



INTEGRATIVE APPROACHES FOR MUSCULOSKELETAL HEALTH, CHRONIC PAIN AND ASSOCIATED CONDITIONS IN VETERANS: A PRAGMATIC RANDOMISED CLINICAL TRIAL

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Background

Despite significant military integration of complementary medicine (CM) in other countries, there appears to have been little integration of CM in the treatment of Australian military personnel, despite high use by that population. Most use of CM by serving personnel and veterans in Australia is self-administered rather than practitioner-assisted. This project will examine the clinical and societal impact of incorporating evidence-based CM (acupuncture, naturopathy and massage) into the care of serving and ex-serving personnel, and assess clinical improvements, resource or costs savings, or other benefits for patients, by conducting the first ever clinical trial of integrative care in Australian veterans.

KEY MESSAGES

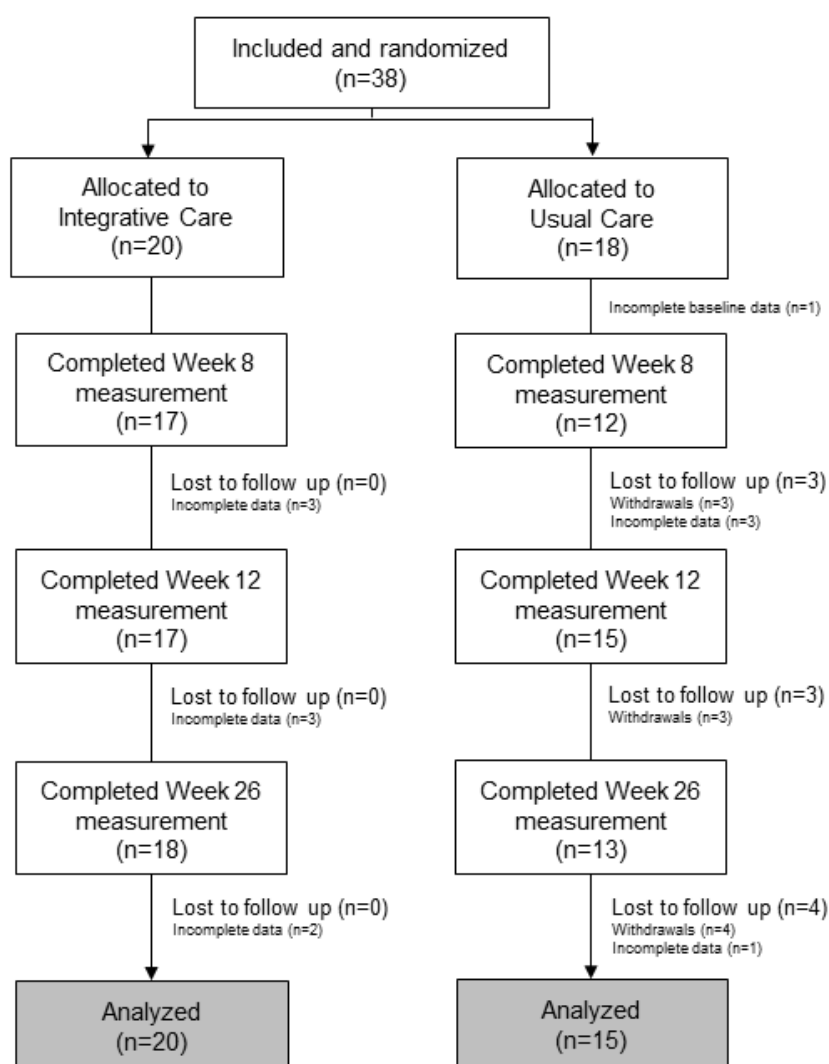
1. The intervention was feasible and safe, with a small number of adverse events only. Conducting a trial within a health care facility created several challenges with regards to participant and data management, which needs to be addressed in future trials.
2. The intervention resulted in a larger reduction in pain intensity in the Integrative Care Group compared to Usual Care, with a moderate effect size.
3. The feedback from participants was overall positive, highlighting the need for programs to manage chronic pain.

RESULTS

Participants recruitment

38 participants met inclusion criteria and were enrolled. The most common reasons for excluding individuals were not meeting the inclusion criteria, or lost interest in the study.

During the study a total of four participants were lost to follow-up, three at the Week 8 assessment, and another one on the Week 26 assessment. Several participants did not provide sufficient data for single assessments, but for follow-up assessments. Data of 35 participants could be analyzed using intention-to-treat, see figure 1 for CONSORT flowchart.



Baseline characteristics

Table 1: Baseline characteristics of trial participants according to study arms

Item	Integrative Care N=20	Usual Care N=18
Age in years	37.65±8.85 Range 25-57	41.00±11.38 Range 25-62
Gender, female / male	1/19	4/14
BMI, in kg/m ²	28.83±3.74	28.00±4.66
Country of birth, AUS/overseas	18/2	18/0
Lifestyle factors		
Currently smoking	1/17	2/16
Currently using illicit substances	0/16	2/15
Currently exercising	16/18	13/14
Medications		
Medications, including over-the-counter	11/17	12/16
Complementary medicines	4/16	4/15
Health care utilization history		
GP	10/20	10/18
Specialist	7/20	3/18
Mental Health	7/20	4/18
Physiotherapist	12/20	7/18
Massage therapist	4/20	4/18
Dietician/Nutritionist	3/20	2/18
Exercise physiologist	7/20	6/18
Yoga	2/20	1/18
Acupuncture	3/20	2/18
Predicted risk of long-term disability (OMSQ)		
Low risk	3	2
Moderate risk	2	6
High risk	15	19

Outcome measures

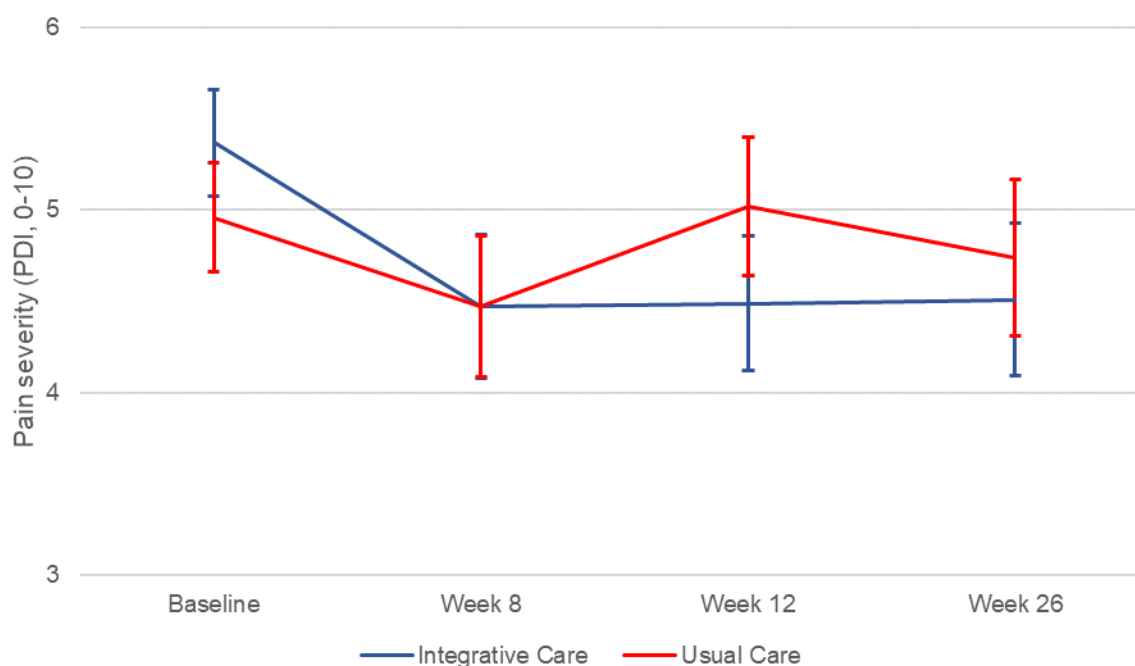


Figure 2: Course of pain severity over the study period, for integrative care vs. usual care. The error bars indicate standard errors.

The outcomes are shown in Table 2. The trial resulted in small to moderate effect sizes for Integrative Care compared to Usual Care. Based on the effect size for pain severity at Week 12, a sample size of 124 will be required in a confirmatory trial on the efficacy of an Integrative Care model compared to Usual Care, with a power of 0.9, a two-sided test, and a significance level of 5%.

The percentage of participants who reported clinically important improvements after 12 weeks, as indicated by a pain reduction of at least one third on the Brief Pain Inventory, was 30% in the Integrative Care group, and 16.7% in the Usual Care group.

Safety

At Week 8, one adverse event was reported. A participant in xxx group underwent spinal surgery, related to the pre-existing back pain.

At Week 12, three adverse were reported. One participant experienced COVID-19, another on underwent neck and shoulder surgery for a pre-existing condition. These events were considered unrelated to the intervention. Another participant experienced acute and chronic knee and shoulder pain, which may be related to the intervention.

At Week 26, three adverse were reported. One participant experienced had a rupture in the knee due to a motorcycle accident, another participant experienced PTSD and was later diagnosed with Addison's disease. One participant had a neck spine surgery for a pre-existing condition. All events were considered unrelated to the intervention.

Table 2: Results of the statistical group comparisons

	Integrative care				Usual care				Estimated group difference (95%CI)	Estimated effect size, Cohen's d
	Mean±SD				Mean±SD					
	Baseline	Week 8	Week 12	Week 26	Baseline	Week 8	Week 12	Week 26	Week 12	Week 12
Pain severity (PDI)	5.37±1.30	4.47±1.76	4.49±1.64	4.51±1.86	4.96±1.27	4.47±1.64	5.02±1.62	4.74±1.82	-0.76 (-1.75; 0.24)	0.59
Pain interference (PDI)	6.09±2.27	5.2±2.53	4.71±2.45	4.77±2.44	5.61±2.08	5.69±2.47	5.55±2.62	5.67±2.69	-1.20 (-2.49; 0.10)	0.66
Quality of life – mental (SF-36)	35.83±11.45	37.25±11.74	36.07±10.11	38.89±8.97	41.18±12.59	39.60±13.29	37.42±10.02	40.73±9.32	1.66 (-3.48; 6.79)	0.44
Quality of life – physical (SF-36)	30.75±6.81	34.47±7.43	33.98±8.32	35.43±11.37	29.93±5.69	31.14±7.14	31.21±7.01	32.21±7.65	2.49 (-2.48; 7.46)	0.23
Quality of life (EQ-5D index)	0.47±0.24	0.49±0.22	0.54±0.23	0.54±0.27	0.56±0.28	0.60±0.26	0.51±0.24	0.54±0.29	0.08 (-0.05; 0.21)	0.56
Pain self-efficacy (PSEQ)	35.4±11.68	-	-	33.67±15.87	33.42±14.53	-	-	30.49±14.15	1.31 (-5.21; 7.82)	0.11

Note: group differences are estimate