point. Participants with symptomatic and radiographic knee OA were recruited from Melbourne and Brisbane, Australia and randomized to one of three groups (i) Exercise; (ii) PCST; and (iii) Exercise plus PCST. All groups visited a physiotherapist for ten sessions over 12 weeks. Participants also performed home exercise and/or PCST home practice over the trial duration. Primary outcomes were overall average pain in the past week measured using the Visual Analogue Scale (VAS) and self-reported physical function assessed by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Secondary outcomes included global rating of change, WOMAC pain, VAS pain on walking, muscle strength, functional performance, physical activity levels, health-related quality-of-life and psychological factors. Statistical analyses were performed on an intention-to-treat basis using all randomized participants.

Results: Two hundred and twenty two participants were randomized and 184 (82%) completed the 12-month trial. Baseline characteristics were similar between the groups. For the primary outcomes all groups showed significantly improved VAS pain and WOMAC physical function following treatment (Fig. 1) with no between-group differences for pain. However, the integrated program resulted in significantly greater improvements in physical function compared to either intervention alone at all time points ($p < 0.02$). Benefits of the integrated program over both programs alone were also seen for VAS walking pain, WOMAC pain, self-efficacy and quality-of-life ($p < 0.05$). The integrated program generally showed greater improvements in psychological parameters compared to exercise alone and greater improvements in functional performance compared to PCST alone.

Conclusions: Results of this novel study provide evidence of the benefits of an integrated exercise and PCST program for physical function, pain and a range of physical and psychological outcomes in the short- and longer-term for people with knee OA. This highlights the potential for a new model of care involving physiotherapists. Advantages of using physiotherapists to deliver PCST may include better integration with exercise, increased availability of PCST treatment to those who may not have access to a psychologist, reduced time and cost for patients, and reduced overall costs to the health care system.

Outcome	Change within groups			Difference in change between groups †		
	Exercise only	PCST only	PCST and Exercise	PCST only vs Exercise only	Integrated vs Exercise only	Integrated vs PCST
VAS overall pain (0-100)						
Week 0-12	27.4 (24.3)*	24.9 (21.5)*	31.4 (17.9)*	-1.9 [-8.9, 5.1]	4.7 [-2.3, 11.8]	6.7 [-0.4, 13.7]
Week 0-32	22.5 (26.7)*	22.8 (24.1)*	30.8 (20.1)*	0.5 [-7.6, 8.6]	8.0 [-0.07, 16.1]†	7.6 [-0.5, 15.7]
Week 0-52	24.3 (27.1)*	23.2 (22.0)*	26.5 (22.4)*	-0.5 [-8.5, 7.5]	2.7 [-5.3, 10.6]	3.1 [-4.7, 11.0]
WOMAC physical function (0-68)						
Week 0-12	15.1 (10.9)*	11.2 (10.3)*	19.9 (9.1)*	-4.1[-7.4, -0.9]***	4.2 [1.0, 7.5]**	8.3 [5.1, 11.6]**
Week 0-32	12.4 (12.6)*	11.1 (12.3)*	18.0 (10.5)*	-1.6 [-5.6, 2.4]	4.7 [0.7, 8.7]†	6.3 [2.3, 10.3]**
Week 0-52	15.9 (12.5)*	12.3 (10.7)*	19.1 (10.1)*	-3.4 [-7.1, 0.33]	2.5 [-1.2, 6.1]	5.8 [2.2, 9.5]**

† Positive difference in change between groups favours the first named group in the pairwise comparison while a negative difference favours the second named group

VAS=Visual Analogue Scale, WOMAC=Western Ontario and McMaster Universities Osteoarthritis Index

*p≤0.001, **p≤0.01, †p≤0.0

Fig. 1. **Mean (SD) change within groups, and adjusted mean [95% CI] different in the change between groups for primary outcome measures**. The latter were estimated with a mixed effects linear regression model in which physiotherapists were treated as random effects and the baseline scores of the outcome variables were entered as a covariate, together with adjustment for the stratification variable of site.

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SAFETY AND EFFICACY OF MM-II, AN INTRA-ARTICULAR INJECTION OF LIPOSOMES, IN MODERATE KNEE OSTEOARTHRITIS. PROSPECTIVE RANDOMIZED DOUBLE-BLINDED STUDY

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Bio-lubrication is a prerequisite for proper joint mobility and is crucial for prevention of degradative changes of the joint. Phospholipids are components of the synovial fluid and are known to serve as natural lubricants of cartilage surfaces. MM-II is a novel intra-articular bio-lubricant made of liposomes suspended in aqueous solution.

Purpose: To test the safety and effectiveness of intra-articular injection of MM-II in osteoarthritic patients compared with intra-articular hyaluronic acid (HA) up to 3 months of follow-up in a preliminary double-blind, randomized clinical study.

Method: Patients with symptomatic unilateral knee OA meeting ACR criteria, with baseline pain on VAS of more than 40 mm and a stage 2–3 Kellgren Lawrence score on X-ray, were recruited. 40 patients were randomized into two groups of 20, to receive a single intra-articular injection of either MM-II or high molecular weight HA (Durolane®). Effectiveness measures included maximal global pain in the target knee, recorded by a 100 mm VAS; WOMAC subscales; OMERACT OARSI responder criteria; PGA, PASS, PAE questions and consumption of paracetamol/acetaminophen.

Paracetamol/acetaminophen was the only authorized rescue medication. Tolerability was assessed by local manifestation defined by an increase in knee circumference of at least 3 cm in the knee circumference, measured at 2 cm above the upper border of the patella or local pain increase of more than 30 mm on a 100 mm VAS. Adverse events were recorded through 90-days of follow-up.

The study was FIM Exploratory non-powered, with descriptive statistics.

Results: All patients completed the study. In the HA group, the mean patient age was 66.2 years, 9 males and 11females, and the average BMI at baseline was 27.4. In the MM-II group, the mean patient age was 63.0 years, 11 males and 9 females, and the average BMI at baseline was 29.3. The average pain at target knee at baseline was 53.1 mm in the HA group and 55.9 mm in the MM-II group.

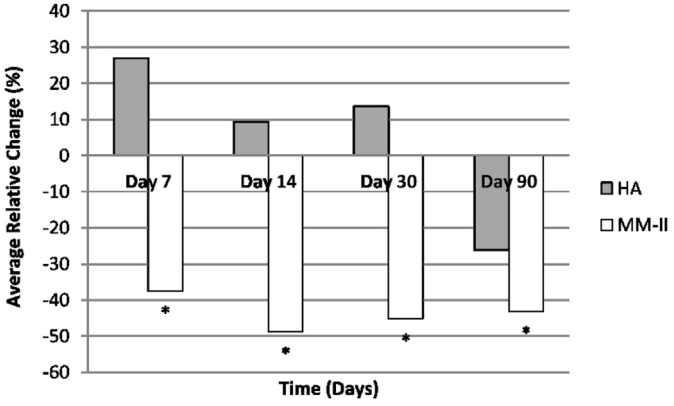
Results relating to WOMAC A pain are summarized in the Fig. 1, and show a faster response with MM-II, with maximal effect observed on day 14, which was maintained over time and was associated with a statistically significant difference from baseline pain from day 7. In the HA group, the onset of pain relief was slower, with an improvement statistically significant change from baseline observed only on day 90.

Daily acetaminophen intake was lower in the MM-II group, with a reduction of more than 50 percent in the number of days and total dose of rescue medication consumption seen following MM-II administration, compared with HA injection.

The percent of responders to treatment according to the OMERAC-OARSI response criteria was 52.6, 66.7, 70 & 60 at the day 7, 14, 30 & 90 respectively compared to 30, 36.8, 25, 45 at the HA group.

Local adverse events (inflammatory flare) were observed in one patient at day 3 in the MM-II group and in 4 patient at day 1, 1 patient at day 3, and 1 patient at day 7 in the HA group.

Patient's Relative Change in WOMAC A in Target Knee over Time



* Statistically significant difference from baseline.

Conclusion: Intra-articular injections of MM-II were found to be safe and effective. The pain-reduction action was more rapid and sustained up to 3 months compared with HA. Larger randomized controlled trials are needed to confirm these encouraging results.