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Using Supported Motivational Interviewing (SUMIT) to increase physical activity for people with knee osteoarthritis. A pilot, feasibility randomised controlled trial.

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3 **Title:** Using Supported Motivational Interviewing (SUMIT) to increase physical activity for people
4 with knee osteoarthritis. A pilot, feasibility randomised controlled trial.
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1
2
3 **1 ABSTRACT**

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5 **2 Word count:** 278/300

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8 **3 Objective:** To determine the feasibility and effectiveness of using Supported Motivational
9 InTerviewing (SUMIT) to increase physical activity in people with knee osteoarthritis (KOA).

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11
12 **5 Design:** Randomised controlled trial.

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14
15 **6 Setting:** We recruited people who had completed Good Life with osteoArthritis Denmark from
16 private, public and community settings in Victoria, Australia.

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18
19 **8 Interventions:** Participants were randomised participants to receive SUMIT or usual care. SUMIT
20 comprised of five motivational interviewing sessions targeting physical activity over 10-weeks, and
21 access to a multimedia web-based platform.

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25 **11 Participants:** Thirty-two participants were recruited (17 SUMIT, 15 control) including 22 females
26 (69%).

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29
30 **13 Outcome measures:** Feasibility outcomes included recruitment rate, adherence to motivational
31 interviewing, ActivPAL wear and drop-out rate. Effect sizes (ES) were calculated for daily steps,
32 stepping time, time with cadence >100 steps per minute, time in bouts >1minute; 6-Minute walk
33 distance, Knee Osteoarthritis Outcome Score (KOOS) subscales (pain, symptoms, function, sport and
34 recreation, and quality of life (QoL)), Euroqual, systolic BP, BMI, waist circumference, 30-second
35 chair stand test, and walking speed during 40m walk test.

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41 **19 Results:** All feasibility criteria were achieved, with 32/63 eligible participants recruited over seven
42 months; with all participants adhering to all motivational interviewing calls and achieving sufficient
43 ActivPAL wear time, and only two drop-outs (6%).

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52 **22** 12/15 outcome measures showed at least a small effect (ES>0.2) favouring the SUMIT group,
53 including daily time with cadence >100 steps per minute (ES=0.43). Two outcomes, walking speed
54 (ES= 0.97) and KOOS QoL (ES=0.81), showed a large effect (ES>0.8).

55
56
57 **25 Conclusion:** SUMIT is feasible in people with knee osteoarthritis. Potential benefits included more
58 time spent walking at moderate intensity, faster walking speeds and better QoL.

59
60 **27 Trial registration:** The trial was registered with Australian New Zealand Clinical Trials Registry
(ANZCTR) (ACTRN12621000267853).

1
2
3 29 **Key words:** Physiotherapy, Rehabilitation, Comorbidities, Behaviour Change, Knee osteoarthritis,
4
5 30 Motivational Interviewing
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9 32 **Strengths and limitations of this study**

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11
12 33 • We modified our trial by increasing recruitment sites, advertising and reducing the
13 34 recruitment target number due to the impact of COVID-19 restrictions, and have reported
14 35 our trial according to the CONSERVE checklist to aide transparency.
15
16
17 36 • We used rigorous randomisation and assessment blinding procedures and accredited
18 37 motivational interviewing training and treatment fidelity so that our methods could be
19 38 repeated.
20
21
22 39 • Our ActivPAL analyses were completed by the same researcher who delivered the SUMIT
23 40 intervention which may present risk of unconscious bias. Future studies should provide a
24 41 provision for a blinded researcher to undertake data analysis.
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27 42 • Our participant groups were different as baseline, possibly due to the small sample size,
28 43 which may have impacted the findings for the secondary aims.
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46 INTRODUCTION

47 Physical activity participation has considerable health benefits.¹⁻³ Meeting physical activity guidelines
48 of at least 150-minutes per week of moderate-vigorous physical activity is considered vital to
49 reducing the risk of development or worsening of at least 35 chronic diseases.¹⁻⁴ For people with
50 knee osteoarthritis, less than half (41%) reached 150-minutes per week,⁵ compared to 73% of adults
51 in the general population.⁶ Knee osteoarthritis and insufficient physical activity are independently
52 associated with greater comorbidity risk, including cardiovascular disease, and earlier mortality.⁷⁻⁹

53 Patient education and exercise-therapy are recommended as first line treatments for knee
54 osteoarthritis in major guidelines,¹⁰ based on their effectiveness to reduce pain and improve knee
55 function.¹¹ Good Living with osteoArthritis from Denmark (GLA:D[®]) is a guideline-based education
56 and exercise-therapy program implemented in nine countries, including Australia.¹² Participation is
57 associated with clinically meaningful improvements in knee pain and joint-related quality of life at 3-
58 months, with these benefits sustained for at least 12 months.^{11,13} People with knee osteoarthritis
59 completing GLA:D[®] also report improved confidence to increase physical activity participation.¹⁴
60 However, completing GLA:D[®] is not associated with increased physical activity participation at 12-
61 months.^{14,15} This is consistent with a recent systematic review indicating exercise-therapy alone does
62 not result in medium (6-12 months) or long-term (>12-months) changes in physical activity
63 compared to non-exercise interventions.¹⁶

64 Increasing physical activity participation in people with knee osteoarthritis may require interventions
65 to address both physical and personal barriers, such as motivation and confidence.¹⁷ Motivational
66 interviewing is a person-centred behaviour change approach involving counselling style sessions
67 with a trained health professional, aiming to address personal barriers to behaviour change.¹⁸ It is
68 associated with moderate benefits for increasing physical activity in people with chronic health
69 conditions when they present to primary care.^{19,20} However in knee osteoarthritis, research on the
70 effects of motivational interviewing is limited. One study reported no increase in moderate-vigorous
71 physical activity compared to usual care in the short- or long-term.²¹ However, sessions were
72 infrequent (every 3-months), which is atypical for motivational interviewing interventions.²⁰ Phone
73 counselling targeting physical activity provided more frequently (biweekly) has been reported to
74 increase moderate-vigorous physical activity in the short-term (>3-months).²²

75 Digital support tools for osteoarthritis are emerging as a cost effective approach to provide
76 information and education, and assist people with osteoarthritis to engage with prescribed exercise
77 to improve patient outcomes.^{23,24} In addition to behaviour change interventions, such as
78 motivational interviewing, they can be used to monitor and/or promote physical activity, and may

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3 79 help to increase physical activity.²⁵ However, the influence of digital support tools on physical
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5 80 activity behaviour change is unknown.²⁵
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7 81 Our primary objective was to determine the feasibility of conducting a fully powered trial evaluating
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9 82 the effectiveness of increasing physical activity using Supported Motivational Interviewing (SUMIT),
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11 83 following completion of an education and exercise-therapy program in people with knee
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13 84 osteoarthritis. Our secondary objective was to determine if a worthwhile treatment effect occurred
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15 85 for physical activity, physical endurance, knee-related quality of life (QoL), health-related QoL and
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17 86 pain.
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20 88 **METHODS**

21 89 **Trial design**

22
23 90 This pilot feasibility randomised controlled trial (RCT) compared an intervention comprising
24
25 91 motivational interviewing and website) with a usual care control group. Ethics approval was
26
27 92 obtained from La Trobe University Human Research Ethics Committee (#HEC20506). The trial was
28
29 93 registered with Australian New Zealand Clinical Trials Registry (ANZCTR) (ACTRN12621000267853).
30
31 94 Study reporting adheres to the Consolidated Standards or Reporting Trials (CONSORT) for pilot and
32
33 95 feasibility trials.²⁶ Due to the interruption from the Coronavirus pandemic (COVID-19), we reported
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35 96 limitations according to the CONSORT and SPIRIT Extension for RCTs Revised in Extenuating
36
37 97 Circumstances (CONSERVE) guidelines.²⁷
38

39 98 **Setting**

40 99 All assessments were conducted at a private hospital in metropolitan Melbourne, Australia, or a
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42 100 private physiotherapy clinic in regional Victoria, Australia. All intervention sessions were completed
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44 101 online via Zoom or phone call (according to participant preference).
45

46 102 **Participants**

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48 103 Adults with a clinical diagnosis of knee osteoarthritis²⁸ who had completed GLA:D[®] within the
49
50 104 previous 2-years¹³ were recruited from March 2021 to April 2022. Participants were deemed
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52 105 ineligible if they i) had a comorbidity preventing them from increasing physical activity levels as
53
54 106 assessed by the Exercise and Sports Science Australia (ESSA) adult pre-screening tool;²⁹ ii) were not
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56 107 proficient in English; and/or iii) had back/ lower limb surgery or knee corticosteroid injection on the
57
58 108 affected limb within 12 months of enrolling.
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60 109 **Deviations from protocol**

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3 110 During piloting, participants did not have a good understanding of motivational interviewing prior to
4
5 111 the intervention. For this reason, the Borcovek and Nau acceptability questionnaire³⁰ (Appendix 1)
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7 112 was removed from the protocol prior to randomisation commencement, as this tool was deemed to
8
9 113 be unclear when answering questions about motivational interviewing. Our protocol indicated the
10
11 114 inclusion of pain and QoL subscales from the Knee Osteoarthritis Outcome Score (KOOS), however
12
13 115 all five domains were included to give us a more detailed understanding of intervention outcomes.

14 116 Recruitment was impacted by the COVID-19 related government restrictions, including limitations on
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16 117 in-person healthcare, gymnasium closures and limitations in allowable time away from personal
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18 118 residence for 25-weeks in 2021. As a result, we expanded the recruitment timeframe from within
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20 119 one-year of completing GLA:D[®] to within two-years. Lockdowns posed a risk of bias to either reduce
21
22 120 (less incidental activity) or amplify (more time for exercise) our intervention. Participants who were
23
24 121 impacted by lockdown at baseline during ActivPAL collection had their ActivPAL reapplied prior to
25
26 122 group allocation.

26 123 **Randomisation and blinding**

27
28 124 Participants were randomised using a computer-generated program with a 1:1 ratio in permuted
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30 125 blocks of 4-6 and stratified by sex. Randomisation was prepared by a member of the research team
31
32 126 not involved in assessment (MFP). Group allocations were concealed in sequentially numbered
33
34 127 opaque envelopes, sealed until the point of group allocation. Participants were informed of their
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36 128 group allocation by the coordinating physiotherapist (ECB). Due to the nature of the study, the
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38 129 outcome assessor was the only person able to be blinded to participant allocation.

39 130 **Intervention**

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42 131 *Motivational interviewing:* All participants randomised to the SUMIT group received five, 30-minute
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44 132 sessions of motivational interviewing over a 10-week period. Sessions were conducted in weeks 1, 2,
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46 133 4, 7, and 10 by an investigator trained in motivational interviewing (ECB). ECB had 5-years of
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48 134 experience as a physiotherapy clinician, completed a two-day motivational interviewing course
49
50 135 online and five 1:1 coaching sessions with a Motivational Interviewing Network Trainer (MINT) and
51
52 136 accredited psychologist (PO). ECB was graded proficient according to the Motivational Interviewing
53
54 137 Treatment Integrity (MITI) assessment tool.³¹

54 138 Motivational interviewing sessions involved collaboration between clinician and participant aiming
55
56 139 to evoke behaviour change to increase physical activity (Appendix 2). Consistent with the principles
57
58 140 of motivational interviewing,¹⁴ sessions followed recommended motivational interviewing
59
60 141 processes: engagement; focusing; evoking; and planning; and were tailored to individual needs and

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3 142 level of preparedness for behaviour change (Appendix 2). Participant importance and confidence of
4
5 143 engaging in physical activity was discussed over the course of the intervention, providing valuable
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7 144 information about shifts in potential barriers and facilitators to activity.¹⁴

8
9 145 *Digital Support Tool:* All participants were encouraged to access the same customised website
10
11 146 (<https://sumit.trekeeducation.org/>) prior to their first motivational interviewing session. The website
12
13 147 included information about physical activity, knee osteoarthritis, goal setting, research and activities,
14
148 and patient stories.

15 149 **Control**

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18 150 The control group (usual care) received no additional interventions or access to the digital support
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20 151 tool. They were permitted to engage in routine services for their knee osteoarthritis management
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22 152 including visits to their general practitioner, physiotherapist or other health professionals.

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24 153 Participants were asked to refrain from knee steroid injections or surgery during the trial. At the
25
26 154 conclusion of the follow-up assessments, control participants were emailed the digital support tool
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28 155 to access if they chose.

29 156 **Outcomes**

30 157 ***Primary: feasibility***

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34 158 The trial was considered feasible if all criteria were met or if reasonable amendments could be made
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36 159 to achieve these criteria in future trials (Table 1a). Recruitment, adherence and retention were
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38 160 calculated excluding the 6-months of COVID-19 related government restrictions during 2021.

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41 **Table 1a.** Measures of feasibility

42 Item	43 Measure of feasibility
44 Number of eligible volunteers	45 Minimum 2-3 participants per site, per month. Totalling 6-9 46 participants being eligible per month.
47 Recruitment rate	48 Minimum 2 participant per site, per month. Totalling 6 49 participants recruited per month.
50 Adherence with motivational 51 interviewing sessions	52 Minimum attendance of 4/5 sessions (80%).
53 ActivPAL use	54 Measured by time worn per participant being >16 hours per day 55 for seven days (to account for waking hours).
56 Drop-out rate	57 <20% of participants drop out of the study.

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3 162 **Adverse events**
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5 163 Participants were asked if they had experienced any adverse events (any injury or illness requiring
6 164 medical attention as a result of participating in the trial) at the 3-month assessment.
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9 165 **Sample size**
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11 166 To test feasibility, we aimed to recruit 42 participants over 5-7 months, which accounting for
12 167 dropouts would allow analysis of at least 33 participants.
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15 168 **Secondary**
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17 169 Secondary outcomes were collected at baseline and 3-months after baseline data collection.
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20 170 **Device-measured physical activity**
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22 171 ActivPAL accelerometers (PAL Technologies, Glasgow, Scotland) were fitted to each participant's
23 172 right thigh with gauze and clear Flexifix for seven days. They are reliable and valid measures of step
24 173 count and cadence,³² accurate in older adults,³³ and do not to provide feedback to participants. We
25 174 extracted average steps, minutes with cadence >100 steps per minute,³⁴ and minutes where bouts
26 175 were >1min in duration per day. Walking cadence >100 steps per minute was chosen as an outcome
27 176 since it predicts lower premature mortality in older adults.³⁵
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33 177 **Self-reported physical activity**
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35 178 To triangulate accelerometer results, we also recorded physical activity using the University of
36 179 California Los Angeles (UCLA) Physical Activity Scale, and the International Physical Activity
37 180 Questionnaire long form (IPAQ-long). UCLA is a reliable and valid tool³⁶ commonly used as a measure
38 181 of physical activity participation in knee osteoarthritis.^{13-15,37} and the IPAQ long provides valuable
39 182 information about the domain in which PA is undertaken.
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45 183 **Physical endurance**
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47 184 Physical endurance was measured using 6-minute walk distance (6MWD), measured in metres,
48 185 which is reliable and valid.³⁸
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51 186 **Knee-related burden**
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53 187 The Knee Injury Osteoarthritis Outcome Score (KOOS) was used to measure knee pain, symptoms,
54 188 function, sport and recreation and QoL.³⁹ The questionnaire produces a score from 0-100 for each
55 189 subscale, higher scores indicate lower burden. All subscales have high reliability and validity.³⁹
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59 190 **Health-related quality of life**
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3 191 The Euro QoL 5-dimension-5 long (EQ-5D-5L) was used to measure participants health-related QoL
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5 192 through five domains, is reliable, valid and responsive in osteoarthritis populations, with the index
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7 193 score ranging from 1 or less, with 1 being optimal health, and negative values indicating a health
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9 194 state worse than death.^{40,41}

11 195 **General health**

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13 196 Body mass index (BMI) (kg/m²), waist circumference (cm) and systolic blood pressure (BP) (mmHg)
14
15 197 were all recorded by a blinded research assessor.

17 198 **Functional performance**

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19 199 The 30-second chair stand, and walking speed (40m walk) tests are both recommended by guidelines
20
21 200 as feasible and reliable performance measures for knee osteoarthritis.⁴²

23 201 **Confidence and importance of physical activity**

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25 202 SUMIT participants were asked in weeks 2 and 10 to rate their confidence and perceived importance
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27 203 of changing physical activity participation on a scale from zero to 10: where zero is not at all
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29 204 important/confident and 10 is maximum importance/confidence.

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31 205 Demographic data collected at baseline via Research Electronic Data Capture (REDCap) included age,
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33 206 sex, body mass index, knee most affected, medication use, employment, and highest level of
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35 207 education. An excel spreadsheet was set up to record adverse events.

36 208 **Statistical Analysis**

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39 209 Statistical analysis was performed using Statistical Package for the Social Services (SPSS) version 28
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41 210 (SPSS, Inc, Chicago, IL, USA). Demographics were reported as frequencies or mean (SD). Feasibility
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43 211 outcomes were reported descriptively. Between group changes for continuous variables were
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45 212 calculated using analysis of covariance (ANCOVA) with Bonferroni adjustment and baseline measures
46
47 213 as covariates.

48
49 214 The UCLA physical activity scale was dichotomised as 'more' and 'less' active, consistent with other
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51 215 similar studies.^{14,37} We defined 'less active' as a score of ≤ 6 ('Regularly participates in moderate
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53 216 activities, such as swimming and unlimited housework or shopping'); and defined 'more active' as ≥ 7
54
55 217 ('Regularly participates in active events such as bicycling') (Appendix 3). Chi-square tests for
56
57 218 independence (χ^2) were used to compare groups for the UCLA physical activity scale (dichotomous).

58
59 219 Desired treatment effects were defined using minimum detectable changes (MDC), which were set
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220 as 8-10 for all KOOS subscales,⁴³ 75m for 6MWD,⁴⁴ 0.07 for health-related QoL,⁴⁰ 2 stands for 30-

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3 221 second chair stand test,⁴⁵ and 0.19 metres per second for 40m walk test.⁴⁵ There is no documented
4 222 MDC for device-measured physical activity, the IPAQ-long, UCLA physical activity scale, BMI, blood
5 223 pressure or waist circumference. Standardised mean differences (effect sizes) based on within group
6 224 changes between SUMIT and control groups were calculated using Review Manager 5.3 (The Nordic
7 225 Cochrane Centre, Copenhagen, Denmark).
8
9 226 Confidence and importance of physical activity were reported descriptively at 2 and 10-weeks as
10 227 mean (SD) using a paired t-test to confirm significance.
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18 229 **RESULTS**19 230 **Primary outcome**20 231 All feasibility criteria were met or could be achieved by using reasonable amendments in future trials
21 232 (Table 1b).
2223 233 Eligibility and recruitment rates were impacted by oscillating COVID-19 lockdowns in Melbourne,
24 234 Australia. We expanded recruitment timeframes (from completing GLA:D[®] within 12-months,
25 235 adjusted to 24-months), and recruitment sites (from three sites to anywhere in Melbourne, Torquay
26 236 or Ballarat, in Victoria, Australia) to increase our yield. Despite this, very few GLA:D[®] programs were
27 237 running effectively until April 2022. We subsequently concluded recruitment at 32 participants
28 238 (instead of 42) (Figure 1).
2930 239 Sixty-nine percent (n=22) of participants were female. Mean (SD) for BMI and waist circumference
31 240 were 30.8 (6.5) kg/m² and 101.6 (14.3) cm respectively. A full summary of the characteristics of
32 241 included participants is provided in Table 2.
33
3435 242 Two (6%) participants dropped out of the trial prior to receiving their group allocation. One
36 243 participant cited concern to be in public places due to the high ongoing risk of contracting COVID-19
37 244 and the other cited lack of time. One participant from the SUMIT group was not able to complete
38 245 their follow-up ActivPAL collection due to COVID-19 lockdown timing and subsequent need for
39 246 surgery, missing the follow-up period. Two participants at baseline and four participants at follow-up
40 247 were undergoing ActivPAL monitoring at a time when new movement restrictions were announced
41 248 (i.e. COVID-19 lockdowns). In these instances, monitoring was ceased, then restarted following the
42 249 removal of movement restrictions.
4344 250 No participants in either group experienced any adverse events as a result of data collection or the
45 251 intervention during the trial. Two participants in the SUMIT group reported back pain prior to the
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252 trial and continued to experience back pain during the intervention period. One participant in the
 253 SUMIT group had a fall one week prior to follow-up, reducing their ability to participate in physical
 254 activities during the ActivPAL recording week.

255 **Table 1b.** Feasibility outcomes

	Criterion	Achieved	Proceed	Proceed with amendments
Eligibility				
Number of eligible participants	2-3 per site, per month, totalling 6-9 per month	63 participants screened in 7 months accounting for lockdowns and community restrictions in Melbourne (13 months elapsed)	Yes*	Strategies to identify more eligible participants.
Recruitment				
Number of participants recruited	2 participants per month, per site, totalling 6 participants per month	32 participants recruited over 7 months (13 months elapsed)	No	Strategies to increase recruitment rate.
Adherence				
Adherence to motivational interviewing sessions	Minimum 4/5 sessions (80%)	100% of motivational interviewing sessions were attended within 1 week of scheduled session time	Yes	-
ActivPAL				
ActivPAL wear time	>16 hours for 7 days	Malfunctioning ActivPAL uploads resulted in 3 missing ActivPAL files.	Yes	-
Drop-outs				
Drop-out rate	<20%	2 drop-outs (6%), both from the control group	Yes	-

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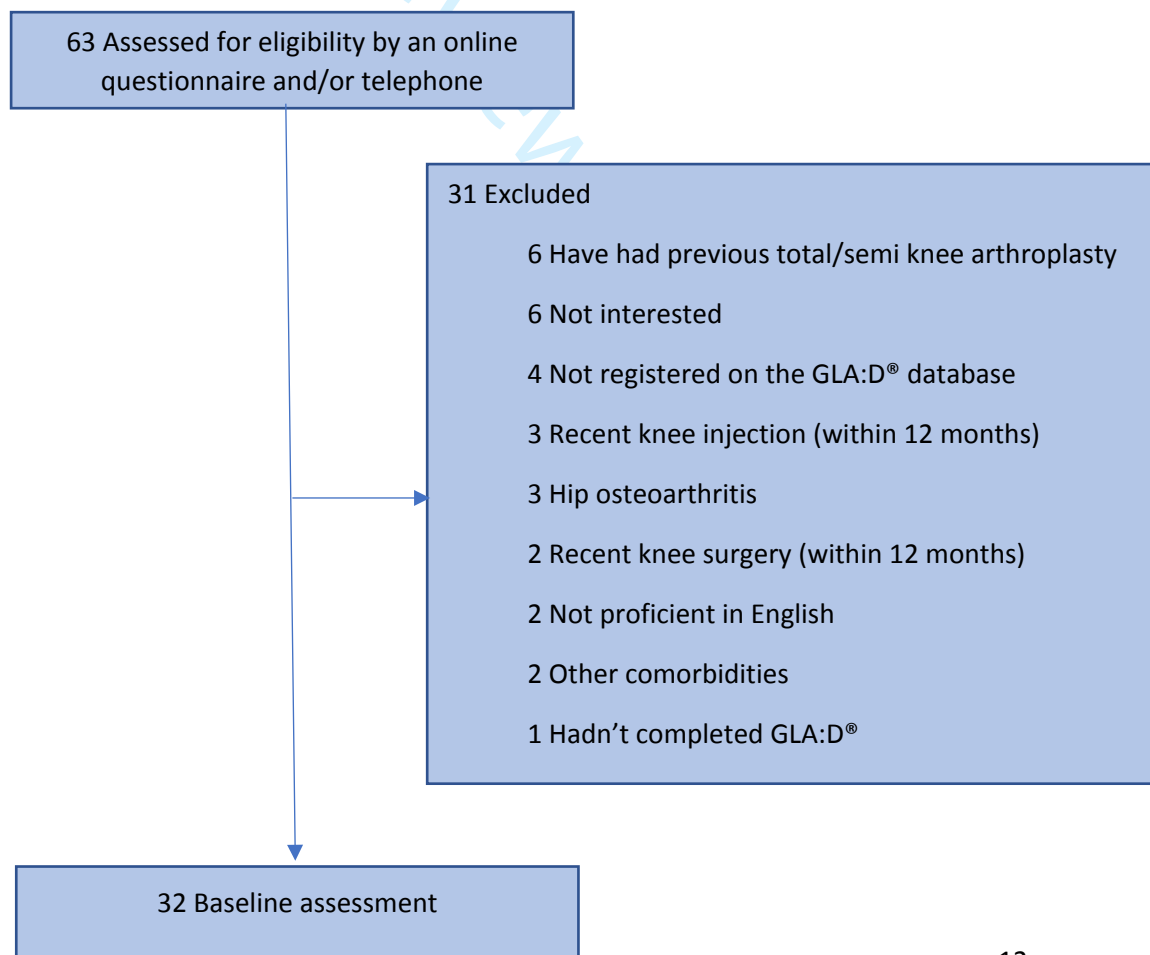
257 *= Proceed with protocol deviation to expand the number of recruitment sites.

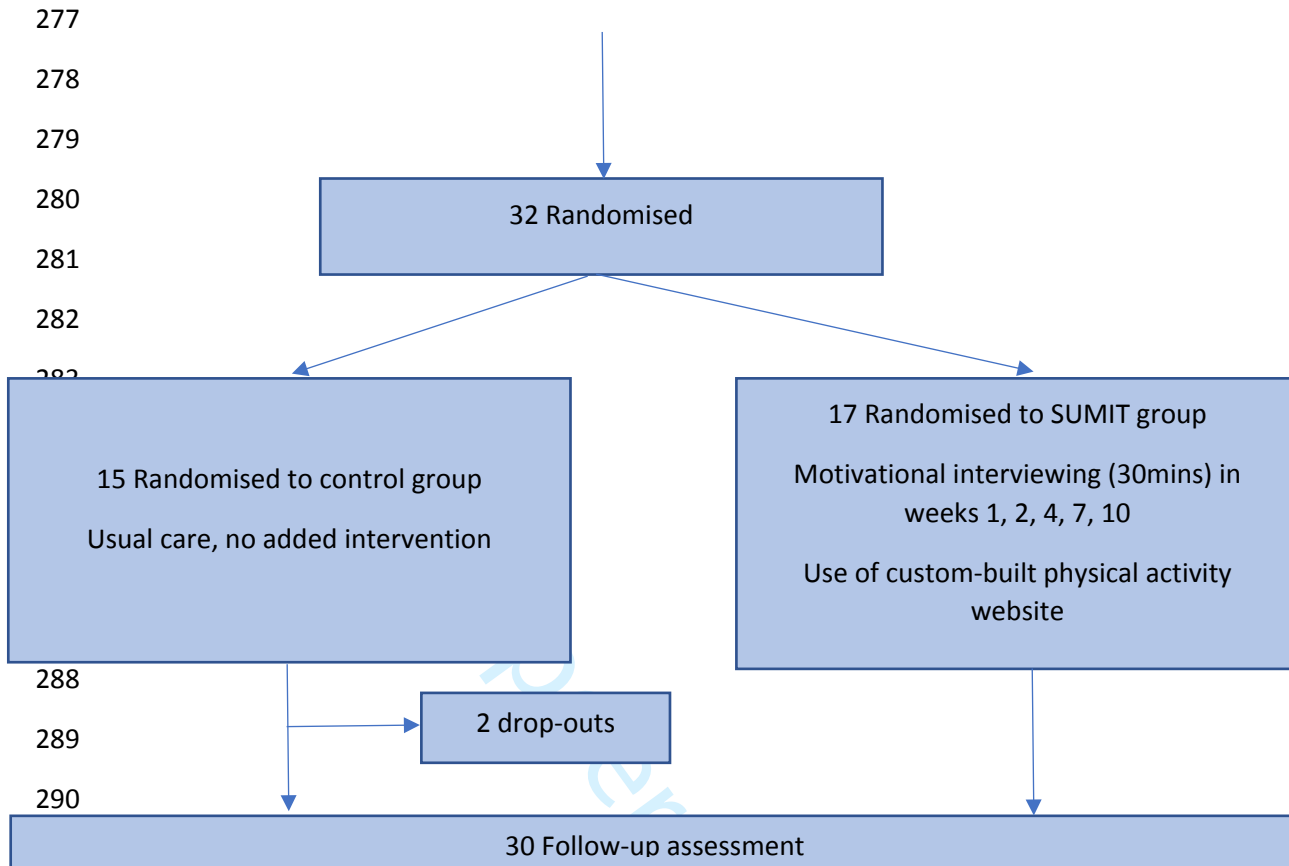
258 **Table 2.** Characteristics of included studies

	Combined Mean (SD) n=32	SUMIT Mean (SD) n=17	Control Mean (SD) n=15
Age, years	71 (7)	68 (5)	73 (9)
Sex, female, n (%)	22 (69%)	11 (65%)	11 (73%)
Height, m	1.69 (0.09)	1.69 (0.09)	1.69 (0.10)
Weight, kg	87 (17)	92.9 (17.6)	79.4 (13.4)
Recruitment			
<i>Private practice</i>	22	14	8
<i>Hospital</i>	7	3	4
<i>Community</i>	3	0	3
Education			
<i>Completed primary school</i>	1	0	1
<i>Completed high school</i>	2	1	1
<i>Completed an apprenticeship</i>	0	0	0
<i>Completed certificate</i>	4	1	3
<i>Completed diploma</i>	2	1	1
<i>Completed undergraduate degree</i>	10	4	6
<i>Completed postgraduate degree</i>	9	4	5
<i>Not reported</i>	4	4	0

Legend: SD= standard deviation, n= number of participants, m= metre, kg= kilogram, kg/m²= kilogram per metre square, cm= centimetres

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31 **Figure 1.** Timeline

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33 **Secondary outcomes**

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36 294 The desired treatment effect was contained within the 95%CI for all KOOS subscales, health-related
37 295 QoL, and walking speed (Table 3, Appendices 7-10). A MDC was achieved for KOOS pain and QoL
38 296 subscales, and health-related QoL (Table 3, Appendices 7a, 7e, 8). The desired treatment effect was
39 297 not met for 6MWD or 30 second chair stand test (Table 3, Appendices 6, 10b). Detailed findings are
40 298 provided in Appendices 4-10.

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44 299 Ten of the thirteen outcome measures (Figure 2a) and two of the three health outcomes (Figure 2b)
45 300 showed at least a small effect favouring the SUMIT group, including two outcomes (walking speed
46 301 and KOOS quality of life) showed a large effect.

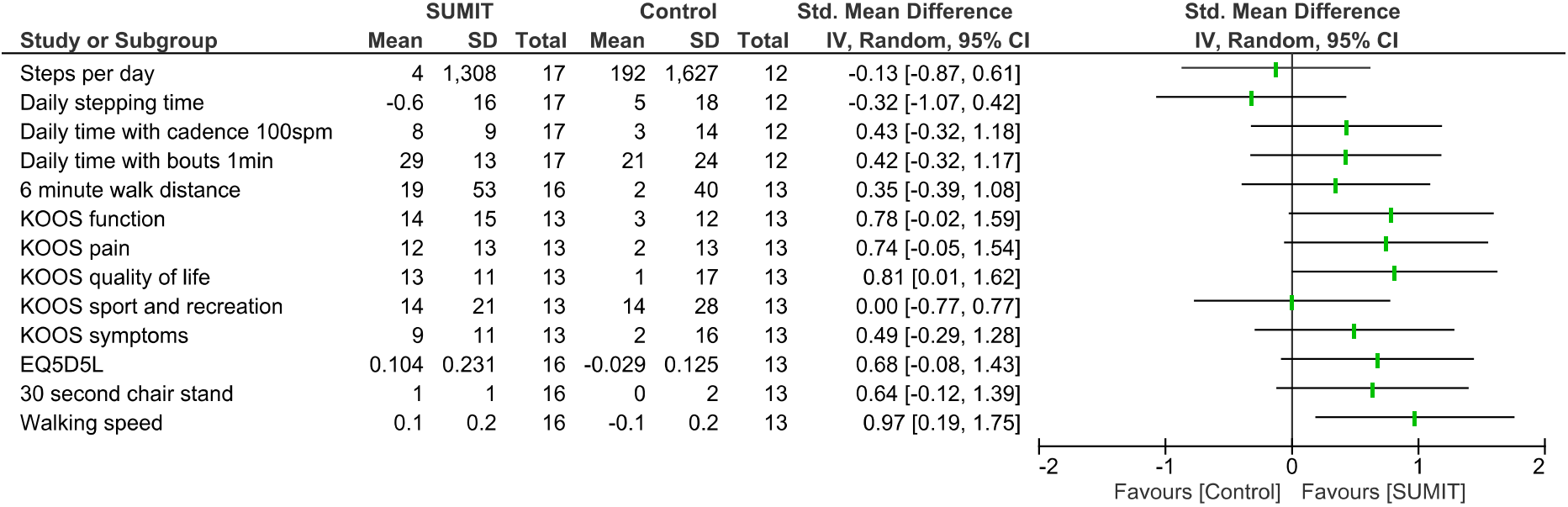
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50 302 For the SUMIT group, both perceived confidence and importance of participating in regular physical
51 303 activity improved between week 2 and week 10, mean (SD): 7.1 (2.2) to 8.8 (0.8) ($p=0.002$) and 8.6
52 304 (0.8) to 9.4 (0.9) ($p=0.006$) respectively.

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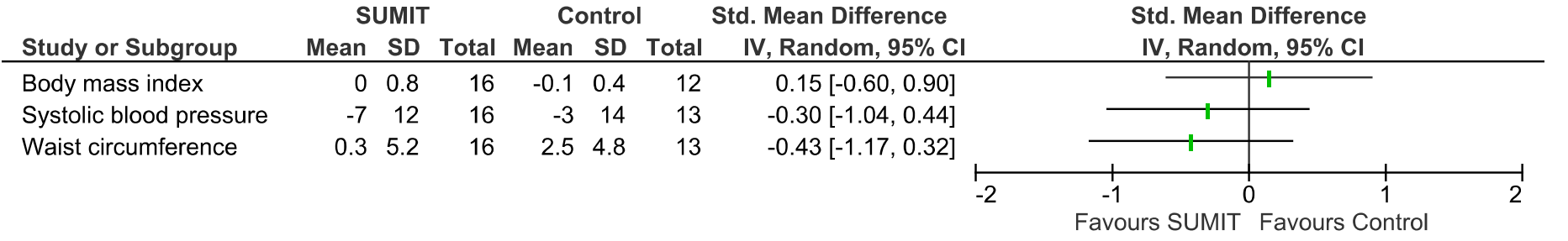


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308 **Figure 2a.** Forest plot comparing within group change scores between SUMIT and control groups

309 Legend: spm= steps per minute, min= minute, KOOS= Knee Osteoarthritis Outcome Score, EQ5D5L= Euroqual 5-dimension 5-long

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312 **Figure 2b.** Forest plot comparing within group change scores between SUMIT and control groups for health outcomes

313 **Table 3.** Within and between group differences for all secondary outcomes

Outcome	Within group differences			Within group differences			Between group differences	
	Week 0 SUMIT Mean (SD) n=17	Week 12 SUMIT Mean (SD) n=17	Week 12 minus Week 0 SUMIT MD (SD) n=17	Week 0 Control Mean (SD) n=13	Week 12 Control Mean (SD) n=13	Week 12 minus Week 0 Control MD (SD) n=13	Week 12 SUMIT minus control MD (95%CI), p- value	Previously published MDC values
Steps per day	7209 (3159)	7213 (2681)	4 (1308)	7484 (2903)^	7676 (2773)^	192 (1627)^	-247 (-1264 to 769), 0.62	N/A
Daily stepping time	92 (37)	92 (32)	-0.6 (16)	98 (37)^	103 (40)^	5 (18)^	-7 (-19 to 6), 0.30	N/A
Daily time with cadence >100spm	7 (9)	15 (12)	8 (9)	7 (9)^	10 (10)^	3 (14)^	5 (-0.4 to 11), 0.67	N/A
Daily time with bouts >1min	23 (19)	52 (20)	29 (13)	23 (19)^	44 (29)^	21 (24)^	8 (-6 to 21), 0.27	N/A
IPAQ bike	21 (42)^	8 (30)^	-13 (55)^	9 (33)	0 (0)	-9 (33)	8 (-9 to 26), 0.35	N/A
IPAQ walk	299 (507)^	187 (224)^	-112 (556)^	205 (387)	171 (370)	-34 (72)	-11 (-220 to 197), 0.91	N/A
IPAQ gardening (vig)	84 (178)^	41 (95)^	-43 (196)^	92 (198)	83 (96)	-9 (198)	-41 (-115 to 32), 0.26	N/A
IPAQ gardening (mod)	252 (429)^	61 (83)^	-191 (398)^	156 (253)	157 (186)	1 (328)	-101 (-209 to 7), 0.07	N/A
IPAQ housework	215 (359)^	217 (318)^	2 (144)^	353 (301)	167 (225)	-187 (368)	123 (-50 to 297), 0.16	N/A
IPAQ leisure walking	94 (140)^	157 (236)^	63(245)^	142 (210)	183 (91)	41 (183)	-12 (-154 to 130), 0.89	N/A

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3	IPAQ leisure (vig)	37 (52)^	27 (72)^	-10 (47)^	39 (81)	5 (17)	-35 (73)	23 (-14 to 59), 0.21	N/A
4									
5	IPAQ leisure (mod)	15 (30)^	52 (76)^	37 (75)^	51 (98)	59 (78)	8 (110)	2 (-59 to 62), 0.96	N/A
6									
7									
8	6MWD, m	484 (114)^	503 (102)^	19 (53)^	525 (97)	527 (106)	2 (40)	11 (-25 to 48), 0.52	75m ⁴⁴
9									
10									
11	KOOS pain	67 (16)^	79 (15)^	12 (13)^*	74 (14)	76 (14)	2 (13)	8 (-3 to 18), 0.14*	8 to 10 points ⁴³
12									
13	KOOS symptoms	65 (12)^	74 (13)^	9 (11)^	74 (11)	77 (14)	2 (16)	2 (-9 to 13), 0.73	8 to 10 points ⁴³
14									
15	KOOS function	70 (19)^	83 (12)^	14 (15)^	78 (12)	81 (15)	3 (12)	7 (-3 to 16), 0.16	8 to 10 points ⁴³
16									
17	KOOS sport and recreation	37 (19)^	52 (21)^	14 (21)^	45 (29)	58 (29)	14 (28)	-2 (-20 to 16), 0.81	8 to 10 points ⁴³
18									
19	KOOS QoL	47 (20)^	60 (20)^	13 (11)^*	54 (18)	55 (20)	1 (17)	10 (-2 to 22), 0.09*	8 to 10 points ⁴³
20									
21									
22	EQ5D	0.69 (0.22)^	0.79 (0.12)^	0.10 (0.23)^*	0.77 (0.10)	0.74 (0.11)	-0.03 (0.13)	0.07 (-0.03 to 0.16), 0.15	0.07 ⁴⁰
23									
24	Body mass index, kg/m²	33 (7)^	33 (6)^	0.0 (0.8)^	28 (6)	28 (6)	-0.1 (0.4)	0.3 (-0.2 to 0.8), 0.23	N/A
25									
26	Systolic blood pressure, mmHg	138 (15)^	131 (11)^	-7 (12)	135 (10)	132 (15)	-3 (14)	-3 (-11 to 6), 0.56	N/A
27									
28	Waist circumference, cm	106 (14)^	106 (14)^	0.3 (5.2)^	95 (13)	98 (13)	2.5 (4.8)	-1.4 (-5.6 to 2.7), 0.47	N/A
29									
30	30 second chair stand test	12 (2)^	12 (3)^	1 (1)^	12 (2)	12 (2)	0 (2)	0.5 (-0.8 to 1.7), 0.44	2 stands ⁴⁵
31									
32	Walking speed, m/s	1.5 (0.3)^	1.7 (0.4)^	0.1 (0.2)	1.7 (0.5)	1.7 (0.4)	-0.1 (0.2)	0.15 (-0.01 to 0.31), 0.06	0.19 m/s ⁴⁵
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3 **Legend:** MD= mean difference, MDC= minimal detectable change, CI= confidence interval, mins= minutes, spm= steps per minute, mmHg= millimetres of mercury,
4 kg/m²,kilogram per metre squared, cm= centimetres, m/s= metres per second, m= metres, IPAQ= International Physical Activity Questionnaire, vig= vigorous, mod=
5 moderate, N/A= not applicable, **bold** denotes confidence intervals which include the defined minimal detectable change, *= mean difference achieved a minimal
6 detectable change
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For peer review only

315 **DISCUSSION**

316 Our findings suggest that it is feasible to proceed to a large-scale RCT to evaluate the effectiveness
317 of motivational interviewing, supported by a digital support tool, on physical activity in people with
318 knee osteoarthritis. All feasibility criteria were either met or could be reasonably altered to be met
319 in future trials. Of those who were screened, more than half were eligible (59%), with a modest
320 recruitment rate achieved (4 per month). The drop-out rate was 6% which is considered
321 acceptable.⁴⁶ However, community restrictions including lockdowns imposed in Melbourne during
322 the trial ⁴⁷ led to the need to broaden recruitment sources, and delays to assessments. Notably, the
323 number of GLA:D[®] completers dramatically reduced during our recruitment period due to
324 restrictions on in-person care, an unlikely problem in future trials. Our adherence was high (100%),
325 which may be attributed to the flexibility of the booking schedule and options (phone or Zoom)
326 provided, a feature that should be adopted in future trials.

327 The desired treatment effects potentially favouring the intervention in this pilot study were
328 contained within the 95% CI for most clinical outcomes. However, steps per day and daily stepping
329 time outcomes favoured the control group. This should be considered in the context of greater
330 improvement in walking speed (40m walk test) and fitness (6MWD) at follow up and increased time
331 spent walking at a cadence of >100 steps per minute or completing daily bouts of physical activity >1
332 minute during the intervention period for the SUMIT group. Combined, these findings may indicate
333 the intervention led to capacity to cover ground in less time, and possible improvement in moderate
334 intensity physical activity following the intervention.³⁴ The SUMIT group reached an average of 15-
335 minutes per day walking with a cadence >100 steps per minute at 3-months, reaching the threshold
336 to reduce all-cause mortality.⁴⁸

337 Additional outcomes favouring the intervention group with moderate to large effects included KOOS
338 symptoms, pain, function and QoL, EQ-5D-5L, 30-second chair stand test, and systolic blood
339 pressure. Health-related QoL and blood pressure are particularly notable as they indicate that the
340 intervention may be associated with improved general health, which would need to be tested in a
341 larger trial. The large effect observed in favour of the SUMIT group for KOOS QoL may be related to
342 benefits experienced due to motivational interviewing or could be related to regular contact with a
343 health professional during COVID-19.

344 While our study showed promising effect sizes favouring the intervention, it was not powered to find
345 between group differences. The lack of between group differences may also be accounted for by
346 differences in baseline characteristics which favoured our control group. There is no recommended
347 dose for motivational interviewing,²⁰ however, it is possible that our intervention did not include

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2
3 348 enough sessions to see a substantial difference between groups. Our intervention included five
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5 349 sessions compared to other studies which have reported that eight weekly motivational interviewing
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7 350 calls resulted in meaningful differences in people with hip fractures.⁴⁹ It is possible that our
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9 351 participants' physical activity was influenced by COVID-19 restrictions/lockdowns.⁵⁰ The impact may
10
11 352 have had mixed effects, including physical activity was negatively influenced by lower incidental
12
13 353 activities, and safety concerns of being outside the home.⁵¹ Conversely, physical activity may have
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15 354 increased for others during COVID-19 restrictions due to increased time and opportunity to access
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17 355 outside activities.⁵¹ Our results contrast another motivational interviewing RCT which reported no
18
19 356 difference in physical activity between groups,²¹ however improvements in pain and function were
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21 357 consistent with our findings and may be explained by our motivational interviewing sessions being
22
23 358 delivered closely together, allowing participants to reinforce behaviour change more effectively.

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25 359 Findings of our study should be interpreted within the context of it's strengths and limitations. We
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27 360 modified our trial by increasing recruitment sites, advertising and reducing the recruitment target
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29 361 number due to the impact of COVID-19 restrictions, and have reported our trial according to the
30
31 362 CONSERVE checklist to aide transparency. At baseline, our participants in both groups were
32
33 363 completing 7,000 to 7,500 steps which may be already adequate to maintain good health,⁵² and
34
35 364 potentially challenging to increase. However, further increases from this relatively high baseline are
36
37 365 still likely to improve health,^{53,54} and increasing cadence^{53,54} during walking as occurred in our
38
39 366 intervention group also provides additional benefits. Our participant groups were different as
40
41 367 baseline, possibly due to the small sample size, which may have impacted the findings for the
42
43 368 secondary aims. We used rigorous randomisation and assessment blinding procedures and
44
45 369 accredited motivational interviewing training and treatment fidelity so that our methods could be
46
47 370 repeated. Our ActivPAL analyses were completed by the same researcher who delivered the SUMIT
48
49 371 intervention which may present risk of unconscious bias. Future studies should provide a provision
50
51 372 for a blinded researcher to undertake data analysis.

52
53 373 Our pilot feasibility trial allowed us to identify areas for improvement in a large-scale RCT. Partnering
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55 374 with high volume GLA:D® clinics would enable early identification of eligible participants, and direct
56
57 375 recruitment for completers. Trial advertising may increase the number of potential participants self-
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59 376 identifying and being screened. Our intervention may be improved by introducing adjunct
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377 accountability methods such as a downloadable self-monitoring tool (e.g. spreadsheet via our SUMIT
378 digital support tool) or formal goal setting tools.⁵⁵ We recommend that future trials use a longer
379 follow-up period to track effectiveness of the intervention on physical activity. Adding booster
380 motivational interviewing sessions have effectively increased physical activity in other
381 musculoskeletal conditions,⁵⁶ and are encouraged in future knee osteoarthritis trials.⁵⁷

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5 383 **CONCLUSION**

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7 384 Our study found that motivational interviewing and a web-based multimedia platform are feasible to
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9 385 target physical activity in people with knee osteoarthritis. Secondary findings indicate this
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11 386 intervention may be associated with improved moderate physical activity, but this requires testing in
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13 387 a larger high-quality RCT. We have provided recommendations to improve future trials including
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15 388 refining recruitment strategies, reducing participant burden, and optimising motivational
16
17 389 interviewing dose.

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19
20 391 **Author contributions:** Ms Bell and Associate Professor Barton take responsibility for the integrity of
21
22 392 the data and correctness of the data analysis. Ms Bell is a PhD candidate and this trial is contributing
23
24 393 to her doctoral dissertation.

25
26 394 Concept and Design: ECB, CJB, PO, JAW

27
28 395 Acquisition of the data: ECB, research assistants

29
30 396 Analysis or interpretation of the data: All

31
32 397 Drafting of the manuscript: ECB, PO, JAW, CJB, KMC

33
34 398 Critical revision of the manuscript: All

35
36 399 Obtained funding: All

37
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39
40 401 relation to this study.

41
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43
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45
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47
48 405 Trobe University.

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50 406 **Role of the Funder:** Funders had no role in the design and conduct of the study; collection,
51
52 407 management, analysis and interpretation of the data; preparation, review or approval of the
53
54 408 manuscript or decision to submit the manuscript for publication.

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2
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6
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8
9 412 **Data sharing:** Data are available upon request from ECB (E.Bell@latrobe.edu.au). This includes de-
10
11 413 identified quantitative outcomes which are available for 7 years for use before they are destroyed
12
13 414 according to ethics requirements. Data may be used for systematic reviews or secondary analyses.

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16 416 **REFERENCES**

- 17
18 417 1. Caspersen C, Powell K, Christenson G. Physical activity, exercise, and physical fitness:
19 418 definitions and distinctions for health-related research. *Public Health Rep.* 1985;100:126-131.
20
21 419 2. Booth F, Roberts C, Laye M. Lack of exercise is a major cause of chronic diseases. *Compr*
22 420 *Physiol.* 2012;2(2):1143-1211. doi:10.1002/cphy.c110025
23 421 3. World Health Organization. Global health risks: mortality and burden of disease attributable
24 422 to selected major risks. *Geneva: WHO Press.* 2009;
25 423 4. Booth F, CK. R, Laye M. Lack of exercise is a major cause of chronic diseases. *Compr Physiol.*
26 424 2012;2:1143-1211. doi:<https://doi.org/10.1002/cphy.c110025>
27 425 5. Wallis JA, Webster KE, Levinger P, Taylor NF. What proportion of people with hip and knee
28 426 osteoarthritis meet physical activity guidelines? A systematic review and meta-analysis.
29 427 *Osteoarthritis Cartilage.* 2013;11:1648-59. doi:10.1016/j.joca.2013.08.003
30
31 428 6. Australian Bureau of Statistics. Physical activity.
32 429 [https://www.abs.gov.au/statistics/health/health-conditions-and-risks/physical-activity/latest-](https://www.abs.gov.au/statistics/health/health-conditions-and-risks/physical-activity/latest-release)
33 430 [release](https://www.abs.gov.au/statistics/health/health-conditions-and-risks/physical-activity/latest-release)
34 431 7. Wallis JA, Webster KE, Levinger P, J. SP, Fong C, F. TN. Perceptions about participation in a
35 432 12-week walking program for people with severe knee osteoarthritis: a qualitative analysis. *Disabil*
36 433 *Rehabil.* 2017;30:1-7. doi:10.1080/09638288.2017.1408710
37 434 8. Veronese N, Cereda E, Maggi S, et al. Osteoarthritis and mortality: A prospective cohort
38 435 study and systematic review with meta-analysis. *Semin Arthritis Rheum.* 2016;46(2):160-7.
39 436 doi:10.1016/j.semarthrit.2016.04.002.
40
41 437 9. Nüesch E, Dieppe P, Reichenbach S, Williams S, Iff S, Jüni P. All cause and disease specific
42 438 mortality in patients with knee or hip osteoarthritis: population based cohort study. *BMJ.*
43 439 2011;342:d1165. doi:10.1136/bmj.d1165
44 440 10. The Royal Australian College of General Practitioners. Guideline for the management of knee
45 441 and hip osteoarthritis. . 2018;
46 442 11. Skou S, Roos E. Good Life with osteoArthritis in Denmark (GLA:D™): evidence-based
47 443 education and supervised neuromuscular exercise delivered by certified physiotherapists
48 444 nationwide. *BMC Musculoskeletal Disorders.* 2017;18:72. doi:[https://doi.org/10.1186/s12891-017-](https://doi.org/10.1186/s12891-017-1439-y)
49 445 [1439-y](https://doi.org/10.1186/s12891-017-1439-y)
50
51 446 12. GLA:D(R) Australia, 2019. *Annual report 2019.* Retrieved on GLA:D(R) Australia's website
52 447 <https://gladaustralia.com.au/wp-content/uploads/2020/10/GLAD-ANNUAL-REPORT-2019.pdf>.
53 448 13. Barton C, Kemp J, Roos E, et al. Program evaluation of GLA:D® Australia: Physiotherapist
54 449 training outcomes and effectiveness of implementation for people with knee osteoarthritis.
55 450 *Osteoarthritis and Cartilage Open.* 2021;3(3)doi:10.1016/j.ocarto.2021.100175
56 451 14. Bell E, O'Halloran P, Pazzinatto M, et al. "I feel more confident": A mixed-methods
57 452 evaluation of the influence of GLA:D® on physical activity participation, capability, barriers and
58 453 facilitators in people with knee osteoarthritis. [UNDER REVIEW]. *Braz J Phys Ther.* xxxx;

- 1
2
3 454 15. Skou ST, Roos EM. Good Life with osteoArthritis in Denmark (GLA:D™): evidence-based
4 455 education and supervised neuromuscular exercise delivered by certified physiotherapists
5 456 nationwide. *BMC Musculoskeletal Disorders*. 2017;18(72)doi:10.1186/s12891-017-1439-y
6 457 16. Bell E, Wallis J, Goff A, Crossley K, O'Halloran P, Barton C. Does land-based exercise-therapy
7 458 improve physical activity in people with knee osteoarthritis? A systematic review with meta-
8 459 analyses. *Osteoarthritis and Cartilage*. 2022;30(11):1420-1433. doi:10.1016/j.joca.2022.07.008
9 460 17. Kanavaki A, Rushton A, Efstathiou N, et al. Barriers and facilitators of physical activity in knee
10 461 and hip osteoarthritis: a systematic review of qualitative evidence. *BMJ Open*.
11 462 2017;7(12)doi:10.1136/bmjopen-2017-017042
12 463 18. Miller W, Rollnick S. *Motivational interviewing: Helping people change*. 3rd ed. The Guilford
13 464 Press; 2013.
14 465 19. O'Halloran P, Blackstock F, Shields N, et al. Motivational interviewing to increase physical
15 466 activity in people with chronic health conditions: a systematic review and meta-analysis. *Clinical*
16 467 *Rehabilitation*. 2014;28(12):1159-1171. doi:10.1177/0269215514536210
17 468 20. O'Halloran P, Blackstock F, Shields N, et al. Motivational interviewing to increase physical
18 469 activity in people with chronic health conditions: a systematic review and meta-analysis. *Clinical*
19 470 *Rehabilitation*. 2014;28:1159.
20 471 21. Gilbert A, Lee J, Linda Ehrlich-Jones L, et al. A randomized trial of a motivational interviewing
21 472 intervention to increase lifestyle physical activity and improve self-reported function in adults with
22 473 arthritis. *Semin Arthritis Rheum*. 2018;47(5):732-740. doi:10.1016/j.semarthrit.2017.10.003
23 474 22. Li L, Feehan L, Xie H, et al. Effects of a 12-Week Multifaceted Wearable-Based Program for
24 475 People With Knee Osteoarthritis: Randomized Controlled Trial. *JMIR Mhealth and Uhealth*.
25 476 2020;8(7):e19116. doi:10.2196/19116
26 477 23. Ekman B, Nero H, Lohmander L, Dahlberg L. Costing analysis of a digital first-line treatment
27 478 platform for patients with knee and hip osteoarthritis in Sweden. *PLoS ONE*. 2020;15(8):e0236342.
28 479 doi:10.1371/journal.pone.0236342
29 480 24. Gao Z, Lee J. Emerging Technology in Promoting Physical Activity and Health: Challenge and
30 481 Opportunities. *J Clin Med*. 2019;8(11):1830. doi:10.3390/jcm8111830
31 482 25. Hinman R, Lawford B, Nelligan R, Bennel K. Virtual Tools to Enable Management of Knee
32 483 Osteoarthritis. *Curr Treatm Opt Rheumatol*. 2023;(Epub):1-21. doi:10.1007/s40674-023-00202-2
33 484 26. Eldridge S, Chan C, Campbell M, et al. CONSORT 2010 statement: extension to randomised
34 485 pilot and feasibility trials. *BMJ*. 2016;355:i5239.
35 486 27. Orkin A, Gill P, Ghersi D, Campbell L, Sugarman J, Chan A. Guidelines for Reporting Trial
36 487 Protocols and Completed Trials Modified Due to the COVID-19 Pandemic and Other Extenuating
37 488 Circumstances. The CONSERVE 2021 Statement. *JAMA*. 2021;326(3):257-65.
38 489 doi:10.1001/jama.2021.9941
39 490 28. National Institute for Health and Clinical Excellence. NICE guideline on osteoarthritis: The
40 491 care and management of osteoarthritis in adults, NICE clinical guideline 177. 2014;
41 492 29. Exercise & Sports Science Australia. Adult pre-exercise screening system (APSS) V2. 2023.
42 493 https://www.essa.org.au/Public/ABOUT_ESSA/Pre-Exercise_Screening_Systems.aspx
43 494 30. Devilly G, Borkovec T. Psychometric properties of the credibility/expectancy questionnaire.
44 495 *Journal of Behavior Therapy and Experimental Pschiatry*. 2000;31:73-86. doi:10.1016/S0005-
45 496 7916(00)00012-4
46 497 31. Moyers T, Rowell L, Manuel J, Ernst D, Houck J. The Motivational Interviewing Treatment
47 498 Integrity Code (MITI 4): Rationale, Preliminary Reliability and Validity. *J Subst Abuse Treat*.
48 499 2016;65:36-42. doi:10.1016/j.jsat.2016.01.001
49 500 32. Ryan C, Grant P, Tigbe W, Granat M. The validity and reliability of a novel activity monitor as
50 501 a measure of walking. *Br J Sports Med*. 2006;40:779-784. doi:10.1136/bjism.2006.027276
51 502 33. Grant P, Dall P, Mitchell S, Granat M. Activity-monitor accuracy in measuring step number
52 503 and cadence in community-dwelling older adults. *J Aging Phys Act*. 2008;16(2):201-14.
53 504 doi:10.1123/japa.16.2.201

- 1
2
3 505 34. Tudor-Locke C, Han H, Aguiar E, et al. How fast is fast enough? Walking cadence (steps/min)
4 506 as a practical estimate of intensity in adults: a narrative review. *Br J Sports Med*. 2018;52(12):776-
5 507 788. doi:10.1136/bjsports-2017-097628
6 508 35. Brown J, Harhay M, Harhay M. Walking Cadence and Mortality Among Community-Dwelling
7 509 Older Adults. *J Gen Intern Med*. 2014;29(9):1263-9. doi:10.1007/s11606-014-2926-6
8 510 36. Terwee CB, Bouwmeester W, van Elstrand SL, de Vet HCW, Dekker J. Instruments to assess
9 511 physical activity in patients with osteoarthritis of the hip or knee: a systematic review of
10 512 measurement properties. *Osteoarthritis and Cartilage*. 2011/06/01/ 2011;19(6):620-633.
11 513 doi:<https://doi.org/10.1016/j.joca.2011.01.002>
12 514 37. Bell E, Pazzinatto M, Wallis J, et al. Association of baseline physical activity participation with
13 515 participant characteristics and outcomes following education and exercise-therapy in people with
14 516 knee osteoarthritis: A GLA:D® Australia prospective cohort study. [UNDER REVIEW]. *Arthritis Care &*
15 517 *Research*. xxxx;xx(xx):xxx-xxx. doi:xxxxxxxxxxxxxxxxxxxx
16 518 38. Ateef M, Kulandaivelan S, Tahseen S. Test-retest Reliability and Correlates of 6-minute Walk
17 519 Test in Patients with Primary Osteoarthritis of Knees. *Indian Journal of Rheumatology*. 2016;11:192-
18 520 6.
19 521 39. Collins N, Prinsen C, Christensen R, Bartels E, Terwee C, Roos E. Knee Injury and
20 522 Osteoarthritis Outcome Score (KOOS): systematic review and meta-analysis of measurement
21 523 properties. *Osteoarthritis and Cartilage*. 2016;24:1317-29.
22 524 40. Bilbao A, García-Pérez L, Arenaza JC, et al. Psychometric properties of the EQ-5D-5L in
23 525 patients with hip or knee osteoarthritis: reliability, validity and responsiveness. *Quality of Life*
24 526 *Research*. 2018;27:2897-908. doi:10.1007/s11136-018-1929-x
25 527 41. Busija L, Ackerman I, Haas R, et al. Adult measures of general health and health-related
26 528 quality of life (invited). *Arthritis Care Res*. 2020;72(S10):522-564. doi:10.1002/acr.24216
27 529 42. Dobson F, Hinman R, Hall M, Terwee C, Roos E, Bennell K. Measurement properties of
28 530 performance-based measures to assess physical function in hip and knee osteoarthritis: a systematic
29 531 review. *Osteoarthritis and Cartilage*. 2012;20:1548-62. doi:10.1016/j.joca.2012.08.015
30 532 43. Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from
31 533 joint injury to osteoarthritis. *Health and Quality of Life Outcomes*. 2003;64(1)doi:10.1186/1477-
32 534 7525-1-64
33 535 44. Benaim C, Blaser S, Leger B, Vusistiner P, Luthi F. "Minimal clinically important difference"
34 536 estimates of 6 commonly-used performance tests in patients with chronic musculoskeletal pain
35 537 completing a work-related multidisciplinary rehabilitation program. *BMC Musculoskelet Disord*.
36 538 2019;20:16. doi:10.1186/s12891-018-2382-2
37 539 45. Dobson F, Hinman R, Hall M, et al. Reliability and measurement error of the Osteoarthritis
38 540 Research Society International (OARSI) recommended performance-based tests of physical function
39 541 in people with hip and knee osteoarthritis. *Osteoarthritis and Cartilage*. 2017;25(11):1792-6.
40 542 doi:<https://doi.org/10.1016/j.joca.2017.06.006>
41 543 46. Furlan A, Pennick V, Bombardier C, van Tulder M. 2009 Updated Method Guidelines for
42 544 Systematic Reviews in the Cochrane Back Review Group. *Spine*.
43 545 2009;34(18)doi:10.1097/BRS.0B013E3181B1C99F
44 546 47. Victorian Department of Health. Pandemic Order Register.
45 547 <https://www.health.vic.gov.au/covid-19/pandemic-order-register>
46 548 48. Wen C, Wai J, Tsai M, et al. Minimum amount of physical activity for reduced mortality and
47 549 extended life expectancy: a prospective cohort study. *Lancet*. 2011;378(9798):1244-53.
48 550 doi:10.1016/S0140-6736(11)60749-6
49 551 49. O'Halloran P, Shields N, Blackstock F, Wintle E, Taylor N. Motivational interviewing increases
50 552 physical activity and self-efficacy in people living in the community after hip fracture: a randomized
51 553 controlled trial. *Clinical Rehabilitation*. 2016;30(11):1108-1119. doi:10.1177/0269215515617814

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3 554 50. Stockwell S, Trott M, Tully M, et al. Changes in physical activity and sedentary behaviours
4 555 from before to during the COVID-19 pandemic lockdown: a systematic review. *BMJ Open Sport &*
5 556 *Exercise Medicine*. 7(1)doi:10.1136/bmjsem-2020-000960
6
7 557 51. Park A, Zhong S, Yang H, Jeong J, Lee C. Impact of COVID-19 on physical activity: A rapid
8 558 review. 2022;12doi:10.7189/jogh.12.05003
9 559 52. Lee IM, Shiroma E, Kamada M, Bassett D, Matthews C, Buring J. Association of Step Volume
10 560 and Intensity With All-Cause Mortality in Older Women. *JAMA Internal Medicine*.
11 561 2019;179(8)doi:10.1001/jamainternmed.2019.0899
12 562 53. del Pozo Cruz B, Ahmadi M, Lee IM, Stamatakis E. Prospective Associations of Daily Step
13 563 Counts and Intensity With Cancer and Cardiovascular Disease Incidence and Mortality and All-Cause
14 564 Mortality. *JAMA Internal Medicine*. 2022;182(11):1139-1148.
15 565 doi:10.1001/jamainternmed.2022.4000
16 566 54. Saint-Maurice P, Troiano R, Bassett Jr D, et al. Association of Daily Step Count and Step
17 567 Intensity With Mortality Among US Adults. *JAMA*. 2020;323(12):1151-1160.
18 568 doi:10.1001/jama.2020.1382
19 569 55. Whittaker J, Truong L, Losciale J, et al. Efficacy of the SOAR knee health program: protocol
20 570 for a two-arm stepped-wedge randomized delayed-controlled trial. *BMC Musculoskelet Disord*.
21 571 2022;23(85)doi:10.1186/s12891-022-05019-z
22 572 56. Fjeldsoe B, Neuhaus M, Winkler E, Eakin E. Systematic review of maintenance of behavior
23 573 change following physical activity and dietary interventions. *Health Psychol*. 2011;30(1):99-109.
24 574 doi:10.1037/a0021974
25 575 57. Lilienthal K, Pignol A, Holm J, Vogeltanz-Holm N. Telephone-Based Motivational Interviewing
26 576 to Promote Physical Activity and Stage of Change Progression in Older Adults. *Journal of Aging and*
27 577 *Physical Activity*. 2014;22:527-535. doi:10.1123/JAPA.2013-0056
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Appendices

Appendix 1. Borcovek and Nau acceptability questionnaire

1. How logical does the therapy offered to you seem?
2. How successfully do you think this treatment will be?
3. How confident would you be in recommending this treatment to a friend?
4. How much improvement in your physical activity do you think will occur?
5. How much do you really <i>feel</i> that therapy will help you to increase your physical activity?
6. How much improvement in your physical activity do you really <i>feel</i> will occur?

For peer review only

Appendix 2. Motivational interviewing

Motivational interviewing is an evidence based person-centred counselling intervention, used to target a particular behaviour change. To facilitate delivery of motivational interviewing as intended, the interviewer must undergo an accredited 2-day training program (delivered by a clinician from the motivational interviewing network of trainers (MINT)), 1:1 coaching and be graded proficient according to the motivational interviewing treatment integrity (MITI) code. Motivational interviewing incorporates microskills such as open-ended questions, affirmations, reflective listening and summarising (OARS). These microskills are delivered within the motivational interviewing spirit which includes partnership, acceptance, evocation and compassion. Motivational interviewing encompasses four key processes: engagement, focusing, evoking and planning.

Engagement: to develop a working relationship with the interviewee. This is an ongoing and important part of the process as you are seeking to change their behaviour.

Focusing: to focus on what the interviewee is wants to and is willing to change at the time. E.g. the interviewee may not be willing to make big changes initially so it is important to work with them where they are, not where the interviewer thinks they should be.

Evoking: to draw out the interviewee's own motivation and ideas for behaviour change. E.g. a therapist may want a patient to increase their physical activity to help their functional outcomes, compared to the patient who wants to be able to get on and off the ground easily to play with their grandchildren. Evoking the patient's motivation is far more powerful and more likely to lead to behaviour change.

Planning: to develop goals collaboratively and make a plan for how to achieve them. E.g. the interviewee may have an idea of what they can do to get started right away, and may be able to develop a plan to gradually make additional changes as time goes on.

It is important to acknowledge that multiple processes may occur at one time, and may not be in a linear sequence. The pace and sequence will be different for each individual and it is up the interviewer and interviewee to navigate this together during each session.

A real-life example of the processes from this trial includes:

Participant 3 (P3) had never been exposed to motivational interview before, learned from GLA:D® that they should be doing regular exercise for their knee and had previously had fluctuating dedication to gym since being aged in their 20's. **Engagement:** P3 talked with their physio about their love of gardening, social events, seeing family and volunteering. The practitioner using MI connects with their client through displaying an interest through open ended questions (e.g. *tell me more about what you like about gardening*) and demonstrating active listening through use of reflective listening (e.g. *family is really important to you*) **Focusing:** P3 wanted to make a lasting change to their physical activity participations because they had seen and felt the benefits of being active as well as continuing to incorporate knee strength exercises in their life. Being active brought P3 joy, and facilitated other important activities. The practitioner using MI facilitates this process through open ended questions (e.g. *what are the major benefits of you being more active*) and reflections (e.g., *being more active would make a real difference to your life and you're ready to do more*). **Evoking:** The practitioner using MI utilises evocation throughout the session, for instance with respect to helping the client focus open ended questions such as *what would you be willing to do to increase your activity?* can assist to facilitate such as P3 noting they are willing to incorporate more walking and add some upper body exercises to their gym routine for a full body workout **Planning:** Planning relates to evoking specifics from the client about what they will do and when. In this context P3 planned add walks on days they didn't attend the gym, and started using their smart phone step count to see how far they walked with certain activities, which could be used to measure future increases to walking.

1
2 **Appendix 3.** University of California Los Angeles Physical Activity Scale
3

4 **Question**

Answer options:

5 *Please indicate which*
6 *level of activity applies*
7 *to you*
8
9

1 Wholly inactive: dependent on others: cannot leave residence

2 Mostly inactive: restricted to minimal activities of daily living

3 Sometimes participates in mild activities

4 Regularly participates in mild activities, such as walking, limited housework, and limited shopping

5 Sometimes participates in moderate activities

6 Regularly participates in moderate activities, such as swimming and unlimited housework or shopping

7 Regularly participates in active events, such as bicycling

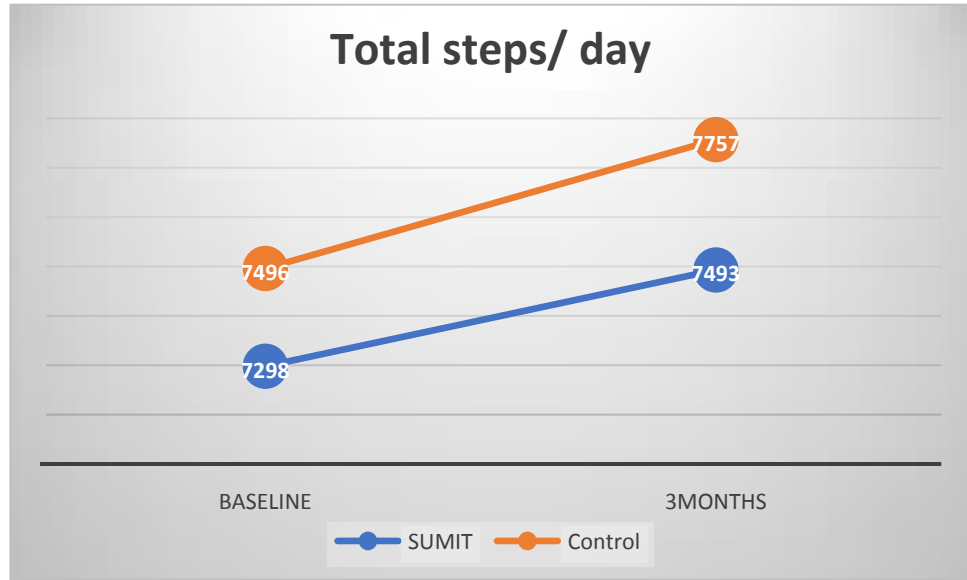
8 Regularly participates in very active events such as bowling or golf

9 Sometimes participates in impact sports

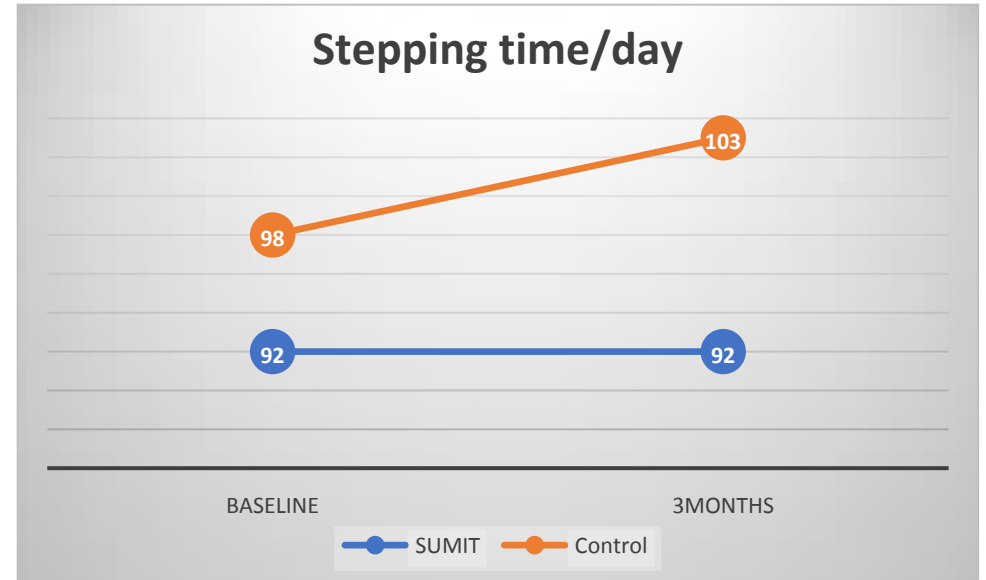
10 Regularly participates in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labour, or backpacking

27 Legend: 'Less' active = responses 1-6 in yellow, 'more' active = responses 7-10 in green.
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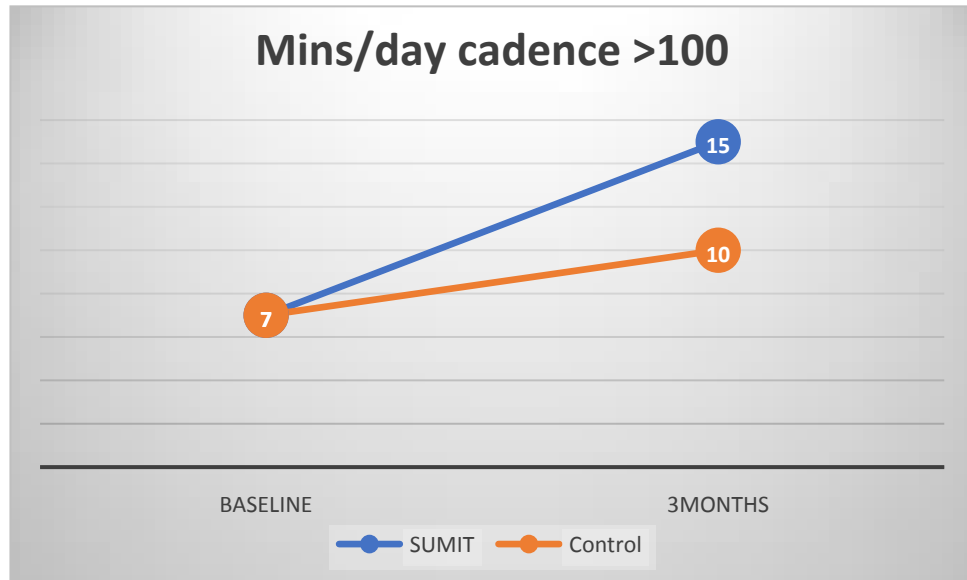
Appendix 4a. Total steps per day for SUMIT and control groups at baseline and 3-months



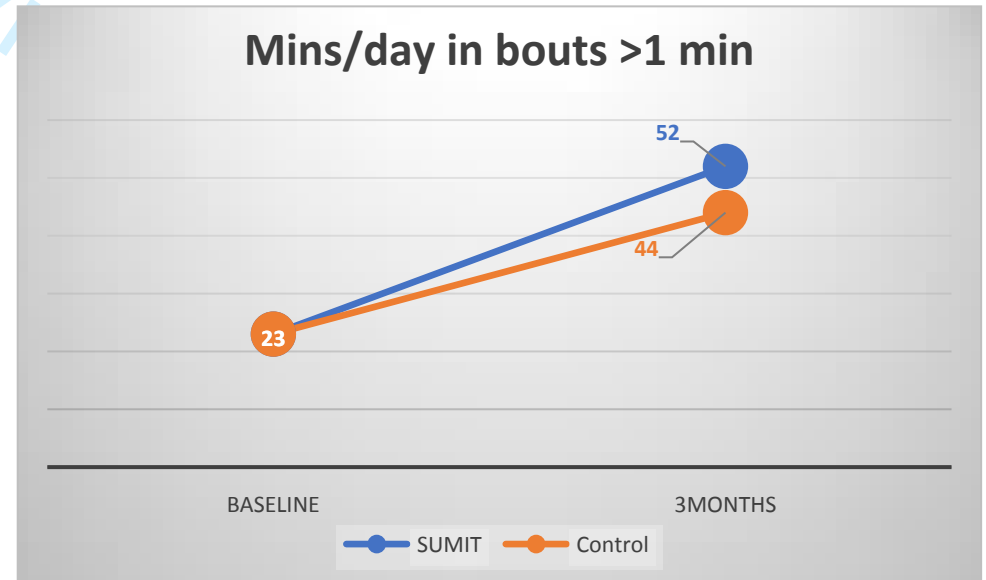
Appendix 4b. Stepping time per day (mins) for SUMIT and control groups at baseline and 3-months



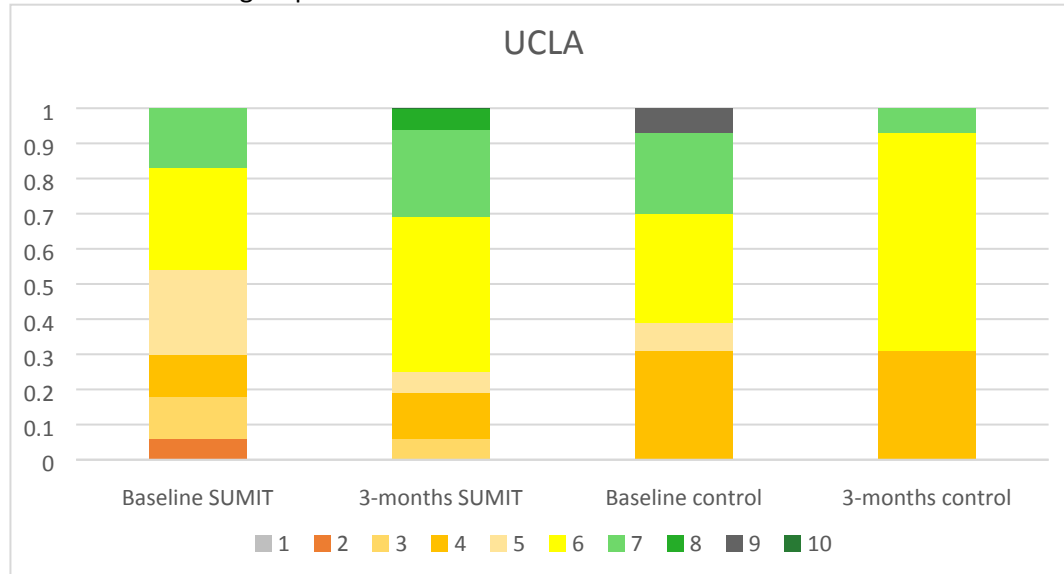
Appendix 4c. Minutes per day with cadence >100 for SUMIT and control groups at baseline and 3-months



Appendix 4d. Minutes per day in bouts >1min for SUMIT and control groups at baseline and 3-months

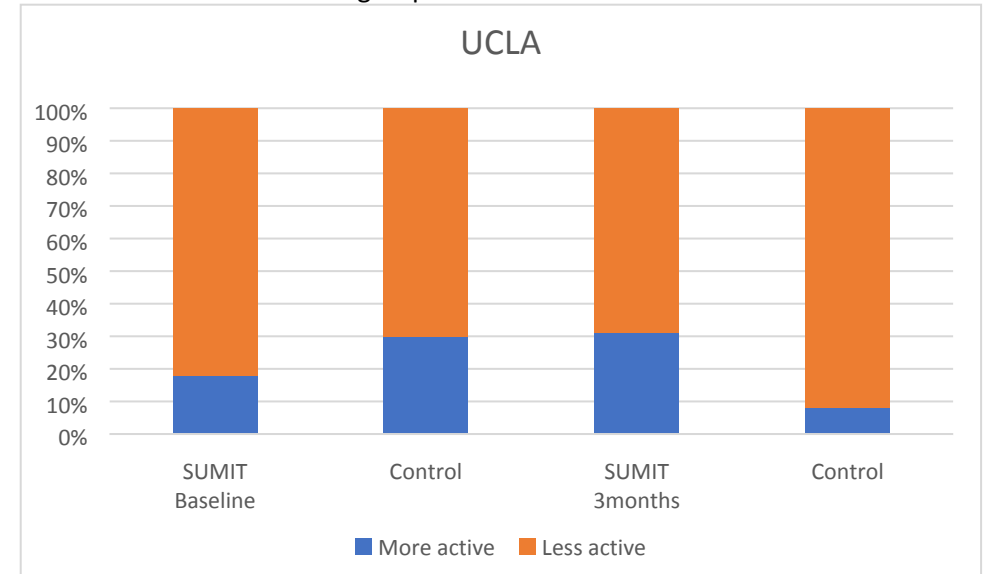


Appendix 5a. University of California Los Angeles physical activity scale raw scores for SUMIT and control groups at baseline and 3-months

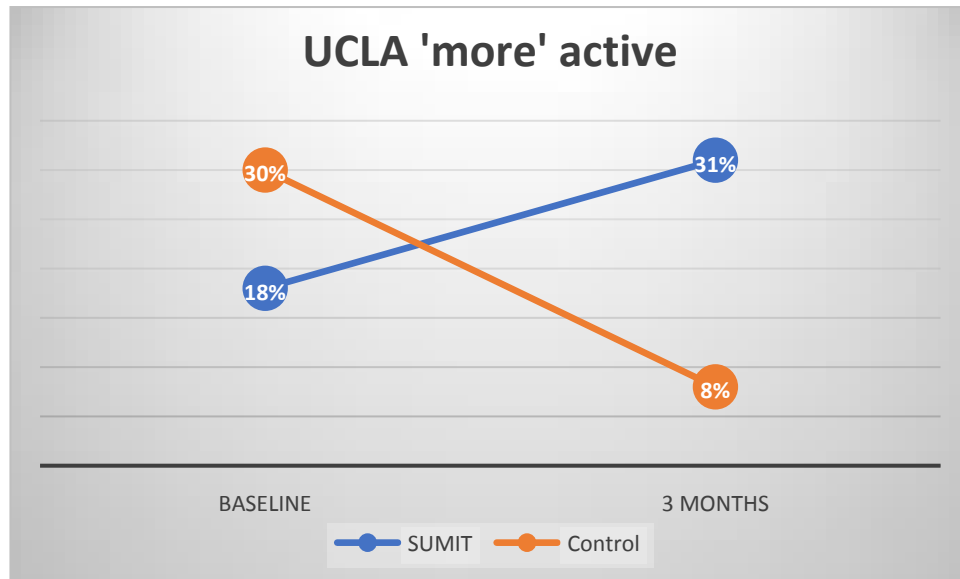


Appendix 5c. Proportion of participants who are 'more' or 'less' active using the University of California Los Angeles physical activity scale for SUMIT and control groups at baseline and 3-months

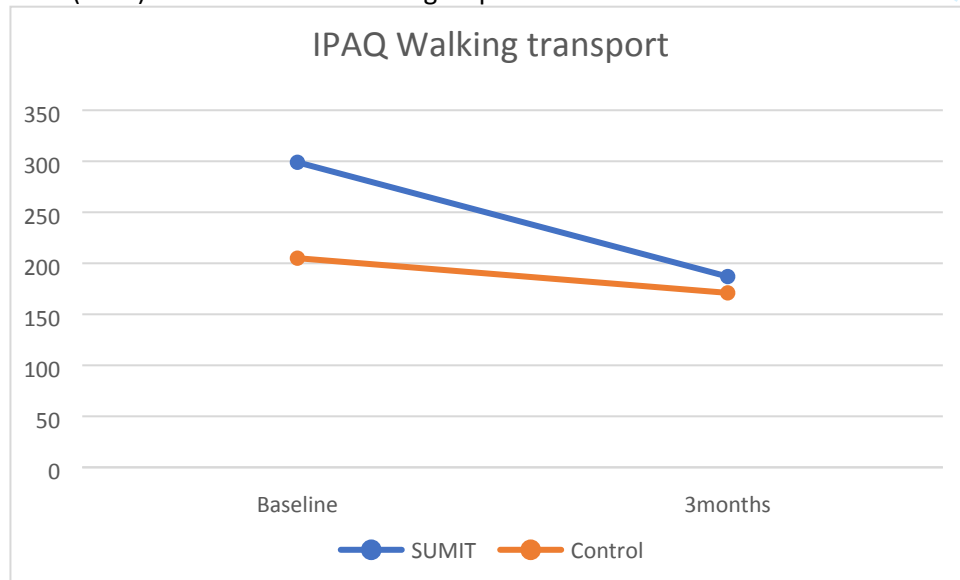
Appendix 5b. Dichotomised University of California Los Angeles physical activity scale for SUMIT and control groups at baseline and 3-months



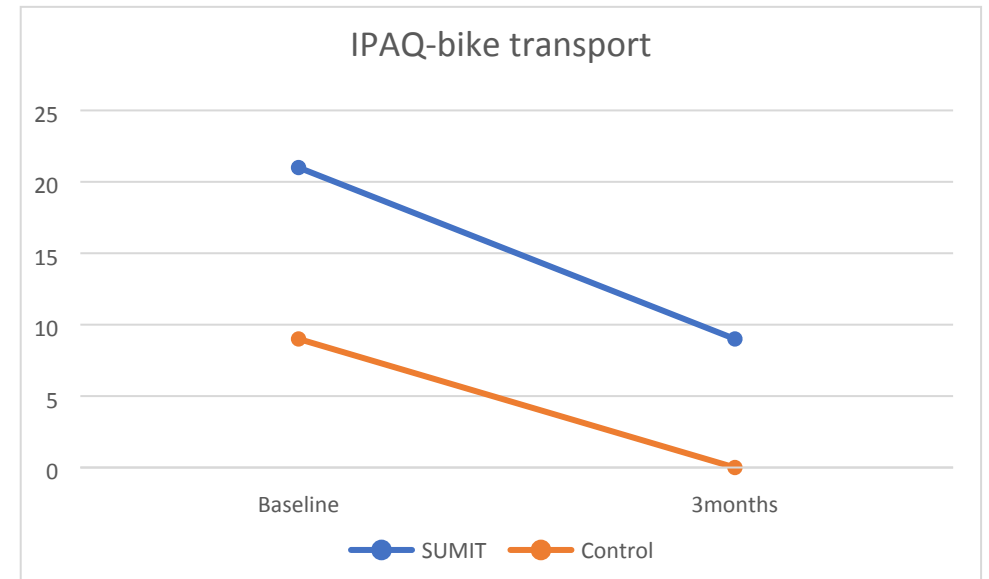
Appendix 5d. International Physical Activity Questionnaire long form bike transport time (mins) for SUMIT and control groups at baseline and 3-months



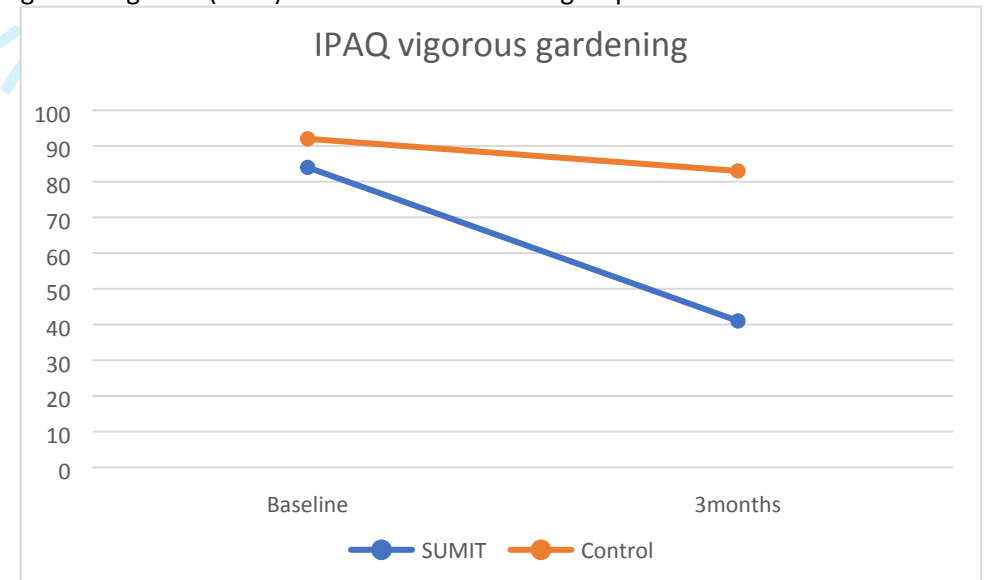
Appendix 5e. International Physical Activity Questionnaire long form walking transport time (mins) for SUMIT and control groups at baseline and 3-months



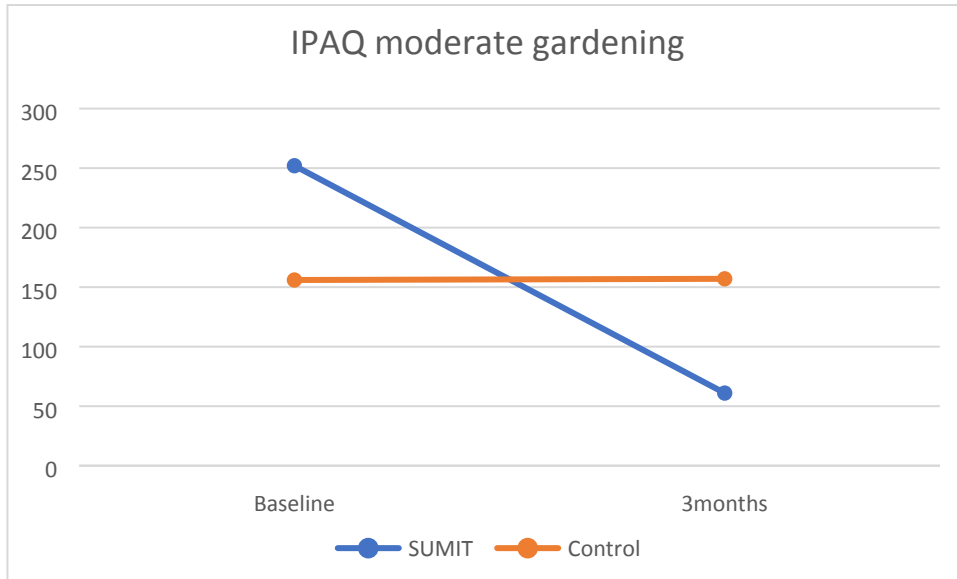
Appendix 5g. International Physical Activity Questionnaire long form moderate gardening time (mins) for SUMIT and control groups at baseline and 3-months



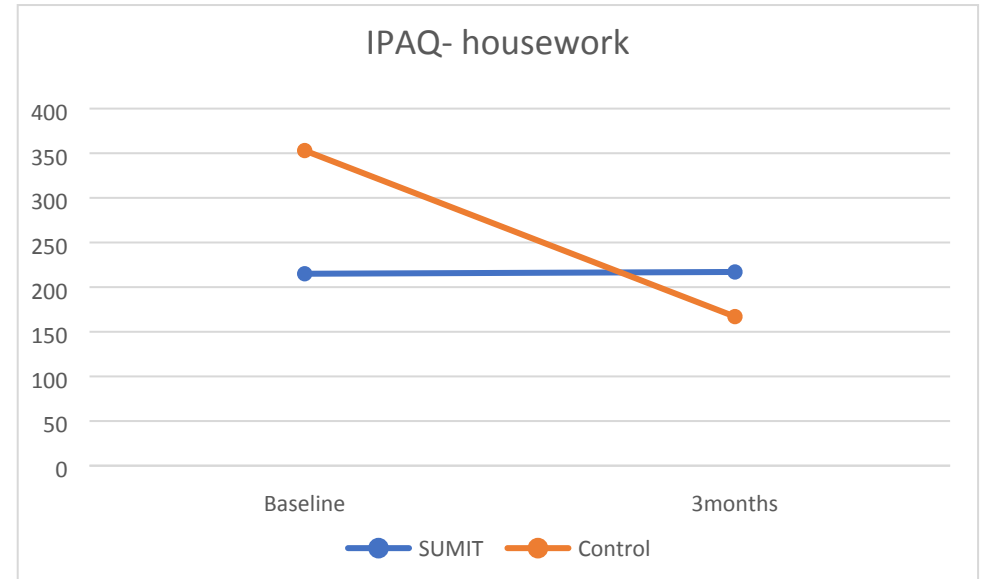
Appendix 5f. International Physical Activity Questionnaire long form vigorous gardening time (mins) for SUMIT and control groups at baseline and 3-months



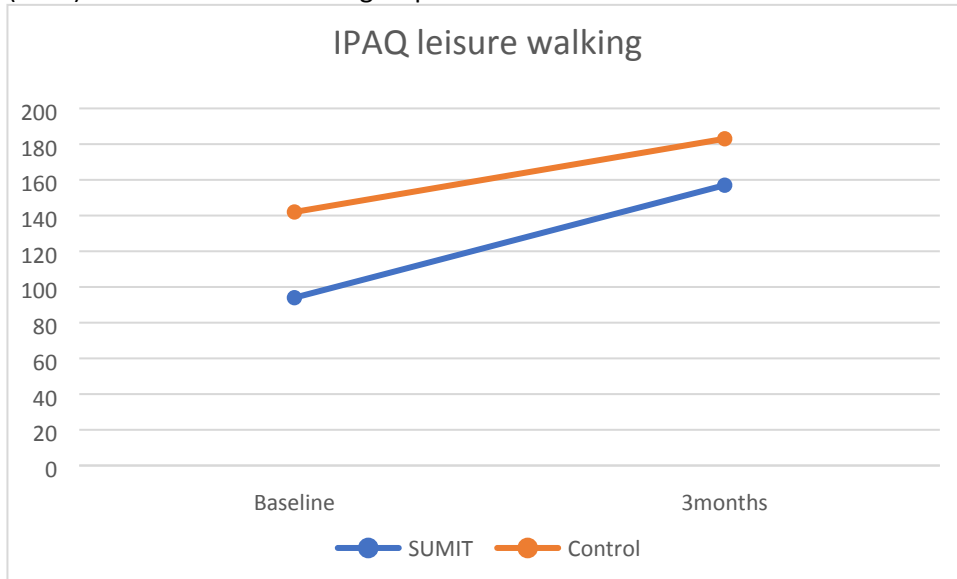
Appendix 5h. International Physical Activity Questionnaire long form housework time (mins) for SUMIT and control groups at baseline and 3-months



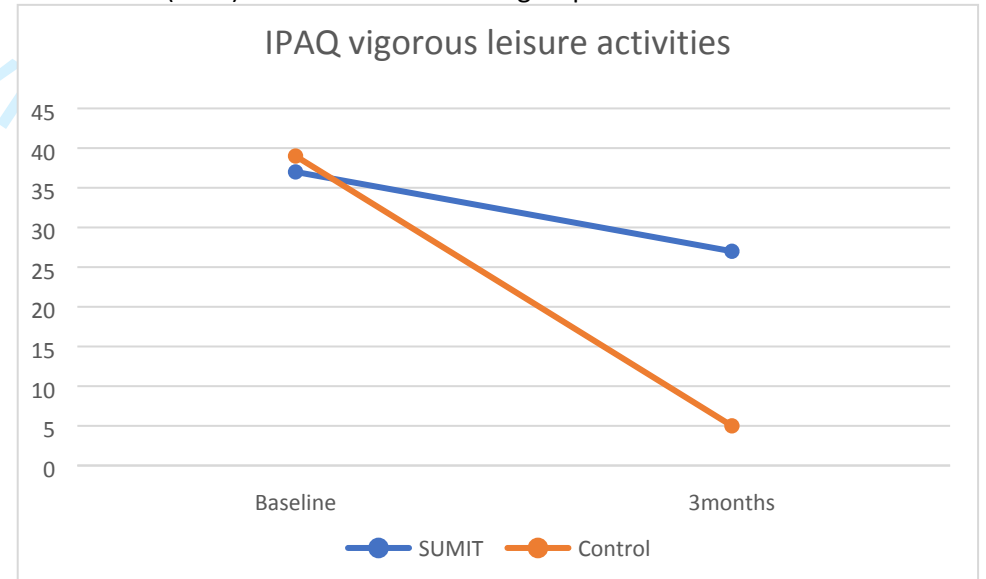
Appendix 5i. International Physical Activity Questionnaire long form leisure walking time (mins) for SUMIT and control groups at baseline and 3-months

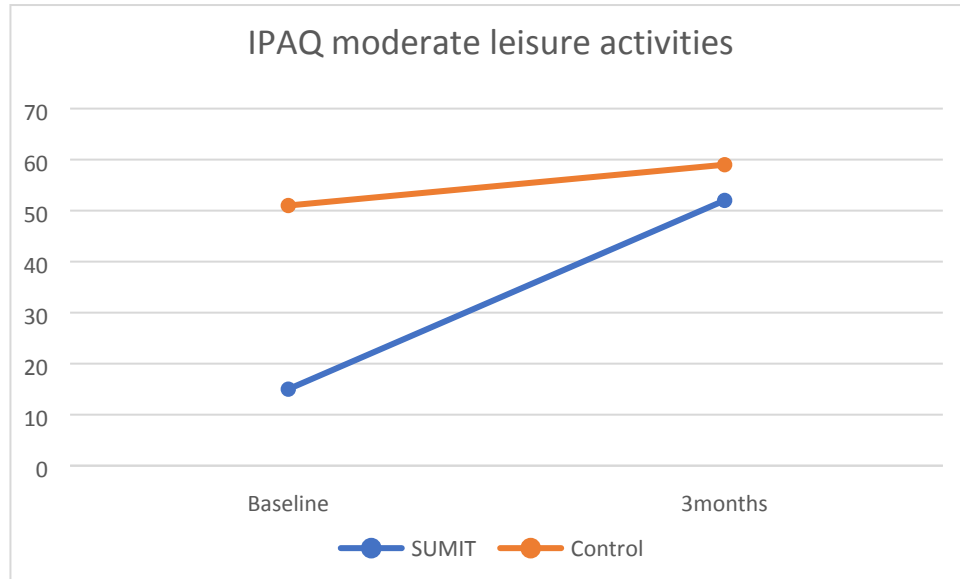


Appendix 5j. International Physical Activity Questionnaire long form vigorous leisure time (mins) for SUMIT and control groups at baseline and 3-months

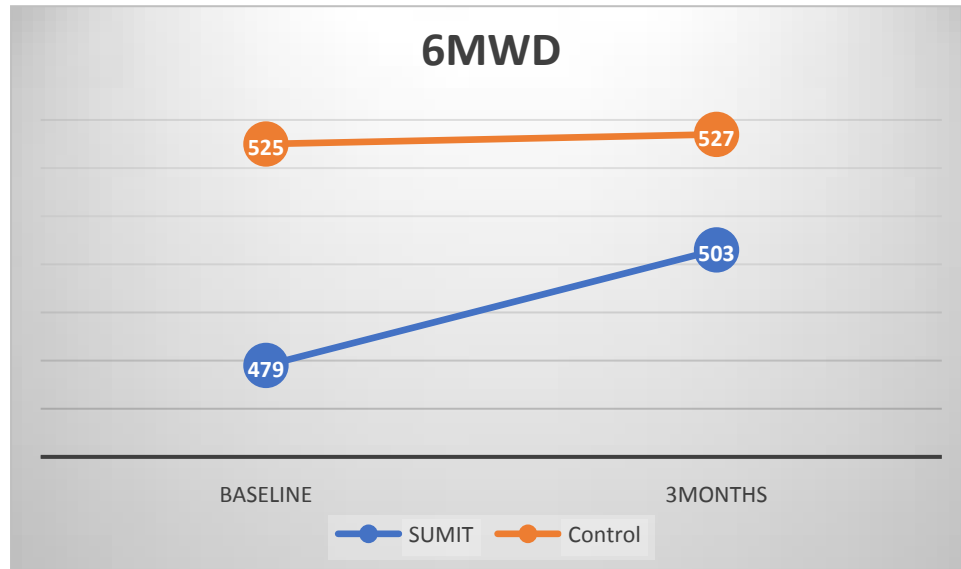


Appendix 5k. International Physical Activity Questionnaire long form moderate leisure time (mins) for SUMIT and control groups at baseline and 3-months

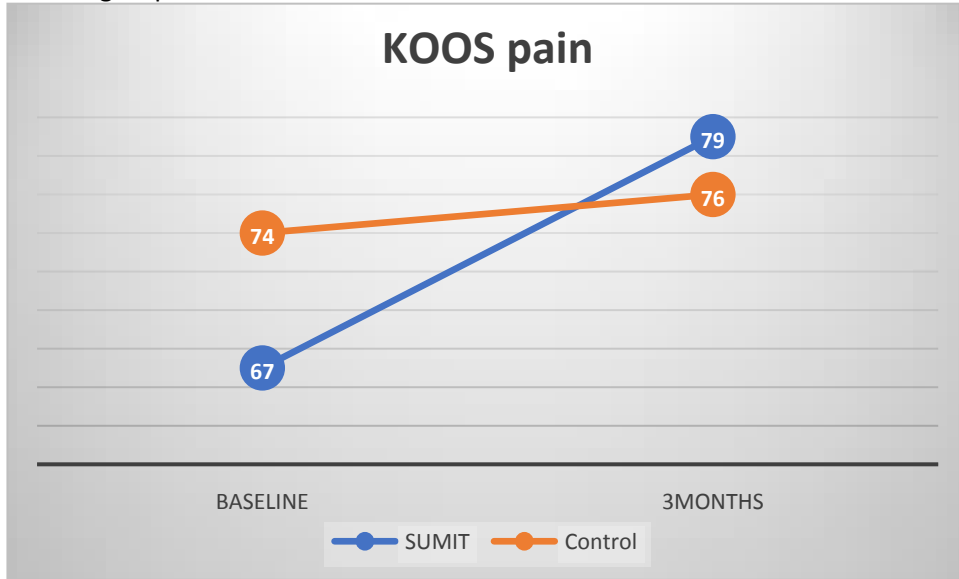




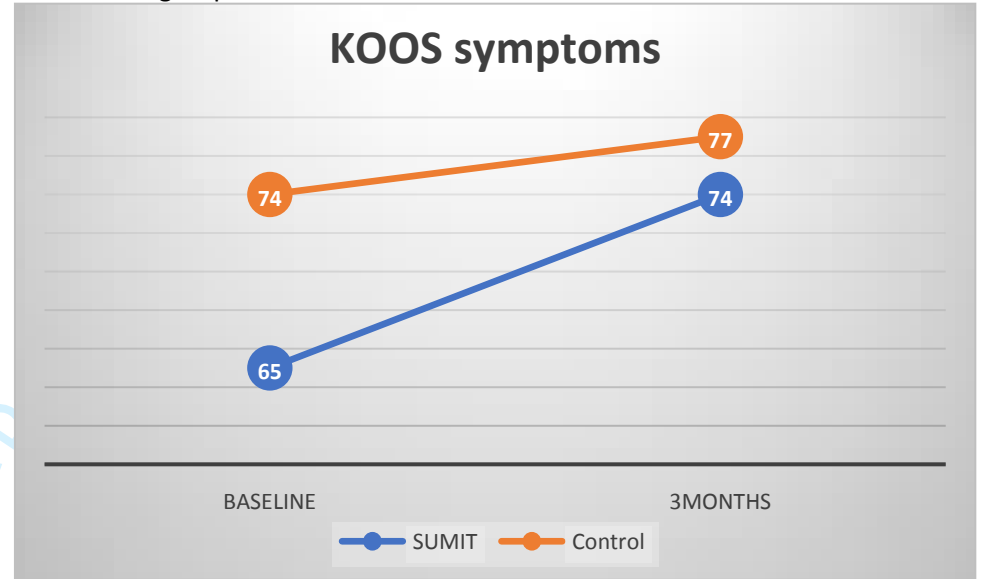
Appendix 6. 6-minute walk distance (m) for SUMIT and control groups at baseline and 3-months



Appendix 7a. Knee Osteoarthritis Outcome Score pain subscale for SUMIT and control groups at baseline and 3-months

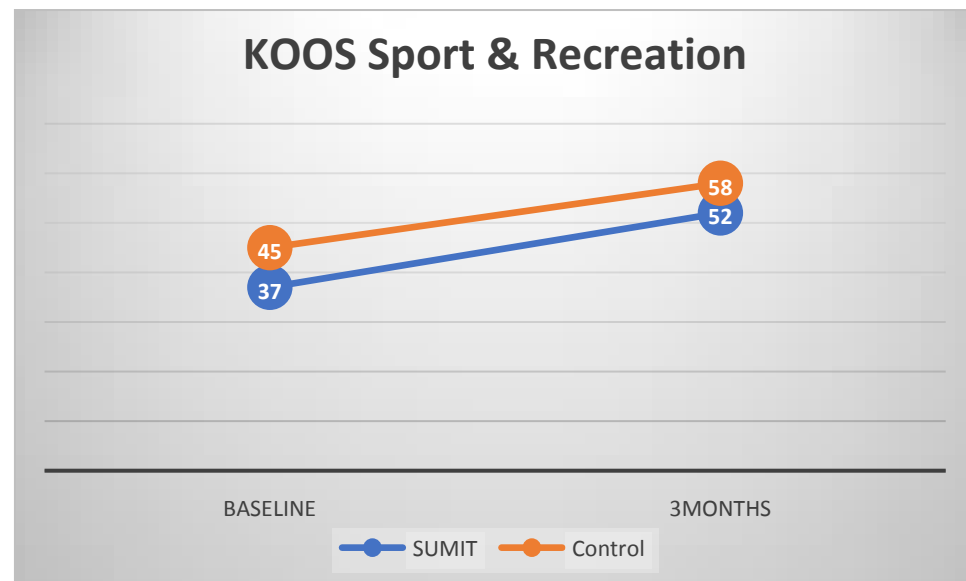
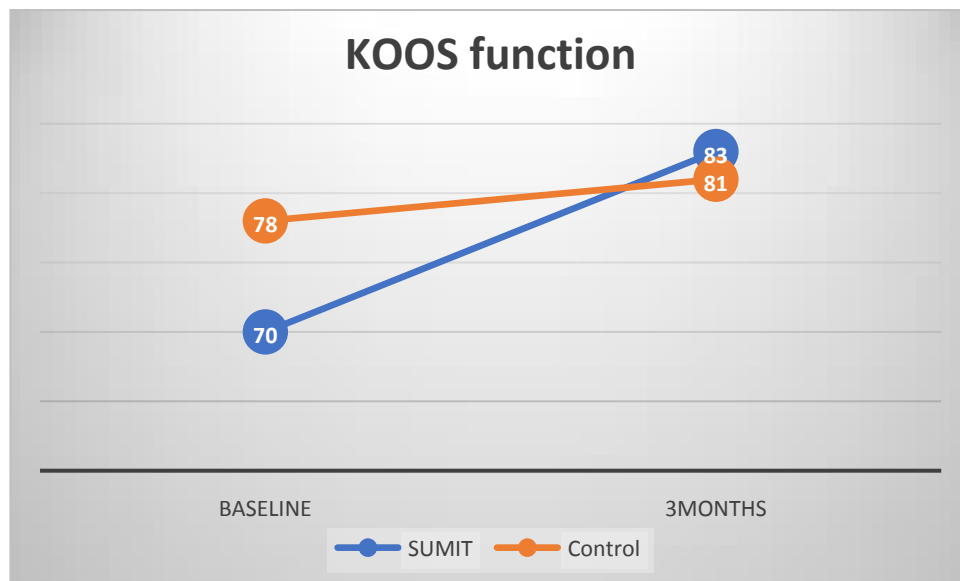


Appendix 7b. Knee Osteoarthritis Outcome Score symptoms subscale for SUMIT and control groups at baseline and 3-months

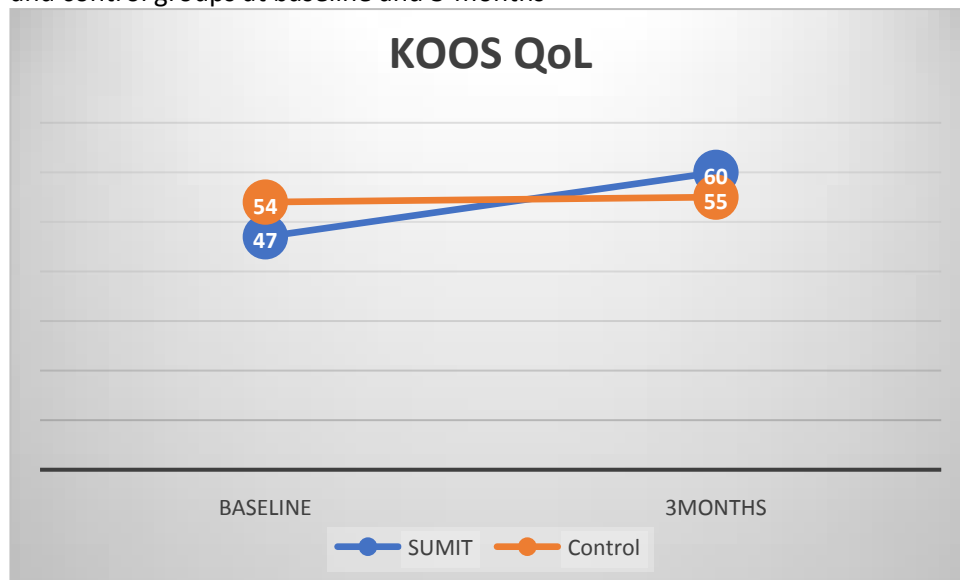


Appendix 7c. Knee Osteoarthritis Outcome Score function subscale for SUMIT and control groups at baseline and 3-months

Appendix 7d. Knee Osteoarthritis Outcome Score sport & recreation subscale for SUMIT and control groups at baseline and 3-months

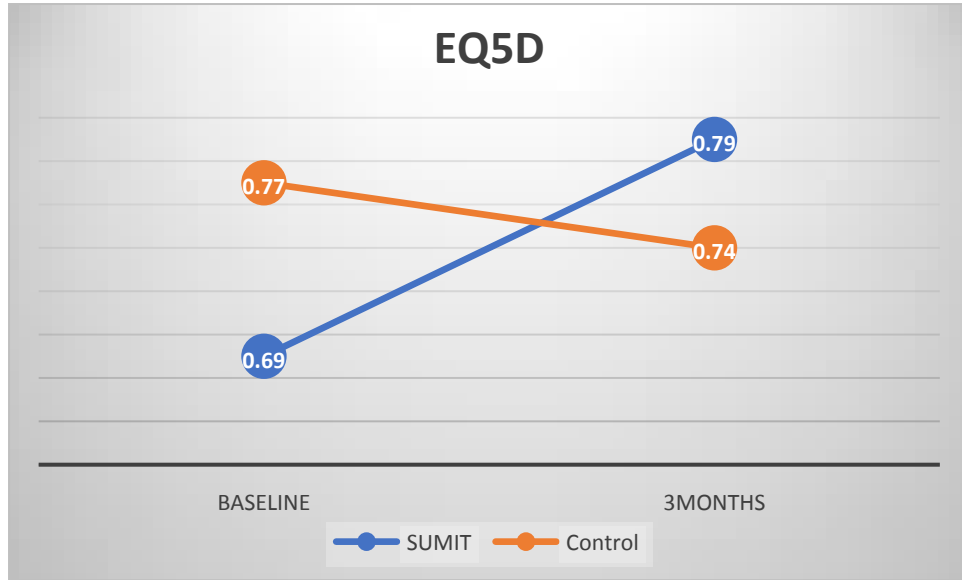


Appendix 7e. Knee Osteoarthritis Outcome Score quality of life subscale for SUMIT and control groups at baseline and 3-months



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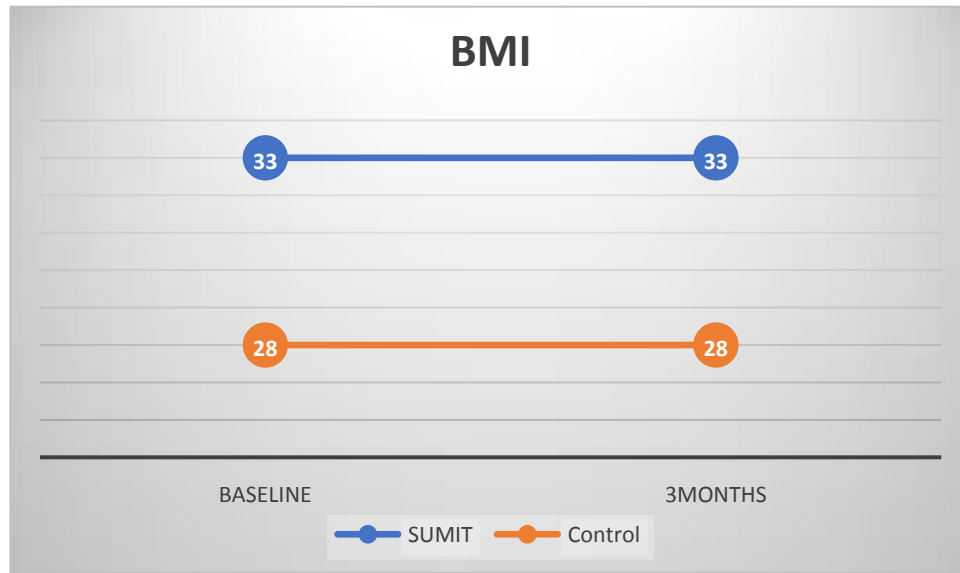
Appendix 8. Health-related quality of life for SUMIT and control groups at baseline and 3-months



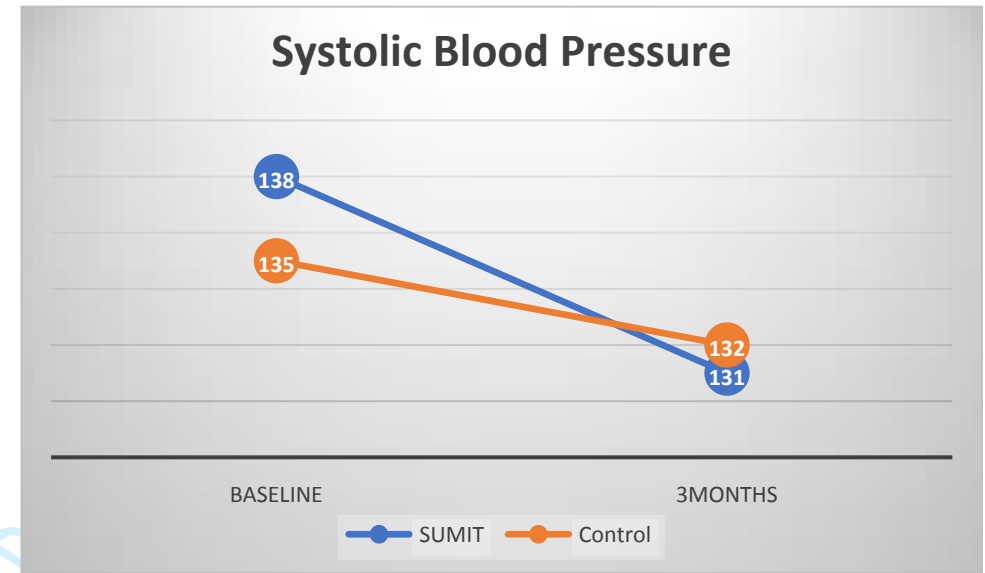
Legend: EQ5D= Euroqual 5-dimension 5-long

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2 **Appendix 9a.** BMI for SUMIT and control groups at baseline and 3-months

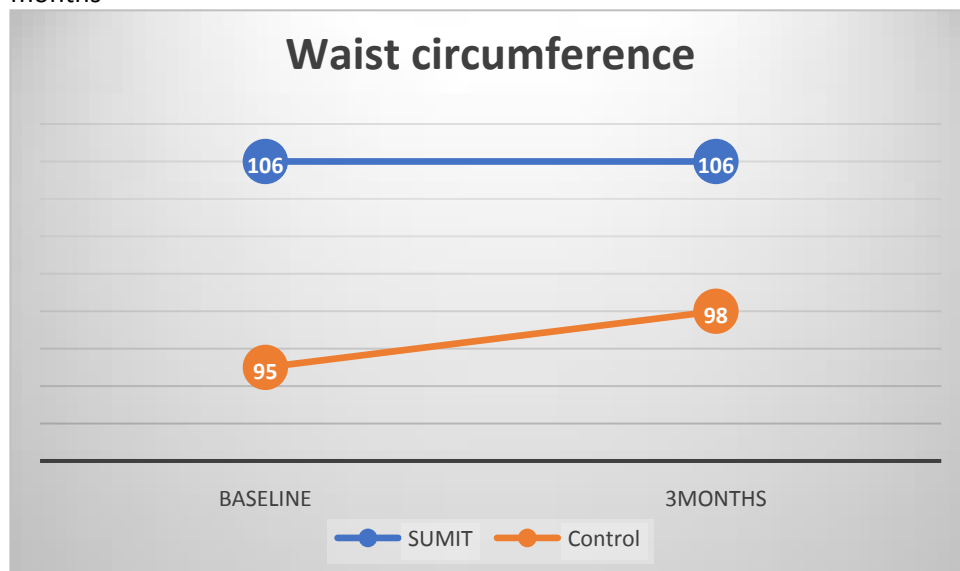


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20 **Appendix 9b.** Systolic blood pressure for SUMIT and control groups at baseline and 3-months

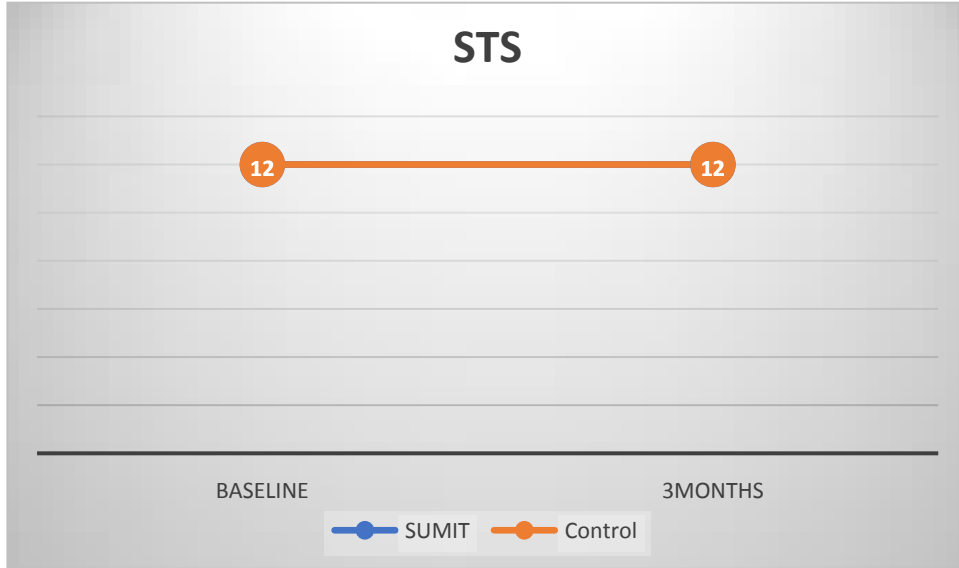


40 **Legend:** BMI- body mass index

41 **Appendix 9c.** Waist circumference for SUMIT and control groups at baseline and 3-months



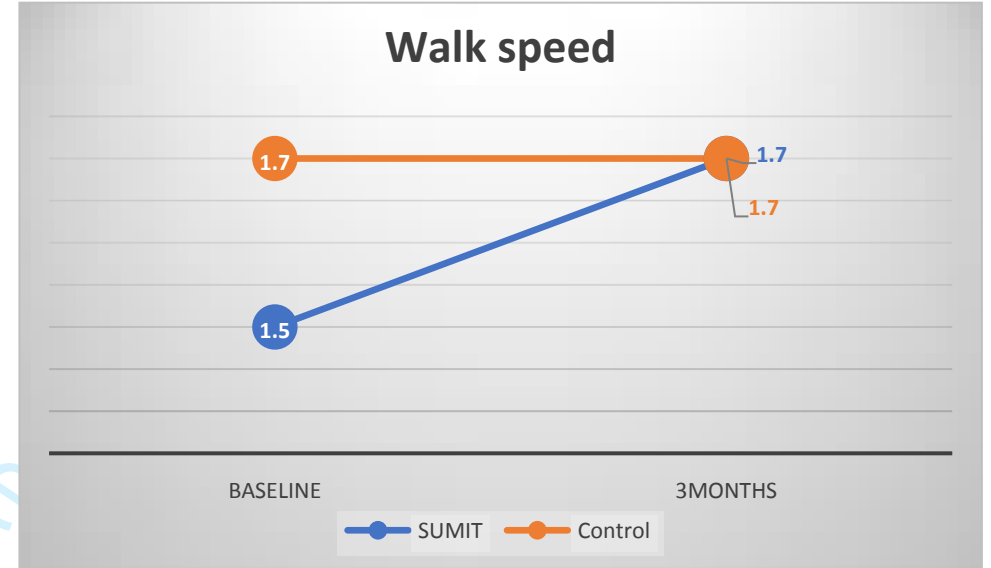
Appendix 10a. 30 second chair stand test for SUMIT and control groups at baseline and 3-months



Legend: STS= sit to stand

*Both groups were the same and are overlapped

Appendix 10b. Walking speed measured by 40mWT for SUMIT and control groups at baseline and 3-months



Legend: 40mWT= 40 metre walk test



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5-6
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	6-7
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9-10
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1, p12
	13b	For each group, losses and exclusions after randomisation, together with reasons	10
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	6, 10
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2, p12
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 3, p14
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	14
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	14-16
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	10-11
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	3, 19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	18-20
Other information			
Registration	23	Registration number and name of trial registry	5
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	20

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Supplement 2
for
Guidelines for reporting trial protocols and completed trials modified due to the COVID-19 pandemic and other extenuating circumstances: The CONSERVE 2020 Statement

For peer review only

CONSERVE Checklists

Use CONSERVE-CONSORT for completed trial reports and CONSERVE-SPIRIT for trial protocols.

CONSERVE-CONSORT Extension: [DATE]					
Item	Item Title	Description	Page No.		
I.	Extenuating Circumstances	Describe the circumstances and how they constitute extenuating circumstances.	5-6		
II.	Important Modifications	a. Describe how the modifications are important modifications.	6		
		b. Describe the impacts and mitigating strategies, including their rationale and implications for the trial.	(see below) 6		
		c. Provide a modification timeline.	6, 11		
III.	Responsible Parties	State who planned, reviewed and approved the modifications.	6		
IV.	Interim data	If modifications were informed by trial data, describe how the interim data were used, including whether they were examined by study group, and whether the individuals reviewing the data were blinded to the treatment allocation.	N/A		
CONSORT Number and Item		For each row, if important modifications occurred check "direct impact" and/or "mitigating strategy" and describe the changes in the trial manuscript or supplement. Check "no change" for items that are unaffected in the extenuating circumstance.			
		No Change	Impact*	Mitigating Strategy**	Page No.
1	Title and abstract	X			
2	Introduction	X			
3	Methods: Trial Design	X			
4	Methods: Participants		X		5
5	Methods: Interventions	X			
6	Methods: Outcomes	X			
7	Methods: Sample Size		X		10
8-10	Methods: Randomisation		X		6

11	Methods: Blinding	X			
12	Methods: Statistical methods	X			
13	Results: Participant flow	X			
14	Results: Recruitment		X	X	10
15	Results: Baseline data	X			
16	Results: Numbers analysed		X		10
17	Results: Outcomes and estimation		X		11
18	Results: Ancillary analyses	X			
19	Results: Harms	X			
20	Discussion: Limitations		X		19
21	Discussion: Generalisability	X			
22	Other information: Registration	X			
23	Other information: Protocol	X			
24	Other information: Funding	X			

*Aspects of the trial that are directly affected or changed by the extenuating circumstance and are not under the control of investigators, sponsor or funder.

**Aspects of the trial that are modified by the study investigators, sponsor or funder to respond to the extenuating circumstance or manage the direct impacts on the trial.

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CONSERVE-SPIRIT Extension: [DATE]					
Item	Item Title	Description			Page No.
I.	Extenuating Circumstances	Describe the circumstances and how they constitute extenuating circumstances.			
II.	Important Modifications	a. Describe how the modifications are important modifications.			
		b. Describe the impacts and mitigating strategies, including their rationale and implications for the trial.			(see below)
		c. Provide a modification timeline.			
III.	Responsible Parties	State who planned, reviewed and approved the modifications.			
IV.	Interim data	If modifications were informed by trial data, describe how the interim data were used, including whether they were examined by study group, and whether the individuals reviewing the data were blinded to the treatment allocation.			
SPIRIT Item and Number		For each row, if important modifications occurred, check one or both of "impact" and/or "mitigating strategy" and describe the changes in the protocol. Check "no change" for items that are unaffected in the extenuating circumstance.			Page No.
		No Change	Impact*	Mitigating Strategy**	
1	Title				
2	Trial registration				
3	Protocol version				
4	Funding				
5	Roles and responsibilities				
6	Background and rationale				
7	Objectives				
8	Trial design				
9	Study setting				
10	Eligibility criteria				
11	Interventions				
12	Outcomes				

13	Participant timeline				
14	Sample size				
15	Recruitment				
16	Allocation				
17	Blinding (masking)				
18	Data collection methods				
19	Data management				
20	Statistical methods				
21	Data monitoring				
22	Harms				
23	Auditing				
24	Research ethics approval				
25	Protocol amendments				
26	Consent or assent				
27	Confidentiality				
28	Declaration of interests				
29	Access to data				
30	Ancillary and post-trial care				
31	Dissemination policy				
32	Informed consent materials				
33	Biological specimens				
<p>*Aspects of the trial that are directly affected or changed by the extenuating circumstance and are not under the control of investigators, sponsor or funder. **Aspects of the trial that are modified by the study investigators, sponsor or funder to respond to the extenuating circumstance or manage the direct impacts on the trial.</p> <p>The CONSERVE-SPIRIT Checklist is licensed by the CONSERVE Group under the Creative Commons Attribution-NonCommercial-NoDerivs 4.0 International license.</p>					

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Using Supported Motivational Interviewing (SUMIT) to increase physical activity for people with knee osteoarthritis. A pilot, feasibility randomised controlled trial.

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2
3 **Title:** Using Supported Motivational Interviewing (SUMIT) to increase physical activity for people
4 with knee osteoarthritis. A pilot, feasibility randomised controlled trial.
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1
2
3 **1 ABSTRACT**

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5 **2 Word count:** 278/300

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8 **3 Objective:** To determine the feasibility and effectiveness of using Supported Motivational
9 InTerviewing (SUMIT) to increase physical activity in people with knee osteoarthritis (KOA).

10
11
12 **5 Design:** Randomised controlled trial.

13
14
15 **6 Setting:** We recruited people who had completed Good Life with osteoArthritis Denmark from
16 private, public and community settings in Victoria, Australia.

17
18
19 **8 Interventions:** Participants were randomised participants to receive SUMIT or usual care. SUMIT
20 comprised of five motivational interviewing sessions targeting physical activity over 10-weeks, and
21 access to a multimedia web-based platform.

22
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24
25 **11 Participants:** Thirty-two participants were recruited (17 SUMIT, 15 control) including 22 females
26 (69%).

27
28
29
30 **13 Outcome measures:** Feasibility outcomes included recruitment rate, adherence to motivational
31 interviewing, ActivPAL wear and drop-out rate. Effect sizes (ES) were calculated for daily steps,
32 stepping time, time with cadence >100 steps per minute, time in bouts >1minute; 6-Minute walk
33 distance, Knee Osteoarthritis Outcome Score (KOOS) subscales (pain, symptoms, function, sport and
34 recreation, and quality of life (QoL)), Euroqual, systolic BP, BMI, waist circumference, 30-second
35 chair stand test, and walking speed during 40m walk test.

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41 **19 Results:** All feasibility criteria were achieved, with 32/63 eligible participants recruited over seven
42 months; with all participants adhering to all motivational interviewing calls and achieving sufficient
43 ActivPAL wear time, and only two drop-outs (6%).

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51
52 **22** 12/15 outcome measures showed at least a small effect (ES>0.2) favouring the SUMIT group,
53 including daily time with cadence >100 steps per minute (ES=0.43). Two outcomes, walking speed
54 (ES= 0.97) and KOOS QoL (ES=0.81), showed a large effect (ES>0.8).

55
56
57 **25 Conclusion:** SUMIT is feasible in people with knee osteoarthritis. Potential benefits included more
58 time spent walking at moderate intensity, faster walking speeds and better QoL.

59
60 **27 Trial registration:** The trial was registered with Australian New Zealand Clinical Trials Registry
(ANZCTR) (ACTRN12621000267853).

1
2
3 29 **Key words:** Physiotherapy, Rehabilitation, Comorbidities, Behaviour Change, Knee osteoarthritis,
4
5 30 Motivational Interviewing
6

7 31
8

9 32 **Strengths and limitations of this study**

- 11
12 33 • We modified our trial by increasing recruitment sites, advertising and reducing the
13 34 recruitment target number due to the impact of COVID-19 restrictions, and have reported
14 35 our trial according to the CONSERVE checklist to aide transparency.
15
16
17 36 • We used rigorous randomisation and assessment blinding procedures and accredited
18 37 motivational interviewing training and treatment fidelity so that our methods could be
19 38 repeated.
20
21
22 39 • Our ActivPAL analyses were completed by the same researcher who delivered the SUMIT
23 40 intervention which may present risk of unconscious bias. Future studies should provide a
24 41 provision for a blinded researcher to undertake data analysis.
25
26
27 42 • Our participant groups were different as baseline, possibly due to the small sample size,
28 43 which may have impacted the findings for the secondary aims.
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46 INTRODUCTION

47 Physical activity participation has considerable health benefits.(1-3) Meeting physical activity
48 guidelines of at least 150-minutes per week of moderate-vigorous physical activity is considered vital
49 to reducing the risk of development or worsening of at least 35 chronic diseases.(1-4) For people
50 with knee osteoarthritis, less than half (41%) reached 150-minutes per week,(5) compared to 73% of
51 adults in the general population.(6) Knee osteoarthritis and insufficient physical activity are
52 independently associated with greater comorbidity risk, including cardiovascular disease, and earlier
53 mortality.(7-9)

54 Patient education and exercise-therapy are recommended as first line treatments for knee
55 osteoarthritis in major guidelines,(10) based on their effectiveness to reduce pain and improve knee
56 function.(11) Good Living with osteoArthritis from Denmark (GLA:D®) is a guideline-based education
57 and exercise-therapy program implemented in nine countries, including Australia.(12) Participation
58 is associated with clinically meaningful improvements in knee pain and joint-related quality of life at
59 3-months, with these benefits sustained for at least 12 months.(11, 13) People with knee
60 osteoarthritis completing GLA:D® also report improved confidence to increase physical activity
61 participation.(14) However, completing GLA:D® is not associated with increased physical activity
62 participation at 12-months.(14, 15) This is consistent with a recent systematic review indicating
63 exercise-therapy alone does not result in medium (6-12 months) or long-term (>12-months) changes
64 in physical activity compared to non-exercise interventions.(16)

65 Increasing physical activity participation in people with knee osteoarthritis may require interventions
66 to address both physical and personal barriers, such as motivation and confidence.(17) Motivational
67 interviewing is a person-centred behaviour change approach involving counselling style sessions
68 with a trained health professional, aiming to address personal barriers to behaviour change.(18) It is
69 associated with moderate benefits for increasing physical activity in people with chronic health
70 conditions when they present to primary care.(19, 20) However in knee osteoarthritis, research on
71 the effects of motivational interviewing is limited. One study reported no increase in moderate-
72 vigorous physical activity compared to usual care in the short- or long-term.(21) However, sessions
73 were infrequent (every 3-months), which is atypical for motivational interviewing interventions.(20)
74 Phone counselling targeting physical activity provided more frequently (biweekly) has been reported
75 to increase moderate-vigorous physical activity in the short-term (>3-months).(22)

76 Digital support tools for osteoarthritis are emerging as a cost effective approach to provide
77 information and education, and assist people with osteoarthritis to engage with prescribed exercise
78 to improve patient outcomes.(23, 24) In addition to behaviour change interventions, such as

1
2
3 79 motivational interviewing, they can be used to monitor and/or promote physical activity, and may
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5 80 help to increase physical activity.(25) However, the influence of digital support tools on physical
6
7 81 activity behaviour change is unknown.(25)

8
9 82 Our primary objective was to determine the feasibility of conducting a fully powered trial evaluating
10
11 83 the effectiveness of increasing physical activity using SUpported Motivational InTerviewing (SUMIT),
12
13 84 following completion of an education and exercise-therapy program in people with knee
14
15 85 osteoarthritis. Our secondary objective was to determine if a worthwhile treatment effect occurred
16
17 86 for physical activity, physical endurance, knee-related quality of life (QoL), health-related QoL and
18
19 87 pain.
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21 88

21 89 **METHODS**

22 90 **Trial design**

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24
25 91 This pilot feasibility randomised controlled trial (RCT) compared an intervention comprising
26
27 92 motivational interviewing and website) with a usual care control group. Ethics approval was
28
29 93 obtained from La Trobe University Human Research Ethics Committee (#HEC20506). The trial was
30
31 94 registered with Australian New Zealand Clinical Trials Registry (ANZCTR) (ACTRN12621000267853).
32
33 95 Study reporting adheres to the Consolidated Standards or Reporting Trials (CONSORT) for pilot and
34
35 96 feasibility trials.(26) Due to the interruption from the Coronavirus pandemic (COVID-19), we
36
37 97 reported limitations according to the CONSORT and SPIRIT Extension for RCTs Revised in Extenuating
38
39 98 Circumstances (CONSERVE) guidelines.(27)

39 99 **Setting**

40
41
42 100 All assessments were conducted at a private hospital in metropolitan Melbourne, Australia, or a
43
44 101 private physiotherapy clinic in regional Victoria, Australia. All intervention sessions were completed
45
46 102 online via Zoom or phone call (according to participant preference).

47 103 **Participants**

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49
50 104 Women and men with a clinical diagnosis of knee osteoarthritis(28) who had completed GLA:D®
51
52 105 within the previous 2-years(13) were recruited from March 2021 to April 2022 and provided written
53
54 106 informed consent. Knee osteoarthritis was guided by the NICE guidelines including i) being aged > 45
55
56 107 years, ii) activity-related knee pain, and iii) morning stiffness of the knee which lasts less than 30
57
58 108 minutes or no knee stiffness.(28) GLA:D® involves two education and 12 supervised exercise-therapy
59
60 109 sessions.(13) Education covers information about osteoarthritis, treatment options, exercise and
110
110 110 physical activity, and self-management.(13) Exercise-therapy includes neuromuscular, resistance-

1
2
3 111 training and functional exercises.(13) Participants were deemed ineligible if they i) had a comorbidity
4 112 preventing them from increasing physical activity levels as assessed by the Exercise and Sports
5 113 Science Australia (ESSA) adult pre-screening tool;(29) ii) were not proficient in English; and/or iii) had
6 114 back/ lower limb surgery or knee corticosteroid injection on the affected limb within 12 months of
7 115 enrolling.

116 **Patients and public involvement**

117 Design of the motivational interviewing sessions took place with consultation between
118 physiotherapists and a psychologist. Design of the multimedia website took place prior to consumer
119 consultation. People with knee osteoarthritis were provided the website link and asked what
120 improvements could be made to suit their needs. They also provided patient stories about their
121 experience of the benefits of physical activity for their knee and overall health. Findings of the study
122 will be emailed to participants. A subsequent qualitative analysis will take place to determine the
123 acceptability of the intervention and participant ideas for improvement.

124 **Deviations from protocol**

125 During piloting, participants did not have a good understanding of motivational interviewing prior to
126 the intervention. For this reason, the Borcovek and Nau acceptability questionnaire(30) (Appendix 1)
127 was removed from the protocol prior to randomisation commencement, as this tool was deemed to
128 be unclear when answering questions about motivational interviewing. Our protocol indicated the
129 inclusion of pain and QoL subscales from the Knee Osteoarthritis Outcome Score (KOOS), however
130 all five domains were included to give us a more detailed understanding of intervention outcomes.
131 Our registration did not mention exclusion of people who had a corticosteroid injection within 12
132 months of recruitment, however, this criterion was included and adhered to from inception.

133 Recruitment was impacted by the COVID-19 related government restrictions, including limitations on
134 in-person healthcare, gymnasium closures and limitations in allowable time away from personal
135 residence for 25-weeks in 2021. As a result, we expanded the recruitment timeframe from within
136 one-year of completing GLA:D® to within two-years. Lockdowns posed a risk of bias to either reduce
137 (less incidental activity) or amplify (more time for exercise) our intervention. Participants who were
138 impacted by lockdown at baseline during ActivPAL collection had their ActivPAL reapplied prior to
139 group allocation.

140 **Randomisation and blinding**

141 Participants were randomised using a computer-generated program with a 1:1 ratio in permuted
142 blocks of 4-6 and stratified by sex. Randomisation was prepared by a member of the research team

1
2
3 143 not involved in assessment (MFP). Group allocations were concealed in sequentially numbered
4
5 144 opaque envelopes, sealed until the point of group allocation. Participants were informed of their
6
7 145 group allocation by the coordinating physiotherapist (ECB). Due to the nature of the study, the
8
9 146 outcome assessor was the only person able to be blinded to participant allocation.

10 147 **Intervention**

11
12
13 148 *Motivational interviewing:* All participants randomised to the SUMIT group received five, 30-minute
14
15 149 sessions of motivational interviewing over a 10-week period. Sessions were conducted in weeks 1, 2,
16
17 150 4, 7, and 10 by an investigator trained in motivational interviewing (ECB). ECB had 5-years of
18
19 151 experience as a physiotherapy clinician, completed a two-day motivational interviewing course
20
21 152 online and five 1:1 coaching sessions with a Motivational Interviewing Network Trainer (MINT) and
22
23 153 accredited psychologist (PO). ECB was graded proficient according to the Motivational Interviewing
24
25 154 Treatment Integrity (MITI) assessment tool.(31)

26
27 155 Motivational interviewing sessions involved collaboration between clinician and participant aiming
28
29 156 to evoke behaviour change to increase physical activity (Appendix 2). Consistent with the principles
30
31 157 of motivational interviewing,(14) sessions followed recommended motivational interviewing
32
33 158 processes: engagement; focusing; evoking; and planning; and were tailored to individual needs and
34
35 159 level of preparedness for behaviour change (Appendix 2). Participant importance and confidence of
36
37 160 engaging in physical activity was discussed over the course of the intervention, providing valuable
38
39 161 information about shifts in potential barriers and facilitators to activity.(14)

40
41 162 *Digital Support Tool:* All participants were encouraged to access the same customised website
42
43 163 (<https://sumit.trekeeducation.org/>) prior to their first motivational interviewing session. The website
44
45 164 included information about physical activity, knee osteoarthritis, goal setting, research and activities,
46
47 165 and patient stories. Participants were encouraged to access the website prior to their first
48
49 166 motivational interviewing session. Subsequent use was based on individual participant preference.

50
51 167

52 168 **Control**

53
54 169 The control group (usual care) received no additional interventions or access to the digital support
55
56 170 tool. They were permitted to engage in routine services for their knee osteoarthritis management
57
58 171 including visits to their general practitioner, physiotherapist or other health professionals.
59
60 172 Participants were asked to refrain from knee steroid injections or surgery during the trial. At the
61
62 173 conclusion of the follow-up assessments, control participants were emailed the digital support tool
63
64 174 to access if they chose.

175 **Outcomes**176 ***Primary: feasibility***

177 The trial was considered feasible if all criteria were met or if reasonable amendments could be made
 178 to achieve these criteria in future trials (Table 1a). Recruitment, adherence and retention were
 179 calculated excluding the 6-months of COVID-19 related government restrictions during 2021.

14 **Table 1a.** 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.

180

181 **Adverse events**

182 Participants were asked if they had experienced any adverse events (any injury or illness requiring
 183 medical attention as a result of participating in the trial) at the 3-month assessment.

184 **Sample size**

185 To test feasibility, we aimed to recruit 42 participants over 5-7 months, which accounting for
 186 dropouts would allow analysis of at least 33 participants.

187 ***Secondary***

188 Secondary outcomes were collected at baseline and 3-months after baseline data collection.

189 **Device-measured physical activity**

190 ActivPAL accelerometers (PAL Technologies, Glasgow, Scotland) were fitted to each participant's
 191 right thigh with gauze and clear Flexifix for seven days. They are reliable and valid measures of step
 192 count and cadence,(32) accurate in older adults,(33) and do not to provide feedback to participants.
 193 We extracted average steps, minutes with cadence >100 steps per minute,(34) and minutes where

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3 194 bouts were >1min in duration per day. Walking cadence >100 steps per minute was chosen as an
4
5 195 outcome since it predicts lower premature mortality in older adults, and was considered to be
6
7 196 similar to moderate to vigorous physical activity.(35)

197 **Self-reported physical activity**

10
11 198 To triangulate accelerometer results, we also recorded physical activity using the University of
12
13 199 California Los Angeles (UCLA) Physical Activity Scale, and the International Physical Activity
14
15 200 Questionnaire long form (IPAQ-long). UCLA is a reliable and valid tool(36) commonly used as a
16
17 201 measure of physical activity participation in knee osteoarthritis.(13-15, 37) and the IPAQ long
18
19 202 provides valuable information about the domain in which PA is undertaken.

203 **Physical endurance**

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21
22
23 204 Physical endurance was measured using 6-minute walk distance (6MWD), measured in metres,
24
25 205 which is reliable and valid.(38)

206 **Knee-related burden**

26
27
28
29 207 The Knee Injury Osteoarthritis Outcome Score (KOOS) was used to measure knee pain, symptoms,
30
31 208 function, sport and recreation and QoL.(39) The questionnaire produces a score from 0-100 for each
32
33 209 subscale, higher scores indicate lower burden. All subscales have high reliability and validity.(39)

210 **Health-related quality of life**

34
35
36 211 The Euro QoL 5-dimension-5 long (EQ-5D-5L) was used to measure participants health-related QoL
37
38 212 through five domains, is reliable, valid and responsive in osteoarthritis populations, with the index
39
40 213 score ranging from 1 or less, with 1 being optimal health, and negative values indicating a health
41
42 214 state worse than death.(40, 41)

215 **General health**

43
44
45
46 216 Body mass index (BMI) (kg/m^2), waist circumference (cm) and systolic blood pressure (BP) (mmHg)
47
48 217 were all recorded by a blinded research assessor.

218 **Functional performance**

49
50
51
52
53 219 The 30-second chair stand, and walking speed (40m walk) tests are both recommended by guidelines
54
55 220 as feasible and reliable performance measures for knee osteoarthritis,(42) and were completed by a
56
57 221 blinded assessor.

222 **Confidence and importance of physical activity**

223 SUMIT participants were asked in weeks 2 and 10 to rate their confidence and perceived importance
224 of changing physical activity participation on a scale from zero to 10: where zero is not at all
225 important/confident and 10 is maximum importance/confidence.

226 Demographic data collected at baseline via Research Electronic Data Capture (REDCap) included age,
227 sex, body mass index, knee most affected, medication use, employment, and highest level of
228 education. An excel spreadsheet was set up to record adverse events.

229 **Statistical Analysis**

230 Statistical analysis was performed using Statistical Package for the Social Services (SPSS) version 28
231 (SPSS, Inc, Chicago, IL, USA). Demographics were reported as frequencies or mean (SD). Feasibility
232 outcomes were reported descriptively. Between group changes for continuous variables were
233 calculated using analysis of covariance (ANCOVA) with Bonferroni adjustment and baseline measures
234 as covariates.

235 The UCLA physical activity scale was dichotomised as 'more' and 'less' active, consistent with other
236 similar studies.(14, 37) We defined 'less active' as a score of ≤ 6 ('Regularly participates in moderate
237 activities, such as swimming and unlimited housework or shopping'); and defined 'more active' as ≥ 7
238 ('Regularly participates in active events such as bicycling') (Appendix 3). Chi-square tests for
239 independence (χ^2) were used to compare groups for the UCLA physical activity scale (dichotomous).

240 Desired treatment effects were defined using minimum detectable changes (MDC), which were set
241 as 8-10 for all KOOS subscales,(43) 75m for 6MWD,(44) 0.07 for health-related QoL,(40) 2 stands for
242 30-second chair stand test,(45) and 0.19 metres per second for 40m walk test.(45) There is no
243 documented MDC for device-measured physical activity, the IPAQ-long, UCLA physical activity scale,
244 BMI, blood pressure or waist circumference. Standardised mean differences (effect sizes) based on
245 within group changes between SUMIT and control groups were calculated using Review Manager 5.3
246 (The Nordic Cochrane Centre, Copenhagen, Denmark).

247 Confidence and importance of physical activity were reported descriptively at 2 and 10-weeks as
248 mean (SD) using a paired t-test to confirm significance.

249

250 **RESULTS**

251 **Primary outcome**

252 All feasibility criteria were met or could be achieved by using reasonable amendments in future trials
253 (Table 1b).

254 Eligibility and recruitment rates were impacted by oscillating COVID-19 lockdowns in Melbourne,
 255 Australia. We expanded recruitment timeframes (from completing GLA:D® within 12-months,
 256 adjusted to 24-months), and recruitment sites (from three sites to anywhere in Melbourne, Torquay
 257 or Ballarat, in Victoria, Australia) to increase our yield. Despite this, very few GLA:D® programs were
 258 running effectively until April 2022. We subsequently concluded recruitment at 32 participants
 259 (instead of 42) (Figure 1).

260 Sixty-nine percent (n=22) of participants were female. Mean (SD) for BMI and waist circumference
 261 were 30.8 (6.5) kg/m² and 101.6 (14.3) cm respectively. A full summary of the characteristics of
 262 included participants is provided in Table 2.

263 Two (6%) participants dropped out of the trial prior to receiving their group allocation. One
 264 participant cited concern to be in public places due to the high ongoing risk of contracting COVID-19
 265 and the other cited lack of time. One participant from the SUMIT group was not able to complete
 266 their follow-up ActivPAL collection due to COVID-19 lockdown timing and subsequent need for
 267 surgery, missing the follow-up period. Two participants at baseline and four participants at follow-up
 268 were undergoing ActivPAL monitoring at a time when new movement restrictions were announced
 269 (i.e. COVID-19 lockdowns). In these instances, monitoring was ceased, then restarted following the
 270 removal of movement restrictions.

271 No participants in either group experienced any adverse events as a result of data collection or the
 272 intervention during the trial. Two participants in the SUMIT group reported back pain prior to the
 273 trial and continued to experience back pain during the intervention period. One participant in the
 274 SUMIT group had a fall one week prior to follow-up, reducing their ability to participate in physical
 275 activities during the ActivPAL recording week.

276 **Table 1b.** Feasibility outcomes

	Criterion	Achieved	Proceed	Proceed with amendments
	Eligibility			
	Number of eligible participants	2-3 per site, per month, totalling 6-9 per month	63 participants screened in 7 months accounting for lockdowns and community restrictions in Melbourne (13 months elapsed)	Yes* Strategies to identify more eligible participants.
	Recruitment			

Number of participants recruited 2 participants per month, per site, totalling 6 participants per month

32 participants recruited over 7 months (13 months elapsed)

No

Strategies to increase recruitment rate.

Adherence

Adherence to motivational interviewing sessions

Minimum 4/5 sessions (80%)

100% of motivational interviewing sessions were attended within 1 week of scheduled session time

Yes -

ActivPAL

ActivPAL wear time

>16 hours for 7 days

Malfunctioning ActivPAL uploads resulted in 3 missing ActivPAL files.

Yes -

Drop-outs

Drop-out rate

<20%

2 drop-outs (6%), both from the control group

Yes -

277

278 *= Proceed with protocol deviation to expand the number of recruitment sites.

279 **Table 2.** Characteristics of included participants

	Combined Mean (SD) n=32	SUMIT Mean (SD) n=17	Control Mean (SD) n=15
Age, years	71 (7)	68 (5)	73 (9)
Sex, female, n (%)	22 (69%)	11 (65%)	11 (73%)
Height, m	1.69 (0.09)	1.69 (0.09)	1.69 (0.10)
Weight, kg	87 (17)	92.9 (17.6)	79.4 (13.4)
Recruitment			
<i>Private practice</i>	22	14	8
<i>Hospital</i>	7	3	4
<i>Community</i>	3	0	3
Education			
<i>Completed primary school</i>	1	0	1
<i>Completed high school</i>	2	1	1
<i>Completed an apprenticeship</i>	0	0	0
<i>Completed certificate</i>	4	1	3
<i>Completed diploma</i>	2	1	1

<i>Completed undergraduate degree</i>	10	4	6
<i>Completed postgraduate degree</i>	9	4	5
<i>Not reported</i>	4	4	0
Time elapsed since completing GLA:D[®], months	11 (8)	11 (9)	10 (7)
<i>Not reported, n</i>	5	4	1

Legend: SD= standard deviation, n= number of participants, m= metre, kg= kilogram, kg/m²= kilogram per metre square, cm= centimetres

280

For peer review only

1
2
3 282 **[INSERT FIGURE 1 HERE]**
4

5 283 **Secondary outcomes**
6

7
8 284 The desired treatment effect was contained within the 95%CI for all KOOS subscales, health-related
9 285 QoL, and walking speed (Table 3, Appendices 7-10). A MDC was achieved for KOOS pain and QoL
10
11 286 subscales, and health-related QoL (Table 3, Appendices 7a, 7e, 8). The desired treatment effect was
12
13 287 not met for 6MWD or 30 second chair stand test (Table 3, Appendices 6, 10b). Detailed findings are
14
15 288 provided in Appendices 4-10.

16
17 289 Ten of the thirteen outcome measures (Figure 2a) and two of the three health outcomes (Figure 2b)
18
19 290 showed at least a small effect favouring the SUMIT group, including two outcomes (walking speed
20
21 291 and KOOS quality of life) showed a large effect.

22
23 292 The proportion of 'more' active participants was 18% and 31% at baseline for SUMIT and control
24
25 293 groups respectively ($\chi^2= 0.71$, $p= 0.40$), and 31% and 8% at 3-months ($\chi^2= 0.99$, $p= 0.31$) (Appendix
26
27 294 5a-c).

28
29 295 For the SUMIT group, both perceived confidence and importance of participating in regular physical
30
31 296 activity improved between week 2 and week 10, mean (SD): 7.1 (2.2) to 8.8 (0.8) ($p=0.002$) and 8.6
32
33 297 (0.8) to 9.4 (0.9) ($p=0.006$) respectively.

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39 300 **[INSERT FIGURES 2a and 2b HERE]**
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301 **Table 3.** Within and between group differences for all secondary outcomes

Outcome	Within group differences			Within group differences			Between group differences	
	Week 0	Week 12	Week 12 minus Week 0	Week 0	Week 12	Week 12 minus Week 0	Week 12 SUMIT minus control	Previously published MDC values
	SUMIT Mean (SD) n=17	SUMIT Mean (SD) n=17	SUMIT MD (SD) n=17	Control Mean (SD) n=13	Control Mean (SD) n=13	Control MD (SD) n=13	MD (95%CI), p-value	
Steps per day	7209 (3159)	7213 (2681)	4 (1308)	7484 (2903)^	7676 (2773)^	192 (1627)^	-247 (-1264 to 769), 0.62	N/A
Daily stepping time	92 (37)	92 (32)	-0.6 (16)	98 (37)^	103 (40)^	5 (18)^	-7 (-19 to 6), 0.30	N/A
Daily time with cadence >100spm	7 (9)	15 (12)	8 (9)	7 (9)^	10 (10)^	3 (14)^	5 (-0.4 to 11), 0.67	N/A
Daily time with bouts >1min	23 (19)	52 (20)	29 (13)	23 (19)^	44 (29)^	21 (24)^	8 (-6 to 21), 0.27	N/A
IPAQ bike	21 (42)^	8 (30)^	-13 (55)^	9 (33)	0 (0)	-9 (33)	8 (-9 to 26), 0.35	N/A
IPAQ walk	299 (507)^	187 (224)^	-112 (556)^	205 (387)	171 (370)	-34 (72)	-11 (-220 to 197), 0.91	N/A
IPAQ gardening (vig)	84 (178)^	41 (95)^	-43 (196)^	92 (198)	83 (96)	-9 (198)	-41 (-115 to 32), 0.26	N/A
IPAQ gardening (mod)	252 (429)^	61 (83)^	-191 (398)^	156 (253)	157 (186)	1 (328)	-101 (-209 to 7), 0.07	N/A
IPAQ housework	215 (359)^	217 (318)^	2 (144)^	353 (301)	167 (225)	-187 (368)	123 (-50 to 297), 0.16	N/A
IPAQ leisure walking	94 (140)^	157 (236)^	63(245)^	142 (210)	183 (91)	41 (183)	-12 (-154 to 130), 0.89	N/A

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2									
3	IPAQ leisure (vig)	37 (52) [^]	27 (72) [^]	-10 (47) [^]	39 (81)	5 (17)	-35 (73)	23 (-14 to 59), 0.21	N/A
4									
5	IPAQ leisure (mod)	15 (30) [^]	52 (76) [^]	37 (75) [^]	51 (98)	59 (78)	8 (110)	2 (-59 to 62), 0.96	N/A
6									
7									
8	6MWD, m	484 (114) [^]	503 (102) [^]	19 (53) [^]	525 (97)	527 (106)	2 (40)	11 (-25 to 48), 0.52	75m(44)
9									
10									
11	KOOS pain	67 (16) [^]	79 (15) [^]	12 (13)[^]*	74 (14)	76 (14)	2 (13)	8 (-3 to 18), 0.14*	8 to 10 points(43)
12									
13	KOOS symptoms	65 (12) [^]	74 (13) [^]	9 (11)[^]	74 (11)	77 (14)	2 (16)	2 (-9 to 13), 0.73	8 to 10 points(43)
14									
15	KOOS function	70 (19) [^]	83 (12) [^]	14 (15)[^]	78 (12)	81 (15)	3 (12)	7 (-3 to 16), 0.16	8 to 10 points(43)
16									
17	KOOS sport and recreation	37 (19) [^]	52 (21) [^]	14 (21)[^]	45 (29)	58 (29)	14 (28)	-2 (-20 to 16), 0.81	8 to 10 points(43)
18									
19	KOOS QoL	47 (20) [^]	60 (20) [^]	13 (11)[^]*	54 (18)	55 (20)	1 (17)	10 (-2 to 22), 0.09*	8 to 10 points(43)
20									
21									
22	EQ5D	0.69 (0.22) [^]	0.79 (0.12) [^]	0.10 (0.23)[^]*	0.77 (0.10)	0.74 (0.11)	-0.03 (0.13)	0.07 (-0.03 to 0.16), 0.15	0.07(40)
23									
24	Body mass index, kg/m²	33 (7) [^]	33 (6) [^]	0.0 (0.8) [^]	28 (6)	28 (6)	-0.1 (0.4)	0.3 (-0.2 to 0.8), 0.23	N/A
25									
26	Systolic blood pressure, mmHg	138 (15) [^]	131 (11) [^]	-7 (12)	135 (10)	132 (15)	-3 (14)	-3 (-11 to 6), 0.56	N/A
27									
28	Waist circumference, cm	106 (14) [^]	106 (14) [^]	0.3 (5.2) [^]	95 (13)	98 (13)	2.5 (4.8)	-1.4 (-5.6 to 2.7), 0.47	N/A
29									
30	30 second chair stand test	12 (2) [^]	12 (3) [^]	1 (1) [^]	12 (2)	12 (2)	0 (2)	0.5 (-0.8 to 1.7), 0.44	2 stands(45)
31									
32	Walking speed, m/s	1.5 (0.3) [^]	1.7 (0.4) [^]	0.1 (0.2)	1.7 (0.5)	1.7 (0.4)	-0.1 (0.2)	0.15 (-0.01 to 0.31), 0.06	0.19 m/s(45)
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3 303 **Legend:** MD= mean difference, MDC= minimal detectable change, CI= confidence interval, mins=
4 304 minutes, spm= steps per minute, mmHg= millimetres of mercury, kg/m²,kilogram per metre squared,
5 305 cm= centimetres, m/s= metres per second, m= metres, IPAQ= International Physical Activity
6 306 Questionnaire, vig= vigorous, mod= moderate, N/A= not applicable, **bold** denotes confidence
7 307 intervals which include the defined minimal detectable change, *= mean difference achieved a
8 308 minimal detectable change

11 309 **DISCUSSION**

12 310 Our findings suggest that it is feasible to proceed to a large-scale RCT to evaluate the effectiveness
13 311 of motivational interviewing, supported by a digital support tool, on physical activity in people with
14 312 knee osteoarthritis. All feasibility criteria were either met or could be reasonably altered to be met
15 313 in future trials. Of those who were screened, more than half were eligible (59%), with a modest
16 314 recruitment rate achieved (4 per month). The drop-out rate was 6% which is considered
17 315 acceptable.(46) However, community restrictions including lockdowns imposed in Melbourne during
18 316 the trial (47) led to the need to broaden recruitment sources, and delays to assessments. Notably,
19 317 the number of GLA:D® completers dramatically reduced during our recruitment period due to
20 318 restrictions on in-person care, an unlikely problem in future trials. Our adherence was high (100%),
21 319 which may be attributed to the flexibility of the booking schedule and options (phone or Zoom)
22 320 provided, a feature that should be adopted in future trials.

23 321 The desired treatment effects potentially favouring the intervention in this pilot study were
24 322 contained within the 95% CI for most clinical outcomes. However, steps per day and daily stepping
25 323 time outcomes favoured the control group. This should be considered in the context of greater
26 324 improvement in walking speed (40m walk test) and fitness (6MWD) at follow up and increased time
27 325 spent walking at a cadence of >100 steps per minute or completing daily bouts of physical activity >1
28 326 minute during the intervention period for the SUMIT group. Combined, these findings may indicate
29 327 the intervention led to capacity to cover ground in less time, and possible improvement in moderate
30 328 intensity physical activity following the intervention.(34) The SUMIT group reached an average of 15-
31 329 minutes per day walking with a cadence >100 steps per minute at 3-months, reaching the threshold
32 330 to reduce all-cause mortality.(48)

33 331 Additional outcomes favouring the intervention group with moderate to large effects included KOOS
34 332 symptoms, pain, function and QoL, EQ-5D-5L, 30-second chair stand test, and systolic blood
35 333 pressure. Health-related QoL and blood pressure are particularly notable as they indicate that the
36 334 intervention may be associated with improved general health, which would need to be tested in a
37 335 larger trial. The large effect observed in favour of the SUMIT group for KOOS QoL may be related to
38 336 benefits experienced due to motivational interviewing or could be related to regular contact with a
39 337 health professional during COVID-19.

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3 338 While our study showed promising effect sizes favouring the intervention, it was not powered to find
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5 339 between group differences. The lack of between group differences may also be accounted for by
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7 340 differences in baseline characteristics which favoured our control group. There is no recommended
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9 341 dose for motivational interviewing,(20) however, it is possible that our intervention did not include
10
11 342 enough sessions to see a substantial difference between groups. Our intervention included five
12
13 343 sessions compared to other studies which have reported that eight weekly motivational interviewing
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15 344 calls resulted in meaningful differences in people with hip fractures.(49) It is possible that our
16
17 345 participants' physical activity was influenced by COVID-19 restrictions/lockdowns.(50) The impact
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19 346 may have had mixed effects, including physical activity was negatively influenced by lower incidental
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21 347 activities, and safety concerns of being outside the home.(51) Conversely, physical activity may have
22
23 348 increased for others during COVID-19 restrictions due to increased time and opportunity to access
24
25 349 outside activities.(51) Our results contrast another motivational interviewing RCT which reported no
26
27 350 difference in physical activity between groups,(21) however improvements in pain and function
28
29 351 were consistent with our findings and may be explained by our motivational interviewing sessions
30
31 352 being delivered closely together, allowing participants to reinforce behaviour change more
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33 353 effectively.

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35 354 Findings of our study should be interpreted within the context of its strengths and limitations. We
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37 355 modified our trial by increasing recruitment sites, advertising and reducing the recruitment target
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39 356 number due to the impact of COVID-19 restrictions, and have reported our trial according to the
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41 357 CONSERVE checklist to aide transparency. At baseline, our participants in both groups were
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43 358 completing 7,000 to 7,500 steps which may be already adequate to maintain good health,(52) and
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45 359 potentially challenging to increase. Further increases in physical activity in those already more active
46
47 360 are still likely to improve health,(53, 54) and increasing cadence(53, 54) during walking as occurred
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49 361 in our intervention group also provides additional benefits. However, future RCTs may consider
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51 362 targeting 'less' active participants where there is a greater potential for improvement in physical
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53 363 activity participation and health benefits. People who have completed GLA:D® report being more
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55 364 confident to participate in physical activities,(14) therefore, we chose to include this subset of the
56
57 365 knee osteoarthritis population. It is important to note that this group has been willing to participate
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59 366 in an exercise-based intervention previously, and in many cases paid out of pocket and/or claimed
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367 private health insurance to support their participation. This selection bias may limit the external
368 applicability of our findings to the broader knee osteoarthritis population. Recruiting for SUMIT
369 following GLA:D® participation may be more successful due to their change in perception towards
370 physical activity.(14) Nonetheless, our findings indicate SUMIT may be effective and feasible
371 following a widely implemented education and exercise-therapy program (i.e., GLA:D®), which as at

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3 372 December 2022 had been provided to 12,884 people with osteoarthritis.(55) Our participant groups
4
5 373 were different at baseline, possibly due to the small sample size, which may have impacted the
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7 374 findings for the secondary aims. We used rigorous randomisation and assessment blinding
8
9 375 procedures and accredited motivational interviewing training and treatment fidelity so that our
10
11 376 methods could be repeated. Our ActivPAL analyses were completed by the same researcher who
12
13 377 delivered the SUMIT intervention which may present risk of unconscious bias. Future studies should
14
15 378 provide a provision for a blinded researcher to undertake data analysis.

16 379 Our pilot feasibility trial allowed us to identify areas for improvement in a large-scale RCT. Partnering
17
18 380 with high volume GLA:D® clinics would enable early identification of eligible participants, and direct
19
20 381 recruitment for completers. Trial advertising may increase the number of potential participants self-
21
22 382 identifying and being screened. Our intervention may be improved by introducing adjunct
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24 383 accountability methods such as a downloadable self-monitoring tool (e.g. spreadsheet via our SUMIT
25
26 384 digital support tool) or formal goal setting tools.(56) We recommend that future trials use a longer
27
28 385 follow-up period to track effectiveness of the intervention on physical activity. Adding booster
29
30 386 motivational interviewing sessions have effectively increased physical activity in other
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32 387 musculoskeletal conditions,(57) and are encouraged in future knee osteoarthritis trials.(58)

31 388

33 389 **CONCLUSION**

35 390 Our study found that motivational interviewing and a web-based multimedia platform are feasible to
36
37 391 target physical activity in people with knee osteoarthritis. Secondary findings indicate this
38
39 392 intervention may be associated with improved moderate physical activity, but this requires testing in
40
41 393 a larger high-quality RCT. We have provided recommendations to improve future trials including
42
43 394 refining recruitment strategies, reducing participant burden, and optimising motivational
44
45 395 interviewing dose.

46 396

48 397 **Author contributions:** Ms Bell and Associate Professor Barton take responsibility for the integrity of
49
50 398 the data and correctness of the data analysis. Ms Bell is a PhD candidate and this trial is contributing
51
52 399 to her doctoral dissertation.

54 400 Concept and Design: ECB, CJB, PO, JAW

56 401 Acquisition of the data: ECB, research assistants

59 402 Analysis or interpretation of the data: All

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3 403 Drafting of the manuscript: ECB, PO, JAW, CJB, KMC
4

5 404 Critical revision of the manuscript: All
6

7
8 405 Obtained funding: All
9

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11
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13

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15
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17
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19
20 411 Trobe University.
21

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23
24 413 management, analysis and interpretation of the data; preparation, review or approval of the
25
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27

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31
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33

34 418 **Data sharing:** Data are available upon request from ECB (E.Bell@latrobe.edu.au). This includes de-
35
36 419 identified quantitative outcomes which are available for 7 years for use before they are destroyed
37
38 420 according to ethics requirements. Data may be used for systematic reviews or secondary analyses.
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41 REFERENCES

- 42 1. Caspersen C, Powell K, Christenson G. Physical activity, exercise, and physical fitness:
43 definitions and distinctions for health-related research. *Public Health Rep.* 1985;100:126-31.
- 44 2. Booth F, Roberts C, Laye M. Lack of exercise is a major cause of chronic diseases. *Compr*
45 *Physiol.* 2012;2(2):1143-211.
- 46 3. World Health Organization. *Global health risks: mortality and burden of disease attributable*
47 *to selected major risks.* Geneva: WHO Press. 2009.
- 48 4. Booth F, CK. R, Laye M. Lack of exercise is a major cause of chronic diseases. *Compr Physiol.*
49 *2012;2(2):1143-211.*
- 50 5. Wallis JA, Webster KE, Levinger P, Taylor NF. What proportion of people with hip and knee
51 osteoarthritis meet physical activity guidelines? A systematic review and meta-analysis.
52 *Osteoarthritis Cartilage.* 2013;21(11):1648-59.
- 53 6. Australian Bureau of Statistics. *Physical activity: Australian Bureau of Statistics; 2022 [cited*
54 *2023. Available from: [https://www.abs.gov.au/statistics/health/health-conditions-and-](https://www.abs.gov.au/statistics/health/health-conditions-and-risks/physical-activity/latest-release)*
55 *[risks/physical-activity/latest-release.](https://www.abs.gov.au/statistics/health/health-conditions-and-risks/physical-activity/latest-release)*
56
57
58
59
60

- 1
2
3 7. Wallis JA, Webster KE, Levinger P, J. SP, Fong C, F. TN. Perceptions about participation in a
4 12-week walking program for people with severe knee osteoarthritis: a qualitative analysis. *Disabil*
5 *Rehabil.* 2017;41(7):779-85.
- 6 8. Veronese N, Cereda E, Maggi S, Luchini C, Solmi M, Smith T, et al. Osteoarthritis and
7 mortality: A prospective cohort study and systematic review with meta-analysis. *Semin Arthritis*
8 *Rheum.* 2016;46(2):160-7.
- 9 9. Nüesch E, Dieppe P, Reichenbach S, Williams S, Iff S, Jüni P. All cause and disease specific
10 mortality in patients with knee or hip osteoarthritis: population based cohort study. *BMJ.*
11 2011;342:d1165.
- 12 10. The Royal Australian College of General Practitioners. Guideline for the management of knee
13 and hip osteoarthritis. 2018 [cited 2023. Available from: [https://www.racgp.org.au/clinical-](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/knee-and-hip-osteoarthritis)
14 [resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/knee-and-hip-](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/knee-and-hip-osteoarthritis)
15 [osteoarthritis](https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/knee-and-hip-osteoarthritis).
- 16 11. Skou S, Roos E. Good Life with osteoArthritis in Denmark (GLA:D™): evidence-based
17 education and supervised neuromuscular exercise delivered by certified physiotherapists
18 nationwide. *BMC Musculoskeletal Disorders.* 2017;18:72.
- 19 12. GLA:D(R) Australia, 2019. Annual report 2019. Retrieved on GLA:D(R) Australia's website
20 <https://gladaustralia.com.au/wp-content/uploads/2020/10/GLAD-ANNUAL-REPORT-2019.pdf>.
- 21 13. Barton C, Kemp J, Roos E, Skou S, Dundules K, Pazzinatto M, et al. Program evaluation of
22 GLA:D® Australia: Physiotherapist training outcomes and effectiveness of implementation for people
23 with knee osteoarthritis. *Osteoarthritis and Cartilage Open.* 2021;3(3).
- 24 14. Bell E, O'Halloran P, Pazzinatto M, Wallis J, Crossley K, Kemp J, et al. "I feel more confident":
25 A mixed-methods evaluation of the influence of GLA:D® on physical activity participation, capability,
26 barriers and facilitators in people with knee osteoarthritis. *Osteoarthritis and Cartilage.*
27 2023;31:S388-S9.
- 28 15. Skou S, Roos E. Good Life with osteoArthritis in Denmark (GLA:D™): evidence-based
29 education and supervised neuromuscular exercise delivered by certified physiotherapists
30 nationwide. *BMC Musculoskeletal Disorders.* 2017;18(72).
- 31 16. Bell E, Wallis J, Goff A, Crossley K, O'Halloran P, Barton C. Does land-based exercise-therapy
32 improve physical activity in people with knee osteoarthritis? A systematic review with meta-
33 analyses. *Osteoarthritis and Cartilage.* 2022;30(11):1420-33.
- 34 17. Kanavaki A, Rushton A, Efstathiou N, Alrushud A, Klocke R, Abhishek A, et al. Barriers and
35 facilitators of physical activity in knee and hip osteoarthritis: a systematic review of qualitative
36 evidence. *BMJ Open.* 2017;7(12).
- 37 18. Miller W, Rollnick S. Motivational interviewing: Helping people change. 3rd ed. New York:
38 The Guilford Press; 2013.
- 39 19. O'Halloran P, Blackstock F, Shields N, Holland A, Iles R, Kingsley M, et al. Motivational
40 interviewing to increase physical activity in people with chronic health conditions: a systematic
41 review and meta-analysis. *Clinical Rehabilitation.* 2014;28(12):1159-71.
- 42 20. O'Halloran P, Blackstock F, Shields N, Holland A, Iles R, Kingsley M, et al. Motivational
43 interviewing to increase physical activity in people with chronic health conditions: a systematic
44 review and meta-analysis. *Clinical Rehabilitation.* 2014;28(12):1159.
- 45 21. Gilbert A, Lee J, Linda Ehrlich-Jones L, Semanik P, Jing Song J, Pellegrini C, et al. A randomized
46 trial of a motivational interviewing intervention to increase lifestyle physical activity and improve
47 self-reported function in adults with arthritis. *Semin Arthritis Rheum.* 2018;47(5):732-40.
- 48 22. Li L, Feehan L, Xie H, Lu N, Shaw C, Gromala D, et al. Effects of a 12-Week Multifaceted
49 Wearable-Based Program for People With Knee Osteoarthritis: Randomized Controlled Trial. *JMIR*
50 *Mhealth and Uhealth.* 2020;8(7):e19116.
- 51 23. Ekman B, Nero H, Lohmander L, Dahlberg L. Costing analysis of a digital first-line treatment
52 platform for patients with knee and hip osteoarthritis in Sweden. *PLoS ONE.* 2020;15(8):e0236342.
- 53
54
55
56
57
58
59
60

24. Gao Z, Lee J. Emerging Technology in Promoting Physical Activity and Health: Challenge and Opportunities. *J Clin Med*. 2019;8(11):1830.
25. Hinman R, Lawford B, Nelligan R, Bennell K. Virtual Tools to Enable Management of Knee Osteoarthritis. *Curr Treatm Opt Rheumatol*. 2023:1-21.
26. Eldridge S, Chan C, Campbell M, Bond C, Hopewell S, Thaband L, et al. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. . *BMJ*. 2016;355:i5239.
27. Orkin A, Gill P, Ghersi D, Campbell L, Sugarman J, Chan A. Guidelines for Reporting Trial Protocols and Completed Trials Modified Due to the COVID-19 Pandemic and Other Extenuating Circumstances. The CONSERVE 2021 Statement. *JAMA*. 2021;326(3):257-65.
28. National Institute for Health and Clinical Excellence. NICE guideline on osteoarthritis: The care and management of osteoarthritis in adults. 2014.
29. Exercise & Sports Science Australia. Adult pre-exercise screening system (APSS) V2 2019 [Available from: https://www.essa.org.au/Public/ABOUT_ESSA/Pre-Exercise_Screening_Systems.aspx].
30. Devilly G, Borkovec T. Psychometric properties of the credibility/expectancy questionnaire. *Journal of Behavior Therapy and Experimental Pschiatry*. 2000;31(2):73-86.
31. Moyers T, Rowell L, Manuel J, Ernst D, Houck J. The Motivational Interviewing Treatment Integrity Code (MITI 4): Rationale, Preliminary Reliability and Validity. *J Subst Abuse Treat*. 2016;65:36-42.
32. Ryan C, Grant P, Tigbe W, Granat M. The validity and reliability of a novel activity monitor as a measure of walking. *Br J Sports Med*. 2006;40:779-84.
33. Grant P, Dall P, Mitchell S, Granat M. Activity-monitor accuracy in measuring step number and cadence in community-dwelling older adults. *J Aging Phys Act*. 2008;16(2):201-14.
34. Tudor-Locke C, Han H, Aguiar E, Barreira T, Schuna Jr J, Kang M, et al. How fast is fast enough? Walking cadence (steps/min) as a practical estimate of intensity in adults: a narrative review. *Br J Sports Med*. 2018;52(12):776-88.
35. Brown J, Harhay M, Harhay M. Walking Cadence and Mortality Among Community-Dwelling Older Adults. *J Gen Intern Med*. 2014;29(9):1263-9.
36. Terwee CB, Bouwmeester W, van Elstrand SL, de Vet HCW, Dekker J. Instruments to assess physical activity in patients with osteoarthritis of the hip or knee: a systematic review of measurement properties. *Osteoarthritis and Cartilage*. 2011;19(6):620-33.
37. Bell E, Pazzinatto M, Wallis J, Kemp J, Skou S, O'Halloran P, et al. Association of baseline physical activity participation with participant characteristics and outcomes following education and exercise-therapy in people with knee osteoarthritis: A GLA:D® Australia prospective cohort study. *Musculoskeletal Care*. 2023.
38. Ateef M, Kulandaivelan S, Tahseen S. Test–retest Reliability and Correlates of 6-minute Walk Test in Patients with Primary Osteoarthritis of Knees. *Indian Journal of Rheumatology*. 2016;11:192-6.
39. Collins N, Prinsen C, Christensen R, Bartels E, Terwee C, Roos E. Knee Injury and Osteoarthritis Outcome Score (KOOS): systematic review and meta-analysis of measurement properties. *Osteoarthritis and Cartilage*. 2016;24(8):1317-29.
40. Bilbao A, García-Pérez L, Arenaza JC, García I, Ariza-Cadiel G, Trujillo-Martín E, et al. Psychometric properties of the EQ-5D-5L in patients with hip or knee osteoarthritis: reliability, validity and responsiveness. *Quality of Life Research*. 2018;27(11):2897-908.
41. Busija L, Ackerman I, Haas R, Wallis J, Nolte S, Bentley S, et al. Adult measures of general health and health-related quality of life (invited). *Arthritis Care Res*. 2020;72(S10):522-64.
42. Dobson F, Hinman R, Hall M, Terwee C, Roos E, Bennell K. Measurement properties of performance-based measures to assess physical function in hip and knee osteoarthritis: a systematic review. *Osteoarthritis and Cartilage*. 2012;20:1548-62.
43. Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. *Health and Quality of Life Outcomes*. 2003;64(1).

- 1
- 2
- 3
- 4 44. Benaim C, Blaser S, Leger B, Vusistiner P, Luthi F. "Minimal clinically important difference"
- 5 estimates of 6 commonly-used performance tests in patients with chronic musculoskeletal pain
- 6 completing a work-related multidisciplinary rehabilitation program. *BMC Musculoskelet Disord.*
- 7 2019;20(1):16.
- 8 45. Dobson F, Hinman R, Hall M, Marshall C, Sayer T, Anderson C, et al. Reliability and
- 9 measurement error of the Osteoarthritis Research Society International (OARSI) recommended
- 10 performance-based tests of physical function in people with hip and knee osteoarthritis.
- 11 *Osteoarthritis and Cartilage.* 2017;25(11):1792-6.
- 12 46. Furlan A, Pennick V, Bombardier C, van Tulder M. 2009 Updated Method Guidelines for
- 13 Systematic Reviews in the Cochrane Back Review Group. *Spine.* 2009;34(18).
- 14 47. Victorian Department of Health. Pandemic Order Register 2022 [cited 2023. Available from:
- 15 <https://www.health.vic.gov.au/covid-19/pandemic-order-register>.
- 16 48. Wen C, Wai J, Tsai M, Yang Y, Cheng T, Lee M, et al. Minimum amount of physical activity for
- 17 reduced mortality and extended life expectancy: a prospective cohort study. *Lancet.*
- 18 2011;378(9798):1244-53.
- 19 49. O'Halloran P, Shields N, Blackstock F, Wintle E, Taylor N. Motivational interviewing increases
- 20 physical activity and self-efficacy in people living in the community after hip fracture: a randomized
- 21 controlled trial. *Clinical Rehabilitation.* 2016;30(11):1108-19.
- 22 50. Stockwell S, Trott M, Tully M, Shin J, Barnett Y, Butler L, et al. Changes in physical activity
- 23 and sedentary behaviours from before to during the COVID-19 pandemic lockdown: a systematic
- 24 review. *BMJ Open Sport & Exercise Medicine.* 7(1).
- 25 51. Park A, Zhong S, Yang H, Jeong J, Lee C. Impact of COVID-19 on physical activity: A rapid
- 26 review. *J Glob Health.* 2022;12:05003.
- 27 52. Lee IM, Shiroma E, Kamada M, Bassett D, Matthews C, Buring J. Association of Step Volume
- 28 and Intensity With All-Cause Mortality in Older Women. *JAMA Internal Medicine.* 2019;179(8).
- 29 53. del Pozo Cruz B, Ahmadi M, Lee IM, Stamatakis E. Prospective Associations of Daily Step
- 30 Counts and Intensity With Cancer and Cardiovascular Disease Incidence and Mortality and All-Cause
- 31 Mortality. *JAMA Internal Medicine.* 2022;182(11):1139-48.
- 32 54. Saint-Maurice P, Troiano R, Bassett Jr D, Graubard B, Carlson S, Shiroma E, et al. Association
- 33 of Daily Step Count and Step Intensity With Mortality Among US Adults. *JAMA.* 2020;323(12):1151-
- 34 60.
- 35 55. Crossley K, Barton C, Kemp J, Ezzat A, de Oliveria Silva D, Heerey J, et al. GLA:D® Australia
- 36 2022 Annual Report. 2022.
- 37 56. Whittaker J, Truong L, Losciale J, Silvester-Lee T, Miciak M, Pajkic A, et al. Efficacy of the
- 38 SOAR knee health program: protocol for a two-arm stepped-wedge randomized delayed-controlled
- 39 trial. *BMC Musculoskelet Disord.* 2022;23(85).
- 40 57. Fjeldsoe B, Neuhaus M, Winkler E, Eakin E. Systematic review of maintenance of behavior
- 41 change following physical activity and dietary interventions. *Health Psychol.* 2011;30(1):99-109.
- 42 58. Lilienthal K, Pignol A, Holm J, Vogeltanz-Holm N. Telephone-Based Motivational Interviewing
- 43 to Promote Physical Activity and Stage of Change Progression in Older Adults. *Journal of Aging and*
- 44 *Physical Activity.* 2014;22(4):527-35.
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3 **Figure legends:**
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5 **Figure 1.** Study timeline

6 Legend: GLA:D®= Good Life with osteoArthritis Denmark, SUMIT= SUpported Motivational
7 InTerviewing, mins= minutes
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9 **Figure 2a.** Forest plot comparing within group change scores between SUMIT and control groups

10
11 Legend: spm= steps per minute, min= minute, KOOS= Knee Osteoarthritis Outcome Score, EQ5D5L=
12 Euroqual 5-dimension 5-long
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14 **Figure 2b.** Forest plot comparing within group change scores between SUMIT and control groups for
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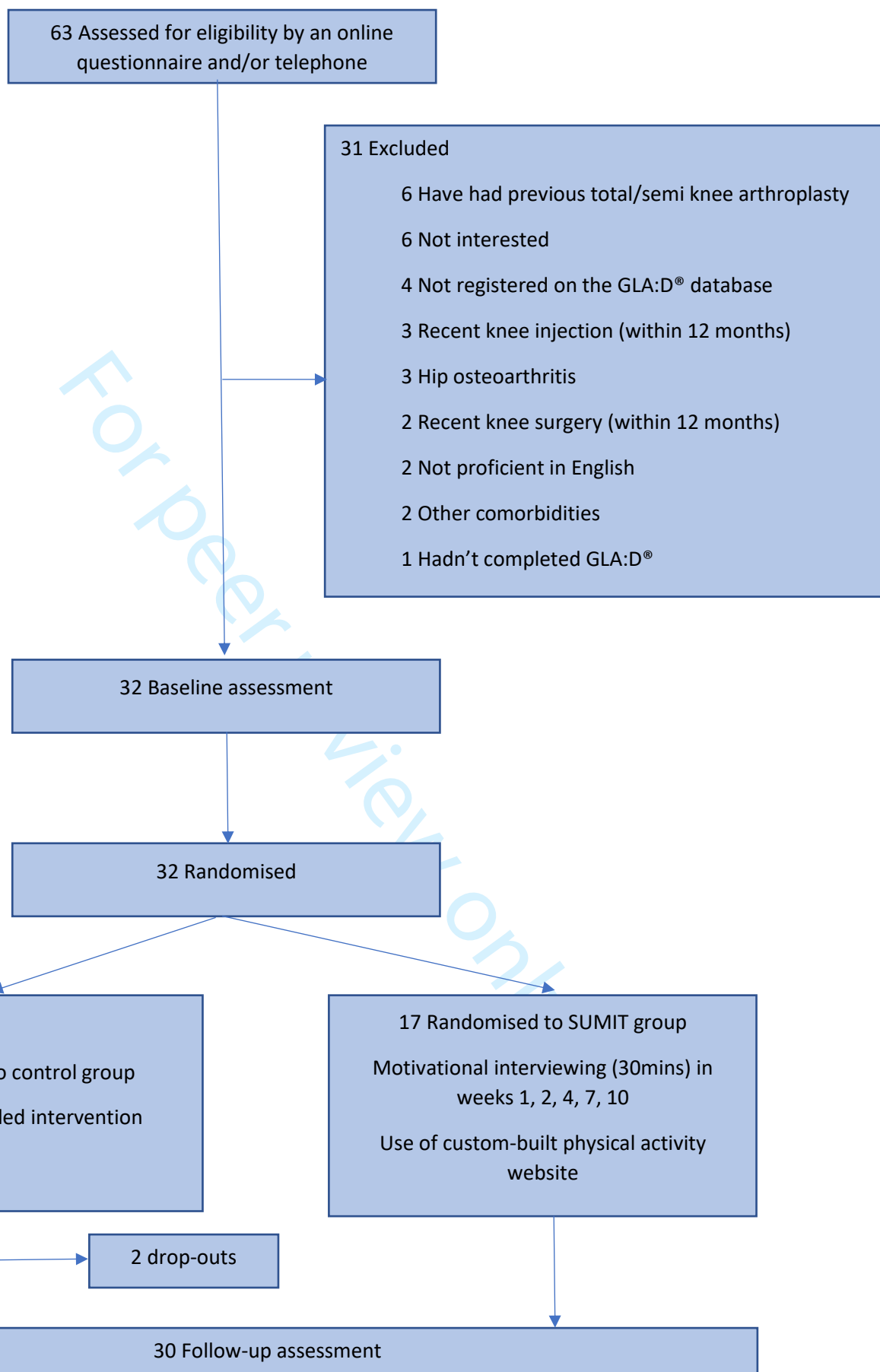


Figure 1. Timeline

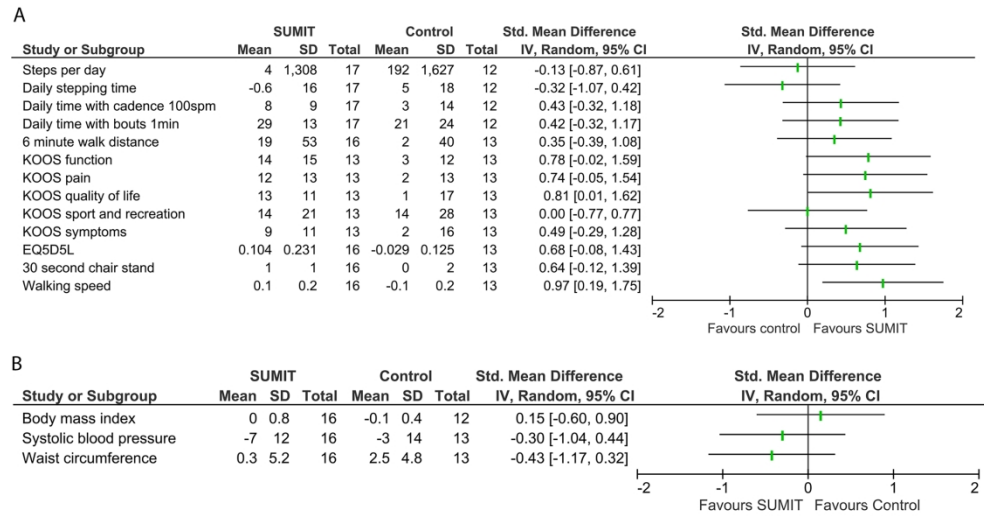


Figure 2a. Forest plot comparing within group change scores between SUMIT and control groups
 Legend: spm= steps per minute, min= minute, KOOS= Knee Osteoarthritis Outcome Score, EQ5D5L= Euroqual 5-dimension 5-long

Figure 2b. Forest plot comparing within group change scores between SUMIT and control groups for health outcomes

203x105mm (300 x 300 DPI)

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Appendices

Appendix 1. Borcovek and Nau acceptability questionnaire

1. How logical does the therapy offered to you seem?
2. How successfully do you think this treatment will be?
3. How confident would you be in recommending this treatment to a friend?
4. How much improvement in your physical activity do you think will occur?
5. How much do you really <i>feel</i> that therapy will help you to increase your physical activity?
6. How much improvement in your physical activity do you really <i>feel</i> will occur?

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9 **Appendix 2. Motivational interviewing**

10 Motivational interviewing is an evidence based person-centred counselling intervention, used to
11 target a particular behaviour change. To facilitate delivery of motivational interviewing as intended,
12 the interviewer must undergo an accredited 2-day training program (delivered by a clinician from the
13 motivational interviewing network of trainers (MINT)), 1:1 coaching and be graded proficient
14 according to the motivational interviewing treatment integrity (MITI) code. Motivational interviewing
15 incorporates microskills such as open-ended questions, affirmations, reflective listening and
16 summarising (OARS). These microskills are delivered within the motivational interviewing spirit which
17 includes partnership, acceptance, evocation and compassion. Motivational interviewing encompasses
18 four key processes: engagement, focusing, evoking and planning.

19 *Engagement:* to develop a working relationship with the interviewee. This is an ongoing and important
20 part of the process as you are seeking to change their behaviour.

21 *Focusing:* to focus on what the interviewee is wants to and is willing to change at the time. E.g. the
22 interviewee may not be willing to make big changes initially so it is important to work with them
23 where they are, not where the interviewer thinks they should be.

24 *Evoking:* to draw out the interviewee's own motivation and ideas for behaviour change. E.g. a
25 therapist may want a patient to increase their physical activity to help their functional outcomes,
26 compared to the patient who wants to be able to get on and off the ground easily to play with their
27 grandchildren. Evoking the patient's motivation is far more powerful and more likely to lead to
28 behaviour change.

29 *Planning:* to develop goals collaboratively and make a plan for how to achieve them. E.g. the
30 interviewee may have an idea of what they can do to get started right away, and may be able to
31 develop a plan to gradually make additional changes as time goes on.

32 It is important to acknowledge that multiple processes may occur at one time, and may not be in a
33 linear sequence. The pace and sequence will be different for each individual and it is up the
34 interviewer and interviewee to navigate this together during each session.

35 A real-life example of the processes from this trial includes:

36 Participant 3 (P3) had never been exposed to motivational interview before, learned from GLA:D® that
37 they should be doing regular exercise for their knee and had previously had fluctuating dedication to
38 gym since being aged in their 20's. **Engagement:** P3 talked with their physio about their love of
39 gardening, social events, seeing family and volunteering. The practitioner using MI connects with their
40 client through displaying an interest through open ended questions (e.g. *tell me more about what you*
41 *like about gardening*) and demonstrating active listening through use of reflective listening (e.g. *family*
42 *is really important to you*) **Focusing:** P3 wanted to make a lasting change to their physical activity
43 participations because they had seen and felt the benefits of being active as well as continuing to
44 incorporate knee strength exercises in their life. Being active brought P3 joy, and facilitated other
45 important activities. The practitioner using MI facilitates this process through open ended questions
46 (e.g. *what are the major benefits of you being more active*) and reflections (e.g., *being more active*
47 *would make a real difference to your life and you're ready to do more*). **Evoking:** The practitioner using
48 MI utilises evocation throughout the session, for instance with respect to helping the client focus open
49 ended questions such as *what would you be willing to do to increase your activity?* can assist to
50 facilitate such as P3 noting they are willing to incorporate more walking and add some upper body
51 exercises to their gym routine for a full body workout **Planning:** Planning relates to evoking specifics
52 from the client about what they will do and when. In this context P3 planned add walks on days they
53 didn't attend the gym, and started using their smart phone step count to see how far they walked with
54 certain activities, which could be used to measure future increases to walking.

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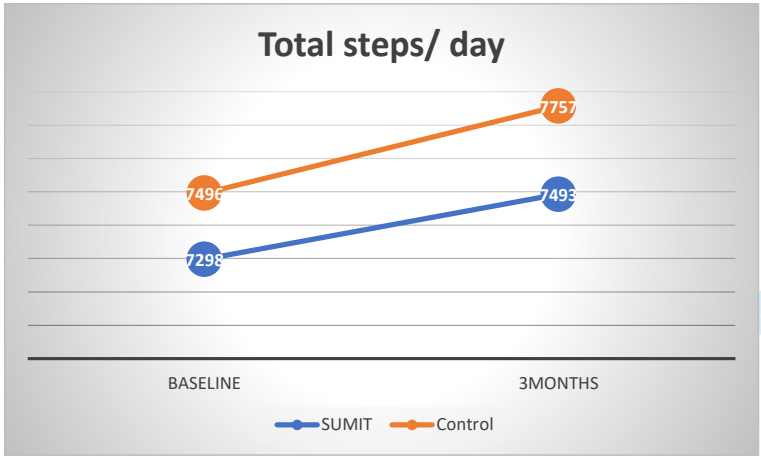
Appendix 3. University of California Los Angeles Physical Activity Scale

Question	Answer options:
<i>Please indicate which level of activity applies to you</i>	1 Wholly inactive: dependent on others: cannot leave residence
	2 Mostly inactive: restricted to minimal activities of daily living
	3 Sometimes participates in mild activities
	4 Regularly participates in mild activities, such as walking, limited housework, and limited shopping
	5 Sometimes participates in moderate activities
	6 Regularly participates in moderate activities, such as swimming and unlimited housework or shopping
	7 Regularly participates in active events, such as bicycling
	8 Regularly participates in very active events such as bowling or golf
	9 Sometimes participates in impact sports
	10 Regularly participates in impact sports such as jogging, tennis, skiing, acrobatics, ballet, heavy labour, or backpacking

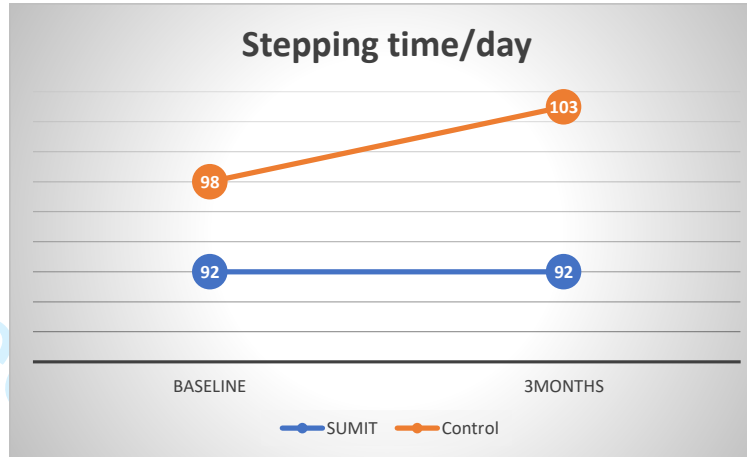
Legend: 'Less' active = responses 1-6 in yellow, 'more' active = responses 7-10 in green.

review only

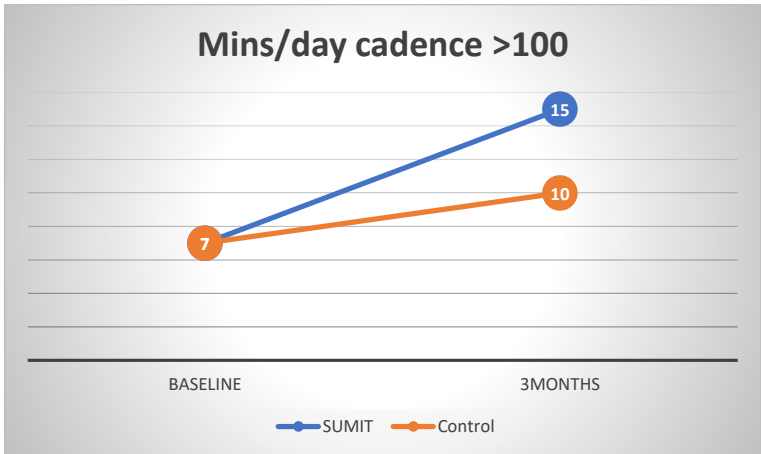
Appendix 4a. Total steps per day for SUMIT and control groups at baseline and 3-months



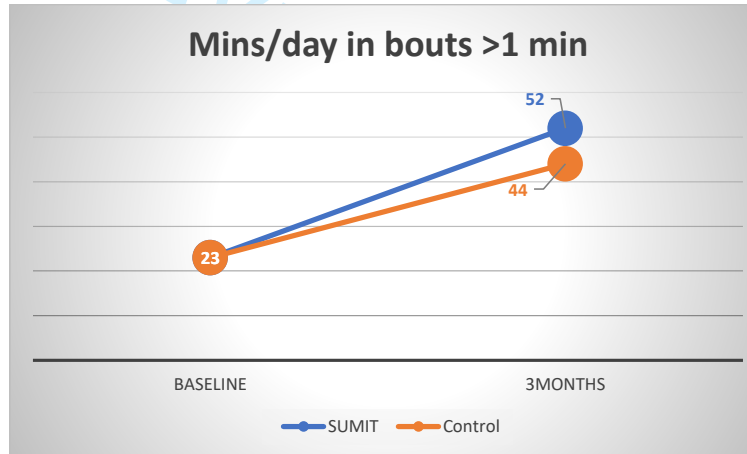
Appendix 4b. Stepping time per day (mins) for SUMIT and control groups at baseline and 3-months



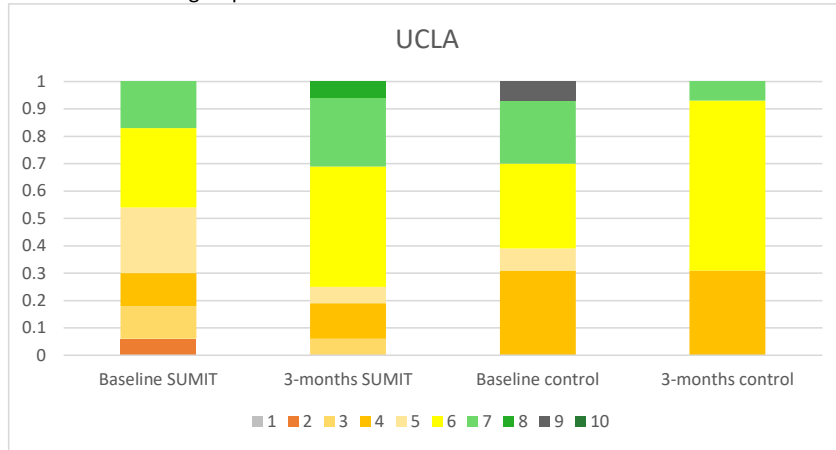
Appendix 4c. Minutes per day with cadence >100 for SUMIT and control groups at baseline and 3-months



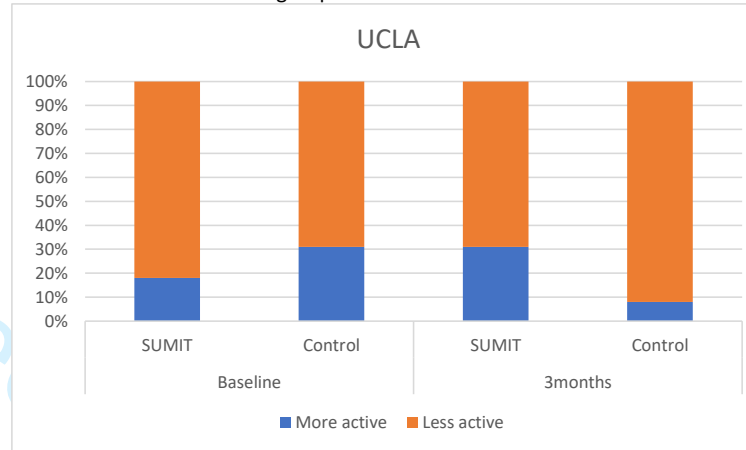
Appendix 4d. Minutes per day in bouts >1min for SUMIT and control groups at baseline and 3-months



Appendix 5a. University of California Los Angeles physical activity scale raw scores for SUMIT and control groups at baseline and 3-months

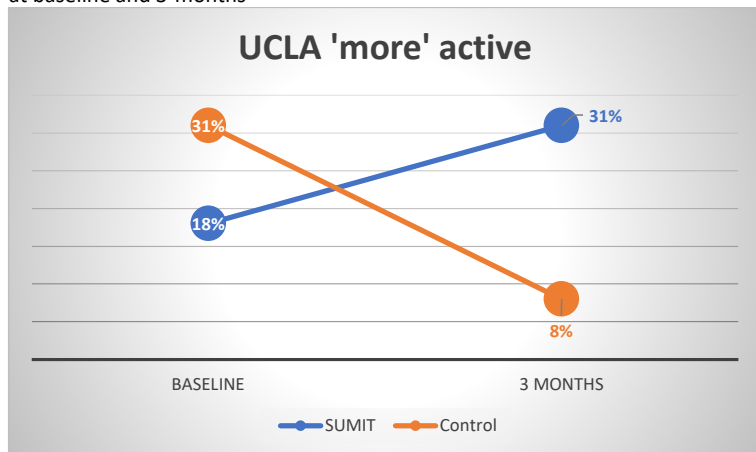


Appendix 5b. Dichotomised University of California Los Angeles physical activity scale for SUMIT and control groups at baseline and 3-months

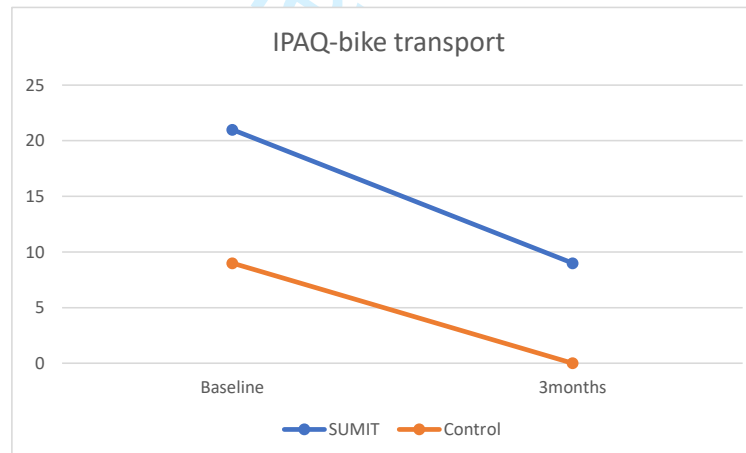


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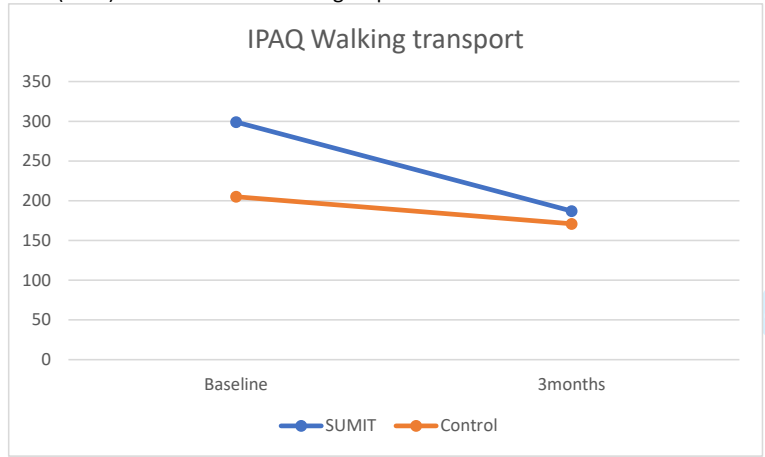
Appendix 5c. Proportion of participants who are 'more' or 'less' active using the University of California Los Angeles physical activity scale for SUMIT and control groups at baseline and 3-months



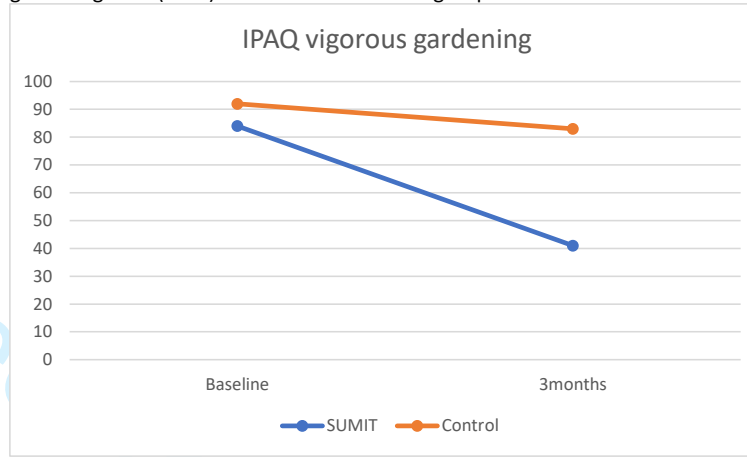
Appendix 5d. International Physical Activity Questionnaire long form bike transport time (mins) for SUMIT and control groups at baseline and 3-months



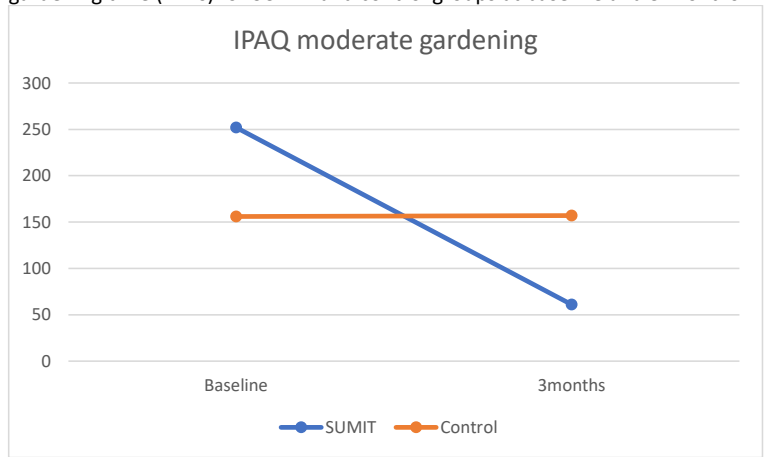
Appendix 5e. International Physical Activity Questionnaire long form walking transport time (mins) for SUMIT and control groups at baseline and 3-months



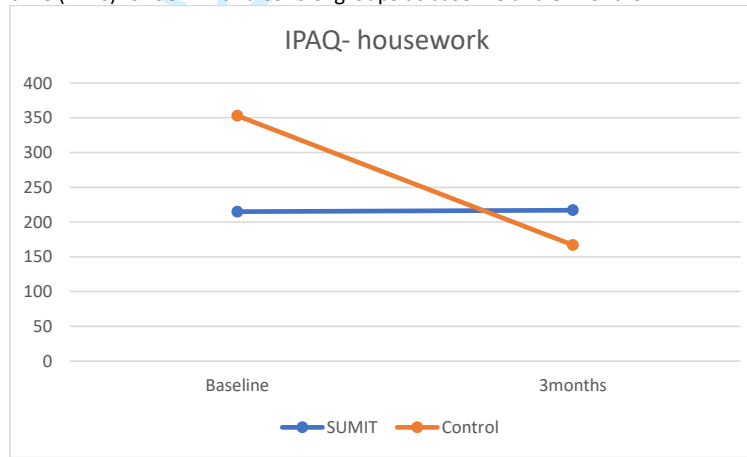
Appendix 5f. International Physical Activity Questionnaire long form vigorous gardening time (mins) for SUMIT and control groups at baseline and 3-months



Appendix 5g. International Physical Activity Questionnaire long form moderate gardening time (mins) for SUMIT and control groups at baseline and 3-months

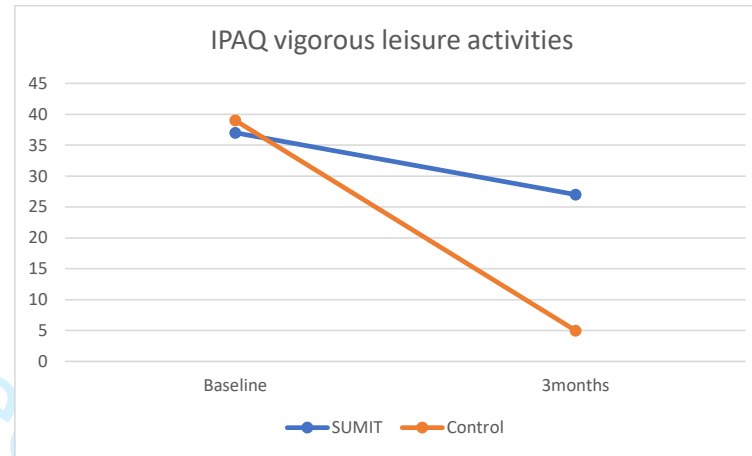
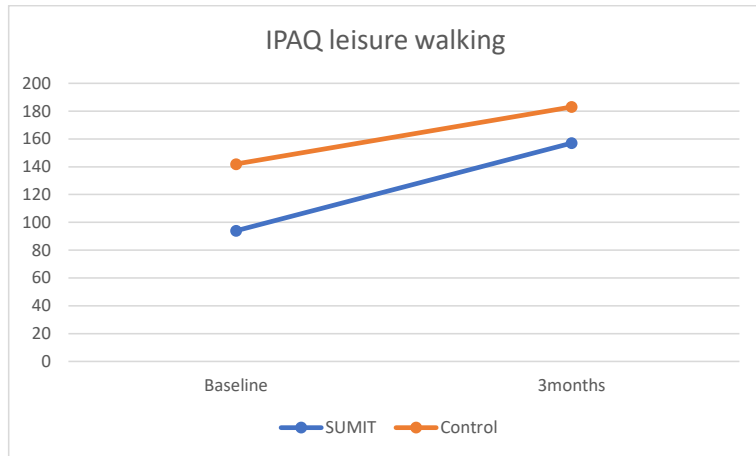


Appendix 5h. International Physical Activity Questionnaire long form housework time (mins) for SUMIT and control groups at baseline and 3-months

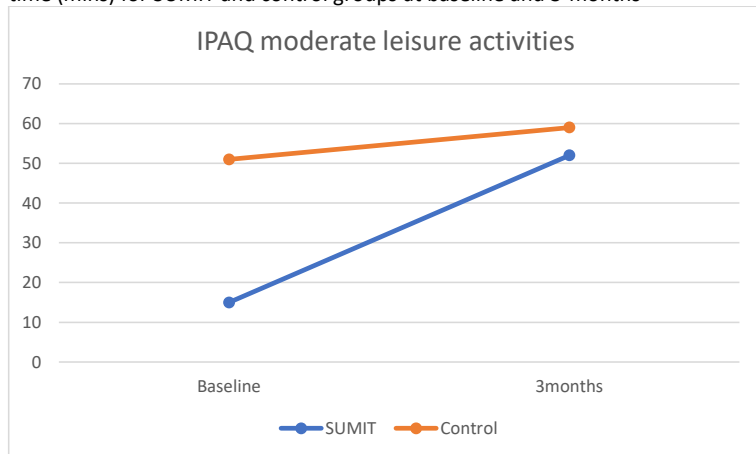


Appendix 5i. International Physical Activity Questionnaire long form leisure walking time (mins) for SUMIT and control groups at baseline and 3-months

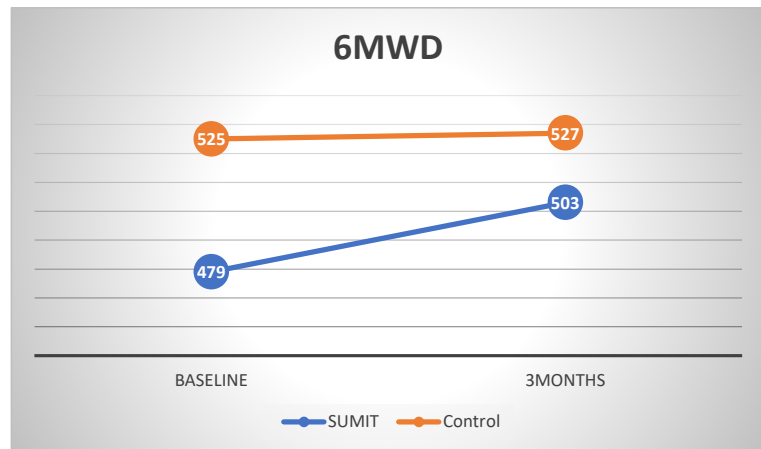
Appendix 5j. International Physical Activity Questionnaire long form vigorous leisure time (mins) for SUMIT and control groups at baseline and 3-months



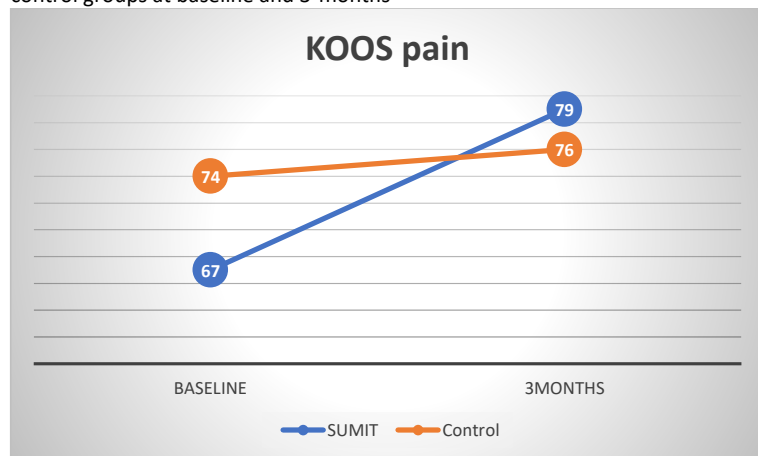
Appendix 5k. International Physical Activity Questionnaire long form moderate leisure time (mins) for SUMIT and control groups at baseline and 3-months



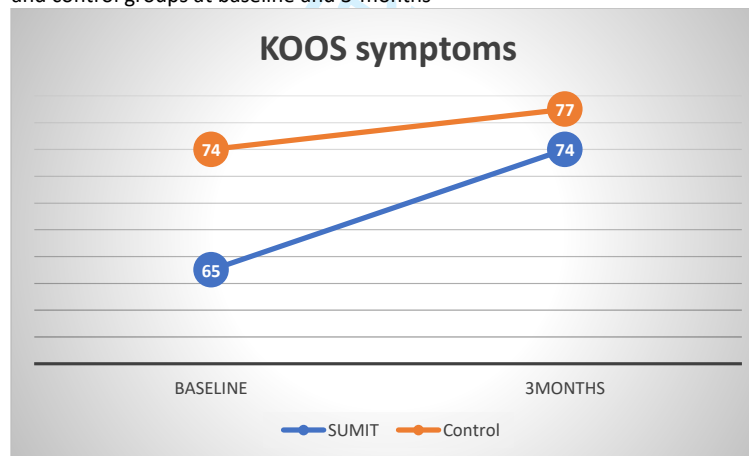
Appendix 6. 6-minute walk distance (m) for SUMIT and control groups at baseline and 3-months



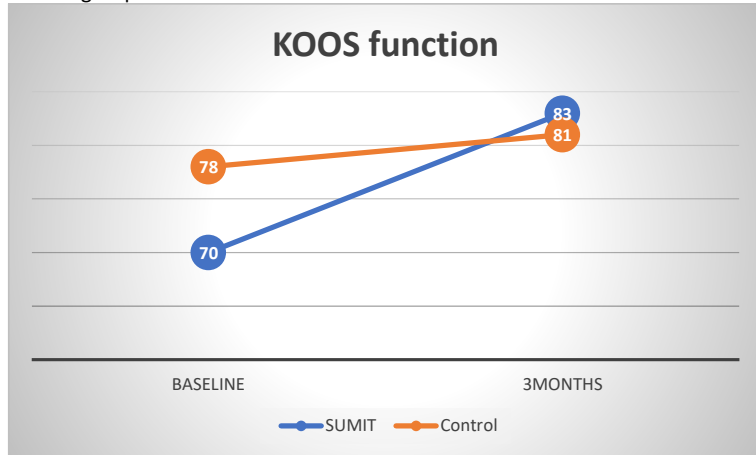
Appendix 7a. Knee Osteoarthritis Outcome Score pain subscale for SUMIT and control groups at baseline and 3-months



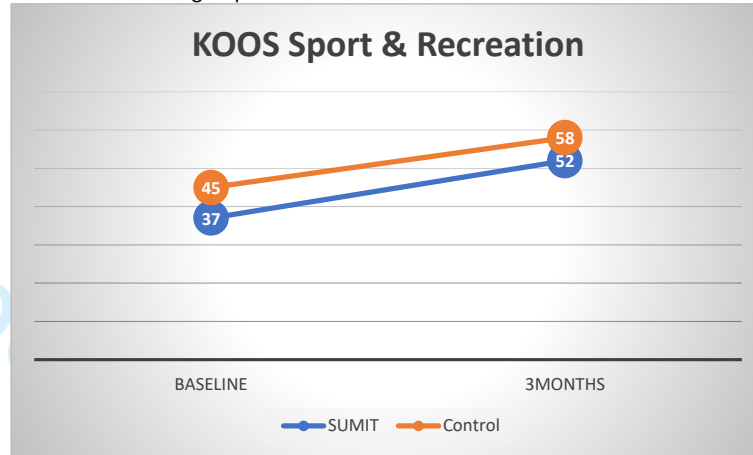
Appendix 7b. Knee Osteoarthritis Outcome Score symptoms subscale for SUMIT and control groups at baseline and 3-months



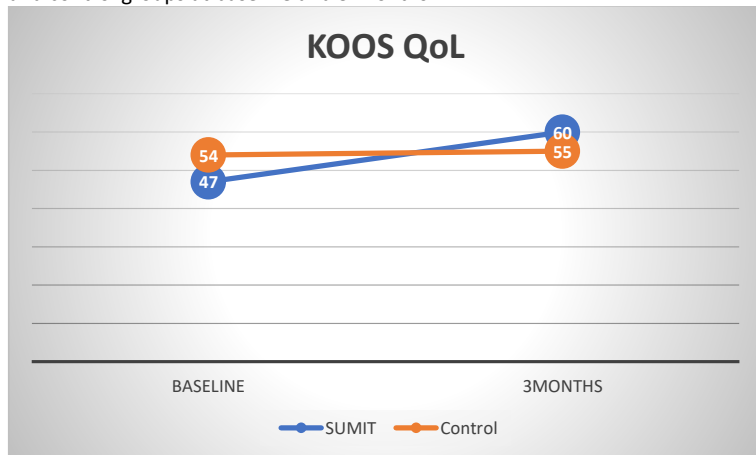
Appendix 7c. Knee Osteoarthritis Outcome Score function subscale for SUMIT and control groups at baseline and 3-months



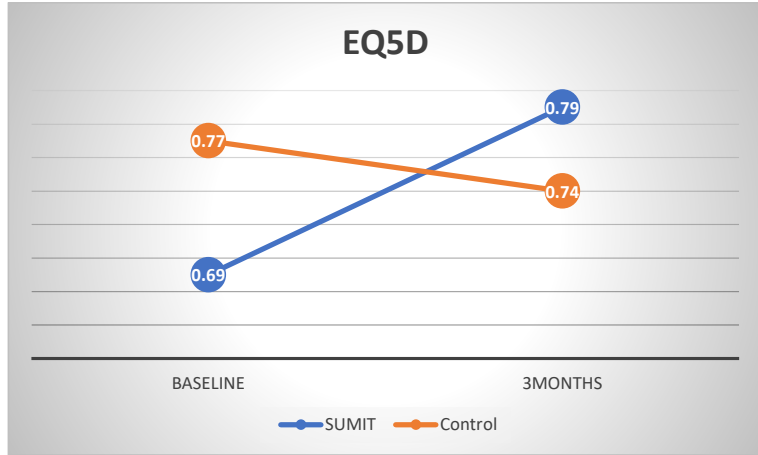
Appendix 7d. Knee Osteoarthritis Outcome Score sport & recreation subscale for SUMIT and control groups at baseline and 3-months



Appendix 7e. Knee Osteoarthritis Outcome Score quality of life subscale for SUMIT and control groups at baseline and 3-months



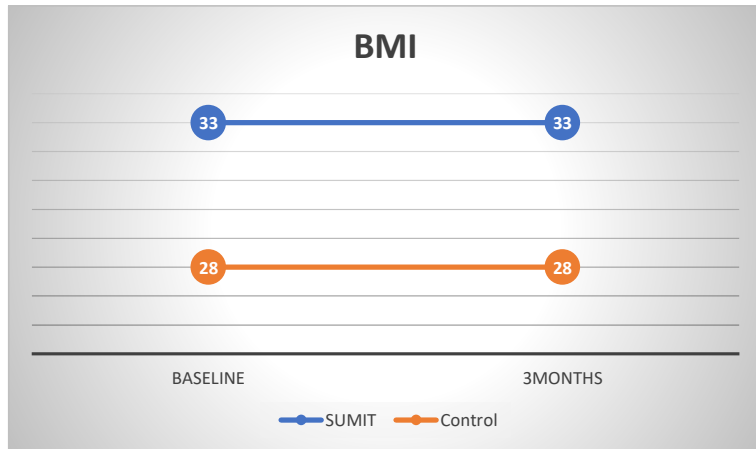
Appendix 8. Health-related quality of life for SUMIT and control groups at baseline and 3-months



Legend: EQ5D= Euroqual 5-dimension 5-long

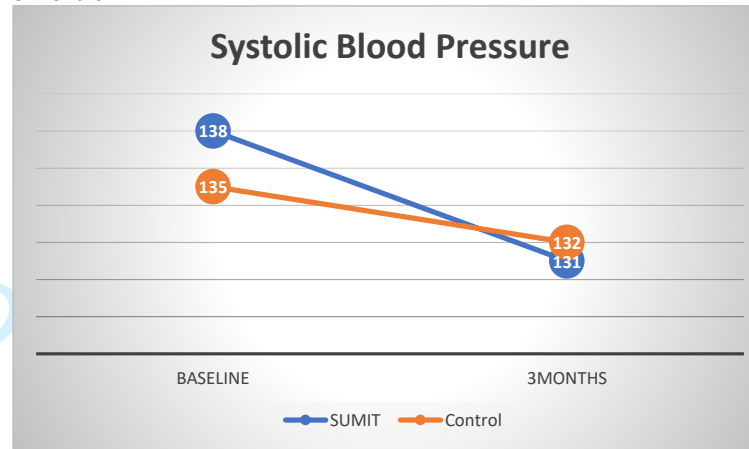
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Appendix 9a. BMI for SUMIT and control groups at baseline and 3-months

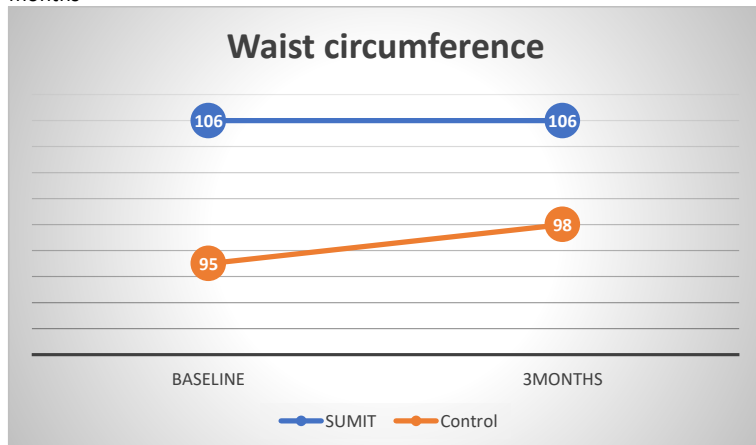


Legend: BMI- body mass index

Appendix 9b. Systolic blood pressure for SUMIT and control groups at baseline and 3-months



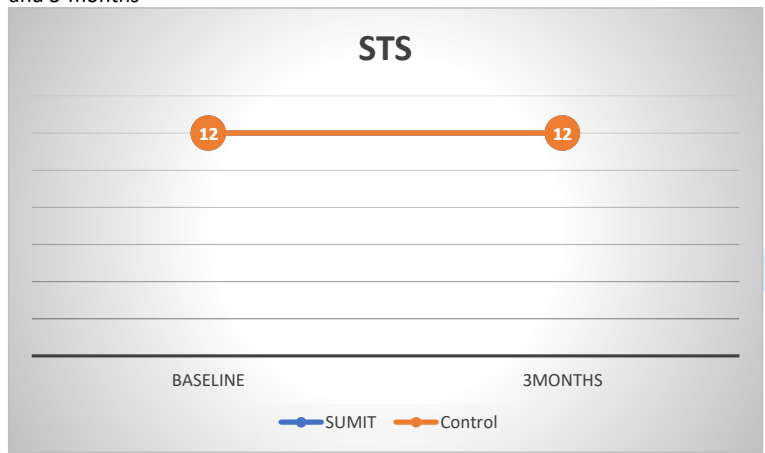
Appendix 9c. Waist circumference for SUMIT and control groups at baseline and 3-months



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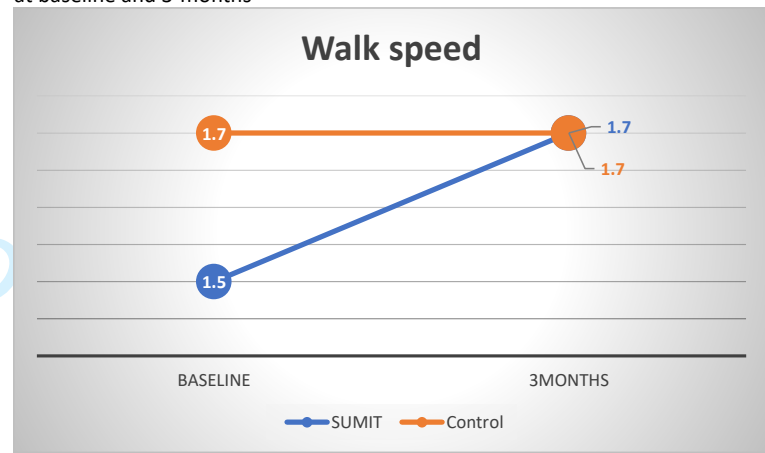
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Appendix 10a. 30 second chair stand test for SUMIT and control groups at baseline and 3-months



Legend: STS= sit to stand
*Both groups were the same and are overlapped

Appendix 10b. Walking speed measured by 40mWT for SUMIT and control groups at baseline and 3-months



Legend: 40mWT= 40 metre walk test



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-4
	2b	Specific objectives or hypotheses	4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5-6
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6-7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	7-8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	6-7
Sample size	7a	How sample size was determined	8
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

1		assessing outcomes) and how	
2		11b If relevant, description of the similarity of interventions	NA
3	Statistical methods	12a Statistical methods used to compare groups for primary and secondary outcomes	9-10
4		12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	9-10
5			
6	Results		
7	Participant flow (a	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and	Figure 1, p12
8	diagram is strongly	were analysed for the primary outcome	
9	recommended)	13b For each group, losses and exclusions after randomisation, together with reasons	10
10	Recruitment	14a Dates defining the periods of recruitment and follow-up	8
11		14b Why the trial ended or was stopped	6, 10
12	Baseline data	15 A table showing baseline demographic and clinical characteristics for each group	Table 2, p12
13	Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was	Table 3, p14
14		by original assigned groups	
15	Outcomes and	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its	14
16	estimation	precision (such as 95% confidence interval)	
17		17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
18	Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	14-16
19		pre-specified from exploratory	
20	Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	10-11
21			
22	Discussion		
23	Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	3, 19
24	Generalisability	21 Generalisability (external validity, applicability) of the trial findings	19
25	Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	18-20
26			
27	Other information		
28	Registration	23 Registration number and name of trial registry	5
29	Protocol	24 Where the full trial protocol can be accessed, if available	5
30	Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	20

36
37 *We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also
38 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.
39 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.
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Supplement 2
for
Guidelines for reporting trial protocols and completed trials modified due
to the COVID-19 pandemic and other extenuating circumstances: The
CONSERVE 2020 Statement

CONSERVE Checklists

Use CONSERVE-CONSORT for completed trial reports and CONSERVE-SPIRIT for trial protocols.

CONSERVE-CONSORT Extension: [DATE]					
Item	Item Title	Description	Page No.		
I.	Extenuating Circumstances	Describe the circumstances and how they constitute extenuating circumstances.	5-6		
II.	Important Modifications	a. Describe how the modifications are important modifications.	6		
		b. Describe the impacts and mitigating strategies, including their rationale and implications for the trial.	(see below) 6		
		c. Provide a modification timeline.	6, 11		
III.	Responsible Parties	State who planned, reviewed and approved the modifications.	6		
IV.	Interim data	If modifications were informed by trial data, describe how the interim data were used, including whether they were examined by study group, and whether the individuals reviewing the data were blinded to the treatment allocation.	N/A		
CONSORT Number and Item		For each row, if important modifications occurred check "direct impact" and/or "mitigating strategy" and describe the changes in the trial manuscript or supplement. Check "no change" for items that are unaffected in the extenuating circumstance.			
		No Change	Impact*	Mitigating Strategy**	Page No.
1	Title and abstract	X			
2	Introduction	X			
3	Methods: Trial Design	X			
4	Methods: Participants		X		5
5	Methods: Interventions	X			
6	Methods: Outcomes	X			
7	Methods: Sample Size		X		10
8-10	Methods: Randomisation		X		6

11	Methods: Blinding	X			
12	Methods: Statistical methods	X			
13	Results: Participant flow	X			
14	Results: Recruitment		X	X	10
15	Results: Baseline data	X			
16	Results: Numbers analysed		X		10
17	Results: Outcomes and estimation		X		11
18	Results: Ancillary analyses	X			
19	Results: Harms	X			
20	Discussion: Limitations		X		19
21	Discussion: Generalisability	X			
22	Other information: Registration	X			
23	Other information: Protocol	X			
24	Other information: Funding	X			

*Aspects of the trial that are directly affected or changed by the extenuating circumstance and are not under the control of investigators, sponsor or funder.

**Aspects of the trial that are modified by the study investigators, sponsor or funder to respond to the extenuating circumstance or manage the direct impacts on the trial.

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CONSERVE-SPIRIT Extension: [DATE]					
Item	Item Title	Description			Page No.
I.	Extenuating Circumstances	Describe the circumstances and how they constitute extenuating circumstances.			
II.	Important Modifications	a. Describe how the modifications are important modifications.			
		b. Describe the impacts and mitigating strategies, including their rationale and implications for the trial.			(see below)
		c. Provide a modification timeline.			
III.	Responsible Parties	State who planned, reviewed and approved the modifications.			
IV.	Interim data	If modifications were informed by trial data, describe how the interim data were used, including whether they were examined by study group, and whether the individuals reviewing the data were blinded to the treatment allocation.			
SPIRIT Item and Number		For each row, if important modifications occurred, check one or both of "impact" and/or "mitigating strategy" and describe the changes in the protocol. Check "no change" for items that are unaffected in the extenuating circumstance.			Page No.
		No Change	Impact*	Mitigating Strategy**	
1	Title				
2	Trial registration				
3	Protocol version				
4	Funding				
5	Roles and responsibilities				
6	Background and rationale				
7	Objectives				
8	Trial design				
9	Study setting				
10	Eligibility criteria				
11	Interventions				
12	Outcomes				

13	Participant timeline				
14	Sample size				
15	Recruitment				
16	Allocation				
17	Blinding (masking)				
18	Data collection methods				
19	Data management				
20	Statistical methods				
21	Data monitoring				
22	Harms				
23	Auditing				
24	Research ethics approval				
25	Protocol amendments				
26	Consent or assent				
27	Confidentiality				
28	Declaration of interests				
29	Access to data				
30	Ancillary and post-trial care				
31	Dissemination policy				
32	Informed consent materials				
33	Biological specimens				
<p>*Aspects of the trial that are directly affected or changed by the extenuating circumstance and are not under the control of investigators, sponsor or funder. **Aspects of the trial that are modified by the study investigators, sponsor or funder to respond to the extenuating circumstance or manage the direct impacts on the trial.</p> <p>The CONSERVE-SPIRIT Checklist is licensed by the CONSERVE Group under the Creative Commons Attribution-NonCommercial-NoDerivs 4.0 International license.</p>					