Osteoarthritis and Cartilage Open 4 (2022) 100308

Contents lists available at ScienceDirect

Osteoarthritis and Cartilage Open

journal homepage: www.elsevier.com/journals/osteoarthritis-and-cartilage-open/2665-9131

Effect of combined exercise training and behaviour change counselling versus usual care on physical activity in patients awaiting hip and knee arthroplasty: A randomised controlled trial

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ARTICLE INFO

Keywords:
Osteoarthritis
Health action process approach
Exercise
Behaviour change
Hip
Knee
Waitlist
Arthroplasty

ABSTRACT

Objective: This study aimed to determine if a novel intervention that combined individualised exercise training with behaviour change counselling based on Health Action Process Approach (HAPA) constructs could elicit long-term increase in physical activity (PA) and reduce comorbidity development among people requiring hip or knee arthroplasty.

Method: A pre-registered two arm, parallel group, randomised controlled trial comparing the effect of a 12-week individualised exercise program combined with behavioural counselling delivered by accredited exercise physiologists, versus usual care to Osteoarthritis (OA) patients on public surgery waitlists. Participants were followed up at 6 months after baseline (pre-surgery) and again at 6 months post-surgery. Within and between group differences in post-surgery PA (as measured by ActivPal accelerometer), pain, function, quality of life, HAPA-based behavioural and psychological constructs, and health risk factors were analysed.

Results: 63 participants (34 Female; Mean age = 66.4 ± 7.2 yrs) consented to participate in this study. At 6 months post baseline and 6 months post-surgery there were significant improvements in PA, pain, function, and quality of life, however there were no significant differences in the between group responses. Significant between group changes were observed in several psychological constructs related to volition at 6 months post baseline; however, these had disappeared by 6 months post-surgery.

Conclusions: An exercise program and HAPA guided counselling intervention can improve psychological constructs related to exercise behaviour; however, these did not result in significant between group changes in PA at the timepoints measured. Further research with larger sample size is required.

Trial Registration: Australian New Zealand Clinical Trials Registry (ACTRN 12617000357358) Date of registration: 08/03/2017.

1. Background

Osteoarthritis (OA) affects over 40% of adults over the age of 70 years [1] and is associated with substantial pain and disability [2]. Patients with advanced OA of the hip or knee are often referred for surgery to replace the affected joints [3]. Waiting time for surgery varies from six to twelve months [4] during which there are progressive increases in pain and disability, and worsening health related quality of life [5]. Physical

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https://doi.org/10.1016/j.ocarto.2022.100308
Received 8 March 2022; Received in revised form 17 August 2022; Accepted 19 August 2022

activity (PA) levels in patients with OA are lower than in non-arthritic older people [6] which exacerbate physical impairments such as muscle weakness resulting in an increased rate of functional decline [7] contributing to the high rates of cardiovascular and metabolic comorbidities observed in people with OA [8]. In contrast, substantial research supports the benefits of regular physical activity in the prevention and treatment of chronic medical conditions including OA [9,10].

Previous research has largely concentrated on the effects of preoperative exercise on post-operative pain and mobility, but not physical activity [11] and where measured, changes in PA prior to surgery are not evident[12]. As patients' adherence to exercise tends to drop over time post-surgery [13] and clinicians often do not promote independent exercise as a treatment option [14], the positive benefits in pain and mobility are often not sustained and long term improvements in PA not observed. The use of an individualised intervention with a behaviour change counselling component may provide a means of addressing the challenge of achieving prolonged increases in PA for patients with OA, with potential benefits to cardiovascular and metabolic health.

The Health Action Process Approach (HAPA) [15,16] is a hybrid model that combines features of stage and continuum social cognition models. The model proposes the involvement of constructs underpinning motivational and volitional processes in the change process and identifies six main constructs considered the core precursors of behaviour: intention, risk perception, outcome expectancies, self-efficacy, planning, and action control [16]. In the motivational phase, outcome expectancies (perceived outcomes of performing the target behaviour, conceptually similar to *attitudes* toward the behaviour) and self-efficacy (perceived capacity to successfully perform a behaviour and overcome barriers to its performance) are constructs that make formation of intentions more likely, with self-efficacy playing a crucial role at all stages of the behaviour change process. The HAPA also posits risk perceptions (perceived severity of a health condition that may arise from not performing the target behaviour and personal vulnerability toward it) as a direct predictor of intention, although substantially smaller effects of risk perceptions on intention, and indirectly, on behaviour have been found suggesting risk perceptions as the HAPA construct has a relatively minor role in determining health-related behaviour [16,17]. In the volitional phase, planning is an important determinant of behaviour, with behavioural maintenance determined by action control. Behavioural intention operates as a bridge between the motivational and volitional phases, while planning serves to link intentions with behaviour. Finally, the HAPA considers individuals' behaviour to be influenced by situational barriers and opportunities, such as supportive social networks and available resources. Empirical evidence has shown support for the HAPA in explaining and changing health behaviour in multiple populations across different contexts [16,17], including PA [18]. The model has also been used to identify PA attributes that are most salient to adults with knee osteoarthritis [19]. However, applying this model to a pre-surgery context is novel.

The aim of this study was to determine if an intervention delivered while waiting for surgery that combined behaviour change counselling based on techniques mapped on the HAPA constructs with an individualised exercise training program could elicit long term increases in PA in patients requiring hip or knee arthroplasty and reduce comorbidity development. We hypothesised that the intervention group would perform more daily steps at both 6 months post baseline and 6 months post-surgery. Secondary outcomes included a range of health risk factors.

2. Methods/design

The ENHANCE (Exercise aNd beHaviour chANge CounsElling) study comprised a pre-registered two arm, parallel group, randomised controlled trial (RCT) with a 1:1 allocation ratio that investigated the effectiveness of exercise and behaviour change counselling versus usual care on physical activity and clinical outcomes in patients on the surgical waiting list for a total knee or hip replacement. The 12-week intervention was delivered by Accredited Exercise Physiologists (AEP) in a university exercise physiology clinic. The study was approved by the Tasmanian Health and Medical Human Research Ethics Committee (H0016201) and was registered with the Australian New Zealand Clinical Trials Registry (ACTRN 12617000357358). Recruitment commenced 11th August 2017 and ceased 26th April 2019. The final participant attended their 6 month post-surgery assessment on 19th January 2021.

2.1. Participants

Patients on the public waiting list for a total hip or knee arthroplasty were eligible to participate in the trial if they had spent less than six months on the waiting list, were aged ≤80 years, could read and understand English, and were willing to participate in a 12-week exercise intervention. Patients are placed on the surgical waiting list only when all non-operative measures as outlined by Osteoarthritis Research Society International (OARSI) [3] are deemed to have failed.

Potential participants were ineligible to participate if they had an unstable medical condition where participation in exercise could present an additional health risk, prior diagnosis of a progressive neurological condition (e.g., Parkinson's disease), or were confined to a wheelchair.

Research nurses from an orthopaedic service, who were not otherwise involved in the research screened potential participants from the surgery wait list. Potential participants were then contacted and provided with an information package and invited to contact a researcher after which they underwent secondary clinically relevant screening for exclusion.

2.2. Description of the intervention

Full details of the ENHANCE intervention have been published previously [20]. Briefly, ENHANCE was a 12-week program consisting of 24 progressive exercise group classes based on clinical evidence for hip and knee OA [21] delivered by an AEP, combined with five group behaviour counselling sessions, based on the HAPA [15]. Participants in the intervention group completed an ENHANCE workbook as part of the behavior change counselling. It included general information and activities related to the benefits of exercise and ways of facilitating successful behaviour change. [20]. Adherence to exercise during the exercise intervention was measured via attendance sheets at group training sessions.

2.3. Usual care

Participants randomised to control received a generic information brochure "Arthritis (osteoarthritis) and exercise" produced by Exercise is Medicine Australia [22] and usual concomitant orthopaedic care.

2.4. Sample size

An *a priori* sample size was calculated to enable detection of a predicted increase of 1200 (24%) daily steps (alpha 0.05, power 0.8) in the intervention compared to the control group based usual changes in step count after lower limb joint replacement [23]. The calculation indicated a required sample of 50 patients in each group, and a low withdrawal rate of 4% [23]. We estimated a 10% withdrawal and hence aimed to recruit 110 participants. Due to lower-than-expected recruitment rate (Fig. 1) and time constraints, recruitment was ceased at 18 months with a total of 63 eligible participants having consented.

2.5. Randomisation

The randomisation schedule and allocation was completed by a researcher independent to the research project using a computer-generated random numbers table. Allocation was concealed until after baseline measures in consecutively numbered, sealed, opaque envelopes kept in a locked cabinet As ENHANCE was an exercise intervention, blinding of the participant and the researcher who conducted the

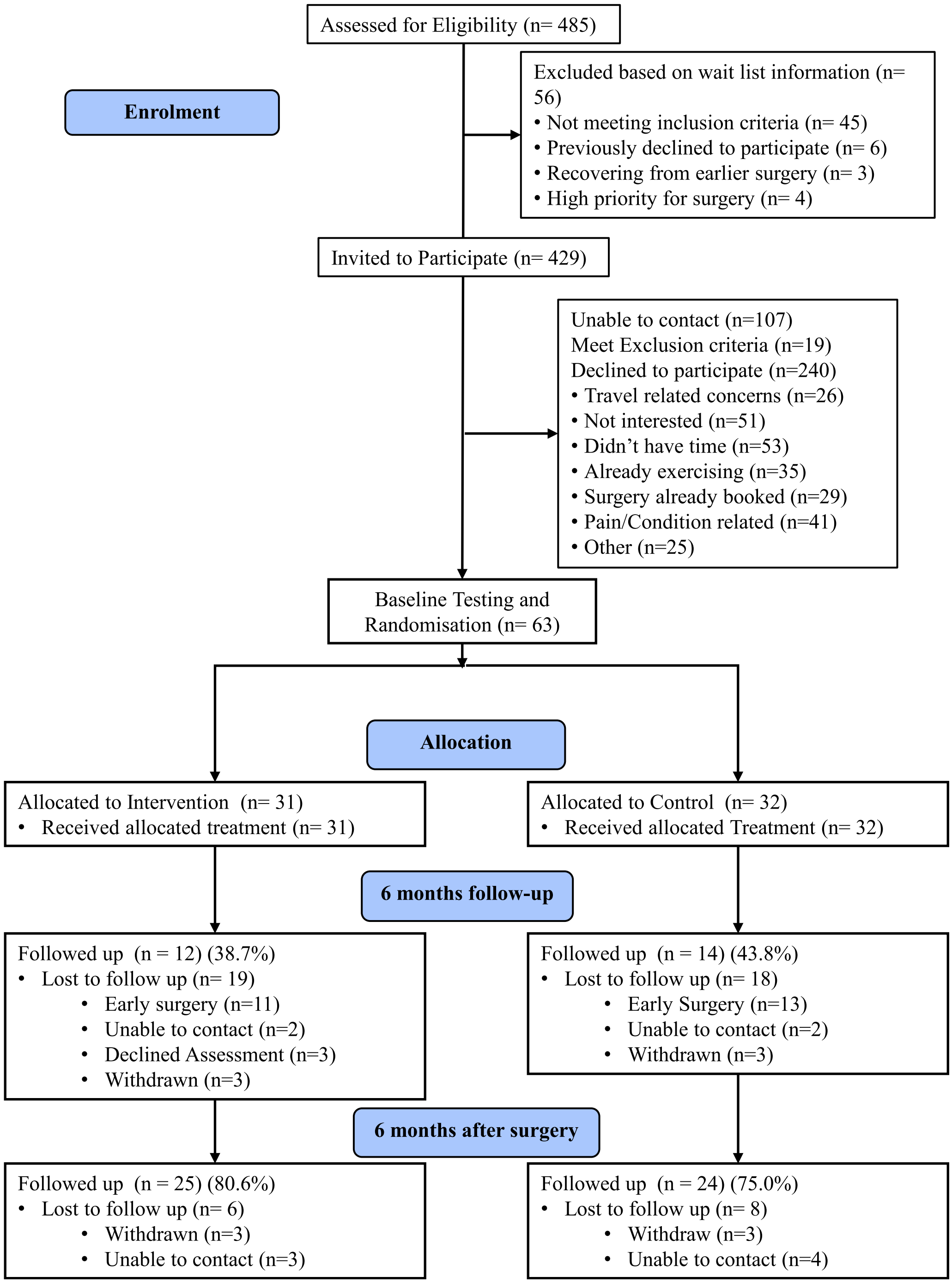

Figure 1. CONSORT flow diagram.

intervention was not possible. Outcome assessors were not involved in delivery of the intervention and were blinded to group allocations.

2.6. *Assessment*

All assessments were completed at baseline, at 6 months after baseline but prior to surgery, and at 6 months post-surgery. Each assessment was conducted at the university exercise clinic. The baseline assessment also included additional demographic information related to health and medical history.

2.7. *Primary outcome measures*

The primary outcome measure was daily physical activity (step count). Participants wore an activity monitor (ActivPAL™, PAL Technologies Ltd, Glasgow, Scotland) for seven consecutive days at each timepoint. Data from the device was recorded and uploaded to a computer and then averaged over the seven days of measurement to calculate a daily step count. Percentage of the day spent active defined as the percentage of the day spent upright or walking was also recorded. Days with less than 20 h of recorded data were excluded from analysis.

2.8. Secondary outcomes

The secondary outcomes included assessment of pain, function, general quality of life, clinical markers, and psychological HAPA-based and behavioural constructs. Pain was measured using a visual analogue scale according to previously described methods [24] and has been shown to be sensitive to clinical change in people with arthritis. Quality of life was evaluated using the Medical Outcomes Short-Form 12-item health survey (SF-12). This survey is validated and has been widely used to measure quality of life in a range of populations [25–27]. Physical function was measured using the Timed Up and Go (TUG) which assesses functional mobility [28], and the Oxford Hip and Knee Function scales [29]. The Oxford Hip and Knee Function scales have good internal validity [29] and are valid, reliable and responsive to change [30]. Clinical markers of cardiovascular and metabolic health were measured using standardised protocols and included systolic and diastolic blood pressure, fasting blood glucose, glycosylated hemoglobin (HbA1c), waist circumference and body mass index (BMI) using standardised methods [20]. Body fat percentage was assessed using bioelectrical impedance analysis (BIA) scales (Tanita BC-1000; Tanita Corp; Tokyo, Japan) [31], a reliable and valid method of assessing body composition.

2.9. Assessment of psychological and behavioural constructs

The psychological and behavioural constructs of current exercise behaviour, habit strength, intention, attitude, social influence (which is referred to as subjective norms and social support), perceived behavioural control, barrier self-efficacy, action planning and action control were assessed through administered questions with answers on multi-item (1 to 7 point) scales as described previously [20].

2.10. Data analysis

Descriptive statistics of baseline characteristics were reported as percentages for categorical and mean (SD) for continuous variables for all participants and by intervention group. To evaluate the intervention effect, we fitted the hierarchical linear mixed model [32] for all outcomes. Prior to analysis the assumption of linear regression analysis was confirmed by checking the normality of the residuals. The repeated measures of the outcomes collected at baseline, 6 months after baseline and 6 months post-surgery were clustered within each individual. A mixed model with the random intercept (individual) was fitted, and then checked if the model with random intercept (individual) and slope (time) fitted better using the likelihood ratio test. The results showed the complex model with random intercept and slope better fitted the data ($p < 0.001$). Therefore, the mixed model with random intercept and slope with “unstructured” covariance structure using the restricted maximum likelihood (REML) [33,34] was selected. This method was chosen instead of the proposed Analysis of Covariance [20] as it is superior in cases of multilevel mixed models, and high missing data patterns.

Data (regression coefficients) were presented as within group differences in the outcome measurements at both 6 months post baseline and 6 months post-surgery compared to baseline; and between group differences (intervention and control) at 6 months post baseline and 6 months post-surgery. The models were adjusted for baseline values of outcome measures and participant gender. We also analysed whether there was a mediating effect of psychological HAPA-based constructs (perceived behavioural control, barrier self-efficacy, intention, action planning, and action control) on primary outcomes using maximum likelihood method by path analysis and found none of these variables showed a significant mediating effect. Data was analysed according to the intention-to-treat principle [35]. Multilevel models consider all the available data and accommodate for missing data at specific timepoints in the analysis. P-values for a level of statistical significance was set at 0.05. Analysis was carried out using STATA (version 16.1; College Station, TX, USA).

3. Results

485 patients on public surgery waiting lists for total hip or knee arthroplasty were assessed for eligibility, with 429 identified as eligible and approached to participate. 63 agreed to participate and underwent randomisation with 31 and 32 participants assigned to the intervention and control groups, respectively. Due to surgery taking place following the 12 week intervention but before the 6 months post baseline assessment for 23 participants, only 12 (38.7%) participants in the intervention and 14 (43.8%) participants in the control group completed outcome assessments at 6 months post baseline. At 6 months post-surgery, 25 (80.6%) participants in the intervention and 24 (75.0%) participants in control group completed the outcome assessments (Fig. 1). However, equipment malfunction reduced the number of complete datasets for PA measures to 19 intervention and 15 control participants at 6 months post-surgery. Reasons for not attending assessments were similar across both groups at all timepoints (Fig. 1). The mean duration in the study (Baseline to 6 month post-surgery testing) for completers was 57 ± 23.5 weeks for the control and 58 ± 23.3 weeks for the intervention group.

The mean age of participants was 66.4 years; 34 (54%) were female and 42 (66.7%) were married. Most trial participants (n = 49, 77.8%) were retired, more than half (53.2%) completed year 10 education and almost half (47.6%) reported their yearly income below AUD $18K (Table 1). 62% of trial participants were awaiting a knee arthroplasty and participants had an average of 3.5 (SD: 1.8) comorbidities. The distribution of the covariates and the outcomes across the intervention groups were similar.

Participants who were randomised to the intervention group attended 12.2 ± 8.3 (mean ± SD) of a potential 24 exercise sessions and 3.5 ± 2.0 (mean ± SD) of a possible 5 behavioural counselling sessions. When attendance data of those intervention participants who withdrew early in

Table 1
Baseline characteristics of the study population, n (%).

Characteristics	Intervention (n = 31)	Control (n = 32)	Total (n = 63)
Gender			
Male	13 (41.9)	16 (50.0)	29 (46.0)
Female	18 (58.1)	16 (50.0)	34 (54.0)
Age years, Mean ± SD	66.2 ± 7.6	66.6 ± 7.0	66.4 ± 7.2
Marital status			
Married	21 (67.7)	21 (65.6)	42 (66.7)
Single[a]	10 (32.3)	11 (34.4)	21 (33.3))
Job			
Not working/retired	25 (80.7)	24 (75.0)	49 (77.8)
Currently working	6 (19.4)	8 (25.0)	14 (22.2)
Education			
Year 10	15 (50.0)	18 (56.3)	33 (53.2)
Year 12	3 (10.0)	5 (15.6)	8 (12.9)
Vocational certificate	7 (23.3)	3 (9.4)	10 (16.1)
Undergraduate	1 (3.3)	3 (9.4)	4 (6.5)
Postgraduate	4 (13.3)	3 (9.4)	7 (11.3)
Income (AU$)			
0–18K	17 (54.8)	13 (40.6)	30 (47.6)
18–37K	9 (29.0)	11 (34.4)	20 (31.8)
37–80K	3 (9.7)	7 (21.9)	10 (15.9)
>80K	2 (6.4)	1 (3.1)	3 (4.8)
Osteoarthritis			
Hip	13 (41.9)	11 (34.4)	24 (38.1)
Knee	18 (58.1)	21 (65.6)	39 (61.9)
Number of Comorbidities (mean ± SD)	3.2 ± 1.7	3.7 ± 1.9	3.5 ± 1.8
Cardiometabolic	21(67)	25(78)	46(73)
Respiratory	7(23)	5(16)	12(19)
Musculoskeletal other than OA	20(65)	25(78)	45(71)
Neurological	0(0)	2(6)	2(3)
Mental Health	7(23)	10(31)	17(27)
Other	15(48)	14(44)	29(46)

OA = Osteoarthritis; SD = Standard deviation; K = thousand.

[a] Single category includes never married, divorced, separated, and widowed.

the intervention (n = 5) or did not receive the full intervention due to receiving their surgery early (n = 5) was excluded, the attendance of the remaining 21 intervention participants was 16.6 ± 5.9 (mean ± SD) exercise sessions and 4.6 ± 1.9 (mean ± SD) behavioural counselling sessions. Of the 21, fourteen had excellent adherence, four good adherence, two moderate adherence, and one poor adherence as defined previously [20]. Assessment of home program adherence was not possible due to failure to provide questionnaires to participants. The intervention was delivered as per protocol with no adaptations indicating high fidelity to protocol. Results of all the outcome measures at baseline and follow-up are presented in Table 2.

3.1. Intervention effects on primary outcomes

There was no significant difference in changes to step count or the percentage of time spent active between the intervention and control groups at any time point (Table 3). The intervention group had significantly higher daily steps at 6 months post-surgery compared to baseline ($b = 802.87$, $p = 0.021$; 95%CI: 122.36, 1483.37). There was one outlier in the control group who reported an average of 23006 daily steps at baseline and 12060 daily steps at 6 months post-surgery. When their data was removed, the within group change for the control group became statistically significant ($b = 1687$, $p = 0.003$; 95%CI: 583.1, 2791.4). However, this did not change the lack of between group significance ($p = 0.378$).

3.2. Intervention effects on secondary outcomes

The effects of the interventions on secondary outcomes are presented in Table 4.

Both the intervention and control groups showed significant improvements in Oxford hip and knee function and pain reduction at 6 months post-surgery compared to baseline ($p<0.001$). The quality of life score increased at 6 months post-surgery in both the intervention ($p<0.001$) and control ($p = 0.006$) groups with the increment observed in physical score in both groups and in mental score only in the intervention group. No difference was observed in these outcomes for either group between baseline or 6 months post-baseline follow up. There were

Table 2
Means and standard deviations of outcome measures for the intervention groups versus the control group at baseline, 6 months follow up, and 6 months post-surgery.

Outcome measures	Intervention			Control		
	n	Mean	SD	n	Mean	SD
Physical activity (daily steps count)						
Baseline (test 1)	29	5110	2454	28	5771	4327
6 months post-baseline (test 2)	9	5551	1715	12	5517	2511
6 months post-surgery (test 3)	19	6130	1996	15	7643	2363
Percent time spent active						
Baseline (test 1)	29	23.05	7.31	28	22.36	7.58
6 months post-baseline (test 2)	9	20.99	5.68	12	22.00	6.26
6 months post-surgery (test 3)	19	23.22	7.83	15	24.59	3.72
Oxford hip and knee function (Range 0–48)						
Baseline (test 1)	31	21.19	8.34	32	22.47	8.84
6 months post-baseline (test 2)	12	23.58	9.12	14	25.50	11.35
6 months post-surgery (test 3)	25	38.60	8.17	24	37.29	8.74
Visual analogue scale (VAS) (Range 0–10)						
Baseline (test 1)	31	6.32	2.41	32	6.05	2.28
6 months post-baseline (test 2)	12	5.78	2.43	14	5.21	2.69
6 months post-surgery (test 3)	25	1.38	2.15	24	1.88	2.06
Quality of life (SF-12) (Range 0–100)						
Baseline (test 1)	31	43.51	19.46	32	45.12	20.48
6 months post-baseline (test 2)	12	52.71	19.99	14	46.43	24.42
6 months post-surgery (test 3)	25	66.45	21.62	24	58.72	24.32
Quality of Life – Physical Score (0–100)						
Baseline (test 1)	31	33.47	20.95	32	37.11	25.30
6 months post-baseline (test 2)	12	45.83	25.05	14	38.39	30.41
6 months post-surgery (test 3)	25	64.00	26.23	24	58.07	28.40
Quality of Life – Mental Score (0–100)						
Baseline (test 1)	31	53.55	21.02	32	53.13	18.62
6 months post-baseline (test 2)	12	59.58	17.67	14	54.46	20.92
6 months post-surgery (test 3)	25	68.90	19.50	24	59.38	23.69
Current exercise behaviour (Range: 0–7)						
Baseline (test 1)	31	1.58	2.63	32	1.50	2.23
6 months post-baseline (test 2)	12	5.17	2.44	12	2.83	2.79
6 months post-surgery (test 3)	22	4.55	2.82	22	3.64	3.09
Habit strength (Range: 0–7)						
Baseline (test 1)	31	3.59	2.09	32	3.52	2.06
6 months post-baseline (test 2)	12	5.10	1.55	14	4.73	2.04
6 months post-surgery (test 3)	25	4.73	1.91	24	4.33	1.94
Intention (Range: 0–7)						
Baseline (test 1)	31	5.25	2.01	32	4.66	2.19
6 months post-baseline (test 2)	12	6.81	0.39	14	5.88	1.74
6 months post-surgery (test 3)	25	6.32	1.50	24	6.04	1.39
Attitude (Range: 0–7)						
Baseline (test 1)	31	5.27	1.80	32	5.43	1.71
6 months post-baseline (test 2)	12	6.11	1.26	14	5.55	1.77
6 months post-surgery (test 3)	25	6.23	1.23	24	6.00	1.57
Subjective norms (Range: 0–7)						
Baseline (test 1)	31	5.89	1.58	32	6.13	1.28
6 months post-baseline (test 2)	12	6.25	1.41	14	5.61	1.88
6 months post-surgery (test 3)	25	6.34	1.25	24	6.10	1.40

(continued on next page)

Table 2 (*continued*)

Outcome measures	Intervention			Control		
	n	Mean	SD	n	Mean	SD
Social support (Range: 0–7)						
Baseline (test 1)	31	5.18	2.23	32	5.17	2.00
6 months post-baseline (test 2)	12	6.04	1.05	14	4.93	1.87
6 months post-surgery (test 3)	25	6.36	1.13	24	5.50	1.72
Perceived behavioural control (Range: 0–7)						
Baseline (test 1)	31	5.48	1.66	32	5.68	1.26
6 months post-baseline (test 2)	12	6.58	0.93	14	5.71	1.65
6 months post-surgery (test 3)	25	6.47	0.76	24	6.03	1.28
Barrier self-efficacy (Range: 0–7)						
Baseline (test 1)	31	4.89	1.88	32	4.67	1.74
6 months post-baseline (test 2)	12	6.20	1.26	14	5.04	1.63
6 months post-surgery (test 3)	25	5.52	1.67	24	5.09	1.32
Action planning (Range: 0–7)						
Baseline (test 1)	31	3.67	2.46	32	3.75	2.52
6 months post-baseline (test 2)	12	6.29	1.48	14	4.11	2.50
6 months post-surgery (test 3)	25	5.17	2.02	24	5.26	1.69
Action control (Range: 0–7)						
Baseline (test 1)	31	3.69	2.07	32	3.71	1.93
6 months post-baseline (test 2)	12	5.94	1.66	14	4.05	2.10
6 months post-surgery (test 3)	25	4.87	1.87	24	4.50	1.78
Body mass index (BMI: kg/m^2)						
Baseline (test 1)	31	31.91	8.09	32	32.17	7.28
6 months post-baseline (test 2)	11	33.66	5.90	14	31.83	6.27
6 months post-surgery (test 3)	24	33.15	6.01	20	31.47	7.56
Body fat (%)						
Baseline (test 1)	29	38.46	9.23	30	35.97	8.41
6 months post-baseline (test 2)	11	39.25	8.13	14	36.21	6.07
6 months post-surgery (test 3)	22	38.44	9.23	20	34.11	8.51
Waist circumference (cm)						
Baseline (test 1)	29	105.9	14.9	30	107.5	16.4
6 months post-baseline (test 2)	10	108.9	14.7	11	108.2	13.7
6 months post-surgery (test 3)	22	106.9	13.8	18	103.3	14.9
Systolic blood pressures (SBP: mmHg)						
Baseline (test 1)	31	136.5	11.9	32	131.9	13.3
6 months post-baseline (test 2)	12	142.1	15.3	14	135.4	15.4
6 months post-surgery (test 3)	25	130.9	13.2	20	132.8	17.8
Diastolic blood pressures (DBP: mmHg)						
Baseline (test 1)	31	80.42	7.65	32	80.03	10.40
6 months post-baseline (test 2)	12	83.58	4.62	14	81.57	12.54
6 months post-surgery (test 3)	25	80.92	8.23	20	76.35	7.60
Blood glucose (mmoL.L^{-1})						
Baseline (test 1)	29	5.92	1.60	31	6.67	2.36
6 months post-baseline (test 2)	10	5.24	0.73	13	7.01	2.44
6 months post-surgery (test 3)	22	5.51	1.68	19	6.28	1.74
Glycosylated hemoglobin (HbA1c: %)						
Baseline (test 1)	28	5.63	0.51	29	5.94	0.80
6 months post-baseline (test 2)	10	5.41	0.21	13	5.90	0.87
6 months post-surgery (test 3)	23	5.56	0.61	16	5.55	0.71
Timed up and go (TUG)						
Baseline (test 1)	31	11.29	3.65	32	9.26	3.23
6 months post-baseline (test 2)	12	11.17	3.20	14	10.38	6.27
6 months post-surgery (test 3)	25	9.06	2.13	18	7.85	1.64

n = number; SD = standard deviation.

Table 3
Effect of the intervention at 6 months follow up and 6 months post-surgery on primary outcomes.[a]

Outcome measures	Within group difference, compared to baseline						Between group difference at specific time		
	Intervention			Control			Intervention vs. control		
	Change ([b])	p	95%CI	Change ([b])	p	95%CI	Change ([b])	p	95%CI
Physical activity (daily steps count)									
6 months post-baseline (test 2)	−257.65	0.585	−1182.90, 667.61	−79.43	0.877	−1085.46, 926.61	−276.68	0.711	−1741.94, 1188.58
6 months post-surgery (test 3)	802.87	**0.021**	122.36, 1483.37	1315.07	0.067	−92.83, 2722.96	−115.08	0.880	−1613.00, 1382.84
Percent time spent active									
6 months post-baseline (test 2)	−1.34	0.407	−4.50, 1.82	−0.20	0.886	−2.96, 2.55	−1.41	0.533	−5.84, 3.02
6 months post-surgery (test 3)	0.05	0.966	−2.28, 2.38	1.57	0.305	−1.43, 4.56	−0.13	0.947	−3.83, 3.58

[a] Adjusted for gender.
[b] = Unstandardized regression coefficient estimated from the multi-level mixed effect models; % = percent; 95%CI = 95% Confidence Interval.

no significant between group differences in function, pain, and quality of life at any follow up.

There were significant improvements in the psychological and behavioural constructs current exercise behaviour, habit strength,

Table 4
Effect of the intervention at 6 months post-baseline follow up and 6 months post-surgery on secondary outcomes.[a].

Outcome measures	Within group difference, compared to baseline						Between group difference at specific time		
	Intervention			Control			Intervention vs. control		
	Change ([b])	*p*	95%CI	Change ([b])	*p*	95%CI	Change ([b])	*p*	95%CI
Oxford hip and knee function									
6 months post-baseline (test 2)	0.68	0.762	−3.74, 5.10	2.39	0.402	−3.21, 7.99	−0.67	0.863	−8.30, 6.95
6 months post-surgery (test 3)	17.62	**<0.001**	13.37, 21.86	14.65	**<0.001**	10.02, 19.28	2.90	0.352	−3.21, 9.01
Visual analogue scale (VAS)									
6 months post-baseline (test 2)	−0.05	0.922	−1.09, 0.99	−0.84	0.181	−2.07, 0.39	0.61	0.501	−1.17, 2.40
6 months post-surgery (test 3)	−4.91	**<0.001**	−6.02, −3.80	−4.11	**<0.001**	−5.12, −3.10	−0.78	0.284	−2.21, 0.65
Quality of life (SF-12)									
6 months post-baseline (test 2)	2.11	0.643	−6.81, 11.04	−0.86	0.867	−10.90, 9.18	3.24	0.657	−11.06, 17.53
6 months post-surgery (test 3)	21.84	**<0.001**	13.28, 30.39	11.72	**0.006**	3.40, 20.04	9.19	0.120	−2.40, 20.78
Quality of life – physical score									
6 months post-baseline (test 2)	7.14	0.268	−5.49, 19.78	−0.14	0.984	−13.61, 13.33	6.94	0.487	−12.64, 26.52
6 months post-surgery (test 3)	30.30	**<0.001**	18.72, 41.87	18.48	**0.001**	7.39, 29.57	10.64	0.188	−5.21, 26.49
Quality of life – mental score									
6 months post-baseline (test 2)	−1.87	0.593	−8.74, 5.00	−1.27	0.763	−9.53, 6.99	−0.27	0.961	−11.17, 10.62
6 months post-surgery (test 3)	13.80	**<0.001**	6.63, 20.98	5.59	0.138	−1.79, 12.97	7.91	0.131	−2.36, 18.18
Current exercise behaviour									
6 months post-baseline (test 2)	3.19	**<0.001**	1.84, 4.54	1.42	0.065	−0.09, 2.94	1.78	0.091	−0.28, 3.85
6 months post-surgery (test 3)	2.89	**<0.001**	1.50, 4.27	2.09	**0.002**	0.77, 3.42	0.75	0.440	−1.16, 2.66
Habit strength									
6 months post-baseline (test 2)	1.14	**0.011**	0.26, 2.03	1.45	**0.003**	0.48, 2.41	−0.22	0.761	−1.65, 1.21
6 months post-surgery (test 3)	1.16	**0.009**	0.29, 2.03	0.54	0.171	−0.24, 1.32	0.58	0.310	−.054, 1.70
Intention									
6 months post-baseline (test 2)	0.81	**0.005**	0.24, 1.38	1.17	**0.032**	0.10, 2.24	−0.01	0.987	−1.38, 1.36
6 months post-surgery (test 3)	1.02	**0.004**	0.33, 1.71	1.35	**0.004**	0.43, 2.28	−0.26	0.653	−1.41, 0.88
Attitude									
6 months post-baseline (test 2)	0.48	0.149	−0.17, 1.13	0.08	0.761	−0.45, 0.62	0.35	0.425	−0.51, 1.21
6 months post-surgery (test 3)	0.96	**0.002**	0.35, 1.57	0.20	0.353	−0.23, 0.63	0.60	0.125	−0.17, 1.36
Subjective norms									
6 months post-baseline (test 2)	0.50	0.189	−0.25, 1.25	−0.54	0.217	−1.41, 0.320	1.04	0.083	−0.14, 2.22
6 months post-surgery (test 3)	0.51	0.098	−0.09, 1.11	−0.08	0.821	−0.80, 0.64	0.56	0.237	−0.37, 1.50
Social support									
6 months post-baseline (test 2)	0.94	**0.012**	0.21, 1.66	−0.29	0.576	−1.33, 0.74	1.23	0.067	−0.09, 2.56
6 months post-surgery (test 3)	1.17	**0.003**	0.41, 1.94	0.26	0.544	−0.58, 1.11	0.86	0.131	−0.26, 1.98
Perceived behavioural control									
6 months post-baseline (test 2)	0.94	**0.002**	0.35, 1.52	−0.01	0.989	−0.73, 0.72	1.01	**0.046**	0.02, 2.01
6 months post-surgery (test 3)	0.97	**0.001**	0.39, 1.55	0.22	0.476	−0.38, 0.81	0.66	0.111	−0.15, 1.48
Barrier self-efficacy									
6 months post-baseline (test 2)	0.78	**0.028**	0.09, 1.47	0.40	0.374	−0.48, 1.28	0.51	0.391	−0.66, 1.69
6 months post-surgery (test 3)	0.52	0.067	−0.04, 1.09	0.40	0.287	−0.33, 1.12	0.18	0.697	−0.74, 1.11
Action planning									
6 months post-baseline (test 2)	2.21	**<0.001**	1.10, 3.32	0.41	0.502	−0.79, 1.62	1.92	**0.027**	0.22, 3.61
6 months post-surgery (test 3)	1.50	**0.001**	0.62, 2.38	1.42	**0.007**	0.38, 2.47	0.11	0.876	−1.28, 150
Action control									
6 months post-baseline (test 2)	1.64	**0.001**	0.70, 2.58	0.34	0.575	−0.84, 1.52	1.62	**0.045**	0.04, 3.20
6 months post-surgery (test 3)	1.14	**0.006**	0.33, 1.95	0.77	0.128	−0.22, 1.76	0.44	0.488	−0.81, 1.70
Body mass index (BMI)									
6 months post-baseline (test 2)	1.31	0.113	−0.31, 2.93	−0.24	0.351	−0.76, 0.27	1.52	0.074	−0.15, 3.20
6 months post-surgery (test 3)	0.93	0.395	−1.21, 3.06	0.09	0.696	−0.37, 0.56	0.94	0.395	−1.23, 3.11
Body fat %									
6 months post-baseline (test 2)	−0.11	0.925	−2.50, 2.27	0.09	0.930	−1.95, 2.13	−0.04	0.980	−3.33, 3.25
6 months post-surgery (test 3)	−0.37	0.731	−2.46, 1.73	−1.31	0.133	−3.03, 0.40	1.05	0.441	−1.63, 3.73
Waist circumference (cm)									
6 months post-baseline (test 2)	−1.30	0.118	−2.92, 0.33	−0.34	0.732	−2.28, 1.60	−1.06	0.426	−3.66, 1.55
6 months post-surgery (test 3)	−0.64	0.593	−2.98, 1.71	0.14	0.859	−1.44, 1.73	−0.08	0.960	−3.05, 2.90
Systolic blood pressures (SBP)									
6 months post-baseline (test 2)	4.22	0.293	−3.64, 12.08	0.34	0.927	−6.94, 7.62	2.62	0.637	−8.26, 13.50
6 months post-surgery (test 3)	−5.90	0.055	−11.93, 0.13	2.51	0.475	−4.37, 9.38	−8.31	0.070	−17.30, 0.67
Diastolic blood pressures (DBP)									
6 months post-baseline (test 2)	2.96	0.204	−1.61, 7.54	−1.13	0.662	−6.19, 3.93	2.32	0.536	−5.04, 9.69
6 months post-surgery (test 3)	0.57	0.795	−3.69, 4.82	−2.14	0.336	−6.52, 2.23	3.17	0.307	−2.91, 9.26
Blood glucose									
6 months post-baseline (test 2)	−0.28	0.272	−0.78, 0.22	−0.17	0.587	−0.77, 0.44	−0.19	0.676	−1.07, 0.69
6 months post-surgery (test 3)	−0.34	0.278	−0.95, 0.27	−0.38	0.194	−0.95, 0.19	0.11	0.796	−0.73, 0.95
Glycosylated hemoglobin (HbA1c)									
6 months post-baseline (test 2)	−0.05	0.549	−0.21, 0.11	−0.08	0.461	−0.29, 0.13	0.02	0.869	−0.25, 0.30
6 months post-surgery (test 3)	−0.08	0.215	−0.22, 0.045	−0.44	**<0.001**	−0.64, −0.24	0.36	**0.002**	0.14, 0.59
Timed up and go (TUG)									
6 months post-baseline (test 2)	0.33	0.62	−0.98, 1.65	0.57	0.327	−0.57, 1.71	−0.82	0.448	−2.94, 1.30
6 months post-surgery (test 3)	−2.30	**<0.001**	−3.60, −1.01	1.14	0.265	−0.87, 3.16	−1.36	0.150	−3.21, 0.49

95%CI = 95% confidence intervals.
[a] Adjusted for gender.
[b] = Unstandardized regression coefficient estimated from the multi-level mixed effect models.

intention to exercise, social support, perceived behavioural control, action planning, and action control in the intervention group at both follow up points compared to baseline (Table 4). Additional improvements were observed in the intervention group in attitude at 6 months post-surgery, and barrier self-efficacy at 6 months post-baseline follow-up. Significant between group differences in favour of the intervention were observed in perceived behavioural control, action planning, and action control at 6 months post baseline (all $p<0.05$).

No within or between groups significant differences were found in BMI, body fat percentage, waist circumference, blood pressure, or blood glucose. HbA1c significantly increased in intervention compared to control group at 6 months post-surgery ($p = 0.002$) which was due to a significant decrease in the control group.

TUG decreased significantly at 6 months post-surgery in the intervention group ($p<0.001$), however there was no significant between group difference at any time point.

4. Discussion

This study found no difference in physical activity between the intervention and control groups, as measured by both step count and percentage of day spent active (Activpal data). Some secondary outcomes including measures of cardiometabolic health risk improved in both groups, with a greater magnitude in the intervention group; however, no statistical difference in any of these factors was seen. Interestingly, HbA1C improved significantly more in the control than the intervention group. The HAPA was used to underpin the group behavioural counselling sessions, designed to change PA behaviours with a focus on walking. Changes in some of the volitional constructs were reported as statistically significant between groups prior to surgery but had disappeared by 6 month post-surgery timepoint.

4.1. Physical activity and health outcomes

Mean daily steps increased in both groups at 6 month post-surgery but was only statistically significant in the intervention group. However, the mean change in steps was higher in the control group with the failure to achieve statistical significance in this group likely due to a large variability in the within group change at 6 months post-surgery. Similar changes were observed with the self-reported current exercise behaviour with similar statistically significant increases in both groups. The observed increase of nearly 1000 daily steps is clinically meaningful as this change has been shown to reduce the risk of developing functional limitations over 2 years [36] and reduce the relative risk of all-cause mortality between 6% and 36% [37,38]. Comparison to other research investigating PA after arthroplasty is hampered by the large variety of assessment tools [39], and contrasting study designs [40–43]. This is the first study to measure physical activity at multiple timepoints in this population before and after surgery. Reductions in PA immediately after arthroplasty are well established [41] and the recovery trajectory is not known, with improvements varying from 3 months [43] to two years [42]. In contrast our study showed improvements at six months. Whilst we do not have longer term data this body of literature indicates longer term follow up in future studies may be warranted.

Despite a lack of between group difference in changes in PA, the intervention group had a significant decrease in TUG while the control group showed a non-significant mean increase in TUG at the final assessment. TUG is a measure of functional mobility of which lower limb strength is a key contributor [44] and the focus on addressing strength deficits within the intervention is a likely reason for this difference. The magnitude of improvement has been shown to be clinically meaningful in this population [45], and as TUG is positively associated with patient reported outcome measures [46] this may be a future positive focus for clinicians and researchers examining changes in function after arthroplasty that are meaningful to their clients.

There were statistically significant improvements in Oxford Hip and Knee score, pain, and quality of life (overall and physical component score) in both groups at 6 months post-surgery with no differences in the change between groups. Interestingly the mean changes in quality of life overall and physical component scores in the intervention were around double those of the control group which may reflect the focus on resistance training [47,48] and the HAPA approach [15,18]. In contrast to the other quality of life components, the Mental component score improved significantly in the intervention group only. We hypothesize that this may be due to improved social support on mental outlook received within the intervention protocol and intrinsic perceptions of control over their health in the intervention group.

4.2. HAPA-based psychological and behavioural outcomes

There were improvements in multiple HAPA-based constructs in both groups over time. However, the changes tended to be larger and across a wider range of constructs in the intervention group particularly the volitional constructs at the 6 month post-baseline timepoint. Individuals in the volitional phase are in an implementation mindset while pursuing their goal [16]. It would be expected therefore that the changes observed in psychological constructs would translate to changes in PA and other health measures. Other than for TUG this was not the case in this study.

The HAPA-based intervention was effective in supporting patients to develop the volitional strategies such as making plans on when, where, how and with whom to conduct regular walking (action planning), and developing strategies to remind them to monitor regular walking (action control) [16,20]. Perceived behavioural control (beliefs about factors that may facilitate or impede performance of the behavior [49], conceptually similar to *self-efficacy* [50]) was also found to change over time. Although there were improvements in some of the psychological constructs, mainly those involved in the volitional phase, there appears to be a disconnect between the psychological constructs and actual behaviour. The greater improvement in psychological constructs observed in the intervention group without the related changes in step count may be partially due to the focus of the intervention. While the behavioural counselling sessions had a strong focus on walking [20], the exercise components of the group program were designed on best practice for OA [21]. These exercises therefore included an individualised combination of strength and aerobic exercise with the emphasis of the aerobic activity being any activity to cause heart rate to increase to target levels for example walking, cycling, or arm ergometry. While the individualised program was considered a strength of the intervention and expected to provide benefits of relevance to each participant, it does not necessarily link well to any single PA outcome measure. Further research is therefore required to understand the benefits of a HAPA-based approach in this population which matches the behavioural counselling components and exercise intervention more closely to the outcome measures that are utilised.

A further learning of this study related to reasons for not participating. Reasons fitted into several major themes; difficulties travelling to the location, lack of time, too much pain to exercise, and some potential participants were already exercising. To alleviate these issues, we recommend future studies consider multiple sites of delivery close to the participant cohort especially if the target population is geographically dispersed. Consideration of eHealth strategies or shorter interventions may also be useful to improve participant uptake.

5. Limitations

A limitation of the present study is the low levels of recruitment (15% of those approached). While this low level may be partially due to participants being focused on surgery as the solution to their condition, fluctuations in access to surgery throughout the study period also hampered data collection and contributed to low participant numbers at six months post baseline. While we used published data to generate the sample size, the differences after surgery in this population were smaller than anticipated and hence an a posteriori analysis of the primary outcome measure data revealed that 90 participants per group would have been required to achieve statistically significant differences. Further, those who agreed to participate may have already had a more positive approach to exercise, resulting in a selection bias that affected both groups, and a sample that was not representative of all patients awaiting joint arthroplasty.

6. Conclusion

An exercise program and HAPA guided counselling intervention can improve psychological constructs related to exercise behaviour and functional mobility; however, these did not produce any between group differences in the increase in daily step count at 6 months post-surgery. The insufficient sample size might have contributed to this non-significant finding and highlights the difficulty of recruiting clients with OA awaiting joint arthroplasty. The present data provides realistic changes in physical activity after surgery that future researchers may use to calculate an appropriate sample size for an adequately powered study.

Authors contributions

Study Design and funding (MLB, AW, JOB, KH, JM, SW), ethical clearance (MLB, AW, JOB, KH, JM, SW), trial registration (JOB), participant recruitment (JM, RM, MC) data collection (AW, JOB) and intervention delivery (MC), data analyses (DT, AW, MLB, MS) and interpretation (DT, AW, MLB, JOB, KH, JM), manuscript preparation (AW, JOB, MS, JM, RM, DT, KH, SW, MC, MLB). The following authors take responsibility for the integrity of the work as a whole, from inception to finished article (AW, JOB, MLB).

Role of funding source

This project was funded by the Clifford Craig Foundation. The funding organisation assisted with the initial identification of eligible participants but had no involvement in the design of the study, collection, analysis and interpretation of the data or in writing or approving the manuscript.

Declaration of competing interest

The authors declare they have no competing interests.

Acknowledgements

The authors wish to acknowledge the assistance of research nurses at the Launceston General Hospital who assisted with recruitment of participants (Jane Niekamp, Michelle Davey, Elizabeth Vardon), Dr Katie-Jane Brickwood for assistance with data collection, and Assoc/Prof James Fell who assisted with the funding application.

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