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ABSTRACT

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

Design: Randomised controlled trial.

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

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

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

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

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

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

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

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

Key words: Physiotherapy, Rehabilitation, Comorbidities, Behaviour Change, Knee osteoarthritis, Motivational Interviewing

Strengths and limitations of this study

- We modified our trial by increasing recruitment sites, advertising and reducing the recruitment target number due to the impact of COVID-19 restrictions, and have reported our trial according to the CONSERVE checklist to aide transparency.
- We used rigorous randomisation and assessment blinding procedures and accredited motivational interviewing training and treatment fidelity so that our methods could be repeated.
- Our ActivPAL analyses were completed by the same researcher who delivered the SUMIT intervention which may present risk of unconscious bias. Future studies should provide a provision for a blinded researcher to undertake data analysis.
- Our participant groups were different as baseline, possibly due to the small sample size, which may have impacted the findings for the secondary aims.

INTRODUCTION

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

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

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

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

help to increase physical activity.[25] However, the influence of digital support tools on physical activity behaviour change is unknown.[25]

Our primary objective was to determine the feasibility of conducting a fully powered trial evaluating the effectiveness of increasing physical activity using SUpported Motivational InTerviewing (SUMIT), following completion of an education and exercise-therapy program in people with knee osteoarthritis. Our secondary objective was to determine if a worthwhile treatment effect occurred for physical activity, physical endurance, knee-related quality of life (QoL), health-related QoL and pain.

METHODS

Trial design

This pilot feasibility randomised controlled trial (RCT) compared an intervention comprising motivational interviewing and website) with a usual care control group. Ethics approval was obtained from La Trobe University Human Research Ethics Committee (#HEC20506). The trial was registered with Australian New Zealand Clinical Trials Registry (ANZCTR) (ACTRN12621000267853). Study reporting adheres to the Consolidated Standards or Reporting Trials (CONSORT) for pilot and feasibility trials.[26] Due to the interruption from the Coronavirus pandemic (COVID-19), we reported limitations according to the CONSORT and SPIRIT Extension for RCTs Revised in Extenuating Circumstances (CONSERVE) guidelines.[27]

Setting

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

Participants

Adults with a clinical diagnosis of knee osteoarthritis[28] who had completed GLA:D® within the previous 2-years[13] were recruited from March 2021 to April 2022. Participants were deemed ineligible if they i) had a comorbidity preventing them from increasing physical activity levels as assessed by the Exercise and Sports Science Australia (ESSA) adult pre-screening tool;[29] ii) were not proficient in English; and/or iii) had back/ lower limb surgery or knee corticosteroid injection on the affected limb within 12 months of enrolling.

Deviations from protocol

During piloting, participants did not have a good understanding of motivational interviewing prior to the intervention. For this reason, the Borcovek and Nau acceptability questionnaire[30] (Appendix 1) was removed from the protocol prior to randomisation commencement, as this tool was deemed to be unclear when answering questions about motivational interviewing. Our protocol indicated the inclusion of pain and QoL subscales from the Knee Osteoarthritis Outcome Score (KOOS), however all five domains were included to give us a more detailed understanding of intervention outcomes.

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

Randomisation and blinding

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

Intervention

Motivational interviewing: All participants randomised to the SUMIT group received five, 30-minute sessions of motivational interviewing over a 10-week period. Sessions were conducted in weeks 1, 2, 4, 7, and 10 by an investigator trained in motivational interviewing (ECB). ECB had 5-years of experience as a physiotherapy clinician, completed a two-day motivational interviewing course online and five 1:1 coaching sessions with a Motivational Interviewing Network Trainer (MINT) and accredited psychologist (PO). ECB was graded proficient according to the Motivational Interviewing Treatment Integrity (MITI) assessment tool.[31]

Motivational interviewing sessions involved collaboration between clinician and participant aiming to evoke behaviour change to increase physical activity (Appendix 2). Consistent with the principles of motivational interviewing,[14] sessions followed recommended motivational interviewing processes: engagement; focusing; evoking; and planning; and were tailored to individual needs and

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

Digital Support Tool: All participants were encouraged to access the same customised website (https://sumit.trekeducation.org/) prior to their first motivational interviewing session. The website included information about physical activity, knee osteoarthritis, goal setting, research and activities, and patient stories.

Control

The control group (usual care) received no additional interventions or access to the digital support tool. They were permitted to engage in routine services for their knee osteoarthritis management including visits to their general practitioner, physiotherapist or other health professionals. Participants were asked to refrain from knee steroid injections or surgery during the trial. At the conclusion of the follow-up assessments, control participants were emailed the digital support tool to access if they chose.

Outcomes

Primary: feasibility

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

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.

Adverse events

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

Sample size

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

Secondary

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

Device-measured physical activity

ActivPAL accelerometers (PAL Technologies, Glasgow, Scotland) were fitted to each participant's right thigh with gauze and clear Flexifix for seven days. They are reliable and valid measures of step count and cadence,[32] accurate in older adults,[33] and do not to provide feedback to participants. We extracted average steps, minutes with cadence >100 steps per minute,[34] and minutes where bouts were >1min in duration per day. Walking cadence >100 steps per minute was chosen as an outcome since it predicts lower premature mortality in older adults.[35]

Self-reported physical activity

To triangulate accelerometer results, we also recorded physical activity using the University of California Los Angeles (UCLA) Physical Activity Scale, and the International Physical Activity Questionnaire long form (IPAQ-long). UCLA is a reliable and valid tool[36] commonly used as a measure of physical activity participation in knee osteoarthritis.[13-15,37] and the IPAQ long provides valuable information about the domain in which PA is undertaken.

Physical endurance

Physical endurance was measured using 6-minute walk distance (6MWD), measured in metres, which is reliable and valid.[38]

Knee-related burden

The Knee Injury Osteoarthritis Outcome Score (KOOS) was used to measure knee pain, symptoms, function, sport and recreation and QoL.[39] The questionnaire produces a score from 0-100 for each subscale, higher scores indicate lower burden. All subscales have high reliability and validity.[39]

Health-related quality of life

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

General health

Body mass index (BMI) (kg/m^2), waist circumference (cm) and systolic blood pressure (BP) (mmHg) were all recorded by a blinded research assessor.

Functional performance

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

Confidence and importance of physical activity

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

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

Statistical Analysis

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

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

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

second chair stand test,[45] and 0.19 metres per second for 40m walk test.[45] There is no documented MDC for device-measured physical activity, the IPAQ-long, UCLA physical activity scale, BMI, blood pressure or waist circumference. Standardised mean differences (effect sizes) based on within group changes between SUMIT and control groups were calculated using Review Manager 5.3 (The Nordic Cochrane Centre, Copenhagen, Denmark).

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

RESULTS

Primary outcome

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

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

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

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

No participants in either group experienced any adverse events as a result of data collection or the intervention during the trial. Two participants in the SUMIT group reported back pain prior to the

trial and continued to experience back pain during the intervention period. One participant in the SUMIT group had a fall one week prior to follow-up, reducing their ability to participate in physical activities during the ActivPAL recording week.

Table 1b. Feasibility outcomes

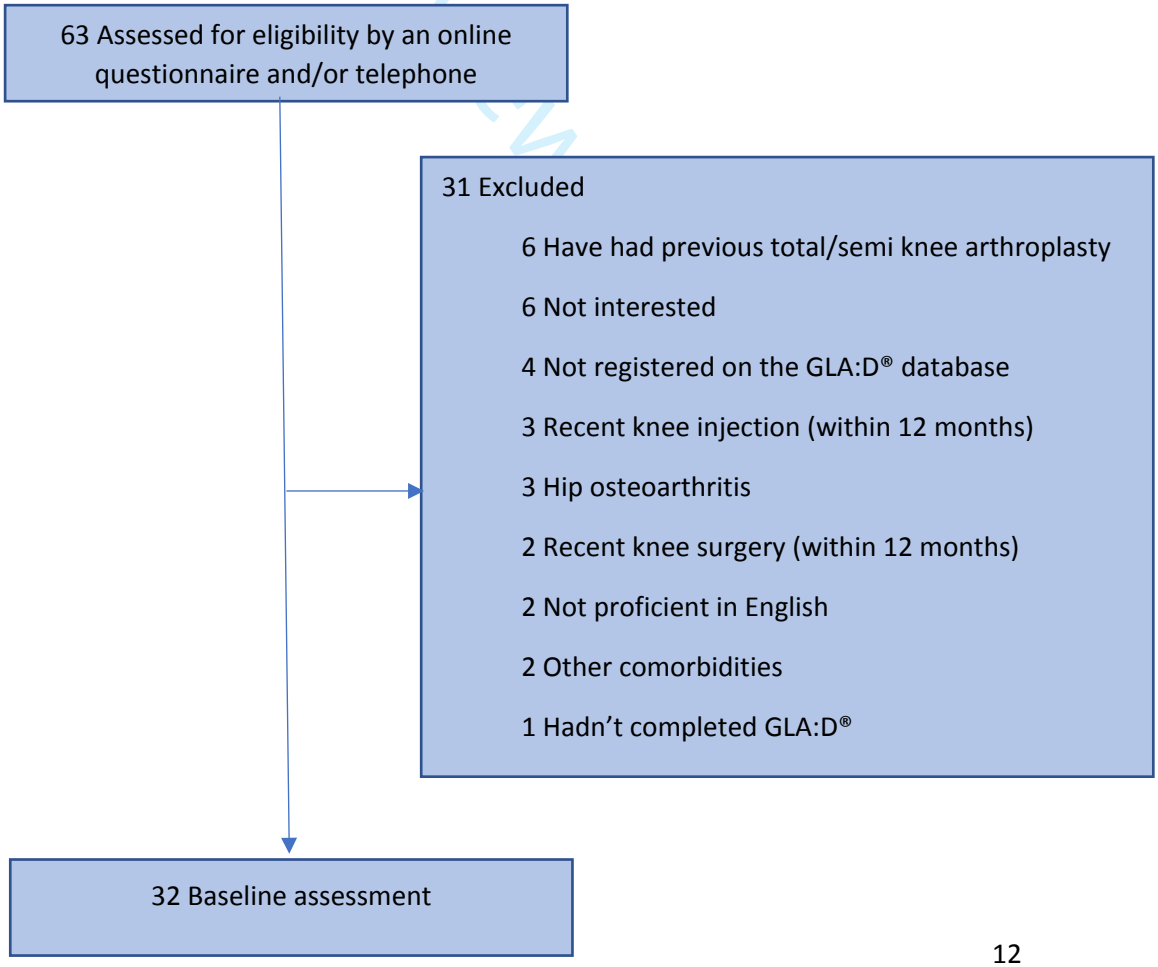
	Criterion	Achieved	Proceed	Proceed with amendments
Eligibility				
Number of eligible participants	2-3 per site, per month, totalling 6-9 per month	63 participants screened in 7 months accounting for lockdowns and community restrictions in Melbourne (13 months elapsed)	Yes*	Strategies to identify more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

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

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			
Private practice	22	14	8
Hospital	7	3	4
Community	3	0	3
Education			
Completed primary school	1	0	1
Completed high school	2	1	1
Completed an apprenticeship	0	0	0
Completed certificate	4	1	3
Completed diploma	2	1	1
Completed undergraduate degree	10	4	6
Completed postgraduate degree	9	4	5
Not reported	4	4	0

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



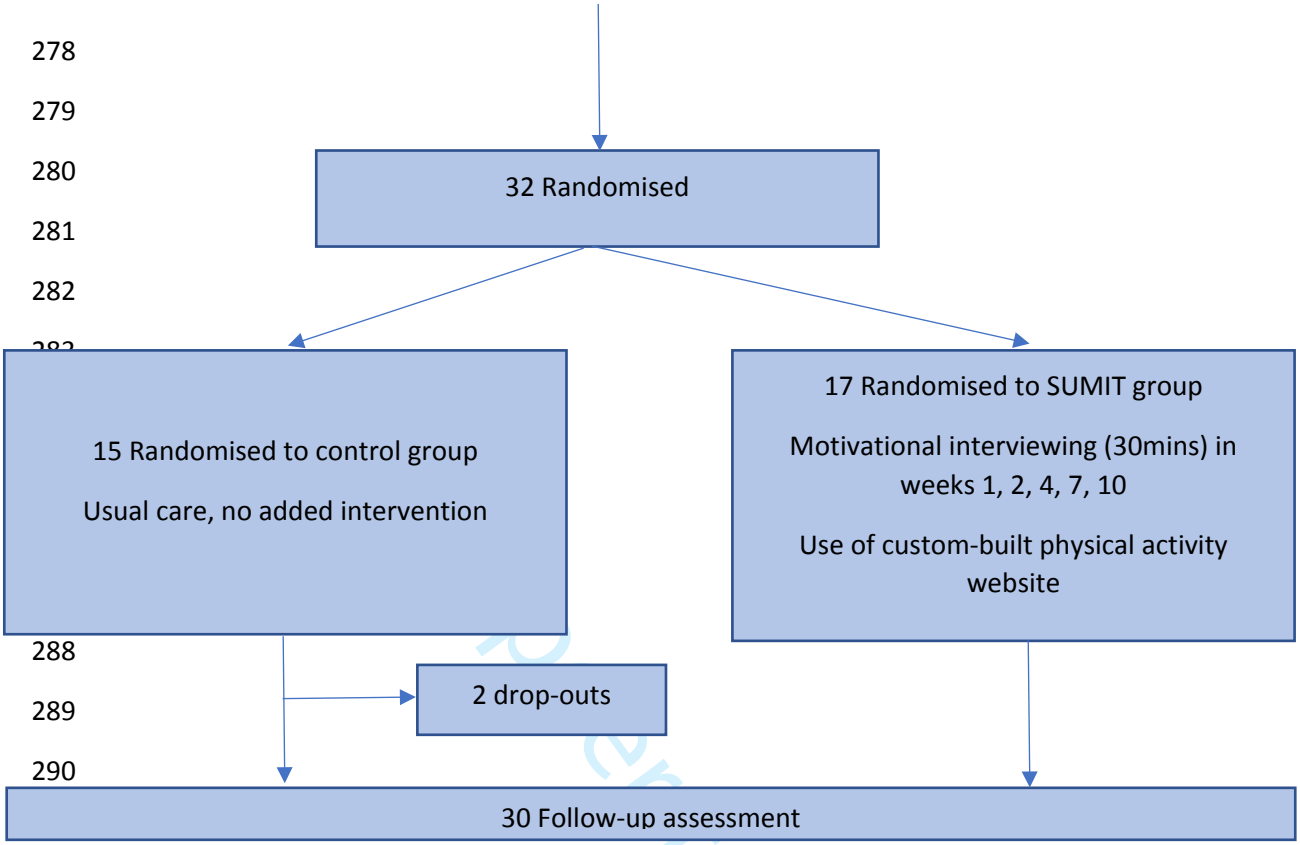


Figure 1. Timeline

Secondary outcomes

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

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

For the SUMIT group, both perceived confidence and importance of participating in regular physical 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 (0.8) to 9.4 (0.9) (p=0.006) respectively.

Study or Subgroup	SUMIT Mean	SUMIT SD	SUMIT Total	Control Mean	Control SD	Control Total	Std. Mean Difference IV, Random, 95% CI
Steps per day	4	1,308	17	192	1,627	12	-0.13 [-0.87, 0.61]
Daily stepping time	-0.6	16	17	5	18	12	-0.32 [-1.07, 0.42]
Daily time with cadence 100spm	8	9	17	3	14	12	0.43 [-0.32, 1.18]
Daily time with bouts 1min	29	13	17	21	24	12	0.42 [-0.32, 1.17]
6 minute walk distance	19	53	16	2	40	13	0.35 [-0.39, 1.08]
KOOS function	14	15	13	3	12	13	0.78 [-0.02, 1.59]
KOOS pain	12	13	13	2	13	13	0.74 [-0.05, 1.54]
KOOS quality of life	13	11	13	1	17	13	0.81 [0.01, 1.62]
KOOS sport and recreation	14	21	13	14	28	13	0.00 [-0.77, 0.77]
KOOS symptoms	9	11	13	2	16	13	0.49 [-0.29, 1.28]
EQ5D5L	0.104	0.231	16	-0.029	0.125	13	0.68 [-0.08, 1.43]
30 second chair stand	1	1	16	0	2	13	0.64 [-0.12, 1.39]
Walking speed	0.1	0.2	16	-0.1	0.2	13	0.97 [0.19, 1.75]

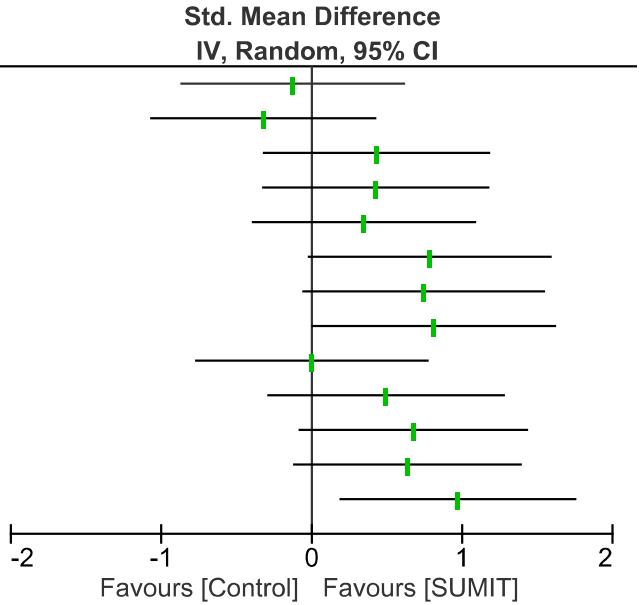


Figure 2a. Forest plot comparing within group change scores between SUMIT and control groups

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

Study or Subgroup	SUMIT Mean	SUMIT SD	SUMIT Total	Control Mean	Control SD	Control Total	Std. Mean Difference IV, Random, 95% CI
Body mass index	0	0.8	16	-0.1	0.4	12	0.15 [-0.60, 0.90]
Systolic blood pressure	-7	12	16	-3	14	13	-0.30 [-1.04, 0.44]
Waist circumference	0.3	5.2	16	2.5	4.8	13	-0.43 [-1.17, 0.32]

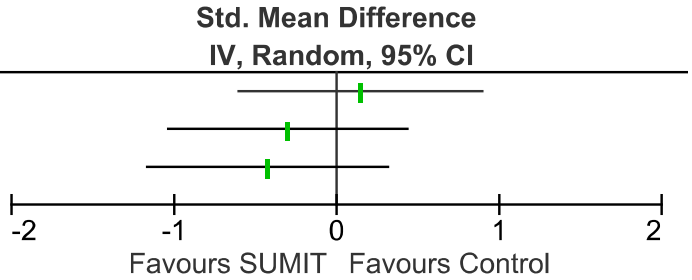


Figure 2b. Forest plot comparing within group change scores between SUMIT and control groups for health outcomes

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

Outcome	Week 0 SUMIT Mean (SD) n=17	Week 12 SUMIT Mean (SD) n=17	Within group differences Week 12 minus Week 0 SUMIT MD (SD) n=17	Week 0 Control Mean (SD) n=13	Week 12 Control Mean (SD) n=13	Within group differences Week 12 minus Week 0 Control MD (SD) n=13	Between group differences 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

IPAQ leisure (vig)	37 (52)^	27 (72)^	-10 (47)^	39 (81)	5 (17)	-35 (73)	23 (-14 to 59), 0.21	N/A
IPAQ leisure (mod)	15 (30)^	52 (76)^	37 (75)^	51 (98)	59 (78)	8 (110)	2 (-59 to 62), 0.96	N/A
6MWD, m	484 (114)^	503 (102)^	19 (53)^	525 (97)	527 (106)	2 (40)	11 (-25 to 48), 0.52	75m[44]
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]
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]
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]
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]
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]
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]
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
Systolic blood pressure, mmHg	138 (15)^	131 (11)^	-7 (12)	135 (10)	132 (15)	-3 (14)	-3 (-11 to 6), 0.56	N/A
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
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]
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]

Legend: MD= mean difference, MDC= minimal detectable change, CI= confidence interval, mins= minutes, spm= steps per minute, mmHg= millimetres of mercury, kg/m^2,kilogram per metre squared, cm= centimetres, m/s= metres per second, m= metres, IPAQ= International Physical Activity Questionnaire, vig= vigorous, mod= moderate, N/A= not applicable, **bold** denotes confidence intervals which include the defined minimal detectable change, *= mean difference achieved a minimal detectable change

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DISCUSSION

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

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

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

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

enough sessions to see a substantial difference between groups. Our intervention included five sessions compared to other studies which have reported that eight weekly motivational interviewing calls resulted in meaningful differences in people with hip fractures.[49] It is possible that our participants' physical activity was influenced by COVID-19 restrictions/lockdowns.[50] The impact may have had mixed effects, including physical activity was negatively influenced by lower incidental activities, and safety concerns of being outside the home.[51] Conversely, physical activity may have increased for others during COVID-19 restrictions due to increased time and opportunity to access outside activities.[51] Our results contrast another motivational interviewing RCT which reported no difference in physical activity between groups,[21] however improvements in pain and function were consistent with our findings and may be explained by our motivational interviewing sessions being delivered closely together, allowing participants to reinforce behaviour change more effectively.

Findings of our study should be interpreted within the context of it's strengths and limitations. We modified our trial by increasing recruitment sites, advertising and reducing the recruitment target number due to the impact of COVID-19 restrictions, and have reported our trial according to the CONSERVE checklist to aide transparency. At baseline, our participants in both groups were completing 7,000 to 7,500 steps which may be already adequate to maintain good health,[52] and potentially challenging to increase. However, further increases from this relatively high baseline are still likely to improve health,[53,54] and increasing cadence[53,54] during walking as occurred in our intervention group also provides additional benefits. Our participant groups were different as baseline, possibly due to the small sample size, which may have impacted the findings for the secondary aims. We used rigorous randomisation and assessment blinding procedures and accredited motivational interviewing training and treatment fidelity so that our methods could be repeated. Our ActivPAL analyses were completed by the same researcher who delivered the SUMIT intervention which may present risk of unconscious bias. Future studies should provide a provision for a blinded researcher to undertake data analysis.

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

CONCLUSION

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

Author contributions: Ms Bell and Associate Professor Barton take responsibility for the integrity of the data and correctness of the data analysis. Ms Bell is a PhD candidate and this trial is contributing to her doctoral dissertation.

Concept and Design: ECB, CJB, PO, JAW

Acquisition of the data: ECB, research assistants

Analysis or interpretation of the data: All

Drafting of the manuscript: ECB, PO, JAW, CJB, KMC

Critical revision of the manuscript: All

Obtained funding: All

Conflict of Interest Disclosures: The authors declare that they have no conflicts of interest in relation to this study.

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

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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 *feel* that therapy will help you to increase your physical activity?
6. How much improvement in your physical activity do you really *feel* will occur?

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:

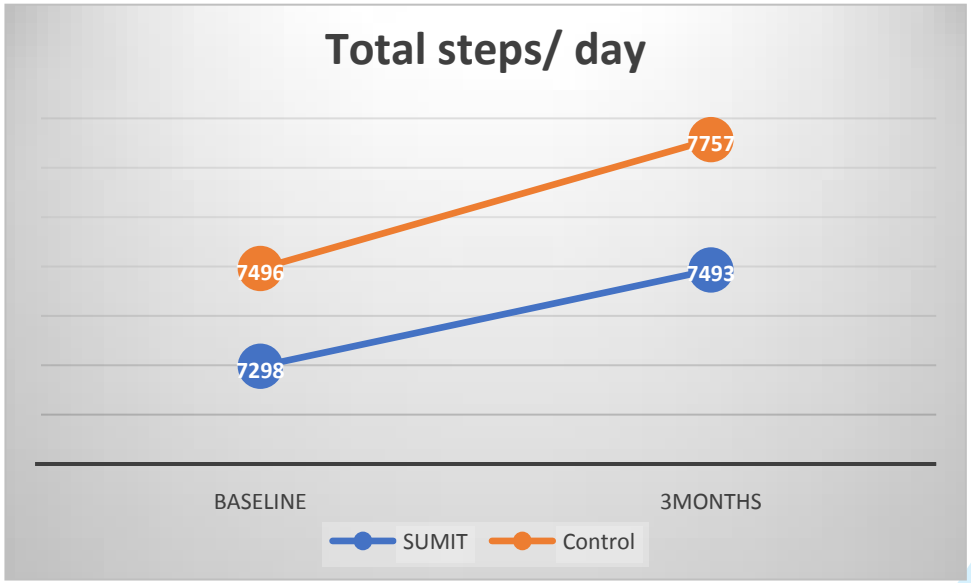
Participant 3 (P3) had never been exposed to motivational interview before, learned from GLA:D® that they should be doing regular exercise for their knee and had previously had fluctuating dedication to gym since being aged in their 20's. **Engagement:** P3 talked with their physio about their love of 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.

Appendix 3. University of California Los Angeles Physical Activity Scale

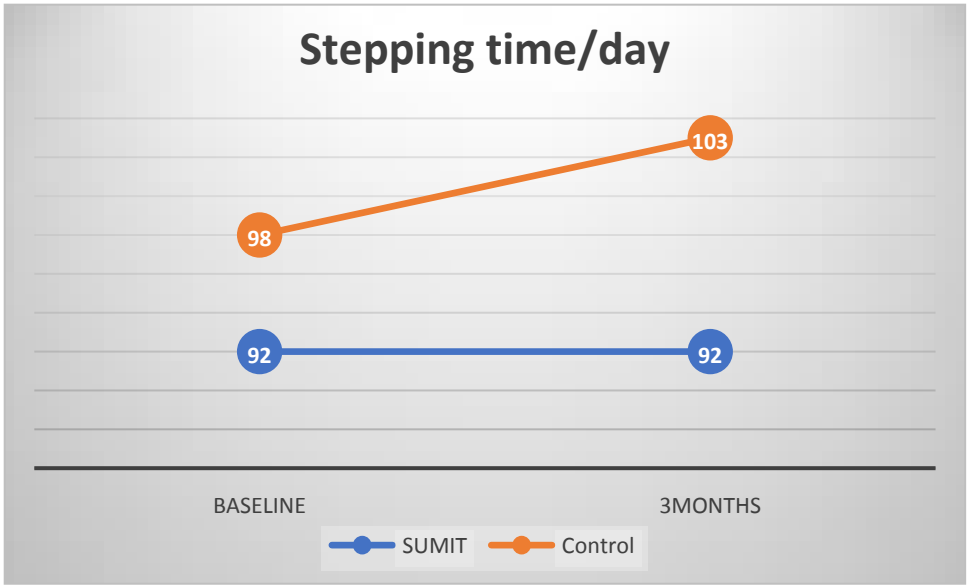
Question	**Answer options:**
Please indicate which level of activity applies to you	1 Wholly inactive: dependent on others: cannot leave residence 2 Mostly inactive: restricted to minimal activities of daily living 3 Sometimes participates in mild activities 4 Regularly participates in mild activities, 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.

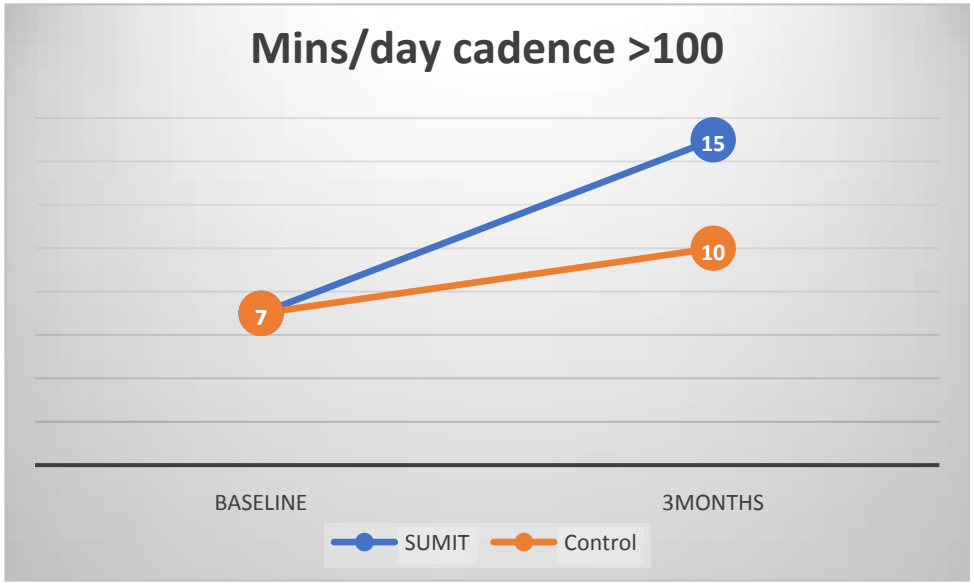
Appendix 4a. Total steps per day for SUMIT and control groups at baseline and 3-months



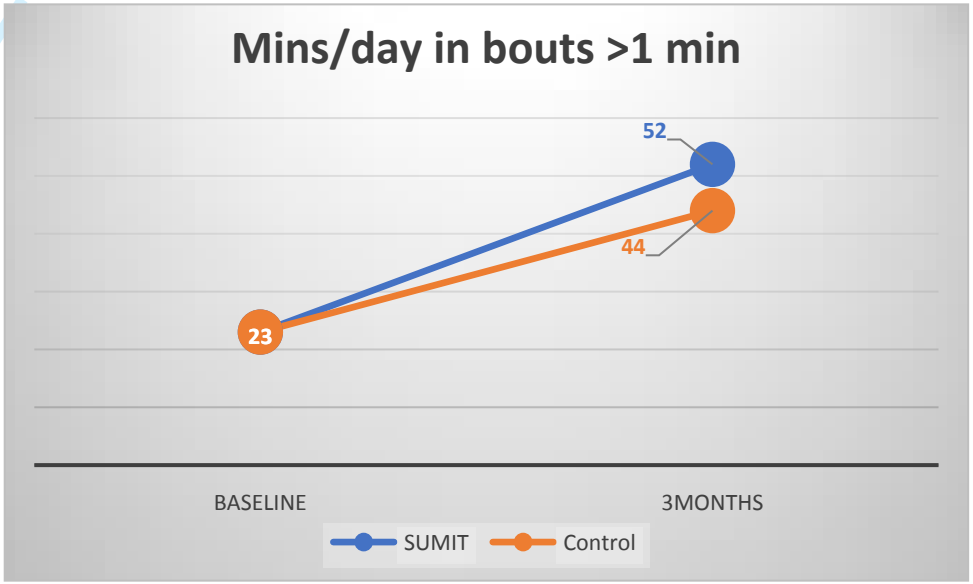
Appendix 4b. Stepping time per day (mins) for SUMIT and control groups at baseline and 3-months



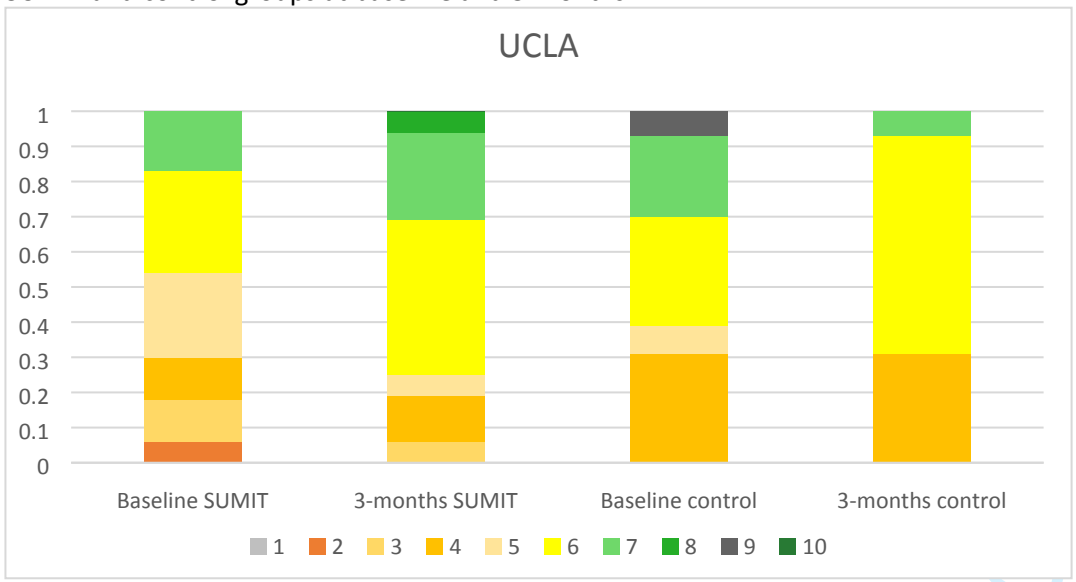
Appendix 4c. Minutes per day with cadence >100 for SUMIT and control groups at baseline and 3-months



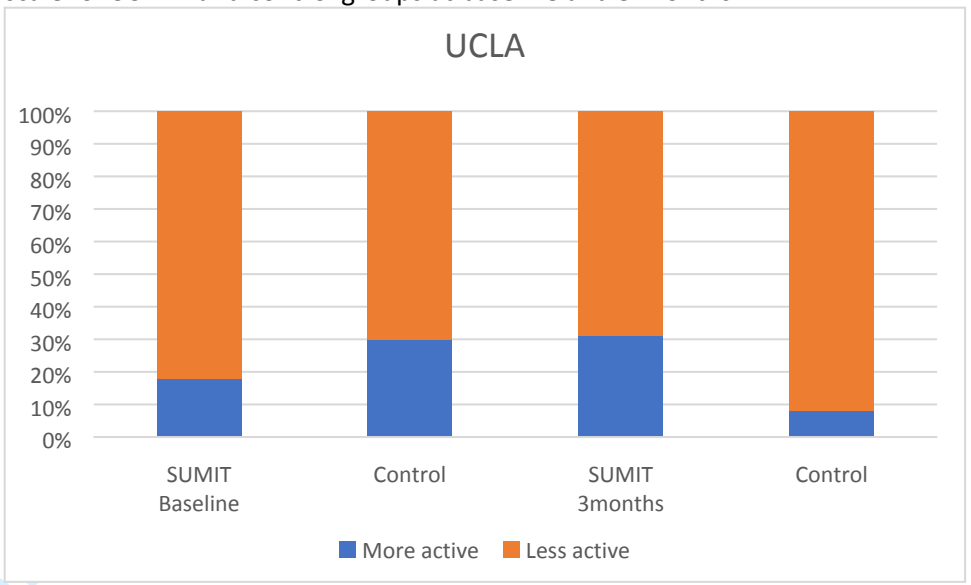
Appendix 4d. Minutes per day in bouts >1min for SUMIT and control groups at baseline and 3-months



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

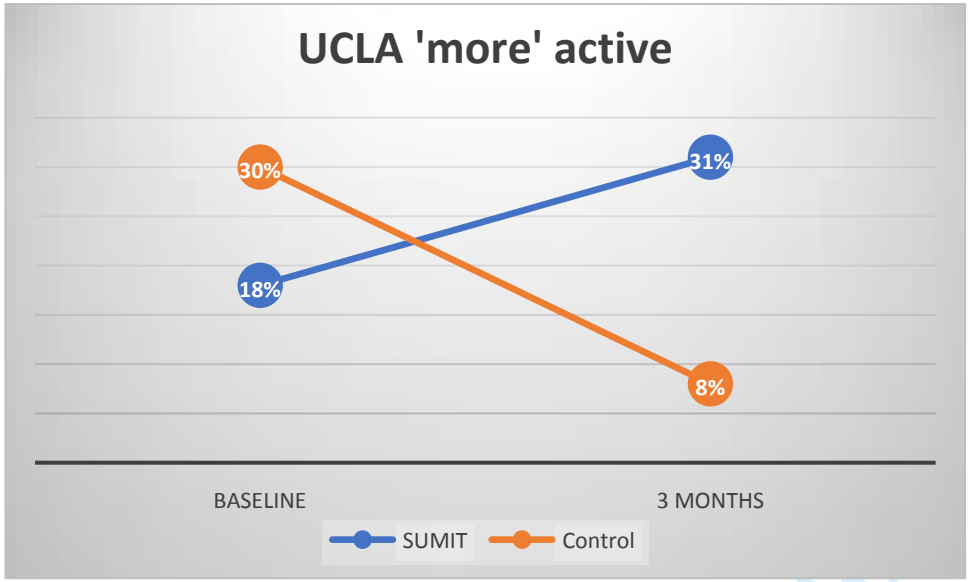


Appendix 5b. Dichotomised University of California Los Angeles physical activity scale for SUMIT and control groups at baseline and 3-months

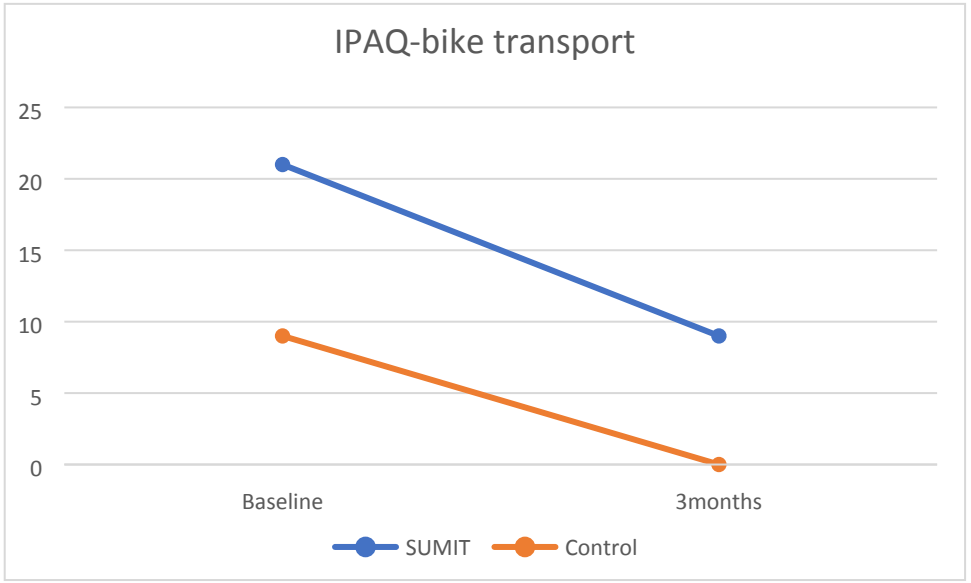


Appendix 5c. Proportion of participants who are 'more' or 'less' active using the University of California Los Angeles physical activity scale for SUMIT and control groups at baseline and 3-months

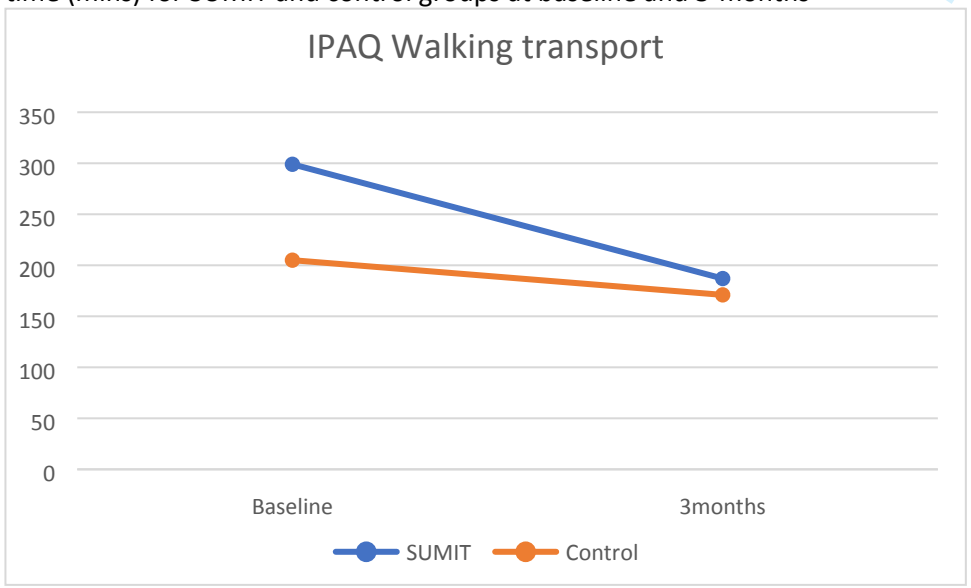
Appendix 5d. International Physical Activity Questionnaire long form bike transport time (mins) for SUMIT and control groups at baseline and 3-months



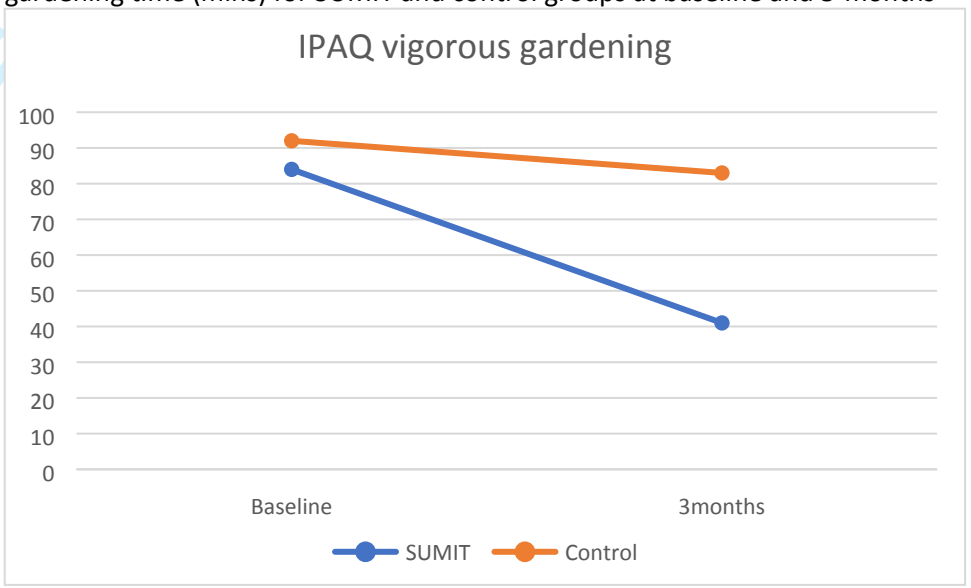
Appendix 5e. International Physical Activity Questionnaire long form walking transport time (mins) for SUMIT and control groups at baseline and 3-months



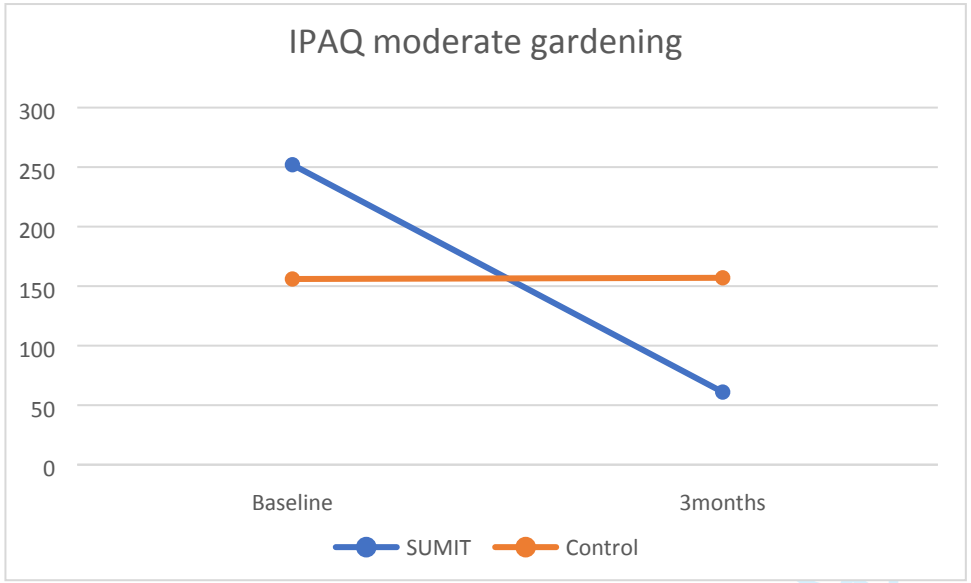
Appendix 5f. International Physical Activity Questionnaire long form vigorous gardening time (mins) for SUMIT and control groups at baseline and 3-months



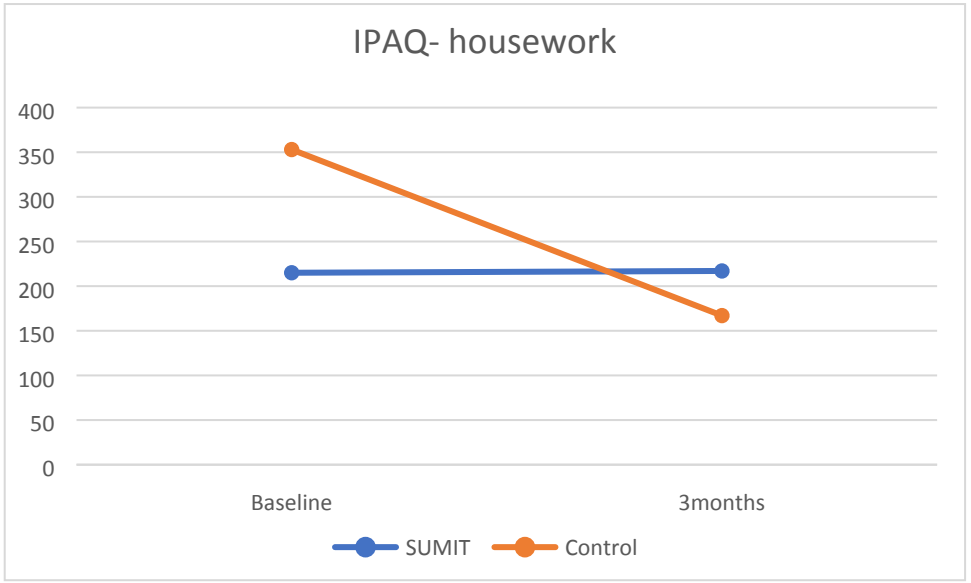
Appendix 5g. International Physical Activity Questionnaire long form moderate gardening time (mins) for SUMIT and control groups at baseline and 3-months



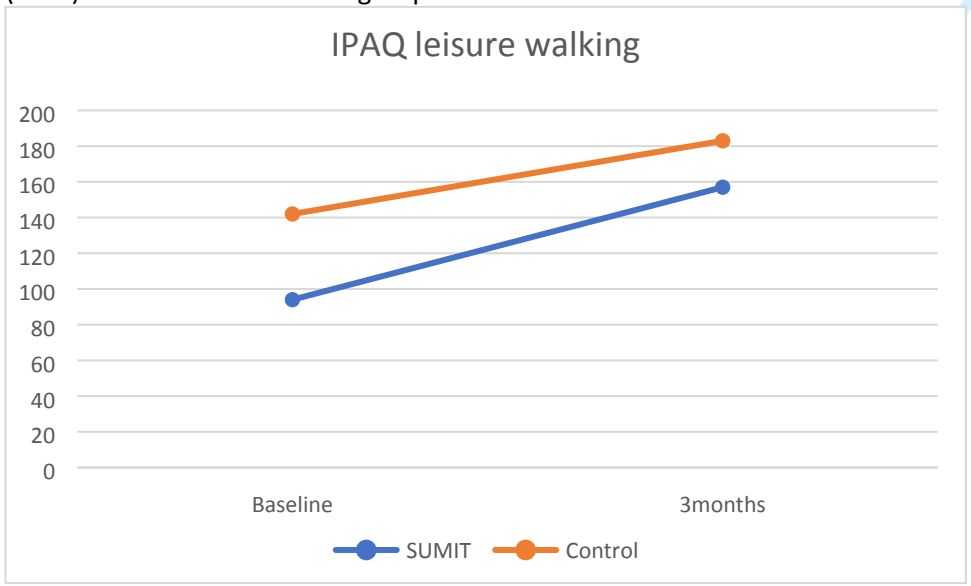
Appendix 5h. International Physical Activity Questionnaire long form housework time (mins) for SUMIT and control groups at baseline and 3-months

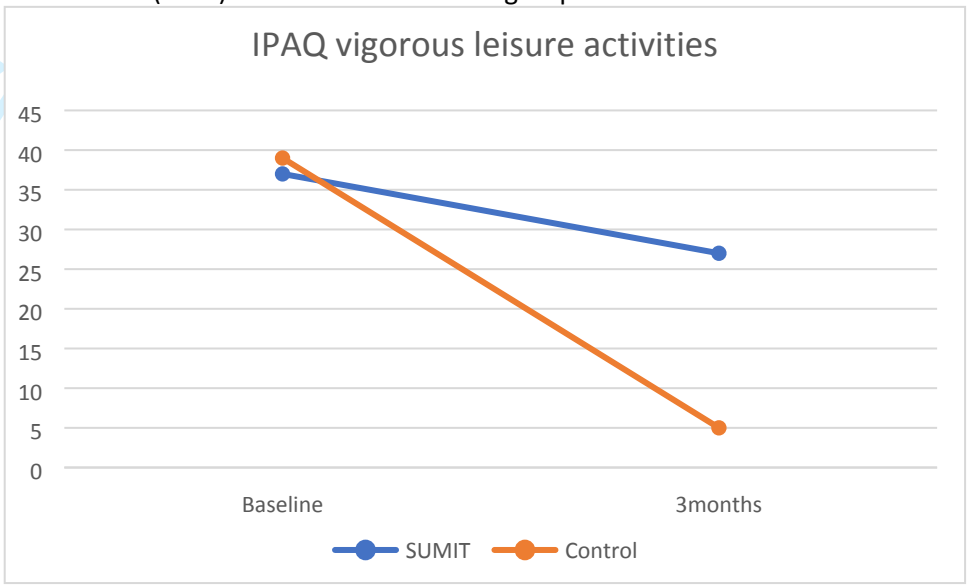


Appendix 5i. International Physical Activity Questionnaire long form leisure walking time (mins) for SUMIT and control groups at baseline and 3-months

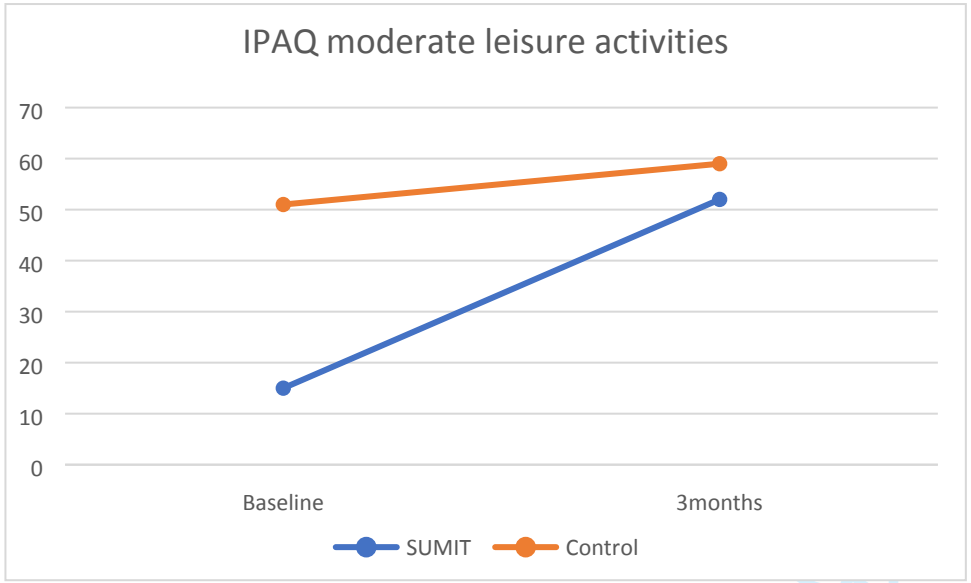


Appendix 5j. International Physical Activity Questionnaire long form vigorous leisure time (mins) for SUMIT and control groups at baseline and 3-months

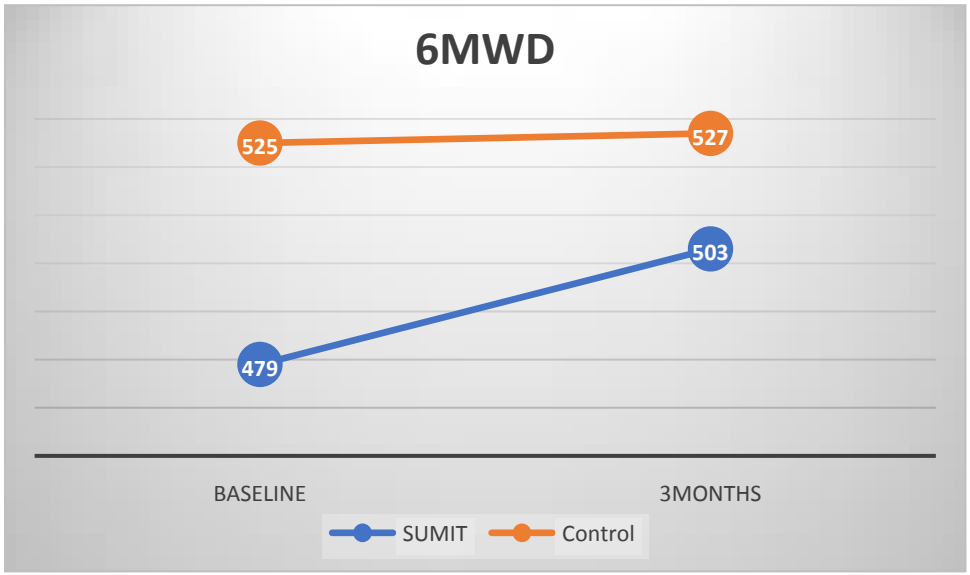




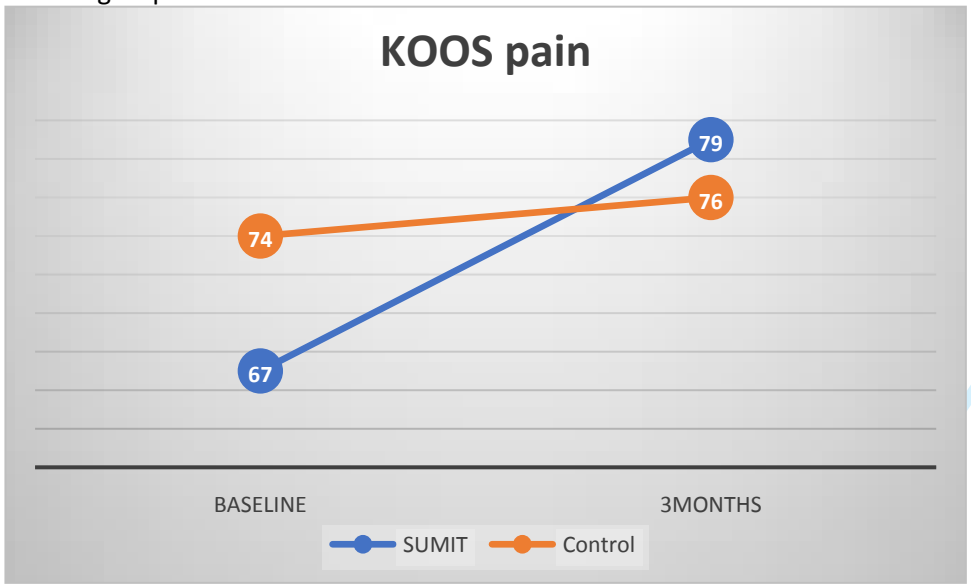
Appendix 5k. International Physical Activity Questionnaire long form moderate leisure time (mins) for SUMIT and control groups at baseline and 3-months



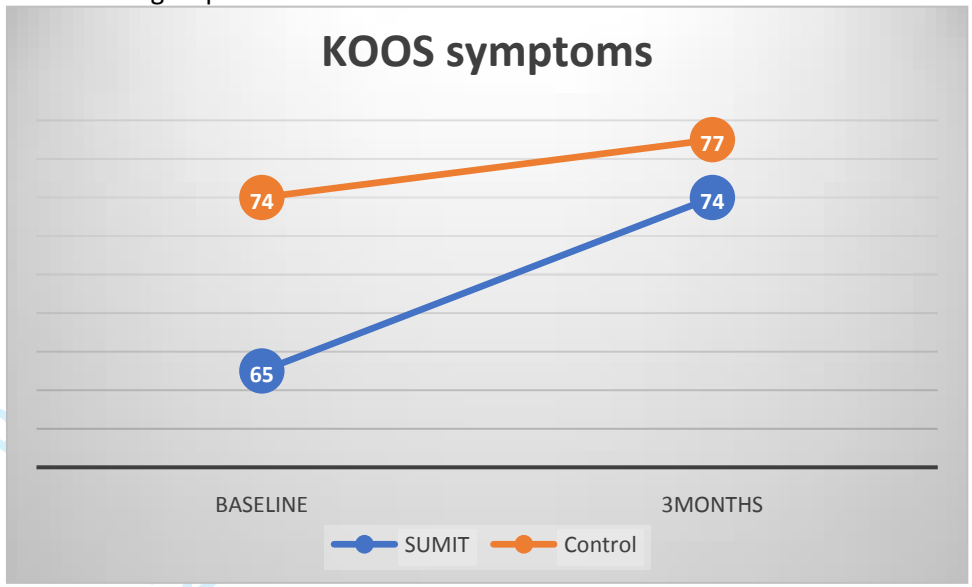
Appendix 6. 6-minute walk distance (m) for SUMIT and control groups at baseline and 3-months



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

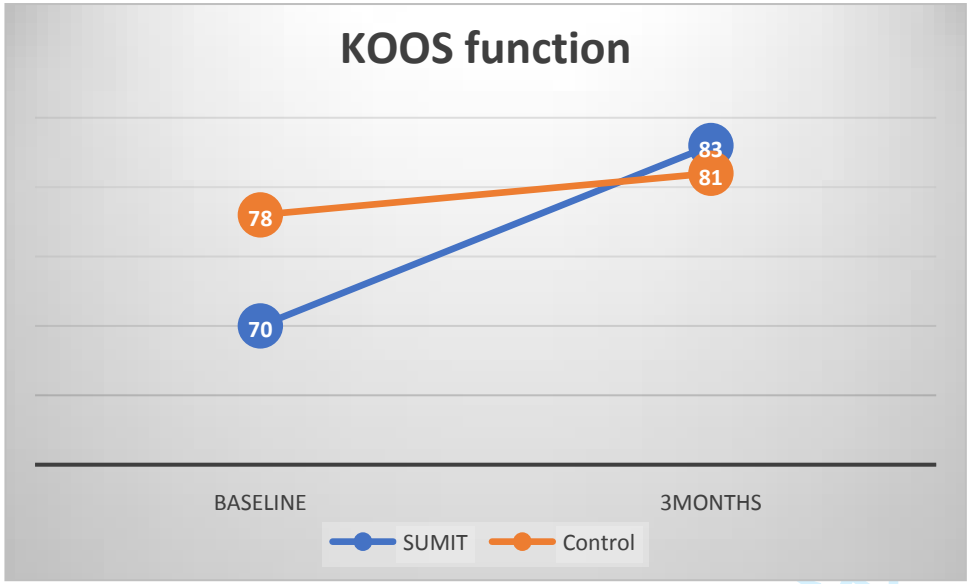


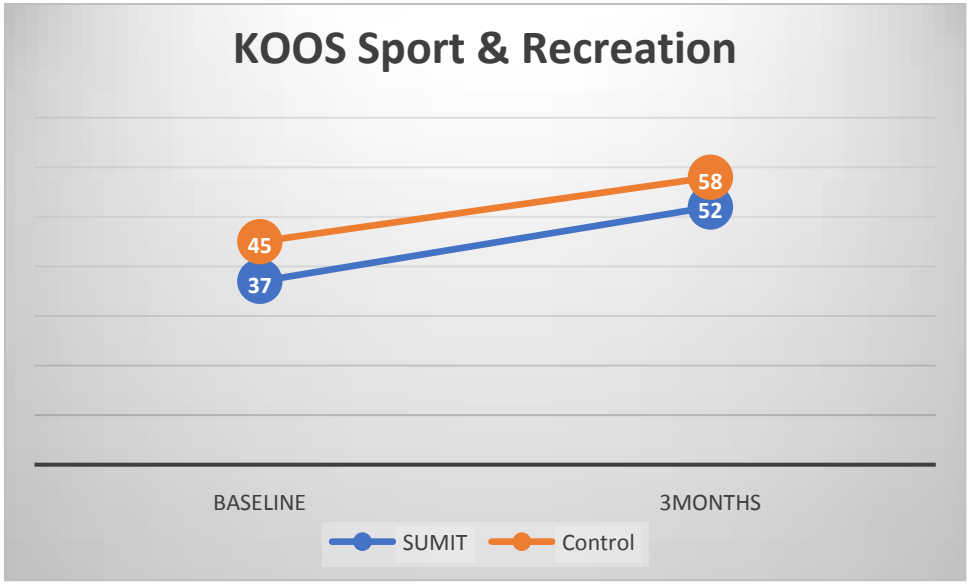
Appendix 7b. Knee Osteoarthritis Outcome Score symptoms subscale for SUMIT and control groups at baseline and 3-months



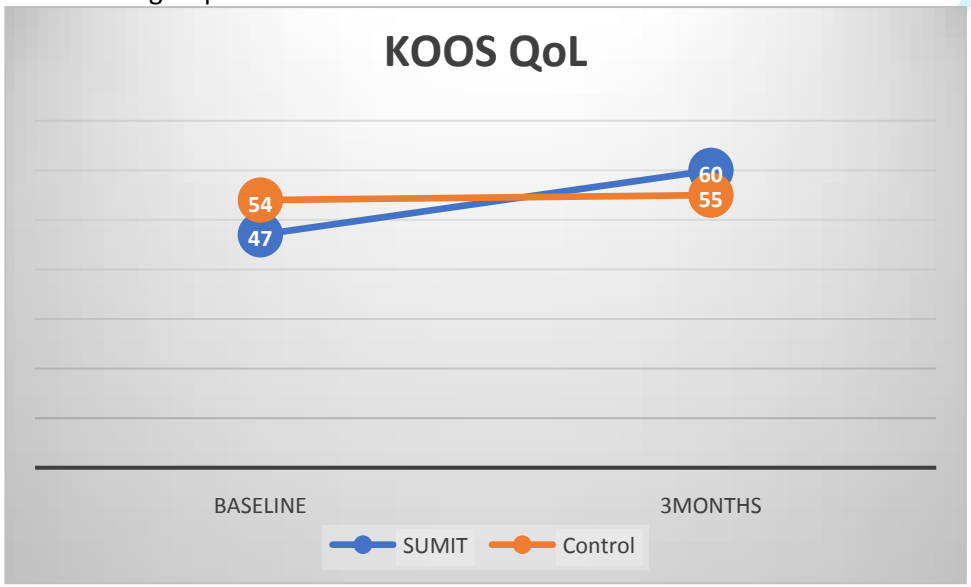
Appendix 7c. Knee Osteoarthritis Outcome Score function subscale for SUMIT and control groups at baseline and 3-months

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

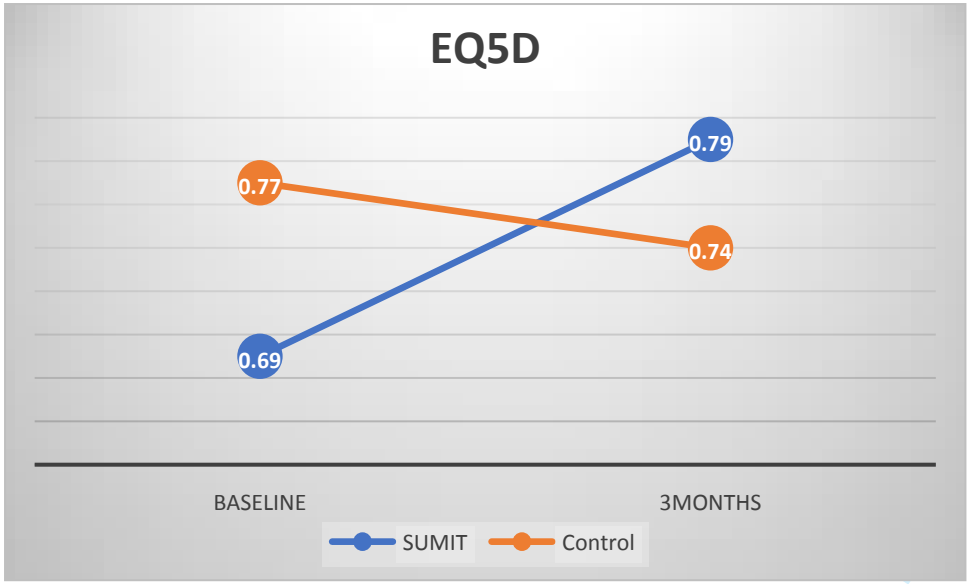




Appendix 7e. Knee Osteoarthritis Outcome Score quality of life subscale for SUMIT and control groups at baseline and 3-months

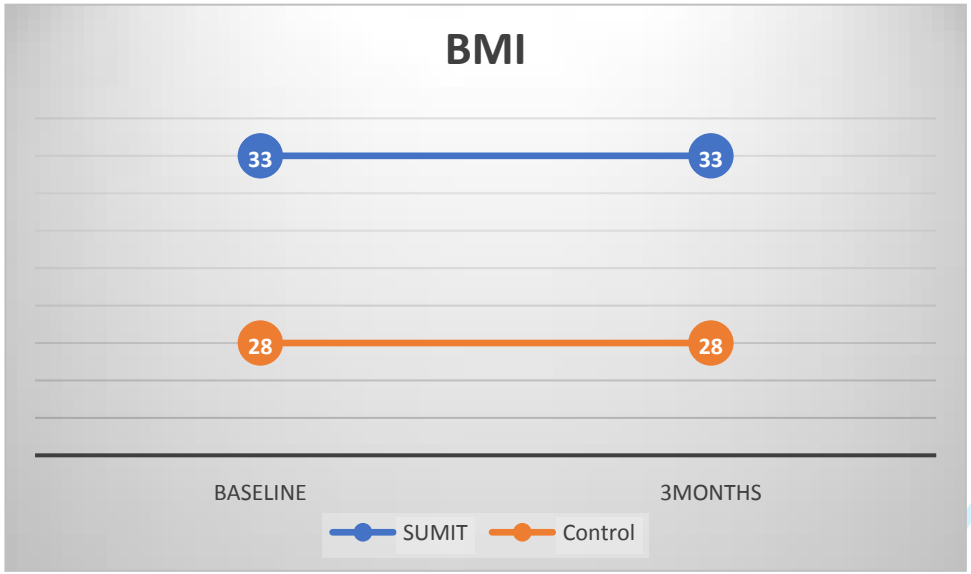


Appendix 8. Health-related quality of life for SUMIT and control groups at baseline and 3-months

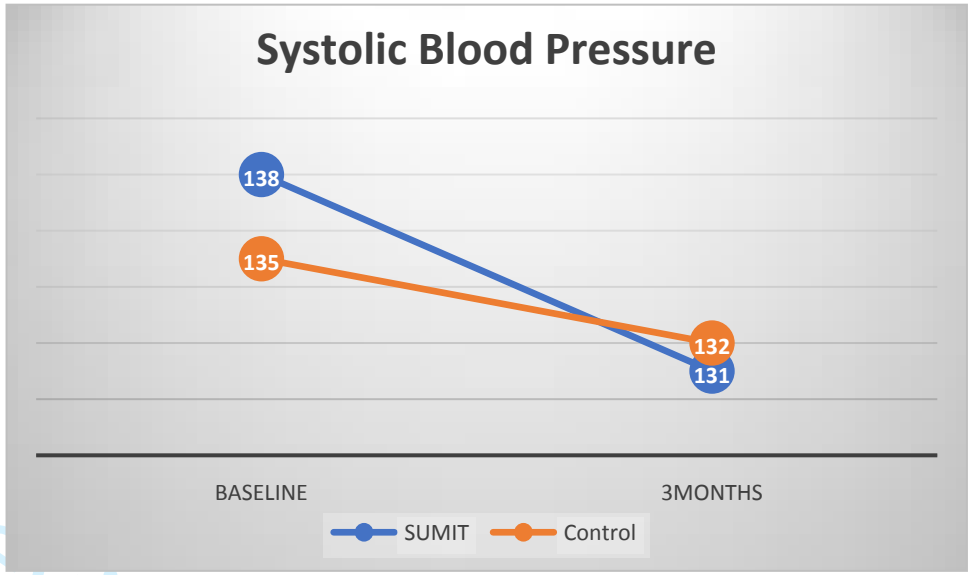


Legend: EQ5D= Euroqual 5-dimension 5-long

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

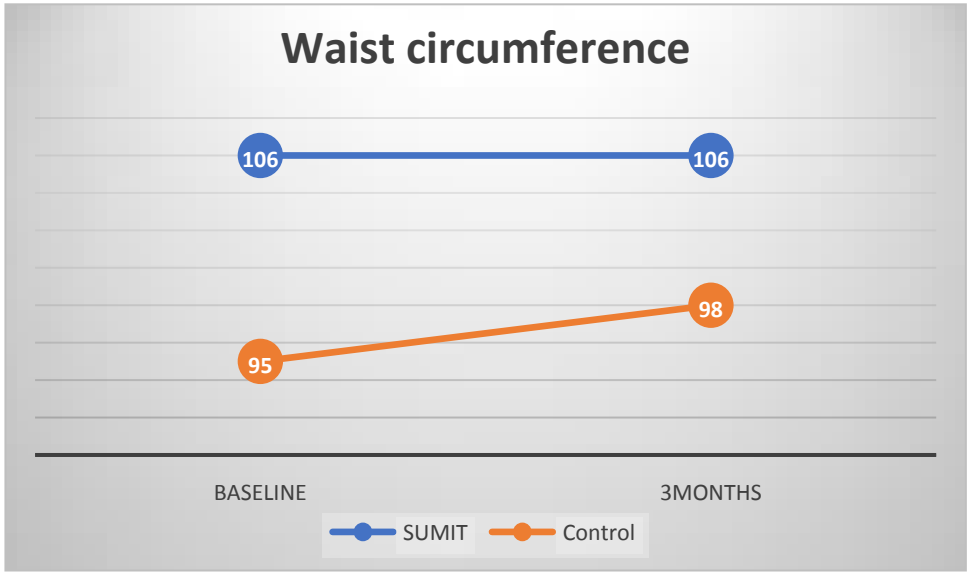


Appendix 9b. Systolic blood pressure for SUMIT and control groups at baseline and 3-months

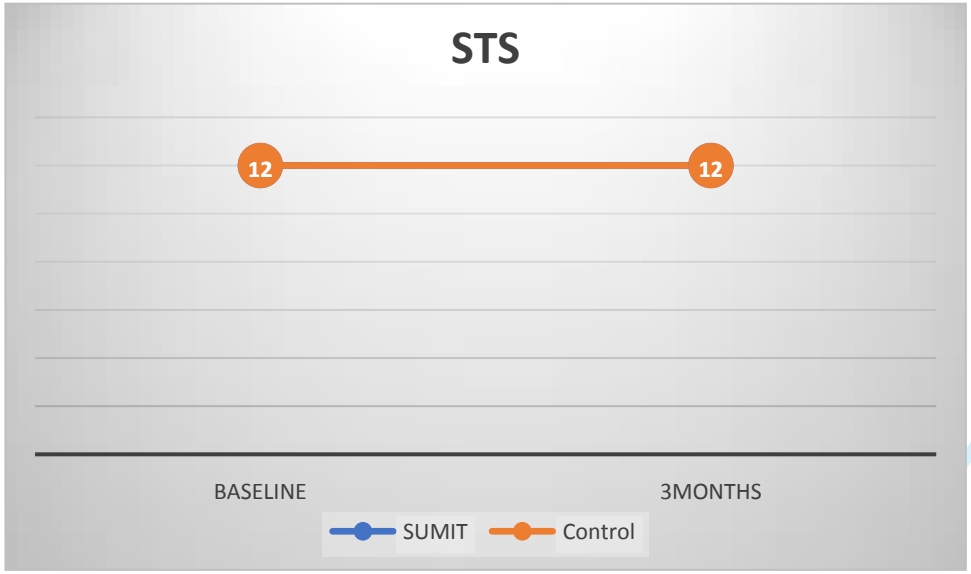


Legend: BMI- body mass index

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.

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.			**Page No.**
		No Change	**Impact***	**Mitigating Strategy****	
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.

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				

*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.

BMJ Open

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

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Manuscript ID	bmjopen-2023-075014.R1
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Primary Subject Heading:	Rehabilitation medicine
Secondary Subject Heading:	Sports and exercise medicine
Keywords:	Knee < ORTHOPAEDIC & TRAUMA SURGERY, Physical Therapy Modalities, REHABILITATION MEDICINE

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

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Word count: 3874/4000

ABSTRACT

Word count: 278/300

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

Design: Randomised controlled trial.

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

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

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

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

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

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

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

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

Key words: Physiotherapy, Rehabilitation, Comorbidities, Behaviour Change, Knee osteoarthritis, Motivational Interviewing

Strengths and limitations of this study

- We modified our trial by increasing recruitment sites, advertising and reducing the recruitment target number due to the impact of COVID-19 restrictions, and have reported our trial according to the CONSERVE checklist to aide transparency.
- We used rigorous randomisation and assessment blinding procedures and accredited motivational interviewing training and treatment fidelity so that our methods could be repeated.
- Our ActivPAL analyses were completed by the same researcher who delivered the SUMIT intervention which may present risk of unconscious bias. Future studies should provide a provision for a blinded researcher to undertake data analysis.
- Our participant groups were different as baseline, possibly due to the small sample size, which may have impacted the findings for the secondary aims.

INTRODUCTION

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

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

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

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

motivational interviewing, they can be used to monitor and/or promote physical activity, and may help to increase physical activity.(25) However, the influence of digital support tools on physical activity behaviour change is unknown.(25)

Our primary objective was to determine the feasibility of conducting a fully powered trial evaluating the effectiveness of increasing physical activity using SUpported Motivational InTerviewing (SUMIT), following completion of an education and exercise-therapy program in people with knee osteoarthritis. Our secondary objective was to determine if a worthwhile treatment effect occurred for physical activity, physical endurance, knee-related quality of life (QoL), health-related QoL and pain.

METHODS

Trial design

This pilot feasibility randomised controlled trial (RCT) compared an intervention comprising motivational interviewing and website) with a usual care control group. Ethics approval was obtained from La Trobe University Human Research Ethics Committee (#HEC20506). The trial was registered with Australian New Zealand Clinical Trials Registry (ANZCTR) (ACTRN12621000267853). Study reporting adheres to the Consolidated Standards or Reporting Trials (CONSORT) for pilot and feasibility trials.(26) Due to the interruption from the Coronavirus pandemic (COVID-19), we reported limitations according to the CONSORT and SPIRIT Extension for RCTs Revised in Extenuating Circumstances (CONSERVE) guidelines.(27)

Setting

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

Participants

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

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

Patients and public involvement

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

Deviations from protocol

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

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

Randomisation and blinding

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

not involved in assessment (MFP). Group allocations were concealed in sequentially numbered opaque envelopes, sealed until the point of group allocation. Participants were informed of their group allocation by the coordinating physiotherapist (ECB). Due to the nature of the study, the outcome assessor was the only person able to be blinded to participant allocation.

Intervention

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

Motivational interviewing sessions involved collaboration between clinician and participant aiming to evoke behaviour change to increase physical activity (Appendix 2). Consistent with the principles of motivational interviewing,(14) sessions followed recommended motivational interviewing processes: engagement; focusing; evoking; and planning; and were tailored to individual needs and level of preparedness for behaviour change (Appendix 2). Participant importance and confidence of engaging in physical activity was discussed over the course of the intervention, providing valuable information about shifts in potential barriers and facilitators to activity.(14)

Digital Support Tool: All participants were encouraged to access the same customised website (https://sumit.trekeducation.org/) prior to their first motivational interviewing session. The website included information about physical activity, knee osteoarthritis, goal setting, research and activities, and patient stories. Participants were encouraged to access the website prior to their first motivational interviewing session. Subsequent use was based on individual participant preference.

Control

The control group (usual care) received no additional interventions or access to the digital support tool. They were permitted to engage in routine services for their knee osteoarthritis management including visits to their general practitioner, physiotherapist or other health professionals. Participants were asked to refrain from knee steroid injections or surgery during the trial. At the conclusion of the follow-up assessments, control participants were emailed the digital support tool to access if they chose.

Outcomes

Primary: feasibility

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

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.

Adverse events

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

Sample size

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

Secondary

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

Device-measured physical activity

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

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

Self-reported physical activity

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

Physical endurance

Physical endurance was measured using 6-minute walk distance (6MWD), measured in metres, which is reliable and valid.(38)

Knee-related burden

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

Health-related quality of life

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

General health

Body mass index (BMI) (kg/m^2), waist circumference (cm) and systolic blood pressure (BP) (mmHg) were all recorded by a blinded research assessor.

Functional performance

The 30-second chair stand, and walking speed (40m walk) tests are both recommended by guidelines as feasible and reliable performance measures for knee osteoarthritis,(42) and were completed by a blinded assessor.

Confidence and importance of physical activity

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

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

Statistical Analysis

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

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

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

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

RESULTS

Primary outcome

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

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

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

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

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

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	-

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

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			
Private practice	22	14	8
Hospital	7	3	4
Community	3	0	3
Education			
Completed primary school	1	0	1
Completed high school	2	1	1
Completed an apprenticeship	0	0	0
Completed certificate	4	1	3
Completed diploma	2	1	1

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

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

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[INSERT FIGURE 1 HERE]

Secondary outcomes

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

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

The proportion of 'more' active participants was 18% and 31% at baseline for SUMIT and control groups respectively (x^2= 0.71, p= 0.40), and 31% and 8% at 3-months (x^2= 0.99, p= 0.31) (Appendix 5a-c).

For the SUMIT group, both perceived confidence and importance of participating in regular physical 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 (0.8) to 9.4 (0.9) (p=0.006) respectively.

[INSERT FIGURES 2a and 2b HERE]

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

Outcome	Week 0	Week 12	Within group differences Week 12 minus Week 0	Week 0	Week 12	Within group differences Week 12 minus Week 0	Between group differences	
							Week 12 SUMIT minus control	
	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	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

IPAQ leisure (vig)	37 (52)^	27 (72)^	-10 (47)^	39 (81)	5 (17)	-35 (73)	23 (-14 to 59), 0.21	N/A
IPAQ leisure (mod)	15 (30)^	52 (76)^	37 (75)^	51 (98)	59 (78)	8 (110)	2 (-59 to 62), 0.96	N/A
6MWD, m	484 (114)^	503 (102)^	19 (53)^	525 (97)	527 (106)	2 (40)	11 (-25 to 48), 0.52	75m(44)
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)
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)
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)
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)
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)
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)
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
Systolic blood pressure, mmHg	138 (15)^	131 (11)^	-7 (12)	135 (10)	132 (15)	-3 (14)	-3 (-11 to 6), 0.56	N/A
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
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)
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)

Legend: MD= mean difference, MDC= minimal detectable change, CI= confidence interval, mins= minutes, spm= steps per minute, mmHg= millimetres of mercury, kg/m^2,kilogram per metre squared, cm= centimetres, m/s= metres per second, m= metres, IPAQ= International Physical Activity Questionnaire, vig= vigorous, mod= moderate, N/A= not applicable, **bold** denotes confidence intervals which include the defined minimal detectable change, *= mean difference achieved a minimal detectable change

DISCUSSION

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

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

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

While our study showed promising effect sizes favouring the intervention, it was not powered to find between group differences. The lack of between group differences may also be accounted for by differences in baseline characteristics which favoured our control group. There is no recommended dose for motivational interviewing,(20) however, it is possible that our intervention did not include enough sessions to see a substantial difference between groups. Our intervention included five sessions compared to other studies which have reported that eight weekly motivational interviewing calls resulted in meaningful differences in people with hip fractures.(49) It is possible that our participants' physical activity was influenced by COVID-19 restrictions/lockdowns.(50) The impact may have had mixed effects, including physical activity was negatively influenced by lower incidental activities, and safety concerns of being outside the home.(51) Conversely, physical activity may have increased for others during COVID-19 restrictions due to increased time and opportunity to access outside activities.(51) Our results contrast another motivational interviewing RCT which reported no difference in physical activity between groups,(21) however improvements in pain and function were consistent with our findings and may be explained by our motivational interviewing sessions being delivered closely together, allowing participants to reinforce behaviour change more effectively.

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

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

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

CONCLUSION

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

Author contributions: Ms Bell and Associate Professor Barton take responsibility for the integrity of the data and correctness of the data analysis. Ms Bell is a PhD candidate and this trial is contributing to her doctoral dissertation.

Concept and Design: ECB, CJB, PO, JAW

Acquisition of the data: ECB, research assistants

Analysis or interpretation of the data: All

Drafting of the manuscript: ECB, PO, JAW, CJB, KMC

Critical revision of the manuscript: All

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

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Figure legends:

Figure 1. Study timeline

Legend: GLA:D®= Good Life with osteoArthritis Denmark, SUMIT= SUpported Motivational InTerviewing, mins= minutes

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

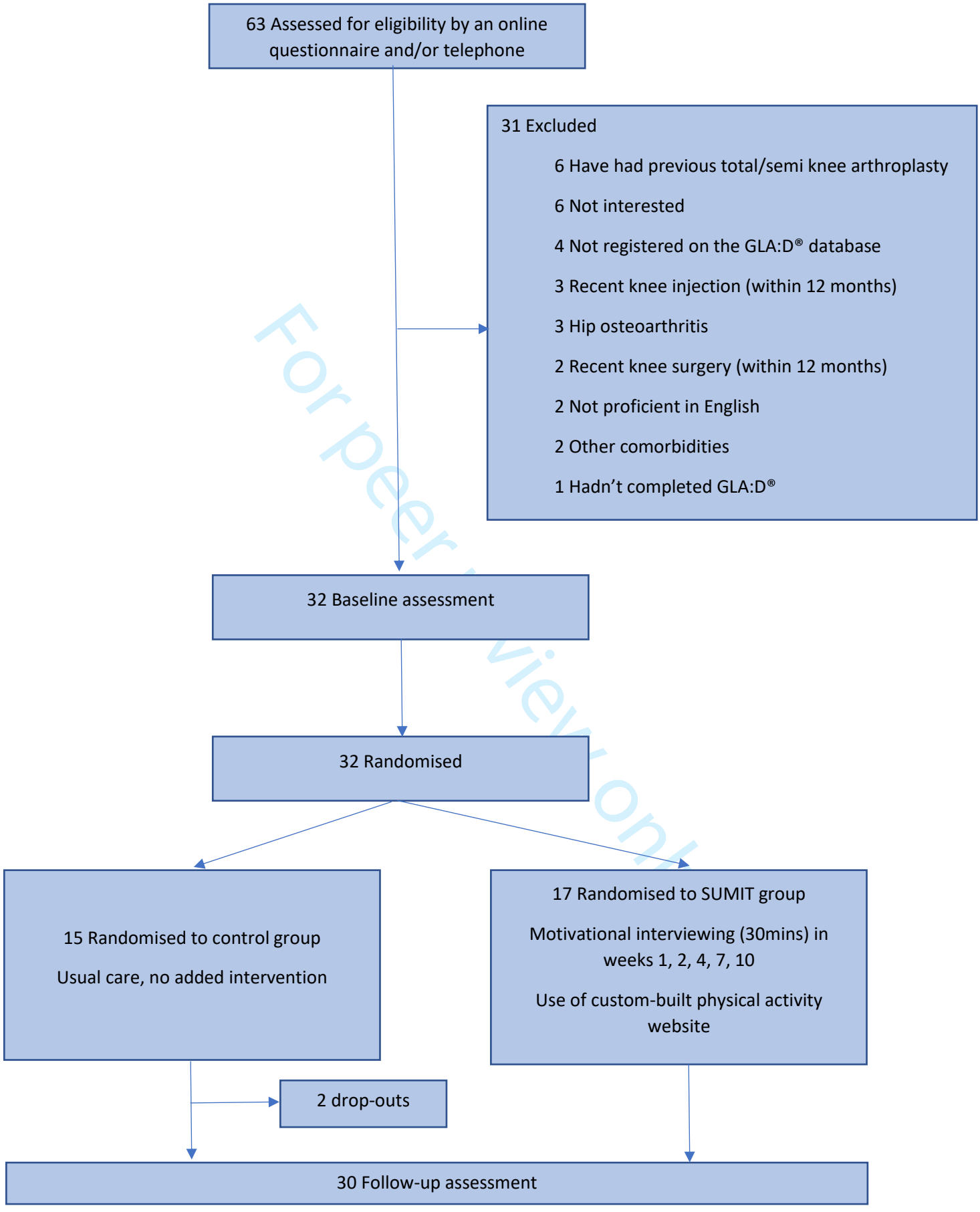


Figure 1. Timeline

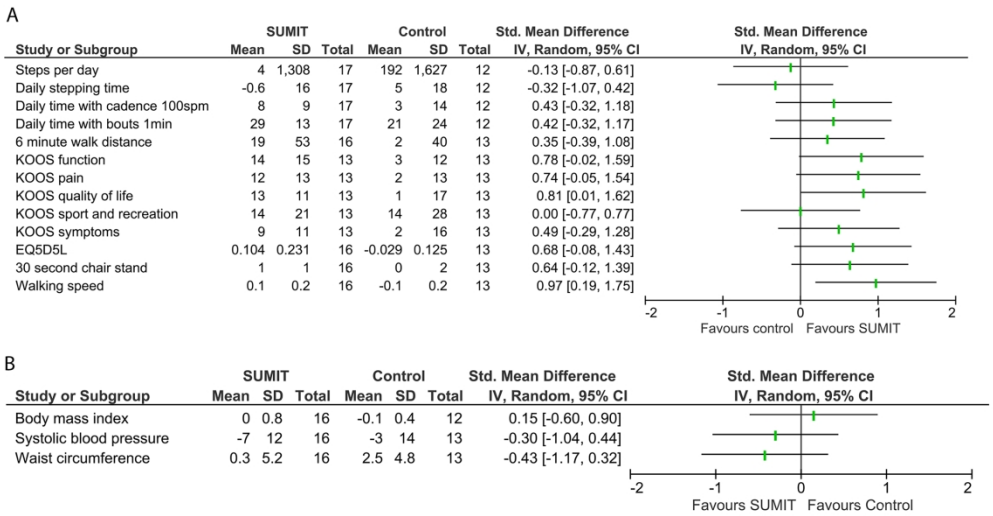


Figure 2a. Forest plot comparing within group change scores between SUMIT and control groups
Legend: spm= steps per minute, min= minute, KOOS= Knee Osteoarthritis Outcome Score, EQ5D5L= Euroqual 5-dimension 5-long
Figure 2b. Forest plot comparing within group change scores between SUMIT and control groups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

203x105mm (300 x 300 DPI)

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 *feel* that therapy will help you to increase your physical activity?
6. How much improvement in your physical activity do you really *feel* will occur?

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:

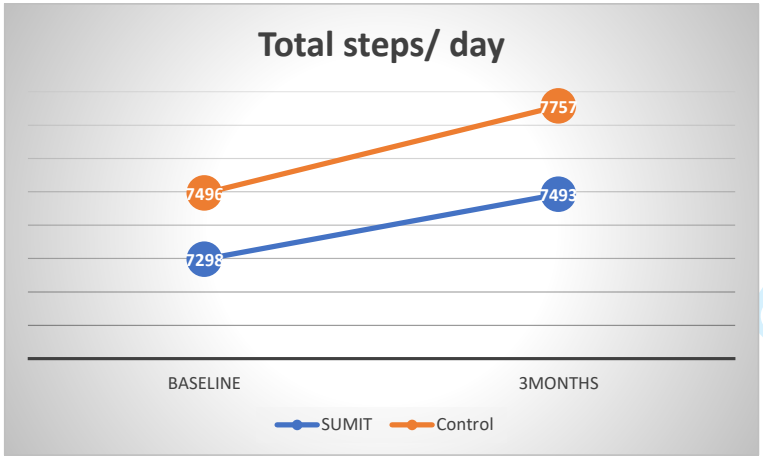
Participant 3 (P3) had never been exposed to motivational interview before, learned from GLA:D® that they should be doing regular exercise for their knee and had previously had fluctuating dedication to gym since being aged in their 20's. **Engagement:** P3 talked with their physio about their love of 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.

Appendix 3. University of California Los Angeles Physical Activity Scale

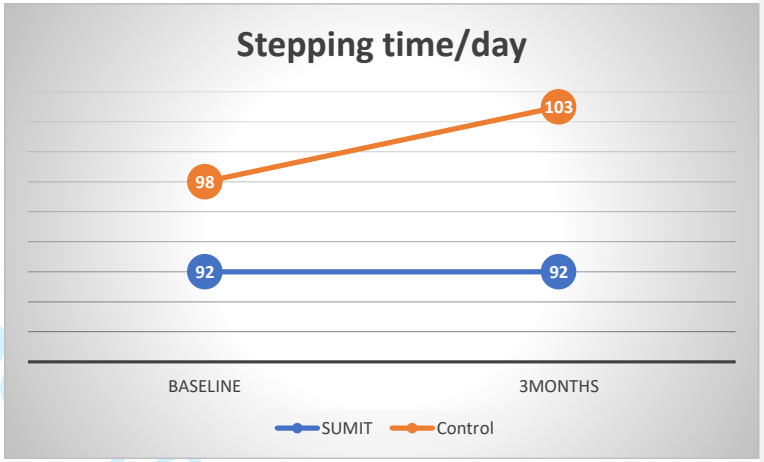
Question	**Answer options:**
Please indicate which level of activity applies to you	1 Wholly inactive: dependent on others: cannot leave residence 2 Mostly inactive: restricted to minimal activities of daily living 3 Sometimes participates in mild activities 4 Regularly participates in mild activities, 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.

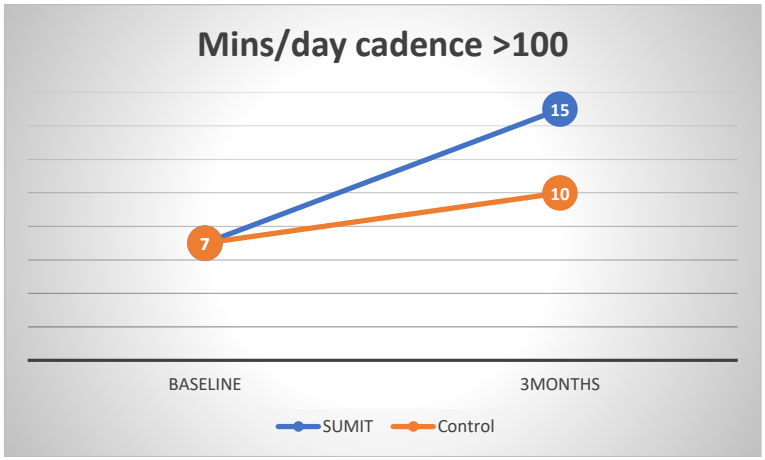
Appendix 4a. Total steps per day for SUMIT and control groups at baseline and 3-months



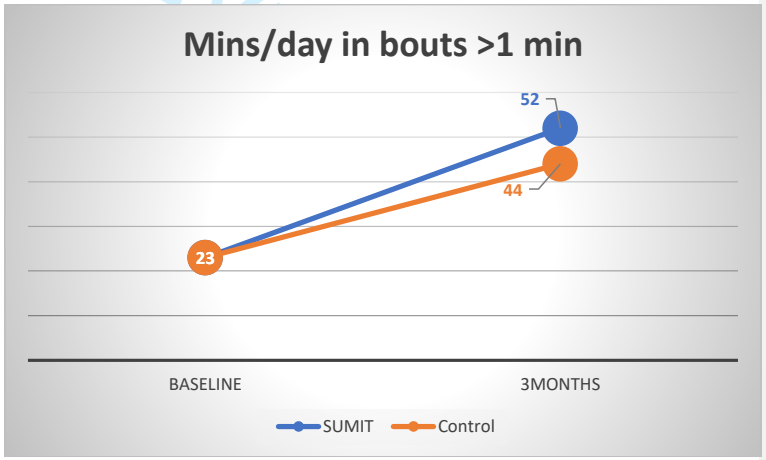
Appendix 4b. Stepping time per day (mins) for SUMIT and control groups at baseline and 3-months



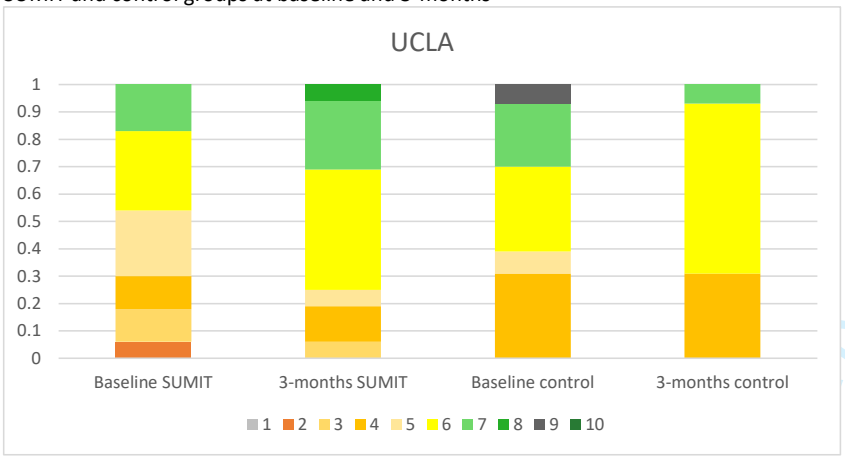
Appendix 4c. Minutes per day with cadence >100 for SUMIT and control groups at baseline and 3-months



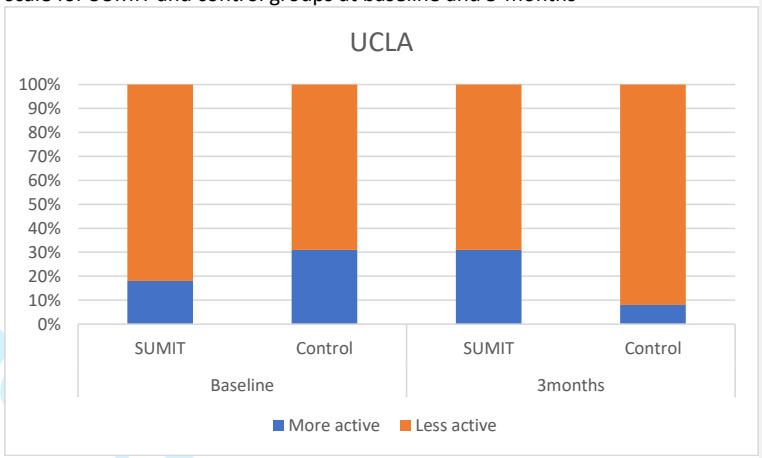
Appendix 4d. Minutes per day in bouts >1min for SUMIT and control groups at baseline and 3-months



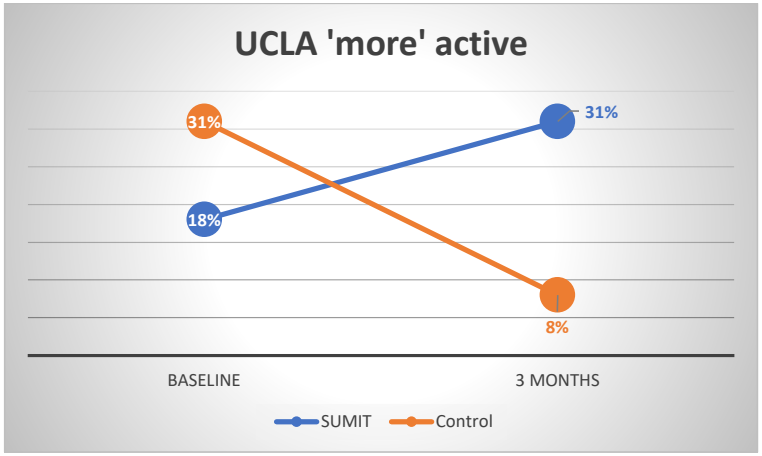
Appendix 5a. University of California Los Angeles physical activity scale raw scores for SUMIT and control groups at baseline and 3-months



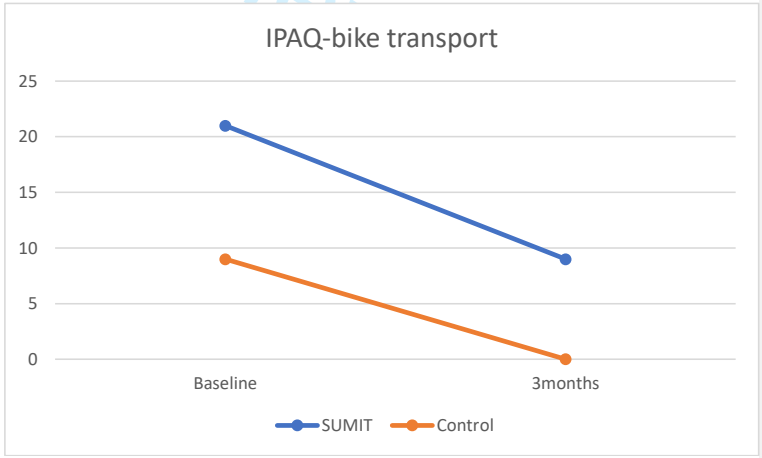
Appendix 5b. Dichotomised University of California Los Angeles physical activity scale for SUMIT and control groups at baseline and 3-months



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



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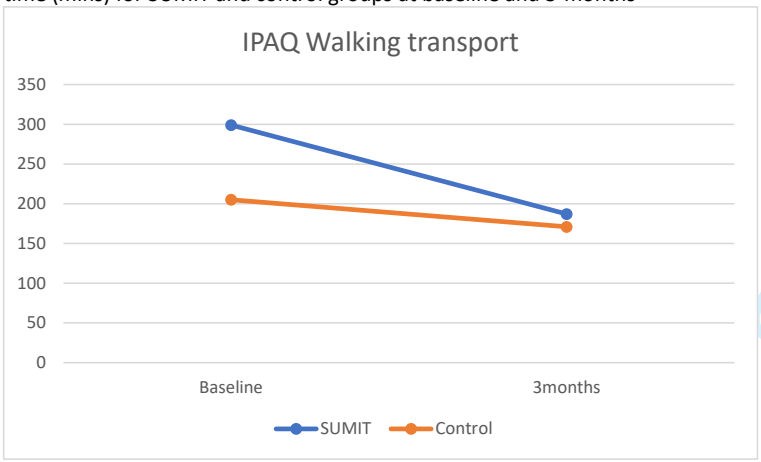
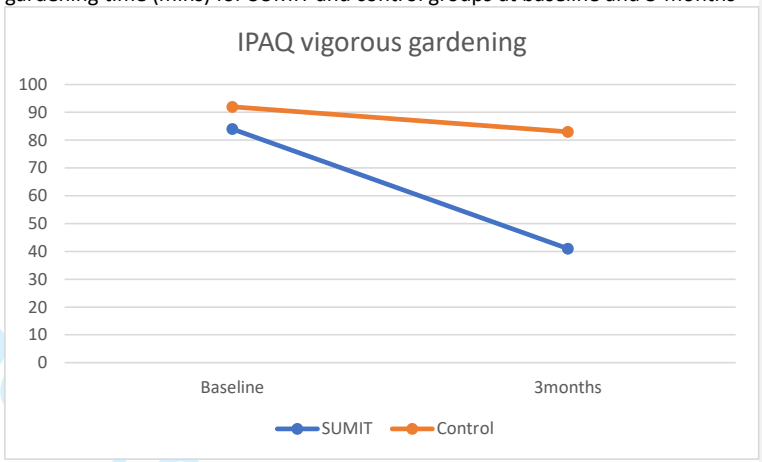
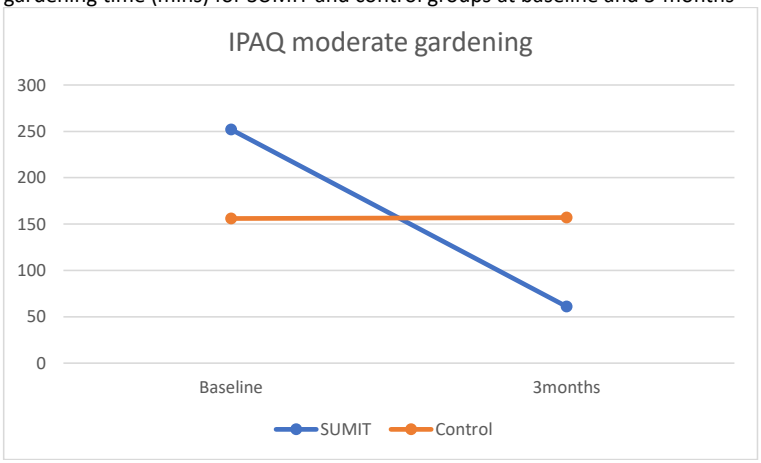
Appendix 5e. International Physical Activity Questionnaire long form walking transport time (mins) for SUMIT and control groups at baseline and 3-months



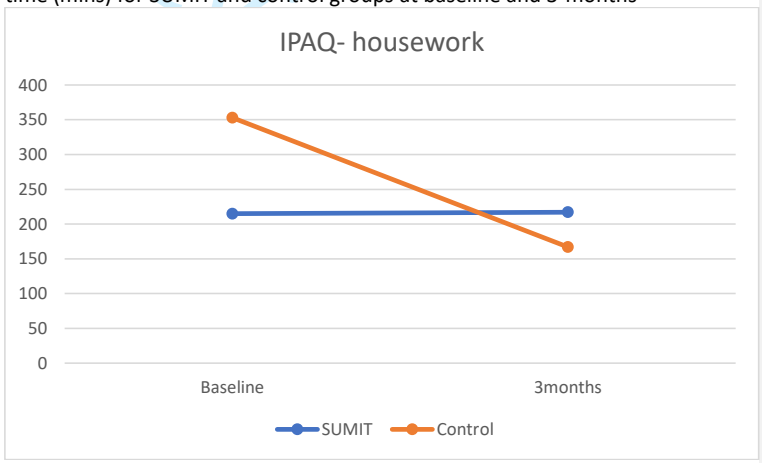
Appendix 5f. International Physical Activity Questionnaire long form vigorous gardening time (mins) for SUMIT and control groups at baseline and 3-months



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

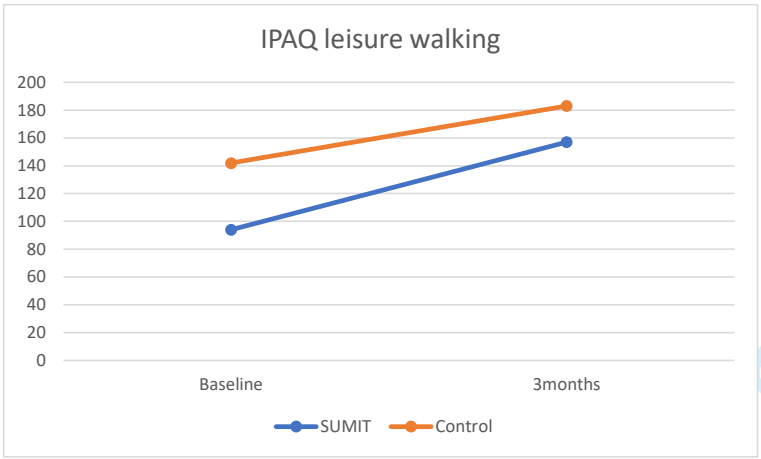


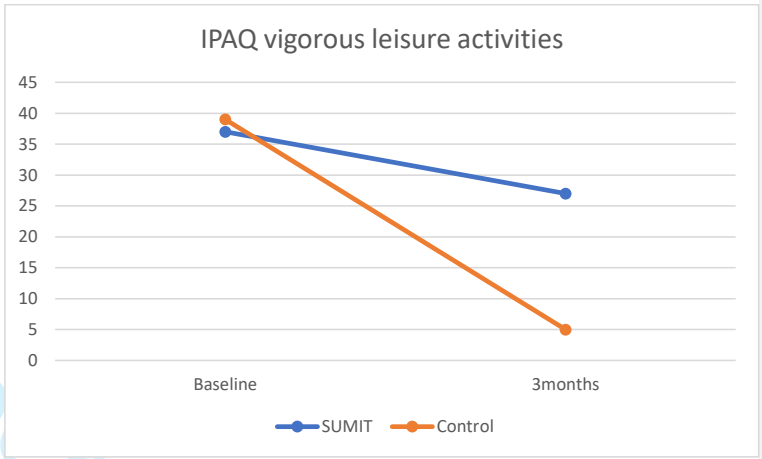
Appendix 5h. International Physical Activity Questionnaire long form housework time (mins) for SUMIT and control groups at baseline and 3-months



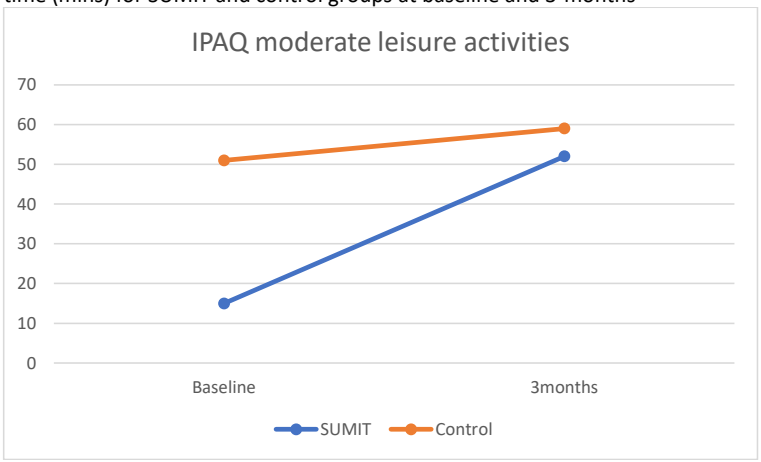
Appendix 5i. International Physical Activity Questionnaire long form leisure walking time (mins) for SUMIT and control groups at baseline and 3-months

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

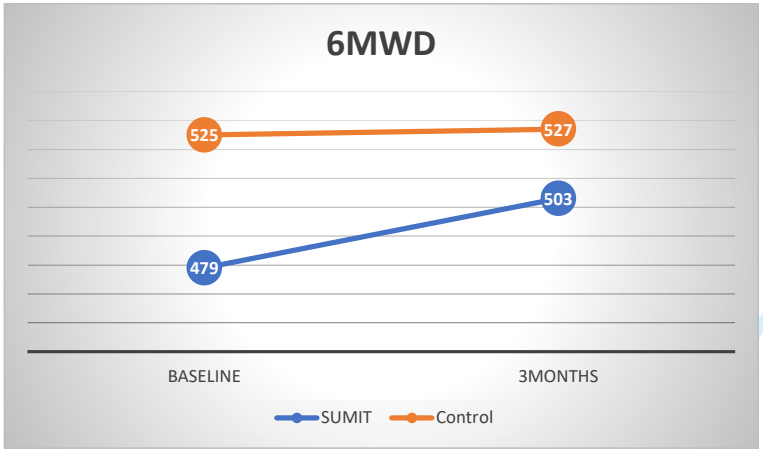




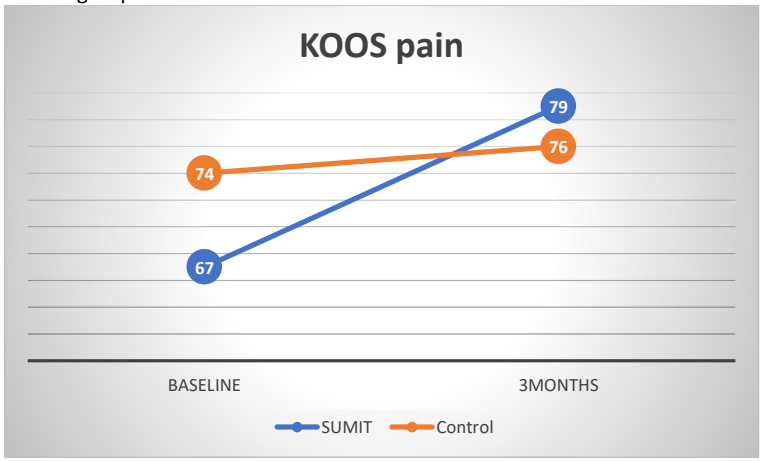
Appendix 5k. International Physical Activity Questionnaire long form moderate leisure time (mins) for SUMIT and control groups at baseline and 3-months



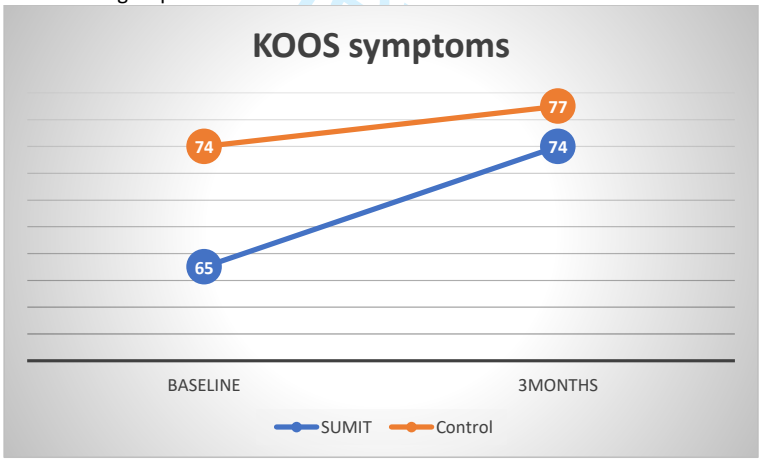
Appendix 6. 6-minute walk distance (m) for SUMIT and control groups at baseline and 3-months



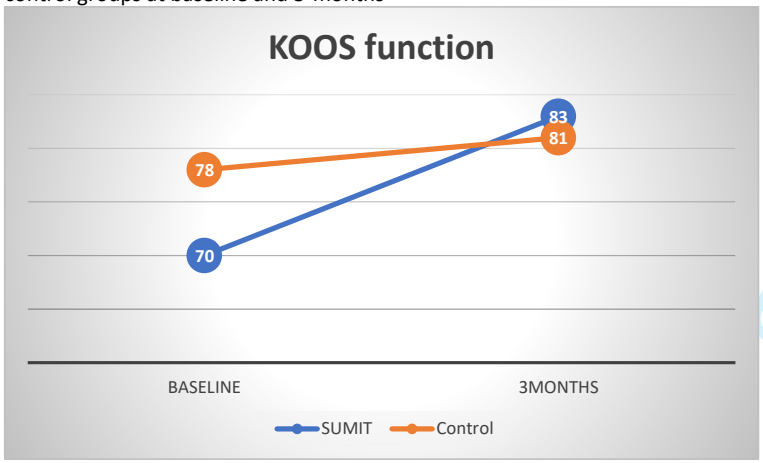
Appendix 7a. Knee Osteoarthritis Outcome Score pain subscale for SUMIT and control groups at baseline and 3-months



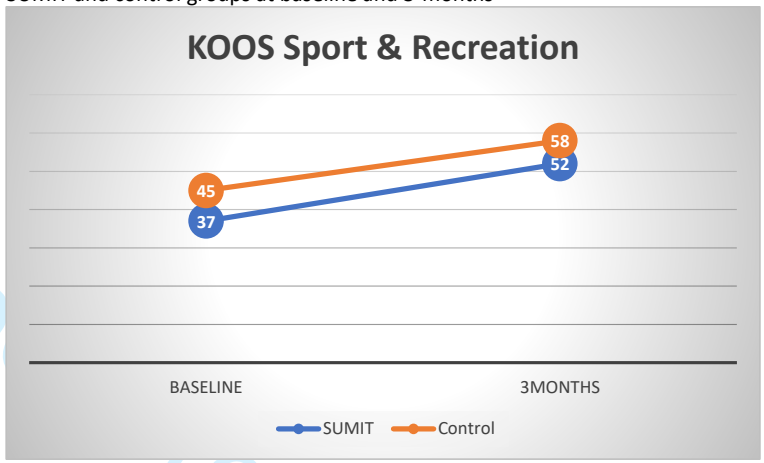
Appendix 7b. Knee Osteoarthritis Outcome Score symptoms subscale for SUMIT and control groups at baseline and 3-months



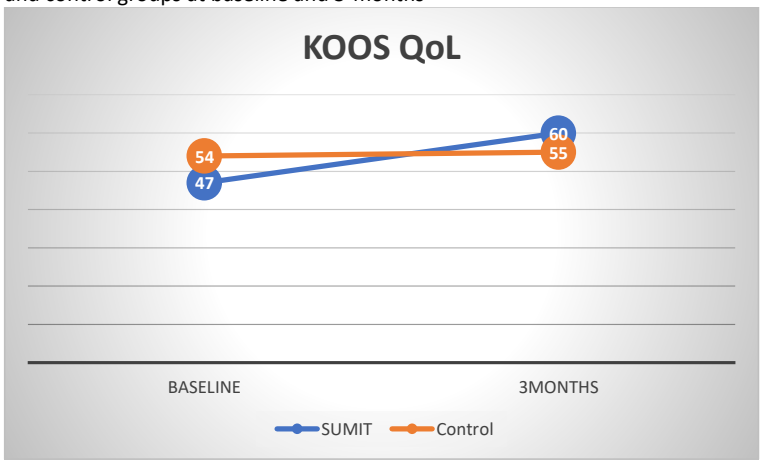
Appendix 7c. Knee Osteoarthritis Outcome Score function subscale for SUMIT and control groups at baseline and 3-months



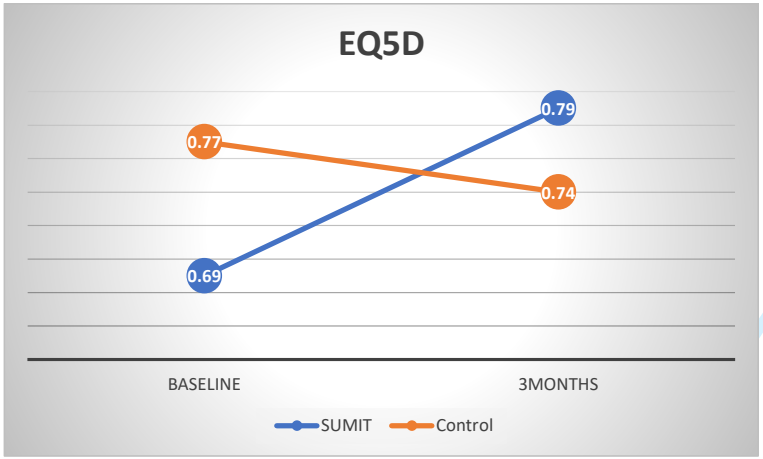
Appendix 7d. Knee Osteoarthritis Outcome Score sport & recreation subscale for SUMIT and control groups at baseline and 3-months



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

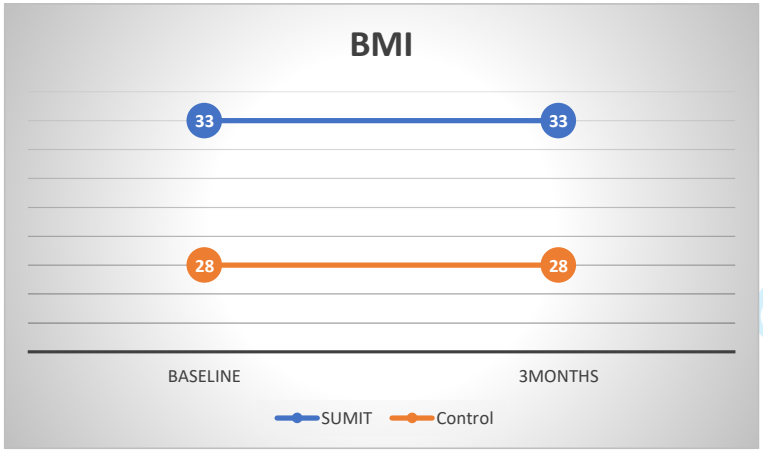


Appendix 8. Health-related quality of life for SUMIT and control groups at baseline and 3-months



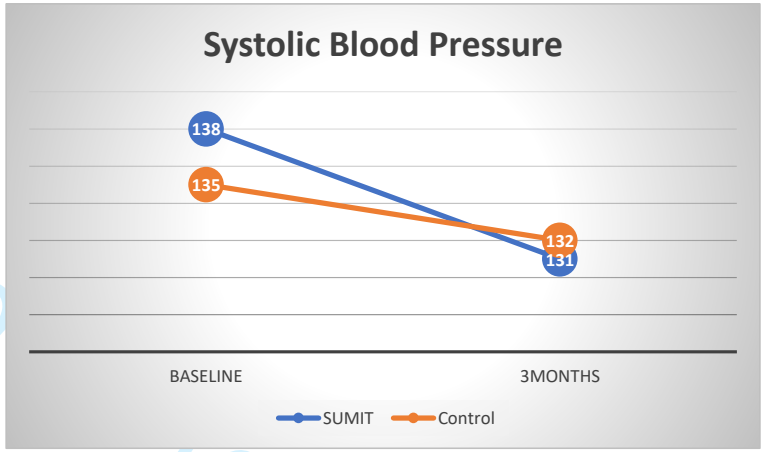
Legend: EQ5D= Euroqual 5-dimension 5-long

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

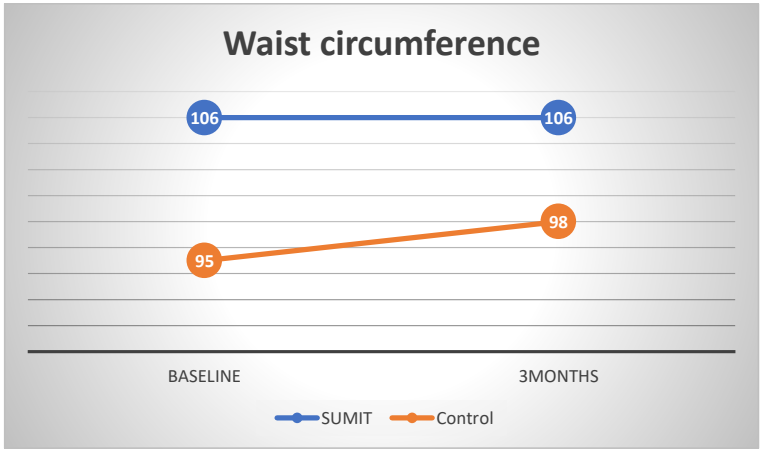


Legend: BMI- body mass index

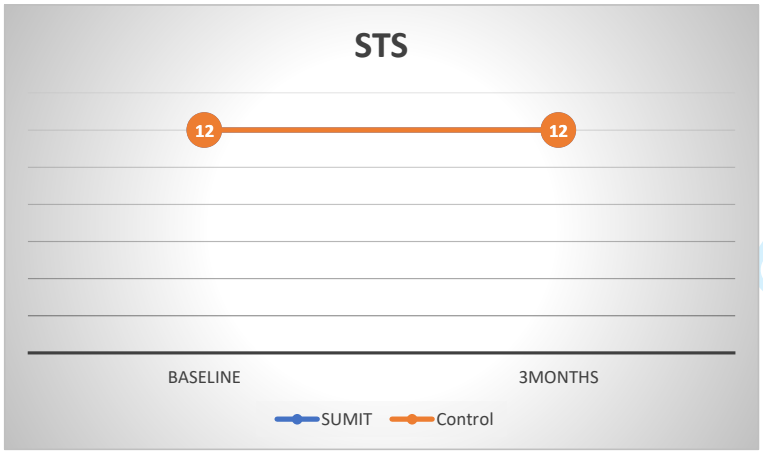
Appendix 9b. Systolic blood pressure for SUMIT and control groups at baseline and 3-months



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

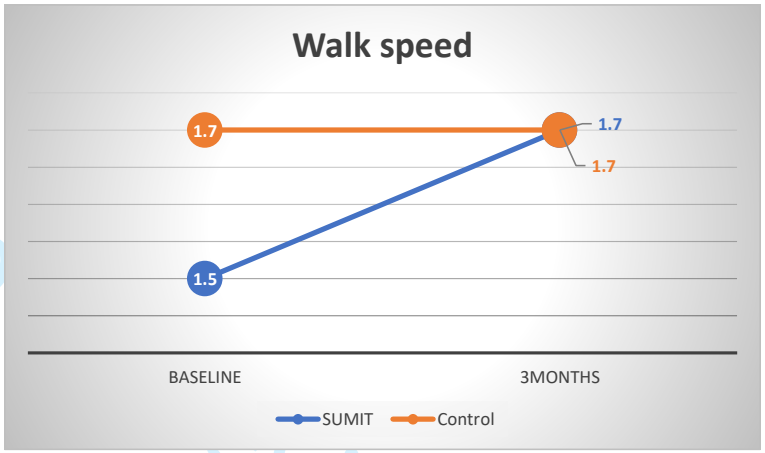


Appendix 10a. 30 second chair stand test for SUMIT and control groups at baseline and 3-months



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.

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.			**Page No.**
		No Change	**Impact***	**Mitigating Strategy****	
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.

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				

*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.