⓪ No ① Yes, (circle): X ray CT MRI Others: _____

Topical ⓪ No ① Yes (circle): analgesic balm Others _____

Oral ⓪ No ① Yes, (circle): paracetamol NSAID others, _____

Injection ⓪ No ① Yes, (circle): NSAID opioid others, :_____

Home-care ⓪ No ① Yes (circle) Ice pack Heat pad brace/splint home exercise others_____

Physiotherapy ⓪ No ① Yes please specify _____

Occupational Therapy ⓪ No ① Yes please specify _____

Prosthesis & Orthosis ⓪ No ① Yes, please specify _____

Local injection ⓪ No ① Yes, please specify frequency: _____ times

Referral ⓪ No ① Yes (circle): Orthopedics, Surgery Chiropractor Others _____

Others ⓪ No ① Yes please specify:_____

Global Rating on Disease Severity

How would you rate the patient's severity of the patient's musculoskeletal problem today?

⓪ No problem ① Mild ② Moderate ③ Severe ④ Very severe

Global Rating on Disease Progression

Compare to the patient's condition on_____(date of recruitment visit), how would you rate the patient's musculoskeletal problem today?

Much worse	Worse	A little worse	No changed	A little better	Better	Much better
☐ +3	☐ -2	☐ -1	☐ 0	☐ +1	☐ +2	☐ +3

Appendix 4: Clinician Report Form (CRF)

Perceived usefulness of the EQ-5D-5L report (for intervention group only)

(Please ✓ the appropriate answer for each question)

Perceived usefulness of the EQ-5D report	Very Strongly Disagree	Strongly Disagree	Disagree	Neutral	Agree	Strongly agree	Very Strongly Agree
1. The EQ-5D data report is clear							
2. The EQ-5D data report is easy to understand							
3. The EQ-5D data report helps me to understand the patient's needs better							
4. Using the EQ-5D-5L data report helps the management for my patient							
5. I wish to have the EQ-5D data report of the patient available to me in future consultations							
6. Apart from the domains included in the EQ-5D, is there any other aspect of the patient's quality of life that you would like to collect before the patient sees you: _____							

Supplemental material

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Appendix 5: Summary of RCT Plan by CONSORT Criteria

CONSORT Criteria	Study Plan
Participants allocation	Random
Rationale	HRQOL data optimize care to address physical, psychological and social needs, resulting in improvement in quality of life & daily function
Eligibility criteria and settings	Adults with chronic MS problems diagnosed by the doctor in study outpatient clinics
Interventions for each group	EQ-5D-5L report to the doctor plus usual care Vs. usual care only
Objectives	Effectiveness of routine measurement of EQ-5D-5L by an electronic platform in improving HRQOL and pain control in patients with chronic MS problems Feasibility of routine measurement of EQ-5D-5L by an electronic platform in busy outpatient clinics
Outcomes	Changes in WAOMAC, pain, SF-6D, clinician rated disease severity, same for both groups
Sample size	543 from primary and specialist orthopedic outpatient clinics to detect an effect size of 0.3 in WOMAC score between groups, allowing 30% attrition.
Randomization -- Sequence generation	Post recruitment 1:1 block randomization
Randomization -- Allocation concealment	Computer generated random number table for each site, concealed to research assistant at recruitment and follow-up assessors.
Randomization -- Implementation	Independent statistician generates the allocation sequence randomly by computer and group allocation by statistician according to computer generated random number sequence
Blinding (masking)	Assessor is blinded
Statistical methods	Descriptive statistics, Paired T tests, ANCOVA, multiple logistic regression