

PROJECT RECIPIENT AND FINAL REPORT

Funded by:	ARA Research Fund (\$30,000)
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Intended Department:	School of Health Sciences, College of Health, Medicine and Wellbeing, The University of Queensland
Project:	A combined program of education and exercise versus general advice for ankle osteoarthritis: A feasibility randomised controlled trial

We are very grateful for the grant funding received from Arthritis Australia in support of our project “A combined program of education and exercise versus general advice for ankle osteoarthritis: A feasibility randomised controlled trial”.

Recipients: Professor Bill Vicenzino, Associate Professor Michelle Smith, Dr Natalie Collins, Professor David Hunter, Dr Nathalia Costa

What question did the grant set out to answer?

Ankle osteoarthritis (OA) is a condition that is characterised by high levels of pain and disability[1]. It can affect individuals in all aspects of their lives, including work, recreation and socialisation [2]. Despite the serious impacts of ankle OA on people’s lives, there is limited research to how best to manage this condition. There are clinical practice guidelines to assist health professionals manage hip and knee OA, but nothing similar for ankle OA [3-6]. Generally, international guidelines on hip and knee OA management recommend education about the condition and how to manage it, weight loss (for people who are overweight or obese) and exercise. This research project applied these recommendations to ankle OA.

The main aim of this study was to determine the feasibility of running a full-scale randomised controlled trial investigating a combined education and exercise program compared to a general advice program for people with ankle OA. Secondly, we aimed to collect data to inform sample size calculations and understand the perspectives of people with ankle OA on their participation in the interventions and project.

What did we do to answer this question?

We recruited 30 individuals with ankle OA from the community. To be eligible to participate in this study, individuals had to be: over 35 years of age, have ankle joint pain on most days for at least 3 months, rate their worst ankle pain in the past week as at least 3/10 on an 11-point numerical rating scale (NRS), have at least grade 2 (Kellgren-Lawrence) radiographic ankle OA on x-ray [7], and be able to understand English and commit to the allocated treatment. People with health problems or pain elsewhere that was more concerning than their ankle OA, previous ankle arthrodesis or joint replacement surgery, or other medical problems were not eligible to participate.

Participants in this study were randomised to receive either physiotherapist-delivered education and exercise, or physiotherapist-delivered general advice. The combined education and exercise program consisted of two group education sessions and 12 group exercise sessions over a 7-week period. The education sessions discussed what OA is, diagnosis and symptoms of ankle OA, international guidelines for the management of OA and evidence-based management of ankle OA. The exercise sessions included an aerobic exercise warm up on a stationary bike, exercises for foot/ankle muscle strength (e.g., resistance band and body weight exercises), compound lower limb exercises (e.g., step ups, squats, bridges), postural control/balance training (i.e., standing on compliant surfaces) and gentle stretching. Exercise resistance and difficulty was customised to the individual based on their ability. The general advice program consisted of a single information session about the importance of keeping active and tips on managing symptoms, based on online resources from Musculoskeletal Australia (Understanding Osteoarthritis) [8] and Arthritis Australia (Information Sheet on Physical Activity) [9].

We collected a range of outcome measures in the study. The primary outcome measure related to the feasibility of conducting a full-scale randomised controlled trial investigating a combined education and exercise program compared to a general advice program for people with ankle OA. We pre-emptively determined criteria to ascertain the feasibility of conducting a full-scale trial using the protocol from this grant. These feasibility outcomes were: a) Consent rate (percentage of consented participants from eligible individuals); b) Participant adherence with their allocated intervention (percentage of sessions attended); c) Physiotherapist fidelity delivering the intervention, evaluated by observation by a researcher and calculated as a percentage [10]; and d) Completion rate (percentage) of participants who completed the severity of ankle pain and Global Rating of Change outcome measures at 3 months. The feasibility criteria are outlined in Table 1. We also recorded number of responses to study advertisements, proportion of eligible individuals from interested individuals, recruitment rate per month, adverse events and proportion of completed outcome measures at 8 weeks. Participant perspectives on the credibility (how believable/logical the treatment is) and expectancy (expectations from treatment) of the intervention were evaluated at baseline, 2 weeks and 8 weeks after commencing the intervention [32].

Table 1. Feasibility criteria for a future randomised controlled trial

	Proceed	Proceed with caution	Do not proceed
Consent rate	>50%	30-50%	<30%
Participant adherence	>60%	30-60%	<30%
Intervention fidelity	>60%	30-60%	<30%
Completion of key PROMs at 3 months	>70%	50-70%	<50%

PROMs=participant-reported outcome measures

The secondary outcome measures in this study were used to calculate variability in measures. They included participant-reported outcomes measures collected at baseline, 8 weeks and 3 months after commencing the intervention, and physical outcomes collected at baseline and 8 weeks post- intervention commencement. The secondary outcome measures are described in Table 2.

Table 2. Secondary outcome measures.

Outcome measure	Description
Global rating of change (GROC)	Perceived overall change in their ankle condition rated on a 7-point Likert scale [11].
Ankle pain severity	Worst and average pain in the last week evaluated on an 11-point numerical rating scale [11].
Ankle stiffness severity	Worst and average stiffness in the last week evaluated on an 11-point numerical rating scale [11].
Patient Acceptable Symptom State (PASS)	Participant's opinion whether or not their current level of pain and function is satisfactory (Yes/No) [12].
Foot and Ankle Ability Measures (FAAM)	Self-report function during activities of daily living (ADL subscale) and sport (Sport subscale) [13].
Foot and Ankle Outcome Score (FAOS)	Self-report measure of ankle pain, symptoms, function and quality of life [14].
Health-related quality of life (EQ-5D)	Health-related quality of life in relation to mobility, self-care, usual activity, pain/discomfort and anxiety/depression [15].
Satisfaction	Satisfaction with treatment rated on a 5-point Likert scale.
40-m walk test	Walking speed over a 40m distance (4 x 10m lengths) [16].
Stairs descent test	Time taken to descend a flight of 10 stairs [1].
Heel raise capacity test	Number of maximal height heel raises until fatigue [17].
Ankle range of motion	The knee to wall test to measure ankle dorsiflexion range of motion during a weight-bearing lunge [18].

We conducted semi-structured interviews with participants at the end of the study to understand their perspectives on the intervention they were allocated to and their participation in the study.

What did we discover during the grant?

A total of 152 individuals responded to study advertisements, of which 31 (20%) were eligible to participate in the study. We recruited 30 participants over 8 months (~4 participants/month): 20 women (67%), median (inter-quartile range) age of 67 (59, 76) years, and body mass index of 29.9 (27.1, 35.7) kg/m². 15 participants were randomised to the combined education plus exercise program, and 15 participants were randomised to the general advice program. There were no adverse events during the study. Over the course of the study, four participants (13%) withdrew from the study due to not having enough time (n=2) or managing other health issues (n=2).

Primary outcome data for the pre-determined feasibility criteria are shown in Table 3. Based on these feasibility criteria, we have determined it is feasible to run a full-scale randomised controlled trial investigating a combined education and exercise program compared to a general advice program for people with ankle OA.

Table 3. Data for feasibility criteria for a future randomised controlled trial

	% obtained	Indication
Consent rate	97%	Proceed
Participant adherence	71%	Proceed
Intervention fidelity	94%	Proceed
Completion of key PROMs at 3 months	77%	Proceed

PROMs=participant-reported outcome measures

Data on participants' perspectives on the credibility and expectancy of their allocated intervention is shown in Table 4 for each group.

Table 4. Credibility and expectancy data (data presented as median (inter-quartile range) unless otherwise specified)

Outcome	Education + exercise program			General advice program		
	Baseline (n=12)	2 weeks (n=12)	8 weeks (n=11)	Baseline (n=14)	2 weeks (n=13)	8 weeks (n=12)
Credibility						
How logical the treatment seems, /9	8 (5, 9)	9 (9, 9)	9 (9, 9)	6 (5, 7)	5 (4, 8)	5 (2, 6)
How successful they think it will be, /9	5 (5, 7)	7 (7, 7)	7 (6, 9)	6 (5, 8)	4 (3, 5)	4 (2, 5)
Confidence recommending to a friend, /9	5 (5, 7)	8 (7, 8)	9 (8, 9)	5 (5, 6)	4 (3, 5)	4 (1, 5)
How much improvement in symptoms they think will occur, /100	45 (28, 50)	60 (38, 70)	50 (20, 75)	40 (20, 50)	20 (10, 20)	5 (0, 25)
Expectancy						
How much they feel the treatment will help, /9	5 (5, 7)	7 (5, 8)	6 (6, 8)	5 (5, 6)	4 (2, 5)	3 (1, 5)
How much improvement in symptoms they feel will occur, /100	45 (28, 53)	55 (38, 70)	50 (30, 70)	40 (20, 50)	20 (10, 20)	5 (0, 23)

A higher number indicates greater perceived credibility and higher expectations.

Data for the participant reported and physical outcome measures collected throughout the study for the combined exercise and education group and general advice group are shown in Table 5.

Table 5. Secondary outcome measures as median (inter-quartile range) unless otherwise specified)

Outcome	Education + exercise program		General advice program	
	Baseline (n=12)	8-weeks (n=11)	Baseline (n=14)	8-weeks (n=12)
GROC, % (n)				
Much better	NA	18.2 (2)	NA	8.3 (1)
Better	NA	27.3 (3)	NA	8.3 (1)
Slightly better	NA	45.5 (5)	NA	16.7 (2)
Same	NA	9.1 (1)	NA	50.0 (6)
Slightly worse	NA	0 (0)	NA	8.3 (1)
Worse	NA	0 (0)	NA	8.3 (1)
Much worse	NA	0 (0)	NA	0 (0)
Worst pain, /10	5.5 (4.8, 6.3)	3.0 (2.0, 4.5)	7.0 (6.3, 8.0)	5.5 (2.0, 8.0)
Average pain, /10	2.5 (2.0, 5.3)	2.0 (1.0, 3.0)	4.0 (3.0, 5.0)	4.0 (2.0, 5.0)
Worst stiffness, /10	5.0 (2.0, 6.5)	3.0 (2.0, 4.0)	7.0 (5.3, 7.0)	6.0 (3.0, 7.3)
Average stiffness, /10	2.5 (1.8, 4.3)	2.0 (1.0, 3.0)	5.0 (3.0, 6.0)	5.0 (2.8, 6.0)
PASS, % (n) yes	8.3 (1)	63.6 (7)	21.4 (3)	50.0 (6)
FAAM-ADL, %	80.4 (60.7, 86.0)	85.7 (72.1, 94.7)	64.9 (61.9, 72.0)	69.6 (62.5, 81.3)
FAAM-Sport, %	57.8 (45.8, 68.8)	65.6 (42.2, 78.1)	43.8 (29.2, 52.3)	50.0 (31.3, 73.4)
FAOS symptoms, /100	53.6 (46.4, 65.2)	62.5 (56.3, 62.5)	50.0 (46.4, 53.6)	57.8 (49.2, 68.8)
FAOS pain, /100	72.2 (61.1, 77.8)	69.4 (66.7, 84.7)	55.6 (52.8, 72.2)	73.6 (44.4, 81.3)
FAOS ADL function, /100	84.6 (74.3, 94.9)	76.5 (70.6, 91.2)	73.5 (70.6, 83, 8)	77.2 (66.9, 88.6)
FAOS sport/recreation, /100	67.5 (55.0, 83.8)	75.0 (42.5, 87.5)	60.0 (50.0, 75.0)	62.5 (45.0, 73.8)
FOAS QoL, /100	46.9 (35.9, 51.6)	50.0 (43.8, 62.5)	37.5 (31.3, 50.0)	50.0 (31.3, 64.1)
QoL EQ-5D UK Index, /1	0.88 (0.81, 0.94)	0.92 (0.82, 0.95)	0.81 (0.75, 0.83)	0.85 (0.77, 0.94)
QoL EQ-5D VAS, /100	82.5 (70.0, 91.0)	85.0 (77.0, 90.0)	75.0 (66.0, 90.0)	83.5 (71.5, 86.3)
Satisfaction, % (n)				
Very	NA	72.7 (8)	NA	8.3 (1)
Somewhat satisfied	NA	27.3 (3)	NA	25 (3)
Neither satisfied or dissatisfied	NA	0 (0)	NA	58.3 (7)
Dissatisfied	NA	0 (0)	NA	(8.3) (1)
Very dissatisfied	NA	0 (0)	NA	0 (0)
40-m walk, s ^b	25.0 (21.5, 28.8)	24.9 (20.4, 26.7)	26.4 (22.8, 30.4)	26.3 (21.8, 31.3)
Stairs descent, s	4.9 (3.8, 5.2)	4.2 (3.3, 5.5)	4.7 (3.7, 6.2)	5.1 (3.9, 5.5)
Heel raise capacity, #	11 (7, 19.5)	15 (7, 20)	11 (7, 13.5)	8.5 (3.5, 12.5)
Dorsiflexion ROM, cm	7.2 (5.6, 13.0)	6.5 (6.0, 11.9)	10.5 (9.6, 12.5)	10.5 (4.8, 12.4)

GROC=global rating of change, PASS=patient acceptable symptom scale, FAAM=foot and ankle ability measures, ADL=activities of daily living, FAOS=foot and ankle outcome score, QoL=quality of life, VAS=visual analog scale ROM=range of motion, NA=not applicable

Have the findings of the research already benefitted people with musculoskeletal disease?

We have published the protocol for this study in which we have fully described the education and exercise intervention. This provides information that health professionals can use when managing patients with ankle OA.

As this was a feasibility study, it did not compare the effectiveness of the two interventions studied (combined education and exercise program vs a general advice program). Its findings indicate conducting a full scale clinical trial to test the effectiveness of the intervention is feasible – a likely benefit for people with ankle OA.

What are the next steps for this research?

Based on this grant demonstrating that it is feasible to run a full-scale trial investigating a combined education plus exercise program compared to a general advice program for people with ankle OA, we will begin planning for a full-scale randomised controlled trial. We will evaluate perspectives of study participants on their participation in the interventions and project – from semi-structured interview data – to inform if adjustments to the protocol are needed before designing and undertaking a full- scale trial. We will apply for funding to undertake a randomised controlled trial based on findings from this feasibility trail..

What is the plan for dissemination of findings?

We have published the protocol for this research study in the Journal of Foot and Ankle Research.

Smith MD, Vuvan V, Collins NJ, Hunter DJ, Costa N, Smith MMF, et al. Protocol for a randomised feasibility trial comparing a combined program of education and exercise versus general advice for ankle osteoarthritis. *J Foot Ankle Res.* 2023;16:72. doi: 10.1186/s13047-023-00669-1.

We have also presented the protocol and rationale for this study at the following conferences:

Smith MD, Smith MM. Ankle Osteoarthritis: Improving skills in managing this commonly forgotten condition. *Sports Medicine Australia*, October 2023.

Smith MD. Managing post-traumatic ankle osteoarthritis. *Queensland Musculoskeletal Outpatients Physiotherapy Network Conference*, November 2023.

We plan to publish the feasibility study in an international peer-review journal and disseminate findings on social media and through our professional networks.

We would like to thank Arthritis Australia for making this research possible and supporting the progression of research to establish evidence-management for ankle OA.

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