**Title:** SUpported Motivational InTerviewing (SUMIT) to improve physical activity for people with knee osteoarthritis. A pilot, feasibility randomised controlled trial.

**Trial registration:** This trial will be registered with the Australian New Zealand Clinical Trial Registry (ANZCTR)

**Funding:** This trial is supported by a Cabrini Foundation Research Grant to the value of $29,999.65. The remaining funds required will be supported by La Trobe University. Cabrini Health will play no role in the design or reporting of the trial.

**Roles and responsibilities:**

|  |  |  |
| --- | --- | --- |
| Role (CI/AI), title, name | Affiliation | Responsibilities |
| CI Miss Emily Bell | La Trobe Sport and Exercise Medicine Research Centre, School of Allied Health, Sport and Human Services, La Trobe University | Trial registration;Website development;Recruitment;Intervention delivery;Data analysis;Manuscript construction;Submission for peer review;Conference presentation |
| CI Dr Christian Barton (Principle) | La Trobe Sport and Exercise Medicine Research Centre, School of Allied Health, Sport and Human Services, La Trobe University | Website development;Recruitment;Intervention delivery (back-up);Data analysis;Manuscript construction;Submission for peer review |
| CI Dr Paul O’Halloran | School of Psychology and Public Health, La Trobe University | Train EB/CB in motivational interviewing;Data analysis;Manuscript construction |
| CI Dr Jason Wallis | Monash Department of Clinical Epidemiology, Cabrini Institute; Physiotherapy department, Cabrini Health | Recruitment;Data analysis;Manuscript construction |
| AI Prof Kay Crossley | La Trobe Sport and Exercise Medicine Research Centre, School of Allied Health, Sport and Human Services, La Trobe University | Data analysis;Manuscript construction |
| AI Miss Alison Gibbs | La Trobe Sport and Exercise Medicine Research Centre, School of Allied Health, Sport and Human Services, La Trobe University; Access Hawthorn | Recruitment;Manuscript construction |
| AI Dr Annemarie Lee | Centre for Allied Health Research and Education; Department of Physiotherapy, Monash University | Data analysis;Manuscript construction |
| AI Miss Sophie Jennings | Centre for Allied Health Research and Education; Department of Physiotherapy, Cabrini Health | Recruitment;Randomisation;Data analysis;Manuscript construction |

Expected date of commencement: 11/1/2021

Expected date of conclusion: 1/4/2022

**Background:**

Physical activity, defined by the World Health Organisation as “any bodily movement produced by skeletal muscles requiring energy expenditure”,39 has numerous health benefits.3, 5 38 Physical inactivity was responsible for 13.4 million disability-affected life-years (DALYs) worldwide.11 Few (13%) people with knee osteoarthritis reach the recommended ≥150 minutes per week of moderate-vigorous physical activity.37 Knee osteoarthritis and physical inactivity are independently associated with greater comorbidity risk, including cardiovascular disease, and earlier mortality.24, 35, 36 Increasing physical activity in people with knee osteoarthritis could improve overall health, including weight control, and the prevention and management of at least 35 chronic diseases.3, 5 38

Exercise-therapy and patient education are recommended as first line treatments for knee osteoarthritis in all major guidelines,9, 19, 34 based on strong evidence supporting their effectiveness to reduce pain and improve knee function.31 Good Living with osteoArthritis from Denmark (GLA:D®) is an internationally recognised osteoarthritis management program28 involving exercise-therapy and patient education. It has been implemented in at least six countries, including Australia (297 sites).18 Participation is associated with 30% reduction in knee pain and 20% improvement in joint-related quality of life, with these benefits sustained for at least 12 months.31 Modest increases in physical activity occur at 3-months following commencement of GLA:D®,40 yet these improvements are not sustained at 12-months.32

While professional support is an enabler for people with knee osteoarthritis to increase physical activity participation, barriers include persistent pain, physical limitation and lack of motivation.20 GLA:D® may address pain and physical capacity to participate in physical activity, but fails to address motivation and facilitate behaviour change in the longer term. Motivational interviewing (MI) is a person-centred behaviour change approach involving counselling style sessions with a trained health professional, which can address personal barriers to behaviour change.22 Motivational Interviewing is reported to be associated with moderate benefits for increasing physical activity in people with chronic health conditions when they present to primary care.26, 27 However, the effect of MI on physical activity in musculoskeletal conditions such as osteoarthritis is largely unknown. Digital support tools for osteoarthritis are emerging as a cost effective approach to provide information and education, and assist people with osteoarthritis to engage with prescribed exercise in order to improve patient outcomes.13 17

This pilot, feasibility randomised controlled trial (RCT) will recruit 42 people with knee osteoarthritis who have completed the GLA:D® Australia program. Consenting participants will be randomised to an additional intervention to promote physical activity (motivational interviewing and web-based support), or usual care (continuation of exercises and self-management learnt in GLA:D®).

**Objectives:**

The primary objective is to determine the feasibility (eligibility and recruitment rates; adherence to motivational interviewing sessions, drop-out rate, credibility of the intervention) of conducting a fully powered trial to evaluate the clinical effectiveness (i.e. increasing physical activity) of using SUpported Motivational InTerviewing (SUMIT) targeting physical activity following completion of a widespread exercise-therapy program (GLA:D®) in people with knee osteoarthritis.

Secondary objectives include:

* To determine if a worthwhile treatment effect could be observed for physical activity, physical endurance, joint-related quality of life (QoL), health-related QoL and pain.
* To refine SUMIT through qualitative feedback from participants.

**Methods:**

**Trial design**

This is an assessor blinded, mixed methods feasibility randomised controlled trial. Reporting of the study will be guided by a GRAMM (Good Reporting of A Mixed Methods) Study Checklist25 and reporting will adhere to the Consolidated Standards or Reporting Trials (CONSORT) for pilot and feasibility trials.14 This trial will be registered with Australian New Zealand Clinical Trials Registry (ANZCTR). This protocol was developed according to the SPIRIT 2013 Checklist.6

**Eligibility criteria**

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| Table 1. Eligibility criteria |
| Inclusion: | Exclusion: |
| * Diagnosis of knee osteoarthritis for participation in GLA:D® is performed by a trained physiotherapist and guided by the NICE guidelines, that is:
1. Aged > 45 years
2. Activity-related knee pain
3. Morning stiffness of the knee which lasts less than 30 minutes or no knee stiffness
* Have completed GLA:D® in the past 12 months at time of recruitment
 | * Comorbidity that would prevent participants from increasing physical activity levels as assessed by the Exercise and Sports Science Australia (ESSA) adult pre-screening tool (appendix 1) e.g. unstable angina. Participants who do not pass the pre-screening tool will require approval from their general practitioner to participate in this trial (Nb: participants will have passed this screening to participate in GLA:D® in the previous 12-months).
* Non-English speaking (would not be able to complete questionnaires or participate in motivational interviewing sessions)
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**Participants**

Adults with knee osteoarthritis who have completed GLA:D®, a widely available exercise-therapy program for osteoarthritis, will be recruited from three sites in Melbourne, Australia: private physiotherapy practice (Complete Sports Care – CI-Barton), a private hospital (Cabrini – CI-Wallis), and community health centre (Access–AI-Gibbs). To participate in GLA:D®, participants can either self-refer, or may be referred by other health professionals including physiotherapists, other allied health professionals, and doctors (e.g. general practitioners, surgeons, rheumatologists, etc.).

Flyers will be posted at the three study sites, Cabrini Hospital, Complete Sports Care and Access Community Health Hawthorn (appendix 2), and an email will be sent to participants who have completed GLA:D® in the past 12 months (appendix 3). Despite COVID-19 restrictions, it is anticipated that recruitment can start immediately, with recruitment of participants who completed GLA:D® face-to-face prior to physical distancing restrictions, and participants who completed GLA:D® via telehealth during restrictions.

**Study Procedure:**

Following reading a patient information and consent form (appendix 4) and being provided an opportunity to ask questions related to the study, participants will be required to sign the informed consent document before commencing baseline assessments. Following preliminary screening via telephone or email, eligible participants will be invited to attend Cabrini Hospital, Malvern. Demographic data to be collected includes age, sex, body mass index, knee most affected, medication use, employment, and highest level of education. All screening, baseline and follow-up data collection will be performed by a (blinded) registered physiotherapist. See figure 1 for a summary of the study procedure.

Participants can choose to withdraw from the study at any point by completing the withdrawal of care document (appendix 4). Participants who choose to withdraw will have their data removed (if requested) from the data pool up until data analysis has been commenced. Participants will be asked at the conclusion of the study whether they experienced any physical or emotional harm directly related/ indirectly related/ unrelated to the study. These data will be recorded by the trial coordinator (EB) and if necessary, reported to the ethics committee.

**Interventions**

***SUMIT:***

Participants allocated to the SUMIT group will receive five physiotherapist led MI sessions16 (30-40-minutes) over 12 weeks to facilitate behaviour change towards increasing physical activity. Each session will be provided via Zoom or phone call depending on patient preference. Participants will be required to book in a time slot with the intervention physiotherapist (CI-Bell) in weeks 1,2,4,7,10. The content of each session will refer to the recommended processes of Engagement, Focusing, Evoking and Planning.23 Participants will have individualised sessions, tailored to their needs at the time of each session. Additional education and behaviour change support related to increasing physical activity will be provided via access to a multimedia website (education resources and goal setting tools) hosted at <https://sumit.trekeducation.org/> (See Table 1).

***Control:***

Participants allocated to the control group will not receive any study intervention – i.e. usual care following GLA:D®, which involves continued used or exercises and self-management strategies learnt during GLA:D®. This population will attend baseline and 3-month follow up assessments. Participants in the control group will be given access to the SUMIT TREK website (<https://sumit.trekeducation.org/>) following 3-month follow-up.

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| Table 1. TIDieR table for interventions |
| **Name** | **Why?** | **What?**  | **Who?** | **How?** | **Where?** |
| SUMIT | Few people with knee osteoarthritis meet physical activity guidelines, increasing their risk of other chronic disease development or worsening. | ***Materials:*** Personal access to a phone and internet services will be required to attend MI sessions and to access our custom built website <https://sumit.trekeducation.org/>.***Procedures:*** Participants allocated to SUMIT will undergo 5 MI sessions in weeks 1,2,4,7,10.  | Physiotherapist trained in motivational interviewing (2-day course and 1:1 coaching from a MINT psychologist). | 1:1 sessions via Zoom or phone (participant preference). | At home or other convenient location. Access to the SUMIT website will be possible anywhere with internet. |
| Control | Usual care i.e. no additional intervention following GLA:D® will give us the most accurate measure of effect size of the SUMIT intervention when comparing between group differences. | ***Materials:*** No new materials are required other than those used during usual care. Access to our custom-built website after the 3-month follow-up assessment.***Procedures:*** Participants allocated to the control group will be instructed to continue their usual lifestyle, and exercises and self-management strategies learnt during GLA:D®. | Usual care. | Usual care. | Usual care. |
| Legend: TIDieR= template for intervention description and replication, SUMIT= SUpported Motivational InTerviewing, MI= motivational interviewing, MINT= motivational interviewing network of trainers,  |

**Outcomes:**

**Primary quantitative:**

The primary outcome is feasibility of conducting a fully powered randomised controlled trial (RCT) to evaluate SUMIT. Feasibility of SUMIT will be assessed by evaluating: i) number of eligible volunteers; ii) recruitment rate; iii) adherence with MI sessions attended as a percentage of the total number of sessions scheduled; iv) ActivPAL wear time; and v) drop-out rate (table 3).

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| **Table 3.** Measures of feasibility |
| Item | Measure of feasibility |
| Number of eligible volunteers | Minimum 2-3 participants per site, per month. Totalling 6-9 participants being eligible per month. |
| Recruitment rate | Minimum 2 participant per site, per month. Totalling 6 participants recruited per month. |
| Adherence with motivational interviewing sessions | Minimum attendance of 4/5 sessions (80%). |
| ActivPAL use | Measured by time worn per participant being >16 hours per day for seven days (to account for waking hours). |
| Drop-out rate | <20% of participants drop out of the study. |

Credibility of the treatment will be evaluated with the Borkovec and Nau questionnaire,10 which consists of six items related to patient expectations of the allocated treatment (i.e. how much the participant believes that the therapy they are receiving will help to increase their physical activity). The questionnaire has good test-retest reliability with intra-class correlation coefficients (ICCs) of 0.82 for expectancy and 0.75 for credibility.10 It will be completed by participants immediately following the first treatment session and at 3-month follow-up. See table 4 for timeline of outcome measures. Feasibility of the use of ActivPAL will include days data are captured.

**Secondary quantitative:**

Secondary outcomes will be collected at baseline and 3-month follow-up (table 4). One trial physiotherapist will conduct all outcome assessments (and one back up trial physiotherapist will be trained). See appendix 5 for outcome assessment forms. Trial physiotherapists will be provided with instructions to correctly fit ActivPAL devices (appendix 6). CI-Bell will be on site during baseline testing to answer queries that arise during outcome assessment.

***Objective physical activity:***ActivPAL, a device worn on the thigh to track body position, will measure step count, active bouts and sedentary time. One-week of data will be extracted from the ActivPal device by an assessor blinded to group allocation at baseline and 3-month follow-up (JW). The ActivPAL (PAL Technologies, Glascow, Scotland) is a reliable (ICC=0.99 for step number, ICC=0.99 for cadence) measure of physical activity.30 ActivPAL was selected as it provides no feedback to participants and thus acts as a measuring device with no intervention.

***Self-reported physical activity:*** The University of California, Los Angeles (UCLA) (appendix 7) physical activity scale will classify activity level from one to ten, and is recommended for observing physical activity levels of osteoarthritis populations, with positive rating for construct validity and reliability.33 To collect data on types of exercise participants undertake, we will use the International Physical Activity Questionnaire- long version (IPAQ-long) (appendix 9). The IPAQ-long covers five domains i) job-related activity; ii) transportation; iii) housework; iv) recreation, sport, and leisure time; v) time spent sitting; and has excellent test-retest reliability overall (ICC=0.81) and for physical activity (ICC=0.84-1.00).8

***Knee-related pain and quality of life (QoL):*** The Knee Osteoarthritis Outcome Score QoL subscale (KOOS-QoL) will be used to measure knee-related QoL (appendix 11).29 KOOS QoL is reliable (ICC=0.87: 95% confidence interval (CI): 0.83-0.9)7, with a low SEM of 6.6 points out of 100, is valid, responsive and with a clinically relevant (MCID) change of 10 points.29

***Health-related QoL:*** The EQ-5D-5L (appendix 10) will measure participants health-related five domains i) mobility; ii) self-care; iii) usual activities; iv) pain/discomfort; and v) anxiety/depression, on a 5 point likert scale. The EQ-5D-5L is reliable, valid and responsive in osteoarthritis populations.2

***Physical fitness:***The six-minute walk test (6MWT) (appendix 11) will measure of physical fitness, and be facilitated by a blinded physiotherapist. Within knee osteoarthritis, 6MWT has excellent test-retest reliability (ICC 0.991, 95% CI 0.986-0.994).1 A strong correlation between 6MWT and KOOS-pain (Spearman correlation=0.605) and very strong correlation with KOOS-QOL (Spearman correlation=0.758).1

***Functional performance:*** Consistent with GLA:D® outcome measures and recommendations from the Osteoarthritis Research Society International recommendations,21 the 30 second chair test and 40 metre fast paced walk test will be measured (appendix 12).12 Both tests have excellent test-retest reliability, ICC 0.91 (0.81, 0.97) and 0.97-0.98 (0.94, 0.99) respectively.12

***Physical health:*** Blood pressure and waist circumference will be recorded as a measure of general physical health.

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| **Table 4.** Timeline for data collection |
| Outcome tool | Baseline | 3-month follow up |
| Borkovec and Nau Questionnaire | x | x |
| Demographics | x |  |
| ActivPAL | x | x |
| IPAQ-long | x | x |
| IPAQ | x | x |
| KOOS | x | x |
| 6MWT | x | x |
| 30 second chair test | x | x |
| 40 metre fast paced walk test | x | x |
| Legend: UCLA= University of California Los Angeles Physical Activity Questionnaire, IPAQ= International Physical Activity Questionnaire, KOOS= Knee Osteoarthritis Outcome Score, 6MWT= 6-minute walk test, IPAQ= International Physical Activity Scale |

**Sample size:**

We aim to recruit and analyse data for 10-12 participants per site, accounting for dropouts we will recruit 14 participants per site, totalling 42 participants.

**Qualitative participant interviews:**

Process evaluation will involve semi-structured interview invitations to all SUMIT (intervention) participants. Interviews will explore barriers and enablers to intervention effectiveness, potential intervention and study design improvements, and other factors that might influence physical activity participation. The interview topic guide (appendix 13) has been created by members of the author team, drawing on their knowledge and experience and previous behaviour change literature. Intervention participants will be invited to take part in a interviews after their 3-month follow-up assessment session. Interviews will take place on Zoom or via phone call (as preferred by the participant) and be recorded via Zoom and held on a password protected computer for transcription and data analysis purposes. Participants will be de-identified following the transcription process.

**Data management:**

Outcomes will be collected through REDCap online. Password protected access will be available to outcome assessors only. Consent forms will be signed in hard copy and scanned and uploaded online to password protected La Trobe servers (Research drive>CENTRE-SHE-LASEM>PROJECT-SHE-SUMIT). Hard copies will be held at La Trobe University (Bundoora) HS3 (room 508 for PICF or 403 for other de-identified data) for a minimum of 7 years following the completion of the trial. Qualitative interviews will be recorded via Zoom, recordings and transcriptions will be held on La Trobe University password protected servers (Research drive>CENTRE-SHE-LASEM>PROJECT-SHE-SUMIT) and will be compliant with Australia data protection law. To maintain confidentiality, data will be stored as de-identified but will be re-identifiable if required. Data will only be able to be accessed by trial staff (chief investigator, co-investigators and research assistant).

Any adverse events or complaints will be reported by either the treating physiotherapist or the participant to the research team or ethics committee, depending on the nature of the issue, and will be outlined in the PIS.

Any communication about adverse events is added to the participant’s REDCap record in the questionnaire “Adverse Events / Additional Information”.

**Allocation and Randomisation**

Following baseline assessment at Cabrini Health, participants will be randomised to intervention (SUMIT) or control (see figure 1). Any additional interventions for both groups (health professional consultation, medications, costs) will be monitored via a custom paper diary (appendix 14). An external person will generate the block (4-6) randomisation sequence using <https://www.sealedenvelope.com/> using a 1:1 ratio. Group allocations will be concealed in opaque envelopes that are sequentially numbered and remain unopened until the point of group allocation. Participants will be informed of their group allocation by the coordinating physiotherapist (EB). Due to the nature of the study, the outcome assessor is the only personnel able to be blinded to participant allocation.

Assessment for eligibility at Cabrini Health, Malvern

Excluded do not meet eligibility criteria

Physical assessment and questionnaires

Semi structured interviews

Allocated to intervention (n= 21)

 5 Motivational interviewing sessions

 Access to our multimedia physical activity website

Physical assessment and questionnaires

Allocated to intervention (n= 21)

 Usual care

 (Will receive access to our multimedia site after follow-up assessment)

## Allocation

## Follow-Up

Randomized (n=42)

## Enrolment

Screening prior to eligibility assessment (via phone)

Excluded do not meet eligibility criteria

## Screening

**Figure 1.** Participant flow chart.

**Planned Statistical Analysis**

Primary feasibility outcomes will be reported descriptively (table 3). Estimates of i) standard deviation of the secondary clinical outcomes; and ii) between-group differences with 95% confidence intervals in secondary clinical outcomes, will be calculated. All participants who complete baseline and follow-up will be included in analysis, following CONSORT guidelines.15

**Qualitative**

Interviews will be transcribed verbatim by a third-party transcription service, ‘Transcription Australia’. Qualitative analysis of the interview data will commence with a close review of each transcript by one researcher (research assistant) to gain an overall picture of the data. Data categories will be developed using inductive thematic analysis.4 This will be supported by NVivo software (QSR International Ptd Ltd, Melbourne, Australia) with one researcher will conduct the initial analysis (EB) with support from a senior researcher (CB). A random sample of 50% of interviews will be coded independently by a second researcher (PO) to substantiate the initial analysis. Themes will be discussed between researchers (EB, PO, CB) until a consensus is reached.

**Ethics**

**Research ethics approval**

Ethics approval will be sought from La Trobe University and a separate governance approval will be sought from Cabrini Health in line with requirements to receive grant funding.

**Protocol amendments**

If necessary, amendments will be communicated to relevant parties (investigators, ethics committees etc.) via email.

**Declaration of interests**

CI Barton is a director at Complete Sports Care. CI’s Bell and Wallis are employees at Cabrini Health. AI Gibbs is an employee at Access Community Health, Hawthorn.

**Ancillary and post-trial care**

No provision is in place for compensation as the intervention represents encouraging best practice for people with knee osteoarthritis. The control group will be provided with access to the website supporting the intervention group.

**Dissemination policy**

Findings will be reported in peer reviewed journal articles, conference presentations and via social media (e.g. *Twitter)*. Authorship for articles will be deemed appropriate for those who meet the International Committee of Medical Journal Editors (ICMJE) guidelines for authorship.

**Appendices:**

**Appendix 1- Exercise and Sports Screening Australia tool**

**Appendix 2- SUMIT Flyer**

**Appendix 3- Example of Recruitment Email**

**Appendix 4- Participant Informed Consent Form**

**Appendix 5- Outcome Assessment Example**

**Appendix 6- Sample Instruction Sheet for Fitting ActivPAL Device**

**Appendix 7- UCLA Physical Activity Scale**

**Appendix 8- IPAQ- Long**

**Appendix 9- KOOS**

**Appendix 10- EQ-5D-5L Sample**

**Appendix 11- 6MWT Protocol**

**Appendix 12- OARSI Functional Measures**

**Appendix 13- Topic Guide for Qualitative Interviews**

**Appendix 14- Participant Diary**

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