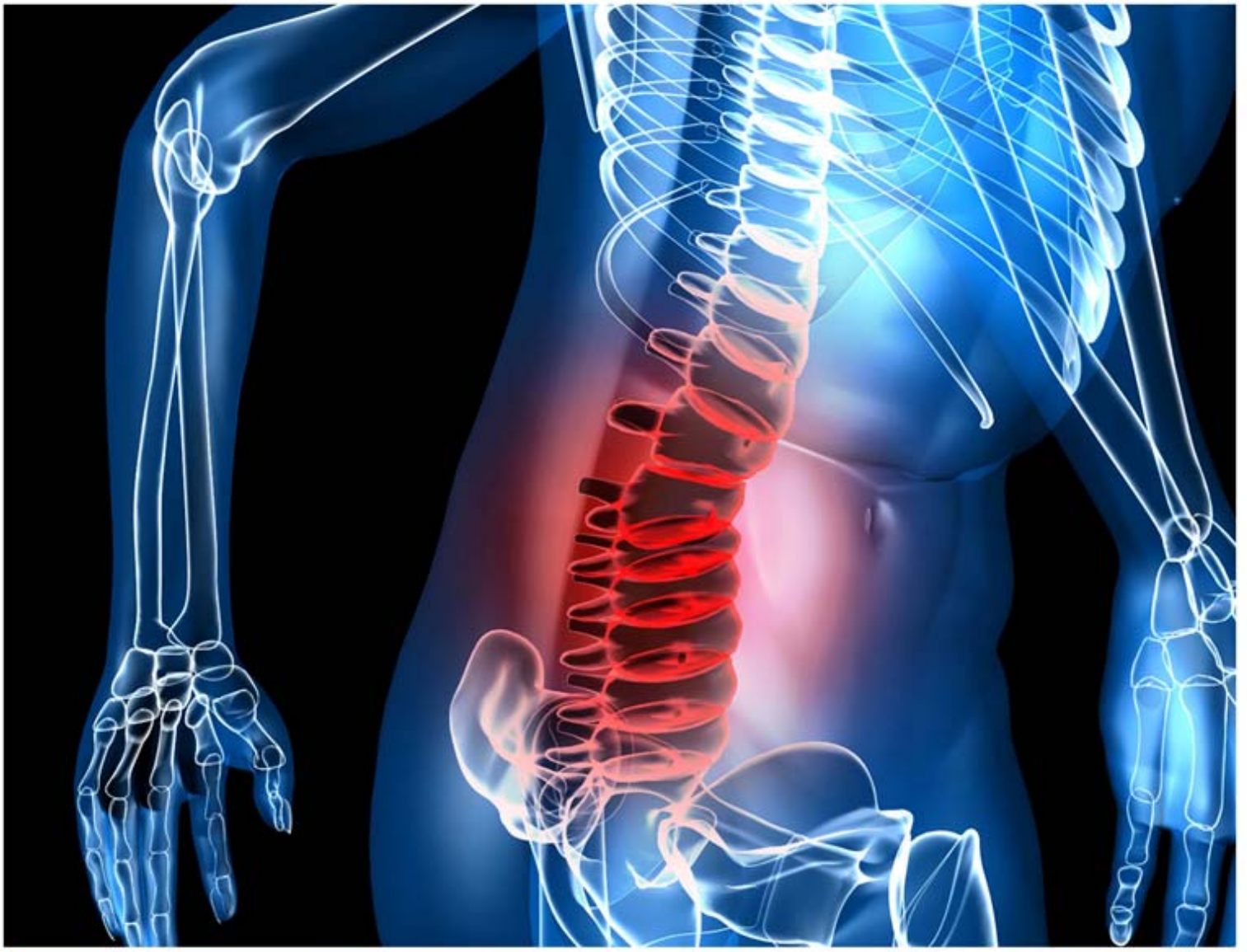

The scope, funding and publication of musculoskeletal clinical trials performed in Australia (2009 - 2013)

Arthritis VICTORIA inc. OSTEOPOROSIS VICTORIA

MONASH University

Cabrini

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Contents

Glossary of Acronyms

ANZCTN	Australian and New Zealand Clinical Trials Number
ANZCTR	Australian and New Zealand Clinical Trials Registry
AUSMUSC	Australian Musculoskeletal Clinical Trials Group
DALYs	Disability-adjusted life years
EU-CTR	European Union Clinical Trials Register
GBD	Global Burden of Disease
ISRCTN	International Standard Randomised Controlled Trial Number Register
MSK	Musculoskeletal
NHMRC	National Health and Medical Research Council
NHPA	National Health Priority Area
RCT	Randomised Controlled Trial
SLE	Systemic Lupus Erythematosus
WHO	World Health Organisation
YLDs	Years lived with disability

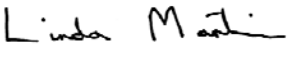
Foreword

Musculoskeletal conditions, such as back pain, osteoarthritis and osteoporosis, are associated with profound personal and societal burden. Research that is well designed and addresses important questions that are relevant to consumers, clinicians, policymakers and other stakeholders is critical to addressing the burden associated with these conditions. Different types of research are needed in the area of musculoskeletal health, such as basic (laboratory) science, epidemiologic studies and clinical trials. Clinical trials are particularly important for providing information about whether interventions are effective and safe and testing strategies to ensure that clinical care is informed by the best evidence. In order to invest in the most appropriate musculoskeletal clinical trials in the future, it is important to have an understanding of the current scope of clinical trials in Australia.

This study, funded by Arthritis and Osteoporosis Victoria, was undertaken to examine the status of musculoskeletal clinical trials in Australia between 2009-2013. The study identifies the trials that are being performed, the conditions and interventions under investigation, and how these trials are being funded. It also investigates whether Australian musculoskeletal trials are internationally competitive by determining where this research is being published and how this relates to contributions from elsewhere.

Relative to the burden of musculoskeletal conditions in Australia, investment in Australian clinical trials is not ideal. While we punch above our weight in terms of numbers of trials, we may not be addressing the most critical issues. This report highlights the urgent need for Australian researchers, clinicians, policy makers and consumers to work collaboratively to ensure that we prioritise the most important questions, maintain a competitive edge in securing research funding, and undertake well-designed trials to deliver best evidence-based care and optimal outcomes for people with musculoskeletal conditions.

Professor Rachelle Buchbinder
Chief Investigator
Cabrini Institute and Monash University
NHMRC Practitioner Fellow



Linda Martin
Chief Executive Officer
Arthritis and Osteoporosis Victoria

Executive Summary

Introduction

Musculoskeletal (MSK) conditions pose a great burden on the Australian population and healthcare systems and this burden is likely to increase with an ageing, increasingly obese and sedentary population. Globally, the 2010 Global Burden of Disease (GBD) study found that MSK conditions account for 6.8% of the total burden of disease (which includes both death and disability). In Australasia, MSK conditions have the second greatest impact on the health of the population after cancer (15.3% versus 16.2% of the overall disease burden).

The aims of this scoping project were to establish what MSK trials are currently being performed in Australia; to identify what MSK conditions and interventions are being studied and by whom; how they are being funded; where they are being published; and how Australia compares to the rest of the world.

Methods

The scope of the review included three components:

1. Examination of National Health and Medical Research Council (NHMRC)[1] funding of MSK trials in the last five years (commencing funding in 2009 to 2013);
2. Examination of MSK trials that have been registered either in the Australian and New Zealand Clinical Trials Registry (ANZCTR) or another trials registry in the last two years (2011 to 2012); and
3. MSK trials published in one of 37 top general and internal medicine or MSK-specific journals, as defined by Impact Factor[2], in the last two years (2011 to 2012).

Results

NHMRC funding

Over the last five years (2009 to 2013 inclusive), NHMRC has awarded 29 project grants (and over $17.6 million) in support of Australian investigator-initiated MSK trials. This represents 0.8% of the total number of NHMRC project grants (29 out of 3,631), 0.8% of total NHMRC project grant funding in monetary terms ($17.6 million out of >$2 billion), and 5% of NHMRC funded clinical trials in monetary terms ($17.6 million out of $354 million). An additional

[1] The National Health and Medical research Council (NHMRC) is Australia's peak body for supporting health and medical research through its management of research project and personnel funding and through its role as an advocate for health advice and ethical behaviour in health care and in the conduct of health and medical research.

[2] The Impact Factor (IF) of an academic journal is used as an indicator of the journal's importance within its field. It is a measure reflecting the average number of citations to recent articles published in the journal.

eight trials to date have been supported by a 2011 NHMRC program grant ($7.6 million over 5 years).

Registered trials

There were 191 Randomised Controlled Trials (RCTs) recruiting participants in Australia that were registered in the ANZCTR and/or WHO Registry Platform in the last two years (2011-2012). Fifty-eight of 59 trials identified in the World Health Organisation (WHO) registry were pharmaceutical or industry-sponsored, and sixteen were trials investigating drug interventions for rheumatoid arthritis. Of the 132 trials registered in the ANZCTR, five trials did not appear to have been initiated by investigators in Australia (they nominated an overseas company or charity as the scientific contact). The remaining 127 trials, as well as one registered within a WHO registry, appeared to be Australian investigator-initiated (with an Australian researcher as the contact person). Twenty of these trials (15.6%) had some industry funding, 19.5% (n = 25) indicated receipt of government funding and 17.2% (n = 22) indicated that they were either self-funded or unfunded. Trials were most commonly for osteoarthritis (n = 45, 35.2%) while 41.4% (n = 53) were for regional conditions (including low back neck and shoulder pain). The most common types of interventions studied were physical therapy (n = 55, 43%) and drug interventions (n = 33, 25.8%).

Published trials

Out of 565 papers reporting the primary results of MSK randomised controlled trials in the top 37 (Impact Factor-ranked) general medical and MSK-specific journals published in the last two years (2011 or 2012), 57 (10.1%) included Australian participants and 30 (5.3%) were initiated in Australia. Of those initiated in Australia, almost half were for osteoarthritis (N=14, 46.7%) and 14 (46.7%) were for regional conditions. More than a third involved physical therapy interventions (N = 14, 46.7%), while drug and surgery interventions accounted for 40% combined (N = 12).

There were no NHMRC-funded MSK trials in the last 5 years (2009-2013), nor any registered or published MSK trials in the last two years (2011-2012) investigating interventions to improve uptake of research findings or guidelines into practice.

Conclusion

While a significant number of Australian MSK trials are being performed, NHMRC funding appears to be disproportionally low when compared with the burden of MSK conditions in Australia. Of the trials published in the highest impact factor medical and MSK-specific journals, there is good Australian representation but there is a paucity of trials investigating interventions to improve the uptake of research findings or clinical guidelines into practice.

Priority setting among a wide range of stakeholders to identify the most important questions is urgently needed. This is likely to include a focus on improving research translation.

1. Introduction

Introduction

The international and national burden of musculoskeletal conditions

According to the recently published 2010 Global Burden of Disease (GBD) study, musculoskeletal (MSK) conditions including inflammatory and non-inflammatory arthritis, regional MSK conditions (e.g., back pain, shoulder pain etc.), osteoporosis, gout and autoimmune diseases have the fourth greatest impact on the health of the world's population, considering both death and disability (1). Globally, MSK conditions account for 6.8% of the total burden of disease measured in disability-adjusted life years (DALYs). In Australasia, MSK conditions are second only to cancer when deaths as well as disability are considered in disease burden attribution (15.3% versus 16.2%). When individual conditions are considered, low back pain has the greatest impact on the health of the population, outranking ischaemic heart disease, chronic obstructive pulmonary disease and major depressive illness, with other MSK conditions ranked sixth (1).

As a group, MSK conditions contribute about a fifth (21.3%) of the total disability burden, measured by years lived with disability (YLDs), worldwide (2). Low back pain is responsible for the most years lived with disability worldwide (83.1 million YLDs or 10.1% of the total YLDs, ranked #1), with neck pain (33.6 million YLDs, ranked #4), osteoarthritis (17.1 million YLDs, ranked #11) and other MSK conditions also being significant contributors.

In Australia, MSK conditions are the leading contributor to total disability burden (27.4%), followed by mental health and substance abuse (22.4%) (2). MSK conditions are also the most common chronic conditions in Australia and are the most common reason for accessing healthcare services in Australia (3). Data from the 2011-2012 National Health Survey estimated that some type of arthritis affects 3.3 million Australians (14.8% of the population) (4). Back pain in particular was estimated as affecting 1 in 11 people in 2007-2008 with over 2 in 5 of those affected having limitations in their activities. In financial terms, arthritis and MSK conditions contribute to 7.5% of total health expenditure (costing around AU$ 4.0 billion) (5). Given the large burden of MSK diseases on the Australian population, MSK conditions were designated as a National Health Priority Area (NHPA) in 2002 (6). Importantly, this burden is likely to increase as the Australian population ages, becomes more obese and has an increasingly sedentary lifestyle. There is therefore an urgent need to prioritise research on the most effective and affordable strategies to deal with these conditions.

The MSK NHPA however only includes osteoarthritis, rheumatoid arthritis and osteoporosis. It currently does not include back pain or neck pain, despite their even greater disability burden on the population, nor does it include other MSK conditions. Integrating other MSK conditions into the NHPA framework has many potential benefits. For example, as outlined previously (7), including back pain could result in more systematic development and

implementation of programs aimed at minimising back pain-related disability by providing a focus for policy, legislation and public awareness; and promotion of best practice management of the condition.

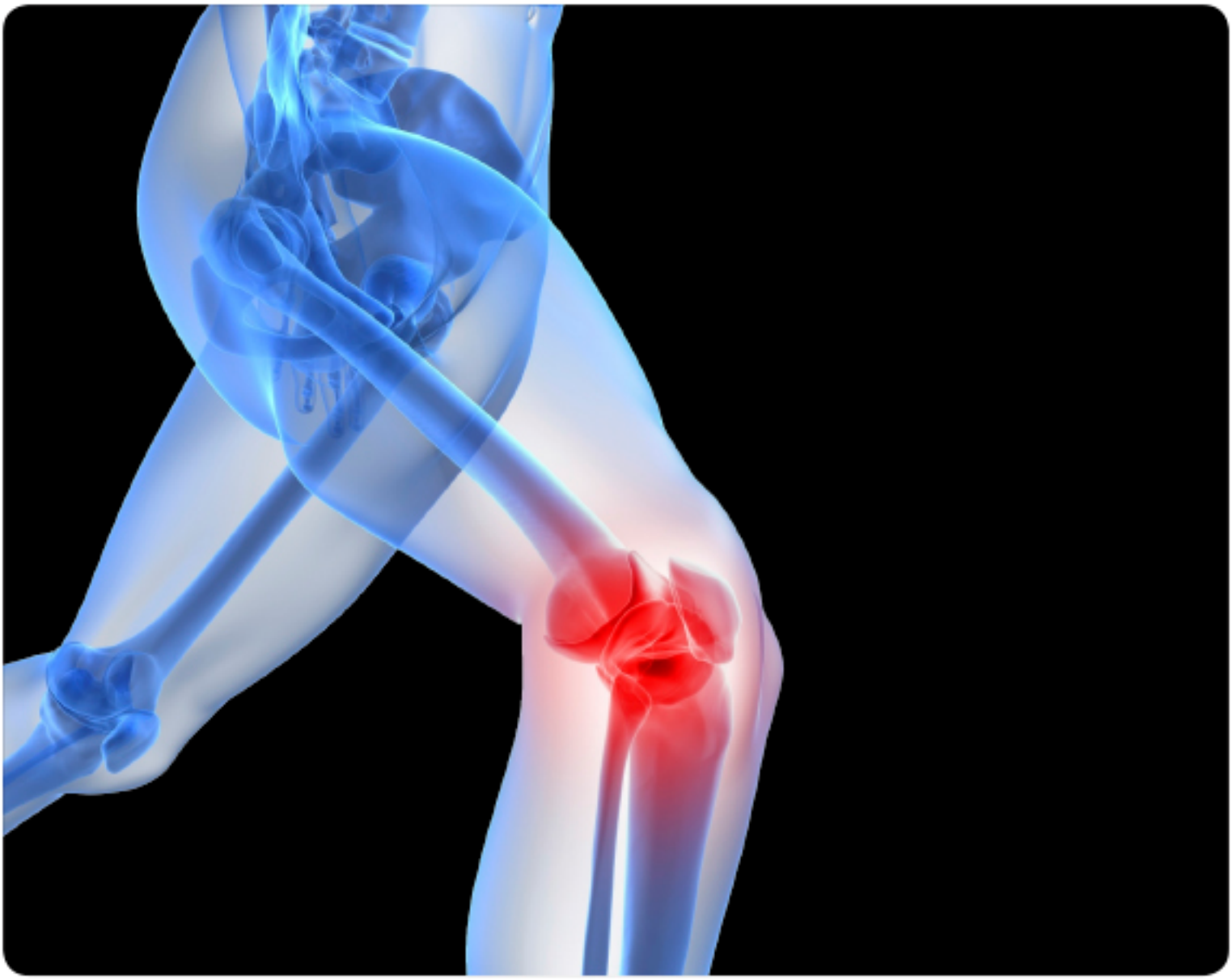
The AUStralian MUSCuloskeletal (AUSMUSC) Clinical Trials Group

Australia is already fortunate to have one of two Editorial Bases of the Cochrane Musculoskeletal Group, which is responsible for publishing, and keeping up to date, systematic reviews of interventions for the prevention and treatment of arthritis and musculoskeletal conditions. By providing up-to-date syntheses of the available evidence, these reviews are useful in identifying where there are gaps in knowledge.

As part of the research effort to address this important area, we have also recently established the Australian MSK (AUSMUSC) Clinical Trials Group. The aim of this collaboration will be to facilitate the conduct of high quality, multicentre investigator-initiated MSK clinical trials in Australia to answer questions of clinical importance, with an emphasis on improving the translation of research findings into clinical practice. Despite the presence of several well-established MSK trialists in Australia, and the existence of 86 Australian collaborative clinical trial groups (personal communication NHMRC), up until now there has been no national collaborative group with a MSK focus. As well, it is recognised that funding support from NHMRC for arthritis and MSK trials in Australia has been less than funding for other chronic conditions (personal communication Professor John Simes), and, importantly, does not reflect the burden of these conditions. The AUSMUSC Clinical Trials Group will develop a process for identifying the most important clinical questions based upon systematic reviews of the literature and stakeholder priorities that require high quality large trials to resolve.

Lack of single data source outlining MSK trials in Australia

There is no single easily accessible data source that clearly outlines what MSK trials are currently being undertaken in Australia, who is conducting them, how they are being funded and where they are being published. The aim of this report is to describe the current scope of MSK clinical trials in Australia; particularly what MSK conditions and interventions are being studied and by whom, how they are funded, where they are being published, and how they compare numerically to MSK trials originating elsewhere in the rest of the world.



2. Methods

Methods

Definitions of Australian MSK trials

Musculoskeletal (MSK) trials were defined as trials in humans investigating interventions for the treatment or prevention of inflammatory and non-inflammatory arthritis, regional musculoskeletal conditions (i.e., back, neck, shoulder/arm, elbow/forearm, hip/thigh, knee/leg, wrist/hand or ankle/foot), gout, osteoporosis or related conditions, autoimmune diseases including systemic lupus erythematosus (SLE) and scleroderma, and fibromyalgia. We included all trials with a MSK focus even if the participants had another primary condition (e.g. interventions to reduce letrozole-induced arthralgia in breast cancer patients). We also included trials that included an MSK outcome as a main outcome even if the study population was not a specific MSK condition (e.g., interventions to improve bone density in obese individuals) and trials involving an MSK population (e.g., people undergoing joint replacement) even if there was not an MSK focus (e.g. wound care following joint replacement). We excluded trials investigating interventions to prevent falls if there was not a main MSK outcome such as fractures. Trials for people with pain were excluded if the site of pain was not specified and trials for people with injury were also excluded unless the injury involved a fracture.

For the review of registered trials we included randomised controlled trials, controlled clinical trials or single-arm trials. For the review of published papers we limited inclusion to randomised controlled trials and only the primary results paper. Trials were considered 'Australian' if Australian participants were being, or had been recruited. For registered trials, trials were considered to be Australian investigator-initiated if they listed an Australian primary contact. For published trials, trials were considered Australian investigator-initiated if they were conducted in Australia by Australian investigators.

Scope of review

The scope of the review included National Health and Medical Research Council (NHMRC) funding of MSK trials in the last five years (commencing funding in 2009 to 2013); MSK trials that have been registered either in the Australian and New Zealand Clinical Trials Registry (ANZCTR) or another trials registry in the last two years (2011 to 2012); and MSK trials published in one of 37 top general and internal medicine or MSK-specific journals in the last two years (2011 to 2012).

NHMRC funding for MSK trials: 2009-2013

We searched the NHMRC website to identify successful MSK trial grants (including project and program grants) whose funding was to commence from 2009 to 2013 inclusive (8). Information about the grant including the commencement year, grant title, trial design

(randomised, controlled or single-arm trial; participant-blinded or open), chief investigator names, type of grant, administering institution and amount funded were recorded. The number of successful MSK trial project grants and funding awarded was compared with the number and funding awarded for all NHMRC-funded clinical trials, and all NHMRC project grants. We also summarised the awarded grants by chief investigators and their discipline(s) and state, MSK condition and intervention(s) studied.

Australian MSK trials registered: 2011-2012

We searched the ANZCTR and World Health Organisation (WHO) Clinical Trials Registry platform (a central database that contains weekly updates of trial registration from the ANZCTR, ClinicalTrials.gov, the EU Clinical Trials Register (EU-CTR), and International Standard Randomised Controlled Trial Number Register (ISRCTN), as well as monthly updates of trials registered in 11 other country-based registries) to identify MSK trials that had been registered in 2011 or 2012) and were currently recruiting, planning to recruit, or had recruited participants in Australia. For the ANZCTR we used the advanced search facility, included both randomised and non-randomised allocation to intervention, and searched all trials categorised by condition as Musculoskeletal, Alternative and Complementary Medicine, Anaesthesiology, Inflammatory and Immune System, Injuries and Accidents, Metabolic and Endocrine, Other, Physical Medicine/Rehabilitation, Public Health and Surgery, recruiting participants in Australia and registered 1 January 2011 to 31 December 2012. We did not limit by gender, age group or recruitment status, and did not exclude healthy volunteers.

For the WHO Clinical Trials Registry, we also conducted an advanced search of both randomised and non-randomised trials restricting our results to those that listed musculoskeletal, injury, inflammation, endocrine, rehabilitation, surgery, alternative medicine, immune or public health as the condition. Since the condition category within the WHO-linked registries is not restricted to a set number of conditions as it is in the ANZCTR, we performed this search using the key words; arthritis, osteoporosis, scleroderma, vasculitis, gout, spondyloarthritis, lupus, back, neck, shoulder, arm, elbow, forearm, wrist, hand, hip, thigh, knee, leg, ankle or foot in the condition category.

Extracted data from the ANZCTR included registration number, date of registration, registration type (prospective or retrospective), research question, health condition studied, stated trial design (randomised, controlled or single arm trial), intervention(s), comparator(s), primary outcome, blinding and sample size. We also recorded the funding source (defined as major source(s) of monetary or material or infrastructure support for the trial), sponsors (defined as individuals, organisations, groups or other legal persons taking on responsibility for securing the arrangements to initiate and/or manage a study, including arrangements to ensure that the design of the study meets appropriate standards and to

ensure appropriate conduct and reporting) and collaborators (defined as additional individuals, organisations or other legal persons, if any, that have agreed with the primary sponsor to jointly take on responsibilities of sponsorship). For the WHO registry search, trial ID, registration date, scientific title, condition studied, trial design, intervention(s), comparator(s), primary outcome, target sample size, main sponsor and recruitment status were extracted.

Registered trials that listed NHMRC funding were cross-checked with the NHMRC search results. As the WHO search also includes the ANZCTR, the WHO search acted as a check for those listed in the ANZCTR. Trials that appeared to be investigator-initiated in Australia (listed an Australian research contact) were analysed to determine key research areas, key intervention types and common funding sources.

Australian MSK randomised controlled trials published in top international general and MSK-specific journals: 2011-2012

We searched journals with the highest 2011 Impact Factor rankings according to Journal Citation Reports in ISI Web of Knowledge (9) in each of the following subject categories: Medicine; general and internal, Rheumatology, Orthopaedics and Rehabilitation and Sports Sciences. As there was no specific category for osteoporosis we searched the subject category Endocrinology and Metabolism for journals that include osteoporosis within their scope and we searched subject category Orthopaedics to identify journals that included spine pain within their scope. We included journals provided at least one MSK randomised controlled trial had been published in 2011 or 2012. Several journals appeared in more than one category and for ease of description we included them in the heading that we thought best described their scope.

To identify potentially relevant trials we searched Ovid MEDLINE 2011 and 2012 using the limit of 'Randomised Controlled Trial'. Two authors screened the search results and retrieved the full text if necessary. The paper was included only if it reported on the primary results of a randomised controlled trial. Papers reporting post-hoc analyses, long-term extension studies (whose primary outcomes had been previously reported), sub-group analyses or other studies using the trial data were excluded as were single-arm trials and controlled trials that were not randomised. To ensure that all randomised controlled trials were identified we also hand searched all issues of journals online and for those with a search facility we searched papers using the term 'trial'.

Publication title, first author, corresponding author, research question, trial design, intervention(s), comparator(s), trial size, funding source (excluding fellowships and scholarships funding individuals) and trial location were extracted. We also identified trials that recruited participants in Australia and trials that were initiated in Australia. The number

of trials published by Australian researchers was compared to the contributions made by other countries.

3. Results

Results

NHMRC funding for MSK trials: 2009-2013

National Health and Medical Research Council (NHMRC) project grants have provided funding of more than $17.6 million for 29 Musculoskeletal (MSK) trials in the last five years (funding commencing in 2009 to 2013 inclusive)(range 2-9 trials per year) (Table 1). This represents 0.8% of all project grants funded, 0.8% of the total funding allocated to project grants ($17.6 million out of >$2 billion) and 5.0% of the total amount of NHMRC funding allocated to clinical trials ($17.6million out of $354 million).

Table 1

Number and amount of funding awarded for National Health and Medical Research Council (NHMRC) musculoskeletal clinical trial project grants, total funding of NHMRC-funded clinical trials* and number and amount of funding awarded for NHMRC-supported project grants over the last 5 years (commencing 2009 to 2013)

Year	Number of NHMRC Project Grants Awarded	Number of Project Grants for MSK Trials	Total NHMRC Funding for Project Grants	Total NHMRC Funding for Clinical Trials	NHMRC Funding for MSK Trials (Project Grants)
	N	N (% all project grants)	$	$	$ (% all clinical trials)
2009	688	4 (0.6%)	357,248,846	44,705,943	2,171,800 (4.9)
2010	683	6 (1.2%)	390,715,106	55,812,016	4,526,514 (8.1)
2011	758	2 (0.2%)	415,484,352	64,833,882	906,723 (1.4)
2012	771	8 (0.9%)	454,826,481	83,365,267	4,140,806 (5.0)
2013	731	9^ (1.3%)	457,858,034	105,677,755	5,866,460 (5.6)
Total	3631	29 (0.8%)	2,076,132,819	354, 394, 863	17,612,303 (5.0)

NHMRC - National Health and Medical Research Council; MSK – Musculoskeletal: * The NHMRC Information Section categorises project grants as clinical trials based upon information provided by Chief Investigators in the grant application. This relies upon key word searches for clinical trial, clinical study, clinical studies, randomised trial, randomised trial or controlled trial. The use of grant synopses and an application question asking if the grant is a clinical trial has enabled more grants to be identified as clinical trials in the last two years (http://www.nhmrc.gov.au/grants/research-funding-statistics-and-data/funding-datasets/clinical-trials). It is therefore possible that total funding for NHMRC funded clinical trials may be underestimated for grants awarded in 2009 to 2011 inclusive.
^One project grant in 2013 was for a clinical trial in addition to a large cross-sectional study of young women.

Table 2 provides a breakdown of the 29 NHMRC-funded MSK trials by state (according to nominated administering institution). Victoria and NSW have received the most funding (11 and 10 trials respectively) accounting for more than $7.3 million in funding combined.

Table 2

Number and amount of funding awarded for National Health and Medical Research Council (NHMRC) musculoskeletal trial project grants per state* (according to nominated administering institution) over the last 5 years (commencing 2009 to 2013)

Year	NSW N ($)	VIC N ($)	QLD N ($)	WA N ($)	SA N ($)	TAS N ($)
2009	2 (1,200,650)	1 (673,275)	1 (297,875)	0	0	0
2010	3 (2,244,550)	2 (1,301,776)	0	0	0	1 (1,211,738)
2011	1 (572,734)	0	0	1 (333,989)	0	0
2012	2 (1,578,708)	3 (1,286,000)	0	0	3 (1,276,098)	0
2013	2 (1,128,125)	5^ (3,122,904)	1 (660,834)	0	0	1 (954,597)
Total	10 (6,724,766)	11 (638,396)	2 (958,709)	1 (333,989)	3 (1,276,098)	2 (1,934,785)

Abbreviations: VIC: Victoria; TAS: Tasmania, WA: Western Australia, NSW: New South Wales, SA: South Australia, QLD: Queensland, ACT: Australian Capital Territory, NT: Northern Territory. * No NHMRC-funded trials in ACT or NT, ^One project grant was for a clinical trial in addition to a large cross-sectional study of young women

Table 3 summarises details for the 29 MSK trials funded by NHMRC project grants (see Appendix 1 for full details of each of the funded trials). Over a third (n = 11, 37.9%) were for interventions for osteoarthritis (knee, n=8; hip n=2, big toe n=1). For knee osteoarthritis there were three trials of drug therapy (atorvastatin, vitamin D, zoledronic acid), and single trials investigating neuromuscular exercise; gait retraining, high protein and low glycaemic diet and/or progressive resistance training in overweight or obese adults; unloading shoes; lap banding in obese people prior to knee joint replacement; and accelerated rehabilitation following arthroscopic autologous chondrocyte implantation. There was also a single trial investigating two types of acupuncture (laser and needle) for people with chronic knee pain. For hip osteoarthritis there was a trial comparing two different joint replacements and a trial investigating multimodal physical therapy while the trial for osteoarthritis of the big toe was investigating rocker-soled shoes.

Table 3

Musculoskeletal (MSK) trials funded by National Health and Medical Research Council (NHMRC) Project grants (commencing 2009 to 2013): Year of commencement of funding, Chief investigator A, amount of funding awarded, co-funding, trial design, trial size, MSK condition, intervention(s), control(s) and Australian New Zealand Clinical Trial Registration (ANZCTR) number [♭]

Year	CIA (*primary discipline)	[#]Administering Institution	Funding ($)	Co-funding	[ϟ]Trial Design	Trial Size	MSK Condition	Intervention(s)	Control(s)	ANZCTR Trial Registration Number
2013	Chung-Wei Christine Lin (PT)	Uni Syd	618,589	NR[ξ]	RCT-PB	204	Sciatica	Pregabalin	Placebo	Not yet registered
2013	Venerina Johnston (PT)	UQ	660,834	No	RCT-O	640	Chronic non-specific neck pain	Workplace based exercise and ergonomic advice	Ergonomic advice	12612001154897
2013	Rana Hinman (PT)	UoM	741,631	NR	RCT-PB	164	Knee osteoarthritis	Unloading shoes	Control shoes	Not yet registered
2013	Graeme Jones (R)	UT	954,597	NR	RCT-PB	260	Knee osteoarthritis	Zoledronic acid	Placebo	Not yet registered
2013	James McAuley (PS)	UNSW	509,536	No	RCT-PB	250	Chronic low back pain	Novel psycho-therapeutic intervention	Sham psycho-therapeutic intervention	12612001180808
2013	Yuanyuan Wang (RA)	MU	971,020	NR	RCT-PB	350	Knee osteoarthritis	Atorvastatin	Placebo	Not yet registered

Year	CIA (*primary discipline)	#Administering Institution	Funding ($)	Co-funding	ϕTrial Design	Trial Size	MSK Condition	Intervention(s)	Control(s)	ANZCTR Trial Registration Number
2013	John Wark (E)	UoM	587,813	NR	RCT-O	234	Musculo-skeletal health in young women^	Behavioural intervention; Vit D	Usual care	Not yet registered
2013	Hylton Menz (P)	LTU	321,325	NR	RCT-PB	80	Big toe joint osteoarthritis	MBT rocker-soled shoes + sham insoles	Normal shoes + sham insoles	Not yet registered
2013	Rachelle Buchbinder (R)	MU	501,115	No	RCT-PB	180	Lateral epicondylitis	Autologous platelet rich plasma injection	Placebo; Gluco-corticoid injection	Not yet registered
2012	Peter Choong (OS)	UoM	643,670	No	RCT-O	120	Knee osteoarthritis in obese people	Laparoscopic adjustable gastric banding prior to joint replacement	Joint replacement alone	12611001178932
2012	Andrew Carr (ID)	UNSW	687,808	No	RCT-O	84	Low bone mineral density in HIV-infected adults taking tenofovir+	Zoledronic acid	Switch from tenofovir to another potent anti-HIV drug (without commencing zoledronic acid)	12612000776808
2012	Maria Crotty (RP)	FU	522,041	No	RCT-O	236	Post-hip fracture treated surgically living in high care aged facility	Rehabilitation program	Usual care	12612000112864
2012	Donna Urquhart (PT)	MU	296,155	No	RCT-PB	150	Chronic, neuropathic low back pain	Low dose amitriptyline	Placebo	12612000131853
2012	Amanda Sainsbury-Salis (MS)	Uni Syd	890,900	No	ND	100	Musculo-skeletal health in obese people§	Very low energy diet	Conventional diet	12612000651886
2012	Peter Ebeling (E)	UoM	346,175	No	RCT	68	Jaw osteo-necrosis in people with cancer	Teriparatide + Calcium + Vitamin D	Placebo + Calcium + Vitamin D	12612000950864
2012	Professor Mark Bartold (D)	Uni Adelaide	544,262	No	RCT-O	90	Periodontal disease in RA	Peridontal examination and treatment	No periodontal examination	12612000446864
2011	Maria Fiatarone Singh (G)	Uni Syd	572,734	No	RCT-O	125	Knee osteoarthritis in overweight or obese adults	Gait retraining (gait group); High protein, low glycaemic load diet (diet group); Progressive resistance training (PRT group); Gait + Diet + PRT (Combined group)	Lifestyle Advice	12612000501842
2011	Jay Ebert (EP)	UWA	333,989	Yes	RCT-PB	70	Knee osteoarthritis following arthroscopic autologous chondrocyte implantation	Accelerated rehabilitation regime	Traditionally conservative rehabilitation regime	12609000756224
2010	Philip Sambrook (dec)(R)	Uni Syd	511,425	Yes	RCT-PB	120	Hip osteo-necrosis	Zoledronic acid	Placebo	12609000104257

Year	CIA (*primary discipline)	[#]Administering Institution	Funding ($)	Co-funding	[♭]Trial Design	Trial Size	MSK Condition	Intervention(s)	Control(s)	ANZCTR Trial Registration Number
2010	Chang-Hai Ding (M)	Menzies	980,188	No	RCT-PB	400	Knee osteoarthritis	Vitamin D	Placebo	12610000495022
2010	Kim Bennell (PT)	UoM	607,488	No	RCT-PB	128	Hip osteoarthritis	Multimodal physiotherapy program	Sham physio-therapy program	12610000439044
2010	Kim Bennell (PT)	UoM	694,288	No	RCT-O	100	Knee osteoarthritis	Neuromuscular exercise	Quadriceps strengthen-ing	12610000660088
2010	Christopher Cowell (PA, E)	Uni Syd	1,305,625	Yes	RCT-PB	140	Childhood femoral head avascular necrosis due to Perthes disease	Zoledronic acid and Vitamin D	Vitamin D	12610000407099
2010	Anne Moseley (PT)	Uni Syd	427,500	No	RCT-O	342	Ankle fracture	Rehabilitation	Advice	12610000979055
2009	Jane Latimer (PT)	Uni Syd	602,625	Yes	RCT-PB	1650	Back pain	Time-contingent Paracetamol; PRN paracetamol	Time-contingent and PRN placebo paracetamol	12609000966291
2009	Chris Maher (PT)	Uni Syd	598,025	Yes	RCT-O	172	Chronic whiplash	Comprehensive exercise program and educational booklet	Educational booklet and one half-hour physio-therapy consultation	12609000825257
2009	Michele Sterling (PT)	UQ	297,875	No	RCT-PB	120	Chronic whiplash	Dry-needling, advice and exercise	Sham dry-needling, advice and exercise	12609000470291
2009	Paul McCrory (N, SP)	UoM	673,275	No	RCT-PB	280	Chronic knee pain	Laser acupuncture; Needle acupuncture	Sham laser acupuncture; no intervention	12609001001280

[♭] Registration as of Dec 31, 2012

*Primary discipline abbreviations: E – endocrinologist, EP – exercise physiologist, G –geriatrician, ID – infectious diseases physician, M – medical doctor, MS – molecular scientist, N – neurologist, OS – orthopaedic surgeon, PA – paediatrician, PS – psychologist, PT – physiotherapist, R – rheumatologist, RA - radiologist, RP – rehabilitation physician, P –podiatrist, SP – sports physician, D – Dentist

[ξ] NR – Not reported

[#] Administering institution abbreviations: Uni Syd – University of Sydney, UoM- University of Melbourne, MU – Monash University, UQ – University of Queensland, UNSW – University of New South Wales, Menzies - Menzies Research Institute – UWA – University of Western Australia, UT – University of Tasmania, LTU – La Trobe university, FA – Flinders University

[♭] Trial Design abbreviations: RCT – randomised controlled trial, PB – participant blind, O – open

^We included this trial as it was concerned with musculoskeletal health including bone density, bone turnover markers, muscle function (comparing behavioral and pharmacological interventions to usual care in raising 25 OHD levels in young women

[+] We included this trial as it was concerned with improving low bone mineral density in HIV-infected adults taking tenofovir

[§] We included this trial as it was concerned with musculoskeletal health; assessing long-term effects of two different diets on adiposity, lean body mass, muscle strength and bone density

There were three trials for low back pain and one trial for sciatica investigating drug therapies (n=3: paracetamol, amitriptyline and pregabalin) or a psychotherapeutic intervention (n=1). Three trials were either for neck pain (n=1) or whiplash (n=2) and were investigating exercise treatment (n=2) or dry needling (n=1). The remaining trials included three that were investigating drug therapy (zoledronic acid) for either avascular necrosis of the hip (one trial in adults and one in children with Perthes disease) or low bone mineral density in people with HIV infection taking tenofovir, and one trial investigating drug

therapy (teriparatide) for osteonecrosis of the jaw in people with cancer. There were also single trials investigating vitamin D and a behavioural intervention for musculoskeletal health in young women, different injection therapies (glucocorticoid and platelet rich plasma injection) for lateral epicondylitis, the influence of periodontal examination and its treatment on rheumatoid arthritis, rehabilitation following surgical treatment of hip fracture in people living in high care aged facilities, very low energy diet for musculoskeletal health in obese people, and rehabilitation for ankle fracture.

An additional $7,570,000 over 5 years was awarded in 2011 for a program grant entitled "Musculoskeletal pain, injury and health: improving outcomes through conservative management" to four researchers (all physiotherapists: Professors Paul Hodges (QLD), Kim Bennell (VIC), Gwendolen Jull (QLD) and Bill Vicenzino (QLD)). From this program grant funding, at least eight MSK trials have been planned to date (Table 4) (five were registered on the ANZCTR website at the time of our search and an additional one was registered in 2013). Four trials are for knee osteoarthritis, one trial is for gluteal tendinopathy, two are for treatments post surgery (post-arthroscopic partial medial meniscectomy and post-arthroscopic management of symptomatic femoroacetabular impingement), and one trial is for heel pain.

Table 4

Musculoskeletal (MSK) trials funded by National Health and Medical Research Council (NHMRC) Program Grant 2011: Musculoskeletal pain, injury and health: improving outcomes through conservative management ($7,570,000 over 5 years, Chief Investigators (all physiotherapists): Paul Hodges, Kim Bennell, Gwendolen Jull, Bill Vicenzino; Administering Institution: University of Queensland)

[b]Trial Design	Trial Size	MSK Condition	Intervention(s)	Control(s)	ACTRN Trial Registration Number	Co-funding
RCT-O	210	Gluteal tendinopathy	Physiotherapy exercise Intervention; glucocorticoid injection	No treatment	12612001126808	Unknown
RCT-PB	168	Knee osteoarthritis	Telephone coaching + physiotherapist-delivered physical activity program	Physiotherapist-delivered physical activity program	12612000308897	No
RCT-PB	62	Post-arthroscopic partial medial meniscectomy	Neuromuscular exercise training	No exercise treatment	12612000542897	No
RCT-O	100	Post-arthroscopic management of symptomatic femoroacetabular impingement	Physiotherapy program	No formal physiotherapist-supervised rehabilitation	12613000282785*	Yes; St Vincent's Private Hospital Fitzroy Campus and the Australian Hip Arthroscopy Education and Research Foundation

[b]Trial Design	Trial Size	MSK Condition	Intervention(s)	Control(s)	ACTRN Trial Registration Number	Co-funding
RCT-O	60	Knee osteoarthritis	Two booster physiotherapy sessions + home exercise	Home exercise	12612000595819	No
RCT-O	150	Heel pain	Contoured flip-flops; contoured in-shoe orthoses	Flat flip-flops	12612000463875	Yes; Industry
RCT	236	Knee osteoarthritis	Exercise; Pain coping skills training	Education	Not yet registered	No
RCT	~160	Knee osteoarthritis	Physiotherapist training including education about evidence-based practice and training in behaviour change support	No additional physiotherapist training	Not yet registered	No

[b]Trial Design abbreviations: RCT – randomised controlled trial, PB – participant blind, O – open
*Trial was registered in 2013 after the date of our trial registry search
ACTRN trial registration number: Australian New Zealand Clinical Trial Registration (ANZCTR) number

Australian MSK trials registered: 2011-2012

We identified 191 MSK trials that involve recruitment of participants in Australia registered within the last two years (2011-2012) (132 registered in the ANZCTR and 59 retrieved from the WHO clinical trials registry; 82 registered in 2011 and 109 registered in 2012) (Table 5; Appendix 2 and 3). There were 83 trials (43.5%) with industry sponsorship and 63 (33%) that listed an overseas industry contact person. One hundred and twenty-eight trials (67%) appeared to be trials initiated within Australia (with an Australian contact person) including 127 registered within the ANZCTR and one trial with an ISRCTN registration number.

Table 5

2011 and 2012 Australia and New Zealand Clinical Trial Registry (ANZCTR) and World Health Organization (WHO) registered clinical trials with Australian recruitment showing details of condition, intervention, controls, trial size and funding sources

Condition	Intervention Category	Trial Design[b]	Intervention(s)	Control(s)	Trial Size	Funding Source
Rheumatoid arthritis	Drugs	RCT-PB (A)	Adalimumab	Placebo	60	Industry
		RCT-PB*	PF-05280586	Two other brands of rituximab	195	Industry
		RCT-PB*	Certolizumab pegol + methotrexate for early active RA	Placebo	800	Industry
		RCT-PB (A)	Methotrexate + MK-8457	Methotrexate + Placebo	178	Industry
		SCT (A)	Oral low dose prednisolone	Uncontrolled	36	Charity

Condition	Intervention Category	Trial Design[¤]	Intervention(s)	Control(s)	Trial Size	Funding Source
		RCT-O (A)	Biologic disease modifying antirheumatic drug (DMARD)	Conventional DMARD therapy	104	Self-funded/Un-funded
		RCT-PB*	Enbrel	Placebo	168	Industry
		RCT-PB*	Baricitinib	Placebo	525	Industry
		RCT-PB*	Baricitinib; Adalimumab	Placebo	1280	Industry
		RCT-PB*	BI 655064	Placebo	130	Industry
		RCT-PB*	Sarilumab	Placebo	522	Industry
		RCT-PB*	Baricitinib	Placebo	525	Industry
		RCT-PB*	Baricitinib	Placebo	660	Industry
		SCT-PB*	Sarilumab SAR153191 (REGN88)	Placebo	522	Industry
		RCT-PB*	Methotrexate (MTX); MK-8457	Placebo	178	Industry
		RCT-PB*	Sirukumab	Placebo	990	Industry
		RCT-PB*	Rituximab	PF-05280586; Rituximab	210	Industry
		RCT-O*	Adalimumab + Methotrexate	Certolizumab Pegol + Methotrexate	892	Industry
		RCT-PB*	Rituximab-EU+ Rituximab-Pfizer	Rituximab-Pfizer (PF-05280586); Rituximab-US + Rituximab-Pfizer	157	Industry
		RCT-PB*	Adalimumab (high levels)	Adalimumab (current levels)	61	Industry
	Physical	RCT-O (A)	Conventional periodontal examination, treatment and follow-up	No examination, treatment or follow-up	90	NHMRC project grant
	Psychological	SCT (A)**	Questionnaire	Uncontrolled	330	Industry
Osteoarthritis[#]	Drugs	RCT-PB (A)	Autologous adipose derived stem cells injection	Placebo	40	Industry
		RCT-PB (A)	Hyaluronidase powder	No hyaluronidase powder	180	Hospital; Charity
		RCT-PB (A)	Platelet-rich plasma injections	Hylan G-F 20 injections	39	Self-funded/Un-funded
		RCT-PB	<5,000 MW Fraction Human Albumin 5% (Ampion) + lignocaine + betamethasone; Ampion + betamethasone	Placebo + lignocaine + betamethasone	60	Industry

Condition	Intervention Category	Trial Design[a]	Intervention(s)	Control(s)	Trial Size	Funding Source
		RCT-PB(A)	Stromal vascular fraction containing adipose-derived stem cells injection	Hylan G-F 20 injections	60	University
		RCT-PB*	Humanised anti-nerve growth factor (NGF) mAb (ABT-110) + Naprosyn®	Placebo + Naprosyn®	390	Industry
		RCT-PB (A)	Adalimumab for hand osteoarthritis	Placebo	40	Industry
		RCT-PB*	Strontium ranelate	Placebo	1206	Industry
		RCT-O (A)	Polyethylene glycol with electrolytes (Movicol) for post-operative constipation after major joint replacement	Usual care	320	Hospital
		RCT-O (A)	Green-Lipped Mussel extract	Glucosamine sulphate	40	Self-funded/Un-funded
		SCT (A)	New Zealand Green-Lipped Mussel extract	Uncontrolled	20	Industry
		RCT-PB*	FX006	Triamcinolone acetonide	152	Industry
		RCT-PB*	FX006	Triamcinolone acetonide	24	Industry
	Surgery	RCT-O (A)	Modified Genesis II Slim for knee replacement	Genesis II	1060	Industry
		RCT-O (A)	Laparoscopic adjustable gastric banding prior to joint replacement in obese patients with OA	Joint replacement alone	120	NHMRC project grant
		RCT-O (A)	Patient matched Instrumentation for total knee replacement	Standard intramedullary alignment systems	200	Industry
		SCT (A)	Patient matched instrumentation for total knee arthroscopy	Uncontrolled	30	Industry
		RCT-O (A)	Negative pressure wound therapy during hip arthroplasty	Standard dressing	80	University
		RCT-PB (A)	Knee arthroscopy under low pressure (30mmHg)	Standard pressure (80mmHg)	50	University
		RCT-O (A)	MACNAV positioning system for hip joint replacement	Other navigation system; no navigation system	60	Industry
		SCT	AVN Cage Prosthesis for hip replacement	Uncontrolled	77	Industry

Condition	Intervention Category	Trial Design[a]	Intervention(s)	Control(s)	Trial Size	Funding Source
		RCT-O (A)	Topical negative pressure dressing for orthopaedic surgery	Standard dressing	1500	University
		SCT (A)	Reinfusion of cell-salvaged whole blood for total hip arthroplasty	Uncontrolled	25	Industry
		RCT-PB (A)	Intra-operative cerebral oximetry for lower limb arthroplasty	Placebo	40	Hospital
		SCT (A)	Multi-modal analgesic pathway for knee arthroplasty	Uncontrolled	100	Self-funded/Un-funded
		SCT (A)	Collarless Polished Tapered stem for hip arthroplasty	Uncontrolled	50	Hospital
		SCT (A)	Mindfulness training for joint arthroplasty	Uncontrolled	30	Self-funded/Un-funded
		SCT (A)	Radiopaque tantalum bead markers for Hip OA	Uncontrolled	35	Industry
		RCT-PB*	Posterior stabilised knee implant	Posterior cruciate retaining knee implant	120	Hospital
		RCT-O (A)	Dexmedetomidine for sedation during hip and knee arthroplasty	Propofol	40	Self-funded/Un-funded
		SCT (A)	Short stem femoral components for hip replacement	Uncontrolled	25	Hospital
		RCT-PB*	Multiple cancellous screws fixation	Sliding hip screw	100	University
	Physical	RCT-O (A)	Two booster physiotherapy sessions + home exercise	Home exercises	60	NHMRC Program grant
		RCT-O (A)	Gait retraining (gait group); High protein, low glycaemic load diet (diet group); Progressive resistance training (PRT group); Gait + Diet + PRT (Combined group)	Lifestyle Advice	125	NHMRC project grant
		RCT-BP (A)	Donjoy unloader knee brace; anterior-posterior support without frontal plane adjustment (unadjusted) for post-traumatic knee osteoarthritis	No treatment	40	University

Condition	Intervention Category	Trial Design[a]	Intervention(s)	Control(s)	Trial Size	Funding Source
		RCT-O (A)	Neuromuscular training program following arthroscopic partial medial meniscectomy	No exercise	62	NHMRC program grant
		RCT-O (A)	McConnell taping	Vitamin E cream	30	Self-funded/Un-funded
		RCT-O (A)	Genutrain knee brace	Neoprene knee orthosis	90	Self-funded/Un-funded; Industry
		RCT-O (A)	Forearm strengthening exercises (hand)	No exercises	66	Self-funded/Un-funded
		RCT-O (A)	Adjustments to the entire kinetic chain (five areas) (hip)	Adjustments to one area	60	Self-funded/Un-funded
		RCT-O (A)	Independent home exercise program following total hip replacement	Supervised exercise class	120	University
		RCT-PB (A)	Low voltage electrical stimulation of muscles following total knee replacement	Sham stimulation	72	Self-funded/Un-funded
		RCT-O (A)	Nintendo Wii-Fit exercises following total knee replacement	Standard treatment	128	Self-funded/Un-funded; Other collaborative funding; Charity
		RCT-O (A)	Extensive rehabilitation	Standard rehabilitation	60	Hospital
		SCT (A)	Pre-operative Education and Exercise program for hip and knee replacement	Uncontrolled	40	Self-funded/Un-funded
		RCT-O*	Hospital Inpatient Rehabilitation	Hybrid Home Programme	220	Industry
	Psychological	RCT-O (A)	Mindfulness training for patients undergoing total hip or knee replacement	No treatment	150	Australian Research Council
	Education/ Self-management	RCT-O (A)	Additional interpreter sessions following total knee replacement	Usual care	44	Hospital
		RCT-O (A)	Self-efficacy based education DVD for joint replacement pain and anxiety management	No DVD	100	Hospital
		SCT (A)	Pre-admission education program for total hip or knee joint replacement	Uncontrolled	200	Hospital

Condition	Intervention Category	Trial Design[a]	Intervention(s)	Control(s)	Trial Size	Funding Source
		RCT-O (A)	Telephone coaching + physiotherapist-delivered physical activity program	Physiotherapist-delivered physical activity program	168	NHMRC program grant
		SCT (A)	Pre-operative Education and Exercise program for hip or knee replacement	Uncontrolled	20	Self-funded/Un-funded
Polymyalgia rheumatica	Drugs	RCT-PB*	Lodotra	Placebo	400	Industry
Spondyloarthritis	Drugs	RCT-PB*	Apremilast	Placebo	456	Industry
Juvenile Arthritis	Drugs	SST*	Enbrel	Uncontrolled	123	Industry
		SCT*	Tocilizumab	Uncontrolled	20	Industry
		SCT*	Etanercept	Uncontrolled	100	Industry
Gout	Drugs	SCT (A)	Various doses of Allopurinol	Uncontrolled	30	NHMRC Safety Grant; Charity
		SCT*	Lesinurad	Uncontrolled	200	Industry
		RCT-PB*	Lesinurad	Placebo	315	Industry
		RCT-PB*	Lesinurad	Placebo	200	Industry
		RCT-PB*	Lesinurad	Placebo	600	Industry
		SCT*	Canakinumab	Uncontrolled	200	Industry
		SCT*	Allopurinol	Uncontrolled	1743	Industry
Psoriatic arthritis	Drugs	RCT-BP*	Secukinumab	Placebo	600	Industry
		RCT-PB*	Apremilast; Etanercept	Placebo	240	Industry
		RCT-PB*	BMS-945429	Placebo	150	Industry
Fibromyalgia	Physical	RCT-PB (A)	Transcranial direct current stimulation	Placebo	32	University
Systemic sclerosis	Drugs	RCT-PB*	Pomalidomide	Placebo	88	Industry
Sjögrens syndrome	Physical	RCT-O (A)	High intensity humidifier machine (AIRVO)	Look alike machine	20	Hospital
Systemic lupus erythematosus	Drugs	RCT-PB*	Soluble Fc-gamma receptor	Placebo	50	Industry
		SCT*	LY2127399	Uncontrolled	1276	Industry
		SCT	Epratuzumab	Uncontrolled	400	Industry
		RCT-PB	Epratuzumab	Placebo	1053	Industry
		SCT (A)	Therapeutic drug monitoring (TDM) guided dosing of EC-MPS	Uncontrolled	32	Hospital; Industry

Condition	Intervention Category	Trial Design[a]	Intervention(s)	Control(s)	Trial Size	Funding Source
		SCT*	Anti-Macrophage Migration Inhibitory Factor (Anti-MIF) Antibody	Uncontrolled	4[B]	Industry
		RCT-PB*	AMG 557	Placebo	32	Industry
		RCT-PB*	BMS-188667 + Mycophenolate mofetil; BMS-188667 + Prednisone for Lupus Nephritis	Placebo + Mycophenolate mofetil; Placebo + Prednisone	400	Industry
		RCT-PB*	BIIB023 for Lupus Nephritis	Placebo	300	Industry
Osteoporosis	Drugs	RCT-PB (A)	Zoledronic acid for anti-epileptic drug-induced bone loss	Placebo	60	Industry
		RCT-PB (A)	Intravenous zoledronic acid for people with osteoporosis and minimal trauma fracture	Placebo	60	Industry
		RCT-PB (A)	Cholecalciferol liquid for bone loss in chronic kidney disease	Placebo	62	Industry
		RCT-PB*	MK-0822 for postmenopausal osteoporosis	Placebo	16300	Industry
		RCT-O (A)	Zoledronic acid for low bone mineral density in HIV-infected adults taking tenofovir	Switch from tenofovir to another potent anti-HIV drug (without commencing zoledronic acid)	84	NHMRC project grant
		RCT-PB (A)	Calcium + vitamin D for low bone density	Placebo	60	University
		RCT - PB (A)	Vitamin D for vitamin D deficiency	Placebo	30	University
		RCT-PB*	AMG785 + denosumab for postmenopausal osteoporosis	Placebo	5600	Industry
		RCT-PB*	AMG 785; AMG 785 + alendronate for post-menopausal osteoporosis	Alendronate	4000	Industry
		RCT-PB*	Teriparatide for low trauma femoral neck fracture (1)	Placebo	1220	Industry
		RCT-PB*	Teriparatide for low trauma femoral neck fracture (2)	Placebo	1220	Industry
		RCT-O (A)	Vitamin D3 for decreasing number of fractures	No treatment	250	Hospital

Condition	Intervention Category	Trial Design[a]	Intervention(s)	Control(s)	Trial Size	Funding Source
		RCT-PB*	Denosumab; Zoledronic acid	Placebo	620	Industry
		RCT-PB*	Romosozumab; Denosumab	Placebo + Denosumab	6000	Industry
		RCT-PB*	Teriparatide; Vitamin D; Calcium	Placebo	122	Industry
	Physical	RCT-O (A)	Pilates exercise program; Pilates exercise program + home exercise	Usual care	80	University
		RCT-O (A)	Rehabilitation program post surgically treated hip fracture & living in high care aged facility	Standard care	236	NHMRC project grant
		RCT-O (A)	Whole body vibration therapy for bone metabolism in breast cancer patients undergoing aromatase inhibitor therapy	No treatment	50	Charity
		RCT-O (A)	Whole body vibration therapy for bone metabolism in prostate cancer with androgen therapy	No treatment	50	Charity
	Education/ Self-management	RCT-O (A)	Sheets with bone health related education	Standard care	10	Charity
Low back pain	Drugs	RCT-PB (A)	Dexamethasone for low back pain and lumbosacral radiculopathy	Placebo	100	Hospital
		RCT-PB*	ABT-110 + Naprosyn® for chronic low back pain	Placebo + Naprosyn®	390	Industry
		RCT-PB (A)	Low-dose amitriptyline for chronic neuropathic low back pain	Placebo	150	NHMRC project grant
	Surgery	RCT-PB (A)	Minimally invasive decompressive laminectomy for degenerative lumbar canal stenosis	Standard decompressive laminectomy	30	Self-funded/Un-funded
	Physical	RCT-O (A)	McKenzie method exercises for chronic low back pain	Motor control exercises	70	Charity
		RCT-O*	Back Strain Monitor device with bio-feedback	Back Strain Monitor device with no bio-feedback	96	Industry

Condition	Intervention Category	Trial Design[a]	Intervention(s)	Control(s)	Trial Size	Funding Source
		RCT-PB (A)	Acupuncture of lumbar spine with sensory discrimination for chronic low back pain	Acupuncture of Lumbar spine without sensory discrimination	25	University
		RCT-PB (A)	Usual chiropractic care for non-specific spinal pain	De-tuned ultrasound and random spinal de-tuned activator treatment	180	Industry
		RCT-O	Hip strengthening; Hip stretching	Hip rotation only	30	Self-funded/Un-funded
		RCT-O (A)	Exercise rehabilitation program for chronic low back pain	General exercise	52	University
		RCT-O (A)[B]	Postural re-education; Progressive resisted back extension exercise; both for thoracic kyphosis	No intervention	160	NHMRC PhD Scholarship; Hospital; Industry
		RCT-PB (A)	Manipulation of the thoracic, abdominal and pelvic organs and their associated supportive ligaments, connective tissue and fascia	Sham manipulation	64	Self-funded/Un-funded
		RCT-PB*	Boston Scientific Precision Plus spinal cord stimulation therapy	ND	1[B]	Industry
	Psychological	RCT-PB (A)	Novel psychotherapeutic intervention	Sham psychotherapeutic intervention	250	NHMRC project grant
	Education/ Self-management	RCT-O (A)	Pamphlet only; Pamphlet with education delivered by pharmacists	Usual care	360	Department of Health WA
Neck pain	Drugs	RCT-PB (A)	Benztropine for acute non-traumatic neck pain	Placebo	30	Self-funded/Un-funded
	Physical	RCT-PB (A)	Passive positioning of the participant	Sham positioning	85	Self-funded/Un-funded
		RCT-O (A)	High force mobilisation for chronic non-specific neck pain	Low force mobilisation; Laser	66	Charity
		RCT-PB (A)	Sustained natural apophyseal glides for dizziness and pain from cervical spine problems	Detuned machine	90	Other collaborative funding
		RCT-O (A)	Workplace based exercise and ergonomic advice for non-specific neck pain	Ergonomic advice	640	NHMRC project grant
		RCT-O	Sensorimotor and kinematic exercises +	Sensorimotor and	60	University

Condition	Intervention Category	Trial Design[a]	Intervention(s)	Control(s)	Trial Size	Funding Source
		(A)	interactive virtual reality exercises for chronic neck pain	kinematic exercises		
		RCT-O (A)	Gradual removal of orthosis for cervical spinal trauma including fractures and ligamentous injuries	Immediate removal of orthosis	80	Hospital
		SCT (A)	Manual therapy treatment	Uncontrolled	20	Self-funded/Un-funded
Shoulder/arm	Drugs	RCT-PB (A)	Glucocorticoid injection+ hydrodilatation for stiff painful shoulder	Glucocorticoid injection	80	Self-funded/Un-funded
		RCT-PB*	Autologous conditioned plasma for Rotator Cuff injury	Placebo	60	NR
		RCT-PB (A)	Glucocorticoid + local anaesthetic for shoulder pain	Usual care	64	Allied Health Workforce & Coordination Unit, Australia
	Surgery	RCT-PB (A)	Varying doses of ropivacaine for shoulder surgery	Dose control	120	Hospital
		RCT-O	Addition of an implanted collagen scaffold for partial thickness, larger partial thickness or small full thickness supraspinatus tendon tears	No collagen scaffold; Standard subacromial decompression and/or repair alone	36	Industry
		RCT-O (A)	External rotation brace for anterior shoulder dislocations	Arthroscopic stabilisation surgery	50	Hospital
	Physical	RCT-O (A)	Nine physiotherapy sessions for anterior shoulder dislocation	Seven physiotherapy sessions	200	University
		RCT-O (A)	Supervised physiotherapy program + pulsed ultrasound + massage for primary anterior shoulder dislocation	Supervised physiotherapy program	200	Hospital; Other collaborative groups; Queensland Health
		RCT-O (A)	Supervised exercise program for shoulder pain due to accessory nerve injury after surgery	Usual care	60	Hospital

Condition	Intervention Category	Trial Design[a]	Intervention(s)	Control(s)	Trial Size	Funding Source
		RCT-O (A)	Ultrasound-guided shockwave therapy for painful soft tissue calcification including tendinopathy	Patient-guided shockwave treatment	120	Industry
		RCT-O (A)	Collar & cuff sling under clothing 90 degrees elbow flexion; posterior plaster of Paris backslab and collar and cuff sling over clothing 50 degrees elbow flexion for supracondylar humeral fracture	Collar and cuff sling under clothing with elbow flexion at 120 degrees	180	Hospital
		RCT-PB (A)	Electrical stimulation therapy for frozen shoulder	Placebo stimulation therapy	40	University
Elbow/forearm	Drugs	RCT-O (A)	Prolotherapy injection for lateral epicondylalgia	Physiotherapy and therapeutic Exercise	120	Charity
	Physical	RCT-PB (A)	Titanium volar locking plate for distal radius fractures	Stainless Steel volar locking plate	130	Hospital
		RCT-O (A)	Immobilisation periods of one and three weeks	Immobilisation period of six weeks	135	Hospital
		RTC-O (A)	Professional advice plus a progressive exercise program	Professional advice	30	Self-funded/Un-funded
Hip/thigh	Drugs	SCT (A)	Autologous tenocyte implantation for gluteal tendinopathy	Uncontrolled	20	Industry
	Surgery	RCT-PB (A)	Intramedullary nail for hip fractures	Sliding hip screw	736	Industry
		SCT (A)	19G spinal needle + air arthrogram for femoroacetabular impingement	Uncontrolled	40	Self-funded/Un-funded
	Physical	RCT-O (A)	Physiotherapy exercise Intervention; glucocorticoid injection for gluteal tendinopathy	No treatment	210	NHMRC program grant
Knee/leg	Drugs	RCT-PB (A)	Glucosamine sulphate for undiagnosed knee pain	Placebo	60	University; Industry
	Physical	RCT-O (A)	Prefabricated, commercially available, full length in-shoe orthoses for anterior knee pain	No treatment	40	Australian Research Council
		RCT-O (A)	Partial immobilisation for patella dislocation	Full immobilisation	60	Self-funded/Un-funded

Condition	Intervention Category	Trial Design[a]	Intervention(s)	Control(s)	Trial Size	Funding Source
		RCT-O (A)	One-on-one and group physiotherapy for lower limb orthopaedic surgery	One-on-one sessions only	89	Hospital
	Surgery	RCT-O (A)	Atorvastatin, Ivabradine for neck of femur fracture	No treatment	200	Hospital
		RCT-O (A)	Limited transthoracic echocardiography for femur surgery	Standard clinical assessment of cardiovascular function	180	University
Wrist/hand	Drugs	SCT*	Xiapex for Dupuytren's contractures	Uncontrolled	600	Industry
		SCT*	AA4500 collagenase clostridium histolyticum for Dupuytren's contractures	Uncontrolled	60	Industry
	Physical	RCT-O (A)	Nerve and tendon gliding exercises for carpal tunnel syndrome	No treatment	30	NHMRC project grant
		RCT-O (A)	Splint which allows wrist motion in the Dart Throwing Plane for scapho-lunate ligament injury	Static splint	20	Hospital
		RCT-O (A)	Nerve and tendon gliding exercises for carpal tunnel syndrome	Splinting	30	Queensland Health Practitioner Research Scheme; NHMRC project grant
		SCT (A)	Custom-made Ulnar gutter splint for wrist pain	Uncontrolled	20	Hospital
Foot/ankle	Physical	RCT-O (A)	Weight-bearing mobilising for ankle fractures	Non weight-bearing mobilising	50	Self-funded/Un-funded
		RCT-O (A)	Low cost, off-the-shelf footwear for foot pain	Usual treatment	120	Australian Department of Veterans' Affairs
	Physical	RCT-O (A)	Contoured flip-flops; contoured in-shoe orthosis for heel pain	Flat flip-flops	150	NHMRC program grant; Industry
	Surgery	RCT-O (A)	Dexamethasone for foot or ankle surgery	No dexamethasone	90	Hospital
	Education/ self-management	SCT (A)	Questionnaire for Plantar Fasciitis	Uncontrolled	150	Charity
		SCT (A)	Multimedia patient education module for foot and ankle surgery	Uncontrolled	500	Charity

Condition	Intervention Category	Trial Design[¤]	Intervention(s)	Control(s)	Trial Size	Funding Source
Musculoskeletal adverse effects of drugs	Drugs	RCT-PB (A)	Crystalline glucosamine sulphate for Letrozole induced arthralgia in breast cancer patients	Placebo	143	Other collaborative funding
		RCT-PB (A)	Teriparatide + Calcium + Vitamin D for osteonecrosis of the jaw	Placebo + Calcium + Vitamin D	68	NHMRC project grant
	Physical	RCT-PB (A)	Acupuncture for arthralgia due to aromatase inhibitor therapy for breast cancer	Sham acupuncture	30	Charity
Un-specified/ Other	Drugs	RCT-PB (A)	Ketamine + ibuprofen for limb injuries	Ibuprofen	80	Charity
		SCT (A)	Intranasal ketamine for MSK injuries	Uncontrolled	60	Hospital
	Education/ Self-management	SCT (A)	Exercise DVD for performance-related musculoskeletal disorders	Uncontrolled	150	Australian Research Council; Australia Council of the Arts
		RCT-O (A)	Exercise class; Alexander Technique for performance-related musculoskeletal disorders	No intervention	150	Australian Research Council; Australia Council of the Arts
		SCT (A)	Physiotherapist advice for Performance-related musculoskeletal disorders	Uncontrolled	150	Australian Research Council; Australia Council of the Arts

[¤]Trial Design Legend: Randomised controlled trial – participant-blinded (RCT-PB); randomised controlled trial - open (RCT-O); single arm clinical trial (SCT); * European Union – Clinical Trial Registry (EU-CTR) registered trials; (A) - Australian-investigator initiated trial. [#]Knee osteoarthritis unless otherwise indicated; [B] indicates trial was terminated; ** Questionnaire also for Psoriatic Arthritis and Ankylosing spondylitis; NR – not reported

The median trial size for all registered trials was 100 participants (range 10-16,300). The median size of Australian investigator-initiated trials was generally smaller (median 65, range 10 - 1650). Of the Australian investigator-initiated trials, two-thirds had a recruitment size of ≤100 (n = 86, 67.2%), 24.2% (n= 31) had a recruitment size between 101 and 200, four (3.1%) had a recruitment size between 201 and 300, and seven (5.5%) had a target recruitment size of 301 or more. Industry-funded trials tended to have larger sample sizes compared with other trials.

From the sources of funding indicated in the trial registries for the 128 Australian-investigator initiated trials, there were 20 (15.6%) with commercial/industry funding (most of which were for drug intervention trials), 25 (19.5%) with government funding, 15 (11.7%)

with university funding, 19 (14.8%) with charity funding, 17 (13.3%) with hospital funding, and 22 (17.2%) that were self-funded or unfunded. Ten trials (7.8%) indicated receipt of funding from more than one source.

Of the Australian-investigator initiated trials, over a third (n=45, 35.2%) were for osteoarthritis. Thirty of these related to joint replacement/arthroscopy including pre-operative preparation such as general and self-efficacy education and mindfulness training; comparison of different operative approaches including different operative procedures, instrumentation or method of wound management; and post-operative management including various types of physical therapy and exercise; and one trial of additional interpreter support. There was also one trial that compared joint replacement with and without laparoscopic adjustable gastric banding in obese patients. Fifty-five trials (43%) were investigating different aspects of physical therapy and exercise and twelve trials (9.4%) were investigating aspects of self-management.

Twelve Australian-investigator initiated trials (9.4%) were for osteoporosis or related conditions. Of seven trials investigating drug therapy for osteoporosis, four were investigating treatment of low bone density associated with other diseases and/or drug therapy. An additional three trials were investigating treatment for MSK complications of drug therapy including two trials for arthralgia related to aromatase inhibitor therapy in breast cancer patients and one trial for osteonecrosis of the jaw. There were only six Australian-initiated trials for rheumatoid arthritis (four of which were drug trials) and one trial for gout also investigating drug therapy. There were 53 (41.4%) Australian investigator-initiated trials for regional conditions, most commonly low back pain (n = 12, 9.4%), shoulder/arm pain (n = 10, 7.8%) and neck pain (n = 8, 6.3%).

Overall, the most common intervention being studied was physical therapy and/or exercise (n = 55, 43%), while 33 (25.8%) were for drug therapies, 23 (18%) were related to surgery, 12 (9.4%) investigating a patient education intervention and four trials (3.1%) investigating a psychological intervention. There were no trials investigating interventions to improve uptake of research findings or guidelines into practice.

Australian MSK trials published in top international general and MSK-specific journals: 2011-2012

We identified 565 papers reporting the primary results of MSK randomised controlled trials in the top 37 (Impact Factor-ranked) general medical and MSK-specific journals published in the last two years (2011 or 2012)(Table 6). Fifty-seven of these (10.1%) included Australian participants and 30 (5.3%) were initiated in Australia. Australian investigator-initiated trials were published across a range of journals, (particularly in the areas of rheumatology, orthopaedics and rehabilitation). Three of five MSK randomised controlled trials (60%)

published in *Journal of Physiotherapy*, which is the official journal of the Australian Physiotherapy Association, were Australian-initiated. No Australian investigator-initiated trials were published in journals that specifically focus on osteoporosis (e.g. Journal of Bone and Mineral Research, Osteoporosis International, Bone).

Table 6

Musculoskeletal trials published in the 37 highest general medical and musculoskeletal-related journals by 2011 *Impact Factor: all musculoskeletal trials, musculoskeletal trials with Australian recruitment and Australian investigator-initiated musculoskeletal trials, 01 January 2011 – 31 December 2012

Journal Category	Journal Name	*Impact Factor	MSK Trials (N = 565) N	MSK Trials with Australian Recruitment (N = 57) N (%)	Australian Investigator-Initiated MSK Trials (N = 30) N
General and internal medicine	New England Journal of Medicine	53.298	7	2 (29)	0
	Lancet	38.278	1	1 (100)	0
	Journal of the American Medical Association	30.026	1	0	0
	Annals of Internal Medicine	16.733	6	0	0
	British Medical Journal	14.093	6	2 (33)	2
Rheumatology	Annals of Rheumatic Diseases	8.727	48	9 (19)	2
	Arthritis & Rheumatism	7.866	37	6 (16)	1
	Arthritis Care & Research	4.851	17	2 (12)	1
	Arthritis Research & Therapy	4.445	17	0	0
	Rheumatology	4.058	13	1 (8)	0
	Osteoarthritis and Cartilage	3.904	12	2 (17)	2
	Journal of Rheumatology	3.695	31	3 (10)	1
	BMC Musculoskeletal Disorders	1.577	26	0	0
Orthopaedics	Journal of Bone & Joint Surgery [AM]	3.272	28	2 (7)	2
	Arthroscopy	3.024	14	0	0
	Journal Bone & Joint Surgery [BR]	2.832	27	2 (7)	2
	Journal of Orthopaedic Research	2.811	7	1 (14)	1
	Journal of Shoulder & Elbow Surgery	2.747	8	0	0
	Clinical Orthopaedics & Related Research	2.533	11	0	0
	Journal of Arthroplasty	2.384	34	3 (9)	3
Sports Sciences	Medicine & Science Sport Exercise	4.431	3	1 (33)	1

Journal Category	Journal Name	*Impact Factor	MSK Trials (N = 565) N	MSK Trials with Australian Recruitment (N = 57) N (%)	Australian Investigator-Initiated MSK Trials (N = 30) N
	British Journal of Sports Medicine	4.144	12	4 (30)	4
	American Journal of Sports Medicine	3.792	20	0	0
	Journal of Science and Medicine in Sport	3.034	3	1 (33)	1
Spine (within Orthopaedics)	Spine Journal	3.29	6	0	0
	Spine	2.078	37	1 (3)	1
	European Spine Journal	1.965	10	0	0
Osteoporosis (within Endocrinology and metabolism)	Journal of Bone Mineral Research	6.373	10	2 (20)	0
	Osteoporosis International	4.58	21	4 (19)	0
	Bone	4.023	3	1 (33)	0
	Calcified Tissue International	2.376	4	1 (25)	0
	Journal of Bone and Mineral Metabolism	2.268	9	0	0
Rehabilitation	Journal of Physiotherapy	3.481	5	3 (60)	3
	Physical Therapy	3.113	12	2 (17)	2
	Journal of Orthopaedic & Sports Physical Therapy	3	13	0	0
	Archives of Physical Medicine and Rehabilitation	2.284	20	1(5)	1
	Clinical Rehabilitation	2.123	25	0	0

*Impact Factor ranking obtained from the Web of Science Journal citation database (2011) (www.thomsonreuters.com/journal-citation-reports), # MSK - Musculoskeletal

Table 7 and Appendix 4 display details of the trials with Australian recruitment. Trials that included Australian participants but were not initiated in Australia (n=27, 4.8% of total MSK trial publications) were all multinational trials, primarily studying the effects of drug therapy for rheumatoid arthritis, osteoarthritis or osteoporosis. These were all funded by the pharmaceutical industry. Industry also supported several trials comparing different surgical strategies for knee arthroplasty.

Table 7

Musculoskeletal-specific randomised controlled trials with Australian recruitment published in the 37 highest general medical and musculoskeletal-related journals by 2011 Impact Factor* between 01 January 2011 and 31 December 2012: Condition, intervention category, trial design, intervention(s), comparator/s, trial size and funding source

Condition	Intervention Category	Trial Design	Intervention(s)	Comparator(s)	Trial Size	Funding Source
Rheumatoid arthritis	Drugs	RCT-PB	Ofatumumab + Methotrexate	Placebo + Methotrexate	260	Industry
		RCT-PB	Golimumab (two different dosages) + Methotrexate	Placebo + Methotrexate; Placebo + Golimumab	444	Industry
		RCT-PB	Rituximab (two different dosages) + Methotrexate	Methotrexate	748	Industry; National Institutes of Health (NIH)
		RCT-PB	Golimumab (two different dosages) + Methotrexate	Placebo + Methotrexate; Placebo + Golimumab	318	Industry
		RCT-PB	Abatacept subcutaneously	Abatacept intravenously	1457	Industry
		RCT-PB	Tocilizumab (two different dosages)	Placebo	1196	Industry
		RCT-PB	Adalimumab + Methotrexate; Adalimumab	Methotrexate	799	Industry
		RCT-PB	Certolizumab (two different dosages) + Methotrexate	Placebo + Methotrexate	784	Industry
		RCT-PB	Golimumab + Methotrexate	Placebo + Methotrexate	592	Industry
		RCT-PB	Tofacitinib (two different dosages); Adalimumab	Placebo	717	Industry
		RCT-PB	Tocilizumab	Placebo	489	Industry
Osteoarthritis	Drugs	RCT-PB (A)	Hylan G-F 20 for knee osteoarthritis	Placebo	151	Australian Podiatry Education and Research Foundation, La Trobe University; Industry
		RCT-PB	Strontium ranelate (two different dosages) for knee osteoarthritis	Placebo	1683	Industry
		RCT-PB (A)	Zoledronic acid for knee osteoarthritis	Placebo	59	Industry; Australian Government; NHMRC; Osteoporosis Australia
		RCT-PB	Cindunistat (2 different doses) knee osteoarthritis	Placebo	1457	Industry
		RCT-PB (A)	4Jointz cream for knee osteoarthritis	Placebo cream	133	Industry
	Surgery	RCT-BP (A)	Computer-assisted total knee replacement	Conventional total knee replacement	115	Industry

Condition	Intervention Category	Trial Design[4]	Intervention(s)	Comparator(s)	Trial Size	Funding Source
		RCT-PB (A)	Bicruciate stabilised design for total knee replacement	Traditional posterior-stabilised design	28	Industry
		RCT-PB (A)	Stryker Full Navigation for total knee replacement	Total knee replacement with Stryker Articular Surface Mounted system	40	Industry
		RCT-PB (A)	36 mm metal femoral head on highly cross-linked polyethylene for hip arthroscopy	28-mm metal femoral head on highly cross-linked polyethylene	644	NHMRC; Industry
		RCT-PB (A)	Subvastus approach for knee arthroplasty	Medial parapatellar approach	90	No external funding
		RCT-PB (A)	Single-incision mini-posterior approach for total hip arthroplasty	Standard posterior approach	22	Industry
	Physical therapy	RCT-O (A)	Wedge insoles	Flat insoles	200	NHMRC project grant
		RCT-PB (A)	Pulsed electrical stimulation for knee osteoarthritis	Sham electrostimulation	70	Arthritis Australia; Physiotherapy Research Foundation
		RCT-O (A)	Internet-based tele-rehabilitation physical therapy program following total knee arthroplasty	Standard physical therapy	65	No external funding
		RCT-O (A)	Standardised athletic shoes + prefabricated medial arch supports knee osteoarthritis	Standardised athletic shoes wearing no medial arch supports	21	Australian Research Council
	Education/ self-management	RCT-O (A)	Stanford arthritis self-management program + self-help book for knee osteoarthritis	Self-help book	120	NHMRC project grant
Systemic Lupus Erythematosus	Drugs	RCT-PB	Belimumbab	Placebo	867	Industry
Psoriatic arthritis	Drugs	RCT-PB	Abatacept (three different dosages)	Placebo	170	Industry
Spondylo-arthritis	Drugs	RTC-PB	Etanercept	Sulfasalazine	566	Industry
		RCT-PB	Adalimumab for axial spondyloarthritis	Placebo	185	Industry
Osteoporosis and related conditions	Drugs	RCT-PB	Alendronate	Placebo	56	Industry
		RCT-O	Alendronate + Vitamin D	Usual care	515	Industry
		RCT-PB	Zoledronic acid	Placebo	1199	Industry
		RCT-PB	Arzoxifene	Raloxifene	320	Industry

Condition	Intervention Category	Trial Design[4]	Intervention(s)	Comparator(s)	Trial Size	Funding Source
		RCT-PB	Strontium ranelate for bone microstructure in women with osteoporosis	Alendronate	83	Industry
		RCT-PB	Zoledronic acid IV + acetaminophen/paracetamol; Zoledronic acid IV + ibuprofen	Zoledronic acid IV + placebo; Placebo IV + placebo	481	Industry
		RCT-PB	Zoledronic acid + Calcium + Vitamin D for osteoporosis in men	Risedronate + Calcium + Vitamin D	265	Industry
		RCT-PB	Ronacaleret (three different dosages) for postmenopausal osteoporosis	Alendronate; Placebo	569	Industry
		RCT-PB	Teriparatide for back pain in postmenopausal women with osteoporotic vertebral fractures	Risedronate	712	Industry
	Physical therapy	RCT-O (A)	Exercise	Usual Care	39	Industry
Fibromyalgia	Drugs	RCT-PB	Pregabalin (three different dosages)	Placebo	747	Industry
Low back pain	Physical therapy	RCT-O (A)	Pilates	General exercise	87	Industry
		RCT-O (A)	Tai chi	No treatment	160	Arthritis Foundation of Australia; Arthritis Care of the UK
		RCT-O (A)	Motor control exercises	Graded activity	172	NHMRC project grant
		RCT-O (A)	Strain-counter strain treatment + Standard exercises	Standard exercises	99	Not specified
	Education/ Self-management	RCT-O (A)	Telephone coaching + physiotherapy care	Physiotherapy care	30	Not specified
Neck pain	Physical therapy	RCT-PB (A)	Electro acupuncture for subacute and chronic whiplash	Simulated electro acupuncture treatment	124	Government funds not described
		RCT-O (A)	Endurance training	Coordination training; Active mobility training	60	NHMRC development grant; Queensland Health; University
		RCT-O (A)	Manual therapy + nerve gliding exercise + education for nerve-related neck and arm pain	Usual activities	60	University

Condition	Intervention Category	Trial Design[♮]	Intervention(s)	Comparator(s)	Trial Size	Funding Source
Shoulder/ arm	Physical therapy	RCT-O (A)	Passive mobilisation + Exercise + Advice for shoulder pain	Exercise + Advice	98	Australian Physiotherapy Research Foundation
Wrist/hand	Physical therapy	RCT-O (A)	Night splinting for carpal tunnel syndrome	Nerve and tendon gliding exercises	21	Queensland Health; NHMRC project grant
Knee/leg	Drugs	RCT-PB (A)	Botulinum toxin type A injection for refractory anterior knee pain	Saline injection	24	Raine Medical Research Foundation at University of WA; Industry
	Physical therapy	RCT-O (A)	Prefabricated orthoses for anterior knee pain	No orthoses	40	Australian Research Council
Ankle/foot	Drugs	RCT-PB (A)	Ultrasound-guided injection of the plantar fascia with corticosteroid for plantar fasciitis	Saline injection	82	Australian Podiatry Education and Research Foundation; Industry
	Surgery	RCT-O (A)	Prolotherapy injections of hypertonic glucose + lignocaine for Achilles tendinosis	Eccentric loading exercises	40	Musculoskeletal Research Foundation of Australia; Australian Podiatry Education and Research Foundation; University
Mixed population[#]	Physical	RCT-O (A)	Gym based exercise	Usual care	106	Arthritis Australia; Royal Adelaide Hospital

[♮]Trial Design Legend: Participant-blinded randomised control trial (RCT-PB); Open randomised control trial (RCT-O); (A) – Australian investigator-initiated; NS – not stated, NHMRC – National Health and Medical Research Council

[#] Planned rehabilitation for spinal or lower limb musculoskeletal impairment, disability or surgery, reduced functional mobility or falls (Participants: chronic pain (n=24), deconditioned (n=35), arthritis (n=22), joint replacement (n=11), fracture (n=14))

*Impact Factor ranking obtained from the Web of Science Journal citation database (2011) (www.thomsonreuters.com/journal-citation-reports)

Journals searched were: Annals of the Rheumatic Diseases; Arthritis & Rheumatism; Arthritis Care & Research; Arthritis Research & Therapy; Rheumatology, The Journal of Rheumatology; Osteoarthritis & Cartilage; Journal of Orthopaedic and Sports Physical Therapy; Journal of Orthopedic Research; Clinical Orthopaedics and Related Research; Medicine & Science in Sports & Exercise; British Journal of Sports Medicine; The American Journal of Sports Medicine; Journal of Science and Medicine in Sport; Journal of Physiotherapy (formerly the Australian Journal of Physiotherapy); Physical Therapy; Archives of Physical Medicine and Rehabilitation; Clinical Rehabilitation; The Spine Journal; Spine; European Spine Journal; BioMed Central Musculoskeletal Disorders; Journal of Bone & Mineral Research; Osteoporosis International; Bone; Calcified Tissue International; Journal of Bone & Mineral Metabolism; Journal of Bone & Joint Surgery [American]; Arthroscopy; Journal of Bone & Joint Surgery [British]; Journal of Shoulder & Elbow Surgery; Journal of Arthroplasty; The New England Journal of Medicine; The Lancet; The Journal of the American Medical Association; Annals of Internal Medicine; British Medical Journal.

Of the 30 Australian-investigator-initiated trial publications, almost half were for osteoarthritis (n=14, 46.7%), and 14 (46.7%) were for regional conditions (back, neck, knee pain etc.) (Table 8; Appendix 4). More than a third of the trials involved physical therapy interventions (n = 14, 46.7%), while drug and surgery interventions accounted for 40% combined (n = 12). There were no published trials investigating interventions to improve uptake of research findings or guidelines into practice. Nearly a quarter of the Australian-

investigator initiated trials (n = 7, 23.3%) received government funding, while four (13.3%) received industry funding.

Table 8

Australian investigator-initiated musculoskeletal-specific trials published in the 37 highest general medical and musculoskeletal-related journals by 2011 Impact Factor* between 01 January 2011 and 31 December 2012: Journal, first author, trial setting, trial design, condition, intervention(s), comparator(s), trial size and funding source(s)

Journal	First Author	Trial Setting	Trial Design[ϟ]	Condition	Intervention(s)	Comparator(s)	Trial Size	Funding Source(s)
British Medical Journal	McMillan A	VIC	RCT-PB	Plantar fasciitis	Ultrasound-guided glucocorticoid injection of the plantar fascia	Saline injection	82	Australian Podiatry Education and Research Foundation; Briggate Medical
	Bennell K	VIC	RCT-O	Knee OA	Wedge insoles	Flat insoles	200	[#]NHMRC project grant
Annals of the Rheumatic Disease	Munteanu SE	VIC	RCT-PB	Knee OA	Hylan G-F 20	Placebo	151	Australian Podiatry Education and Research Foundation; La Trobe University; Genzyme Australasia Pty. Ltd.
	Laslett LL	TAS	RCT-PB	Knee OA	Zoledronic acid	Placebo	59	Novartis Pharma ceuticals Australia; Australian Government; NHMRC; Osteoporosis Australia
Arthritis & Rheumatism	Fary RE	WA	RCT-PB	Knee OA	Pulsed electrical stimulation	Sham electro-stimulation	70	Arthritis Australia; Physiotherapy Research Foundation
Arthritis Care & Research	Hall AM	NSW	RCT-O	Low back pain	Tai chi	No treatment	160	Arthritis Australia; Arthritis Care UK
Osteo-arthritis & Cartilage	Laslett LL	TAS, NSW	RCT-PB	Knee OA	4Jointz cream	Placebo cream	133	Arthritis Relief Plus Ltd (QLD, Australia)

Journal	First Author	Trial Setting	Trial Design[ϟ]	Condition	Intervention(s)	Comparator(s)	Trial Size	Funding Source(s)
	Hinman RS	VIC	RCT-O	Knee OA	Prefabricated medial arch support	No medial arch supports	21	Australian Research Council
Journal of Rheum-atology	Ackerman IN	VIC	RCT-O	Hip or knee OA	Stanford arthritis self-management program + self-help book	Self-help book	120	NHMRC project grant
Journal of Bone & Joint Surgery [American]	Howie D	SA	RCT-PB	Hip OA	36 mm metal femoral head on highly cross-linked polyethylene	28-mm metal femoral head	644	NHMRC; Zimmer
	Russell T	QLD	RCT-O	Knee OA	Internet-based tele-rehabilitation physical therapy following TKR	Standard physical therapy	65	No external funding
Journal of Bone & Joint Surgery [British]	Babazadeh S	VIC	RCT-BP	Knee OA	Computer-assisted TKR	Conventional TKR	115	Not specified
	Ward TR	ACT	RCT-PB	Knee OA	Bicruciate stabilised design	Traditional posterior-stabilised design	28	Smith and Nephew
Journal of Orthopaedic Research	Schmid A	QLD	RCT-O	Carpal tunnel syndrome	Night splinting	Nerve and tendon gliding exercises	21	NHMRC project grant; Queensland Health
Arthroplasty	Harvie P	WA	RCT-PB	Knee OA	Navigated TKR	Conventional TKR	40	Not specified
	Bourke MG	QLD	RCT-PB	Knee OA	Subvastus approach	Medial parapatellar approach	90	No external funding
	Khan RJK	WA	RCT-PB	Knee OA	Single-incision mini-posterior approach	Standard posterior approach	22	Smith and Nephew Surgical Pty Ltd.
Medicine and Science in Sports and Exercise	Wajswelner H	VIC	RCT-O	Low back pain	Pilates	General exercise	87	DMA Clinical Pilates Physiotherapy & Back in Motion Physiotherapy
British Journal of Sports Medicine	Singer BJ	WA	RCT-PB	Anterior knee pain	Botulinum toxin type A injection	Saline injection	24	Raine Medical Research Foundation at UWA; Ipsen

Journal	First Author	Trial Setting	Trial Design[ϟ]	Condition	Intervention(s)	Comparator(s)	Trial Size	Funding Source(s)
	Mills K	ACT	RCT-O	Anterior knee pain	Prefabricated orthoses	No orthoses	40	Australian Research Council
	Yelland MJ	QLD	RCT-O	Achilles tendinosis	Prolotherapy injections of hypertonic glucose + lignocaine	Eccentric loading exercises	40	Australian Musculoskeletal Research Foundation; Australian Podiatry Educ. & Research Foundation; Griffith University
	Foley A	SA	RCT-O	MSK disability or impairment	Gym based exercise	Usual Care	106	Arthritis Australia; Royal Adelaide Hospital
Journal of Science and Medicine in Sport	Bolton KL	VIC	RCT-O	Osteopenia	Exercise	Control	39	Swisse Vitamins
Spine	Cameron ID	NSW	RCT-PB	Subacute and chronic whiplash	Electro-acupuncture	Simulated electro-acupuncture	124	Government funds not described
Journal of Physio-therapy	Iles R	VIC	RCT-O	Low back pain	Telephone coaching + physiotherapy care	Physiotherapy care	30	Not specified
	Lewis C	QLD	RCT-O	Low back pain	Strain-counterstrain treatment + Standard exercises	Standard exercises	99	Not specified
	Nee R	QLD	RCT-O	Nerve-related neck and arm pain	Manual therapy + Nerve gliding exercises + Education	Usual activities	60	University of Queensland
Physical Therapy	Macedo LG	NSW & QLD	RCT-O	Low back pain	Motor control exercises	Graded activity	172	NHMRC project grant
	Yiasemides R	NSW	RCT-O	Shoulder pain	Passive mobilisation + Exercise + Advice	Exercise + advice	98	Australian Physiotherapy Research Foundation
Archives of Physical Medicine & Rehab-ilitation	O'Leary S	QLD	RCT-O	Neck pain	Targeted exercise	Coordination training; active mobility training	60	NHMRC development grant, Queensland Health, University of Queensland

Abbreviations: OA: Osteoarthritis; [#] NHMRC: National Health and Medical Research Council [ϟ]Trial Design; RCT: randomised controlled trial; PB: Participant-blinded; O: Open; CCT: Controlled clinical trial (not randomised). Trial settings: VIC: Victoria; TAS: Tasmania, WA: Western Australia, NSW: New South Wales, SA: South Australia, QLD: Queensland, ACT: Australian Capital Territory *Impact Factor ranking obtained from the Web of Science Journal citation database (2011) (www.thomsonreuters.com/journal-citation-reports)

4. Discussion

Discussion

This study describes the current scope of Musculoskeletal (MSK) clinical trials in Australia. The National Health and Medical Research Council (NHMRC) has funded an average of 5.8 new MSK trials per year through the project grant scheme over the last five years, with an additional eight MSK trials made possible by a single NHMRC Program Grant. Based upon our review of clinical trial registration in the last two years (January 2011 to December 2012), we identified 191 trials that are recruiting Australian participants and 128 trials that were initiated in Australia. Over the last two years, 5.1% (30/565) of all primary publications reporting results of MSK randomised controlled trials published in one of the top 37 (Impact Factor-ranked) general medical and MSK-specific journals were initiated in Australia. Taken together, these data indicate that Australian MSK trialists are productive and internationally competitive.

A significant number of Australian-initiated trials identified investigated treatments for osteoarthritis (11 (37.9%) NHMRC-funded MSK trials in last five years, 45 (34.4%) Australian-initiated trials registered in the last two years and 14 (46.7%) Australian-initiated trials published in the last two years). While this is commensurate with its known significant burden on the population in terms of disability and costs, and its status as a National Health Priority Area (NHPA), there were proportionally fewer trials for the other designated MSK NHPAs, including osteoporosis (4 (13.8%) NHMRC-funded MSK trials in last five years, 12 (9.4%) Australian initiated trials registered in the last two years and one (3.3%) Australian-initiated trial published in the last two years), and rheumatoid arthritis (1 (3.4%) NHMRC-funded MSK trial in the last five years, 6 (4.7%) Australian initiated trial registered in the last two years and no Australian-initiated trial published in the last two years).

There were also comparatively fewer trials for back pain (4 (13.8%) NHMRC-funded MSK trials in last five years, 12 (9.4%) of Australian initiated trials registered in the last two years and five (16.7%) Australian-initiated trials published in the last five years), despite its ranking as the leading cause of disability worldwide; and a paucity of trials for other MSK conditions. There was a wide range of interventions under study, most commonly drug treatments or physical therapies. While a significant number of these included a placebo or usual care comparator, there were no surgical trials investigating the value of surgical intervention compared with placebo and only one that compared surgery with conservative care (a registered trial comparing arthroscopic stabilisation surgery to external rotation brace of anterior dislocation of the shoulder). In addition, apart from one trial involving two states, none of the trials we identified appeared to be multicentre and the overall median size of Australian-initiated trials was relatively small suggesting that they may be at risk of

type II error[3].

Although project grant support for MSK trials amounted to 5% of the total amount of NHMRC funding allocated to clinical trials over the past five years, and while the number and size of project grants for MSK trials has increased over time, MSK trial funding accounted for only 0.8% of the total number of funded project grants (29/3631), and approximately 0.8% of the total funding allocated to project grants ($17.6million out of >$2billion). This suggests that NHMRC funding for MSK trials is disproportionately low in relation to the burden of MSK conditions in Australia and internationally.

A 2000 to 2008 review of NHMRC funding found that some of Australia's NHPAs are better funded than others (10). Over the last ten years, the NHMRC has estimated that it has invested more than $216 million in arthritis and osteoporosis research (based upon annual expenditure for fellowships and all research grants) (http://www.nhmrc.gov.au/node/1493). While the data may not be directly comparable, as estimated funding is based upon identification of Chief Investigator-provided keywords and titles contained in the NHMRC research database, this appears to be less than other NHPAs such as diabetes (more than $475 million) and cardiovascular disease ($795 million). Only one NHMRC program grant relating to arthritis and MSK conditions (totalling approximately $7.5 million) has been awarded in the last five years in contrast to three specifically for diabetes (totalling approximately $31 million), and a further eight supporting cardiovascular clinical research (totalling approximately $72 million).

Our review of NHMRC-funded MSK trials is limited by the fact that we have no information about unsuccessful project or program grant applications, as this information is not publicly available. We also do not know whether or not the successful grants were successful on their first or subsequent applications. The success of grant applications is also dependent upon external and panel peer review and these factors may vary year to year. We think it is unlikely that we missed any NHMRC-funded MSK trials. As well as a search of the NHMRC website, we contacted key Australian MSK trialists and searched the Australian and New Zealand Clinical Trials Registry (ANZCTR) and World Health Organisation (WHO) trial registries. However it is possible that we underestimated the number of other NHMRC-funded trials as prior to 2011 there was no specific category for clinical trials and identification was reliant upon a key word and title search of the NHMRC database using the terms 'clinical trial', 'clinical study', 'clinical studies', 'randomised trial', 'randomised trial' or 'controlled trial'.

It is unlikely that we missed relevant MSK trials registered within the last two years and that were currently recruiting, planning to recruit, or had recruited participants in Australia. The

[3] A type II error is a false negative. In this instance, a type II error would mean the trial may not have shown the treatment to have any effect on the condition, even though it really does work.

ANZCTR and other clinical trial registries have been established to record the existence of all clinical trials, and prior registration is now a requirement of publishing trial research in many journals. We used the advanced search facility of the trial registries to search for all trials categorised as 'musculoskeletal' in the condition category and the recruitment site to Australia. While most registered MSK trials are likely to denote themselves as MSK, we also searched other potentially relevant categories and performed searches using specific MSK conditions (such as arthritis, as well as specific MSK areas such as 'back') to identify trials that might have fulfilled our inclusion criteria but were not denoted in the musculoskeletal category, minimising the likelihood that relevant trials were missed.

It is also unlikely that we missed relevant Australian-initiated MSK trials that had been published in the last two years among the 37 journals that we elected to search. We used two different but complementary strategies to identify potentially relevant papers. Two authors independently searched Ovid MEDLINE 2011 and 2012 using the limit of 'Randomised Controlled Trial' for each journal to identify potentially relevant papers and we retrieved the full text if necessary. One of us also hand searched all issues of journals online, and, for those with a search facility, searched for relevant papers using the term 'trial'. The scope of trials, the conditions and interventions studied, was also broadly similar across all three components of our scoping project further supporting the validity of our findings.

Our scoping review has identified a mismatch between NHMRC funding support for MSK trials in Australia and burden of disease attributable to arthritis and other MSK conditions. While the range of current Australian MSK trials likely reflects the interests and expertise of Australian MSK trialists, our review also suggests that not all Australian MSK trials reflect priorities based upon the greatest burden of disease, the most novel and/or promising interventions, and/or the greatest needs of the population. Many trials may be too small to be of value, many appear to be driven (either directly or indirectly) by commercial imperatives rather than genuine clinical novelty or patient-centred research priorities, and most are unlikely to have much effect on practice.

Identifying and addressing evidence-practice gaps has been identified as a major NHMRC priority (11), yet none of the Australian MSK trials we identified were concerned with interventions to improve uptake of research findings or guidelines into practice. This is in keeping with a previous study that found scarce high-quality intervention trials addressing nine evidence-practice gaps relating to other conditions, and no indication that this had improved over time (12). The NHMRC have now established a Research Translation Faculty to address the challenge of research translation in Australia (13). As part of this process, it has established steering groups to identify major evidence-practice gaps across major health areas including arthritis and musculoskeletal conditions. While the role of each steering group is to develop a single Case for Action that NHMRC could follow to address the most

significant gap, this process may also serve to identify priorities for MSK trials based upon population needs, to complement and enhance current investigator-initiated trials.

More investment to support the conduct of MSK trials in Australia is needed. This includes infrastructure funding in both the public and private sectors, more support for clinical researcher training and supervision and, importantly, greater buy-in from clinicians and patients. Many studies have identified suboptimal clinician buy-in for clinical research particularly those directed towards closing evidence-practice gaps (12, 14, 15). For example, Evenson et al reported that the median consent rate of physicians asked to participate in 28 well-designed studies addressing evidence-practice gaps that they did identify was only 60% (95% CI, 25% to 69%) (12); while a recent Australian study that assessed the appropriateness of healthcare delivery for 22 conditions commonly treated in primary care reported that 56% of healthcare providers refused access to their medical records (14). Further, a recent Australian cluster randomised controlled trial investigating the effect of a theory-informed implementation intervention to improve the management of acute low back pain in general practice reported that only 5% of GP practices and 2% of GPs approached to participate in the trial agreed to participate, while less than two thirds of those who did agree actually participated (15). The lack of clinician buy-in for clinical research directed specifically at improving care, suggests the need for a global culture shift towards clinician (and consumer) participation in research as a matter of course.

There is also an onus on MSK trialists to ensure that they ask the most important clinical questions but evidence suggests that this is not consistently the case. For example, Artus et al assessed the outcomes of each arm of 118 placebo and active controlled trials investigating a wide variety of treatments for acute low back pain (16). They found that the pattern of recovery was similar across all treatment groups regardless of treatment, indicating that specific treatment effects were irrelevant to recovery, and concluded that further trials investigating treatments for acute low back pain are unlikely to alter these conclusions. In discussing the mismatch between what clinical researchers do and what patients need in the area of oncology, Liberati has suggested that inclusion of patients and patient advocacy groups, who spend much time in raising awareness and money to support research hoping to promote improved care, should be at the centre of redefining the research agenda (17). The Arthritis Research UK clinical studies initiative has already taken a strategic approach to prioritisation of clinical study funding for MSK disorders (18). Consultations with consumer representatives and all relevant health care professionals and scientists have led to nationally agreed priorities for MSK clinical trials. It is time to replicate this approach in Australia to ensure that only worthwhile MSK trials are performed and funded.

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Appendix 1

NHMRC-funded MSK Project and Program Grants

Year of Funding Commencement	Title of Application	Chief Investigator A	Scheme	Administrating Institution	Trial Design‡	Funding Amount	Trial Registration Number	Trial Title	Trial Size	Co-funding?
2013	Pregabalin in addition to usual care for sciatica (PRECISE): a randomised, placebo-controlled trial	Doctor Chung-Wei Christine Lin	Project	University of Sydney	RCT-PB	$618,588.99	Not registered	Not registered	ND	ND
2013	A workplace-based exercise intervention to prevent and reduce the economic and personal burden of non-specific neck pain in the office personnel	Doctor Venerina Johnston	Project	University of Queensland	RCT-O	$660,834.43	ACTRN12612001154897	A workplace-based exercise intervention to prevent and reduce the economic and personal burden of non-specific neck pain in office personnel aged 18-65 years.	640	No
2013	Unloading shoes for knee osteoarthritis: a double-blind randomised controlled trial	Associate Professor Rana Hinman	Project	University of Melbourne	RCT-PB	$741,631.31	Not registered	Not registered	ND	ND
2013	A randomised trial of zoledronic acid for osteoarthritis of the knee	Professor Graeme Jones	Project	University of Tasmania	RCT	$954,596.66	Not registered	Not registered	ND	ND
2013	A new approach to prevent chronic low back pain	Doctor James McAuley	Project	University of New South Wales	RCT-PB	$509,536.07	ACTRN12612001180808	A randomised controlled trial to determine whether a novel psychoeducative intervention can prevent patients with recent onset low back pain from developing chronic low back pain	250	No
2013	Does statin use have a disease modifying effect in symptomatic knee osteoarthritis? A multicentre randomised, double-blind, placebo-controlled trial	Doctor Yuanyuan Wang	Project	Monash University	RCT-PB	$971,019.95	Not registered	Not registered	ND	ND
2013	Improving vitamin D status and health in young women	Associate Professor John Wark	Project	University of Melbourne	ND	$587,812.63	Not registered	Not registered	ND	ND
2013	Footwear for osteoarthritis of the big toe joint	Professor Hylton Menz	Project	La Trobe University	ND	$321,324.90	Not registered	Not registered	ND	ND

Year of Funding Commencement	Title of Application	Chief Investigator A	Scheme	Administrating Institution	Trial Design[5]	Funding Amount	Trial Registration Number	Trial Title	Trial Size	Co-funding?
2013	Comparative effectiveness of ultrasound-guided injection with either autologous platelet rich plasma or glucocorticoid for ultrasound-proven lateral epicondylitis: a three-arm randomised placebo-controlled trial	Professor Rachelle Buchbinder	Project	Monash University	RCT-PB	$501,115.05	Not registered	Not registered	ND	ND
2012	The Arthroplasty and Bariatric Surgery (ABS) study: a randomised controlled trial of laparoscopic adjustable gastric banding prior to total knee arthroplasty	Professor Peter Choong	Project	University of Melbourne	RCT-O	$643,670.00	ACTRN12611001178932	The Arthroplasty and Bariatric Surgery (ABS) study: a randomised controlled trial to determine the efficacy of laparoscopic adjustable gastric banding prior to total knee arthroplasty in obese patients with osteoarthritis	120	No
2012	Bisphosphonate Therapy with Zoledronate or tenofovir switching to improve low bone mineral density in HIV-infected adults: a strategic randomised trial	Professor Andrew Carr	Project	University of New South Wales	RCT-O	$687,807.50	ACTRN12612000776808	Bisphosphonate Therapy with Zoledronic acid or Tenofovir Switching to Improve Low Bone Mineral Density in HIV-Infected Adults: a Strategic, Randomised Trial	84	No
2012	Is hip fracture rehabilitation cost effective in residential care? A Randomised Controlled Trial of Hip Fractures	Professor Maria Crotty	Project	Flinders University	RCT-O	$522,041.25	ACTRN12612000112864	SACRED - Southern Adelaide Co-ordinated Regional Hip and Debility Rehabilitation Programme to Improve Quality of Life	236	No
2012	Is low dose amitriptyline more effective than placebo in the management of chronic, neuropathic low back pain? A double-blind, randomised, placebo-controlled trial with an economic evaluation	Dr Donna Urquhart	Project	Monash University	RCT-PB	$296,155.00	ACTRN12612000131853	Is low dose amitriptyline more effective than placebo in the management of chronic, neuropathic low back pain? A double-blind, randomised, placebo-controlled trial with an economic evaluation	150	No

Year of Funding Commencement	Title of Application	Chief Investigator A	Scheme	Administrating Institution	Trial Design[4]	Funding Amount	Trial Registration Number	Trial Title	Trial Size	Co-funding?
2012	A randomised controlled trial examining stability of new types of highly porous surfaced acetabular components in total hip replacement	Professor Donald Howie	Project	University of Adelaide	RCT-PB	$209,795.00	ACTRN12609000678291	The effect of a large 36 mm vs. standard 28 mm articulation in a total hip prosthesis on the incidence of dislocation one year following total hip replacement	650	Yes
2012	Does teriparatide reverse osteonecrosis of the jaw in patients with cancer? A randomised, controlled trial	Prof Peter Ebeling	Project	University of Melbourne	RCT	$346,175.00	ACTRN12612000950864	Does teriparatide reverse osteonecrosis of the jaw in patients treated with either bisphosphonates or denosumab? A randomised, controlled trial.	68	No
2012	Long-term effects of very low energy diet versus conventional diet on adiposity, lean body mass, muscle strength and bone density in obese adults, and mechanisms promoting changes	Associate Professor Amanda Sainsbury-Salis	Project	University of Sydney	ND	$890,900.00	ACTRN12612000651886	Long-term effects of very low energy diet versus conventional diet on adiposity, lean body mass, muscle strength and bone density in obese adults (postmenopausal women), and mechanisms promoting changes	100	No
2012	How are periodontal disease and rheumatoid arthritis inter-related?	Professor Mark Bartold	Project	University of Adelaide	RCT-O	$544,262.50	ACTRN12612000446864	In individuals with both periodontal disease and rheumatoid arthritis does periodontal treatment influence clinical features of rheumatoid arthritis compared with no periodontal treatment?	90	No
2011	Train High Eat Low for Osteoarthritis (THE LO Study): a randomised controlled trial	Professor Maria Fiatarone Singh	Project	University of Sydney	RCT-O	$572,733.80	ACTRN12612000501842	A randomised controlled trial of the effects of progressive resistance training, high protein/low glycaemic index diet and gait re-training on knee adductor moment in	125	No

Year of Funding Commencement	Title of Application	Chief Investigator A	Scheme	Administrating Institution	Trial Design‡	Funding Amount	Trial Registration Number	Trial Title	Trial Size	Co-funding?
								overweight/obese adults with medial knee osteoarthritis.		
2011	Improving patient outcome following arthroscopic autologous chondrocyte implantation	Dr Jay Ebert	Project	University of Western Australia	RCT-PB	$333,989.00	ACTRN12609000756224	Improving Clinical and Radiological Outcomes Following Autologous Chondrocyte Implantation: Accelerated versus Conservative Rehabilitation	70	Yes
2011*	Musculoskeletal pain, injury and health: improving outcomes through conservative management	Professor Paul Hodges	Pro-gram	University of Queensland	ND	$7,570,000 over 5 years	ACTRN12612001126808	To compare the short and long term effectiveness of a specific physiotherapy programme and corticosteroid injection in the management of people with gluteal muscle tendinopathy.	210	No
2010	A randomised controlled trial to evaluate the effectiveness of zoledronate therapy in osteonecrosis of the hip	Professor Philip Sambrook	Project	University of Sydney	RCT-PB	$511,425.00	ACTRN12609000104257	A randomised controlled trial to evaluate the effectiveness of zoledronate therapy in osteonecrosis of the hip	120	Yes
2010	Does vitamin D supplementation prevent progression of knee osteoarthritis? A randomised controlled trial	Dr Chang-Hai Ding	Project	Menzies Research Institute	RCT-PB	$980,188.00	ACTRN12610000495022	Effects of vitamin D supplementation on knee pain, knee structural change, and lower limb muscle strength in patients with symptomatic knee osteoarthritis: A randomised, double-blind, placebo-controlled trial	400	No
2010	Is physiotherapy beneficial for people with hip osteoarthritis?	Professor Kim Bennell	Project	University of Melbourne	RCT-PB	$607,488.00	ACTRN12610000439044	The effects of a physiotherapy program on pain and physical function in individuals with hip joint osteoarthritis: a randomised, double-	128	No

Year of Funding Commencement	Title of Application	Chief Investigator A	Scheme	Administrating Institution	Trial Design[4]	Funding Amount	Trial Registration Number	Trial Title	Trial Size	Co-funding?
								blind, placebo-controlled trial.		
2010	Neuromuscular exercise : a novel treatment to reduce symptoms and joint load in medial knee osteoarthritis	Professor Kim Bennell	Project	University of Melbourne	RCT-O	$694,288.00	ACTRN12610000660088	The effect of neuromuscular exercise on pain, physical function and dynamic knee loading in people with knee osteoarthritis	100	No
2010	Bisphosphonate Treatment of Childhood Femoral Head Avascular Necrosis due to Perthes Disease	Associate Professor Christopher Cowell	Project	University of Sydney	RCT-PB	$1,305,625.00	ACTRN12610000407099	A study to assess the safety and efficacy of bisphosphonate treatment in childhood femoral avascular necrosis due to Perthes Disease compared to the standard orthopaedic treatment and care	140	Yes
2010	Clinical trial of rehabilitation after ankle fracture	Dr Anne Moseley	Project	University of Sydney	RCT-O	$427,500.00	ACTRN12610000979055	In patients after immobilisation for ankle fracture, is a rehabilitation program consisting of exercises prescribed by physiotherapists more effective than a single session of advice in reducing activity limitation and improving quality-adjusted life years?	342	No
2009	The first placebo-controlled trial of paracetamol for back pain	Associate Professor Jane Latimer	Project	University of Sydney	RCT-PB	$602,625.00	ACTRN12609000966291	In patients with acute low back pain is time contingent paracetamol, or pro re nata (PRN) paracetamol, more effective than placebo in speeding recovery from a new episode of low back pain?	1650	Yes
2009	A promising new treatment for chronic whiplash	Professor Chris G Maher	Project	University of Sydney	RCT-O	$598,025.00	ACTRN12609000825257	A randomised clinical trial on the effect of a comprehensive exercise program on	172	Yes

Year of Funding Commencement	Title of Application	Chief Investigator A	Scheme	Administrating Institution	Trial Design[♮]	Funding Amount	Trial Registration Number	Trial Title	Trial Size	Co-funding?
								average weekly pain intensity in chronic whiplash		
2009	Dry-needling, advice and graded exercise for chronic whiplash	Dr Michele Sterling	Project	University of Queensland	RCT-PB	$297,875.00	ACTRN12609000470291	In people with chronic whiplash is combined dry-needling, advice and exercise more effective than combined sham dry-needling, advice and exercise on pain and disability levels	120	No
2009	Laser acupuncture in patients with chronic knee pain:	Associate Professor Paul R McCrory	Project	University of Melbourne	RCT-PB	$673,275.00	ACTRN12609001001280	The effect of acupuncture on pain and physical function in patients with chronic knee pain: a randomised placebo-controlled trial.	280	No

[♮]Trial Design abbreviations: RCT-PB - Randomised controlled trial – participant-blinded; RCT-O - randomised controlled trial - open; ND - not determined.

*denotes NHMRC-funded program grant

Appendix 2

ANZCTR Registered MSK Trials

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
ACTRN12612001291875	13/12/2012	R	In individuals with hamstring tightness and varus and/or flexion deformity undergoing total knee arthroplasty how does additional preoperative and postoperative hamstring stretching compared with standard postoperative physical therapy effect knee range of motion, knee extension angle, fixed flexion deformity, gait mechanics and patient outcomes.	Knee osteoarthritis	RCT-O	Extensive rehabilitation	Standard rehabilitation	Knee extension angle	60	Townsville Hospital Private Practice Research Trust; Orthopaedic Research Institute of Queensland	Orthopaedic Research Institute of Queensland; Dr Peter McEwen	James Cook University	Orthopaedic Research Institute of Queensland	OTR
*ACTRN12612001275853	10/12/2012	P	In adults undergoing a surgical procedure in abdominal, orthopaedic, cardiothoracic, vascular or obstetric surgery is topical negative pressure more effective than standard dressing protocol in the prevention of wound complications?	Abdominal, orthopaedic, cardiothoracic, vascular or obstetric surgery	RCT-O	Topical negative pressure dressing	Standard dressing	Surgical wound dehiscence	1500	Curtin University, WA	Curtin University, WA	Nil	Curtin University, WA	NYR
ACTRN12612001256864	29/11/2012	R	A randomised trial to investigate the effectiveness of exercises targeted at the hip in improving non-specific low back pain	Low back pain	RCT-O	Hip strengthen-ing; Hip stretching	Hip rotation only	Numerical rating scale for pain	30	Self-funded/ Unfunded	Sara Winter, QLD	University of Bath, UK	Sara Winter, QLD	C

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
ACTRN12612001238864	23/11/2012	R	Can splinting and early mobilisation in the dart-throwers plane of motion improve functional outcomes and reduce postoperative complications in people after scapho-lunate ligament repairs? (Pilot Study)	Scapho-lunate ligament injury	RCT-O	Splint which allows wrist motion in the Dart Throwing Plane	Static splint	Pain	20	The Alfred Small Project Grants	The Alfred Hospital, VIC	Nil	The Alfred Hospital, VIC	OTR
ACTRN12612001234808	22/11/2012	R	Assessing the effects of a 12 week program of splinting and activity modification on self-assessed wrist and hand pain in people with ulnar sided wrist pain as result of ulno-carpal abutment	Wrist pain	SCT	Custom-made Ulnar gutter splint	Uncontrolled	Patient Rated Wrist and Hand evaluation	20	Alfred Research Trusts	The Alfred Hospital, VIC	Nil	The Alfred Hospital, VIC	OTR
ACTRN12612001180808	6/11/2012	P	A randomised controlled trial to determine whether a novel psychoeducative intervention can prevent patients with recent onset low back pain from developing chronic low back pain	Low back pain	RCT-PB	Novel psycho-therapeutic intervention	Sham psycho-therapeutic intervention	Incidence proportion of having chronic low back pain	250	NHMRC project grant	NHMRC	Nil	Neuroscience Research Australia (NeuRA), NSW	NYR
ACTRN12612001154897	31/10/2012	P	A workplace-based exercise intervention to prevent and reduce the economic and personal burden of non-specific neck pain in office personnel aged 18-65 years.	Non-specific neck pain	RCT-PB	Individual-ised best practice ergonomic intervention + progressive exercise	Individual-ised best practice ergonomic intervention	Product-ivity loss	640	NHMRC project grant	The University of Queensland QLD; NHMRC	Nil	The University of Queensland, QLD	NYR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
ACTRN12612001156875	31/10/2012	P	In patients booked for joint replacement, is a pre-operative self-efficacy education on pain and anxiety management more effective than no education in reducing post-operative pain and anxiety?	Joint replacement pain and anxiety management	RCT-O	Self-efficacy based education DVD	No DVD	Feasibility of launching a full-scale multi-site efficacy trial	100	Griffith Health Institute, QLD	Griffith University QLD; Queen Elisabeth II Hospital QLD; Robina Hospital QLD	Nil	Griffith University, QLD	NYR
ACTRN12612001155886	31/10/2012	P	Investigating the role of transcranial direct current stimulation for pain relief in fibromyalgia and myalgic encephalomyelitis/chronic fatigue syndrome patients - Deakin University	Fibromyalgia and myalgic encephalo-myelitis	RCT-PB	Transcranial direct current stimulation	Placebo	Pain	32	Deakin University, VIC	Deakin University, VIC	Nil	Deakin University, VIC	NYR
ACTRN12612001132831	24/10/2012	P	In patients over 50 years old attending general practices, do automated opportunistic reminders issued to patients on arrival for consultations increase performance of indicated osteoporosis related care, compared to usual care?	Osteoporosis	RCT-O	Sheets with bone health related education	Care that the general practice usually provides to its patients	Proport-ions of patients who receive selected indicated osteoporosis-related services	10	RACGP Foundation	University of Adelaide, SA	Nil	University of Adelaide, SA	NYR
ACTRN12612001126808	22/10/2012	P	To compare the short and long term effectiveness of a specific physiotherapy programme and corticosteroid injection in the management of people with gluteal muscle tendinopathy.	Gluteal tendinopathy	RCT-O	Physio-therapy Exercise; Steroid injection	Usual Care	Pain (visual analogue pain scores)	210	NHMRC program grant	University of Queensland, QLD	University of Melbourne, VIC	University of Queensland, QLD	NYR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
(A) ACTRN1261200111582 0	18/10/2012	R	A Prospective, Single-arm, Uncontrolled, Multi-centre Study to Evaluate the Safety and Efficacy of the DePuy AVN Cage Prosthesis for the Treatment of Avascular Necrosis of the Hip.	Hip replacement	SCT	AVN Cage Prosthesis	Uncontrolled	Lack of disease progress-ion	77	DePuy International Ltd, UK	DePuy International Ltd, UK; Johnson& Johnson Medical Pty. Ltd. NSW	Nil	DePuy International UK	OTR
ACTRN1261200101088 6	19/09/2012	P	The effect of a targeted brace on biomechanics, pain and function in people with post-traumatic knee osteoarthritis after knee reconstruction	Post-traumatic knee osteoarthritis	RCT-PB	Donjoy unloader knee brace; anterior-posterior support without frontal plane adjustment (unadjusted)	No-treatment	Bio-mechanics	40	The University of Melbourne, VIC	DJO Australasia Pty Ltd	Nil	University of Queensland, QLD	NYR
ACTRN1261200099389 7	17/09/2012	P	Randomised clinical trial to evaluate the effect of prolotherapy (Prt) injections and physiotherapy consisting of Mulligan's MWM and exercise (P/E) used singly and in combination, on pain and function in patients with lateral epicondylalgia (Tennis Elbow).	Lateral epicondylalgia (Tennis Elbow)	RCT-O	Prolotherapy injection	Physio-therapy and Therapeutic Exercise	Assess-ment of pain and functional disability	120	Hacket Hemwall Foundation, USA; Australian Association of Musculo-skeletal Medicine; Australasian Faculty of Musculo-skeletal Medicine (Australian Division)	Griffith University	Nil	Griffith University, QLD	NYR
ACTRN1261200097787 5	11/09/2012	P	Multi-country, cross sectional study to determine patient specific and general beliefs towards medication and their treatment compliance to selected systemic therapies in chronic inflammatory	Rheumatoid Arthritis; Psoriatic Arthritis; Ankylosing Spondylitis	SCT	Question-naire	Uncontrolled	Describe patients' beliefs and risk concerns	330	AbbVie Pty Ltd, NSW	AbbVie Pty Ltd, NSW	Nil	AbbVie Pty Ltd, NSW	OTR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
			diseases (IMID)											
ACTRN1261200096986 4	10/09/2012	R	Clinical and radiological outcomes of stainless steel versus titanium volar multi-axial locking plates for fixation of distal radius fractures in adults	Distal radius fractures	RCT-PB	Titanium volar locking plate	Stainless Steel volar locking plate	Function (Patient Rated Wrist Evaluat-ion)	130	Queen Elizabeth II Hospital, QLD	Queensland Health, QLD	Nil	Queen Elizabeth II Hospital, QLD	OTR
ACTRN1261200095086 4	5/09/2012	P	Does teriparatide reverse osteonecrosis of the jaw in patients treated with either bisphosphonates or denosumab? A randomised, controlled trial.	Osteonecrosis of the jaw	RCT-PB	Calcium + vitamin D + teriparatide injections	Calcium + vitamin D + placebo injections	Clinical staging of osteo-necrosis of the jaw	68	NHMRC project grant	University of Melbourne, VIC; Western Health, VIC; Peter MacCallum Cancer Centre, VIC	Nil	University of Melbourne, VIC	NYR
ACTRN1261200090289 7	24/08/2012	P	A randomised controlled trial investigating the effect of duration of immobilisation on function and pain following open reduction and internal fixation (ORIF) for adult distal radius fractures managed with a locked volar plate	Distal radius fractures	RCT-O	Immobilisa-tion periods of one and three weeks	Immobilisa-tion period of six weeks	Mean score on Patient Rated Wrist Evaluation	135	Western Health, VIC	Western Health, VIC; Monash University, VIC	Monash University, VIC	Western Health Physio-therapy Department Footscray Hospital, VIC	OTR
ACTRN1261200087283 1	17/08/2012	P	Efficacy of low-pressure knee arthroscopy on pain, bone marrow oedema and function in patients with osteoarthritis, 6-weeks post procedure: A prospective single-blinded randomised control trial	Knee arthroscopy	RCT-PB	Knee arthroscopy under low pressure (30mmHg)	Standard pressure (80mmHg)	Knee pain	50	James Cook University, QLD	James Cook University, QLD	Nil	James Cook University, QLD	NYR

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ACTRN12612000873820	17/08/2012	R	To evaluate the efficacy of the anterior approach for blind intra-articular hip injections in patients undergoing hip arthroscopy due to Femoroacetabular Impingement (FAI)	Femoro-acetabular impingement	SCT	19G spinal needle + air arthrogram	Uncontrolled	Validation of the anterior hip injection technique	40	Self funded/ Unfunded	Melbourne Orthopaedic Group, VIC	Nil	Melbourne Orthopaedic Group, VIC	C
ACTRN12612000795897	27/07/2012	P	A randomised controlled trial comparing the effectiveness of intranasal ketamine and fentanyl in the relief of moderate to severe pain in children with limb injuries.	Limb injuries	RTC-PB	Ketamine + ibuprofen	Ibuprofen	Mean reduction in pain scores	80	Jack Brockhoff Foundation, Australia	Southern Health, VIC; Monash University, VIC	Nil	Medicine Monash Medical Centre, VIC	NYR
ACTRN12612000791831	25/07/2012	P	Effect of Adalimumab (Humira) on hand pain in erosive hand osteoarthritis	Hand osteoarthritis	RCT-PB	Adalimumab	Placebo	Visual analogue pain scores	40	Abbott Australasia Pty Ltd	University of Tasmania	Optimus Research, NSW	Menzies Research Institute, University of Tasmania, TAS	NYR
ACTRN12612000780853	24/07/2012	P	Randomised Controlled Non-inferiority Trial Of Minimally Invasive Versus Standard Open Decompression For Degenerative Lumbar Canal Stenosis, comparing functional outcomes, pain scores, and complications in both procedures.	Degenerative lumbar canal stenosis	RTC-PB	Minimally invasive decom-pressive laminectomy	Standard decom-pressive laminectomy	Oswestry disability index	30	Self funded/ Unfunded	Mater Misericord-iae Private Hospital, QLD		Mater Misericord-iae Private Hospital, QLD	NYR
ACTRN12612000776808	23/07/2012	P	Bisphosphonate Therapy with Zoledronic acid or Tenofovir Switching to Improve Low Bone Mineral Density in HIV-Infected Adults: a Strategic, Randomised Trial	Low bone mineral density in HIV patients	RCT-O	Zoledronic acid	Switch from tenofovir to another potent anti-viral drug	lumbar spine bone mineral density	84	NHMRC project grant	St Vincent's Hospital VIC	Alfred Hospital, VIC; University of Melbourne, VIC; St Vincent's Clinic Nuclear Medicine	St Vincent's Hospital, NSW	NYR

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												NSW		
ACTRN12612000774820	20/07/2012	P	A Phase IIa, Randomised, Double-Blind, Placebo-Controlled, Parallel-Group, Multicentre, Worldwide, Proof-of-Concept Clinical Trial to Evaluate the Safety, Tolerability, and Efficacy of MK-8457 in Subjects with Active Rheumatoid Arthritis and an Inadequate Response or Intolerance to Anti-TNF-alpha Therapy	Rheumatoid arthritis	RCT-PB	Metho-trexate + MK-8457	Metho-trexate + Placebo	ACR20 response	178	MSD - Merck Sharp & Dohme (Australia) Pty Limited, NSW	MSD - Merck Sharp & Dohme (Australia) Pty Limited, NSW	Nil	MSD - Merck Sharp & Dohme (Australia) Pty Limited, NSW	NYR
ACTRN12612000691842	27/06/2012	R	Dynamic changes in clot formation using Thromboelastometry after reinfusion of unwashed cell salvaged whole blood in total hip arthroplasty	Total hip arthroplasty	SCT	Reinfusion of cell-salvaged whole blood	Uncontrolled	Standard coagulat-ion test	25	Astra Tech AB, Sweden; BloodSafe, SA; HaemoVIEW Diagnostics Pty Ltd, QLD	Astra Tech AB, Sweden; BloodSafe, SA; HaemoVIEW Diagnostics Pty Ltd, QLD	Nil	Lyell McEwin Hospital, SA	OTR
ACTRN12612000677808	25/06/2012	P	Interactive virtual reality training with sensorimotor and kinematic exercises versus sensorimotor and kinematic exercise only, in management of patients with chronic neck pain- Evaluation of the effect on pain, disability, psychological factors, sensorimotor performance and cervical kinematics.	Chronic neck pain	RCT-O	Sensorimotor and kinematic exercises +interactive virtual reality exercises	Sensorimotor and kinematic exercises	Disability (neck disability index)	60	University of Haifa, Israel	University of Queensland, QLD	University of Haifa, Israel	University OF Queensland, QLD	OTR
ACTRN12612000595819	1/06/2012	R	Effects of limited physiotherapy booster sessions on pain and function	Knee osteoarthritis	RCT-O	Home exercises + two physio-therapy	Home exercises	Overall knee pain	60	NHMRC program grant	University of Melbourne, VIC	Nil	University of Melbourne, VIC	OTR

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			outcomes with home exercise in people with knee osteoarthritis			booster sessions								
ACTRN12612000592842	1/06/2012	P	Effects of vitamin D supplementation on muscle function and neural activity in older women with insufficient serum 25-hydroxyvitamin D levels: A pilot study.	Vitamin D deficiency	RCT-PB	Vitamin D	Placebo	Neural excitability and inhibition	30	Deakin University, VIC	Deakin University, VIC	Nil	Deakin University, VIC	NYR
ACTRN12612000550808	24/05/2012	P	Pilot study of negative pressure wound dressing therapy versus standard care dressing to prevent surgical site infection in patient undergoing hip arthroplasty	Wounds complications in hip arthroplasty	RTC	Negative pressure wound therapy	Standard dressing	Presence of surgical site infection	80	National Health and Medical Research Council Centre of Research Excellence in Nursing Interventions for Hospitalised Patients (NCREN)	National Health and Medical Research Council Centre of Research Excellence in Nursing Interventions for Hospitalised Patients (NCREN)	Nil	Griffith University, QLD	NYR
ACTRN12612000542897	22/05/2012	P	The effect of neuromuscular training post-arthroscopic partial meniscectomy on medial knee joint loading: a randomised, controlled trial.	Arthroscopic partial medial meniscectomy	RCT-O	Neuro-muscular training program	No exercise training	Medial knee joint loading	62	NHMRC program grant	The University of Melbourne, VIC	Nil	The University of Melbourne, VIC	OTR
ACTRN12612000539831	22/05/2012	R	The use of cerebral oximetry to reduce the incidence of peri-operative morbidity and mortality in elderly patients undergoing lower limb arthroplasty or bowel resection.	Lower limb arthroplasty	RCT-PB	Intra-operative cerebral oximetry	Placebo	Incidence of any complication in first five days following surgery	40	Austin Health, VIC	Austin Health, VIC	Nil	Austin Health, VIC	C:FUComp

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ACTRN12612000540819	22/05/2012	P	Effect of therapeutic glucocorticoids on insulin sensitivity, cardiovascular risk and energy metabolism in patients with inflammatory arthritis	Inflammatory arthritis	SCT	Oral low dose prednisolone	Uncontrolled	Change in post-prandial reduction in Augment-ation index	36	Foundation Daw Park, SA; Diabetes Australia Research Trust, ACT	Southern Adelaide Diabetes and Endocrine Services Repatriation General Hospital, SA	Nil	Southern Adelaide Diabetes and Endocrine Services Repatriation General Hospital, SA	NYR
ACTRN12612000532808	21/05/2012	P	A non-inferiority RCT comparing clinician decision making and patient reported outcomes when an experienced physiotherapist or an orthopaedic surgeon prescribes and administers corticosteroid injections for orthopaedic shoulder pain	Shoulder pain	RCT-O	Usual care + cortico-steroid + local anaesthetic	Usual care	Shoulder pain and disability	64	Allied Health Workforce & Coordination Unit, Australia	Gold Coast Health Service District, QLD; Gold Coast Health Service District, QLD	Griffith University, QLD	Gold Coast Health Service District, QLD	NYR
ACTRN12611000517976	18/05/2012	R	A Pilot Trial Assessing the Safety and Efficacy of GlycOmegaTM PLUS [Green-Lipped Mussel Powder] for Osteoarthritis of the Knee	Knee OA	SCT	New Zealand Green-Lipped Mussel extract	Uncontrolled	Lequesne Index; Western Ontario and McMaster Universit-ies (WOMAC); Gastro-intestinal Symptom Rating Scale (GSRS)	20	Aroma New Zealand Ltd, NZ	Good Health Australia Pty Ltd, NSW; The University of Queensland, QLD	Nil	Princess Alexandra Hospital, QLD	C
ACTRN12612000520831	16/05/2012	P	Intramedullary Nail Versus Sliding Hip Screw Inter-Trochanteric Evaluation (INSITE): A multi-centre randomised controlled trial to assess the impact of	Hip fractures	RCT-PB	Intramed-ullary nail	Sliding hip screw	Health-related Quality of Life	736	Stryker Australia Pty Ltd, NSW	Stryker Australia Pty Ltd, NSW	Nil	Stryker Australia Pty Ltd, NSW	NYR

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			intramedullary nails versus sliding hip screws on health-related quality of life in patients with intertrochanteric fractures of the hip											
ACTRN12612000501842	9/05/2012	R	A randomised controlled trial of the effects of progressive resistance training, high protein/low glycaemic index diet and gait re-training on knee adductor moment in overweight/obese adults with medial knee osteoarthritis.	Knee osteoarthritis	RCT-O	Gait re-training; high protein low GI diet; progressive resistance training; combination	Usual care	Change in knee adductor moment	125	NHMRC project grant	University of Sydney, NSW; Concord Repatriation General Hospital, NSW	Nil	University of Sydney, NSW	OTR
ACTRN12612000488866	2/05/2012	P	The effect of three different types of external immobilisation methods comparing pain during application and functional outcome for children with undisplaced supracondylar humeral fractures.	Acute isolated Gartland Type 1 supracondylar humeral fracture confirmed on x-ray	RCT-O	Collar and cuff sling under clothing with elbow flexion at 90 degrees; posterior plaster of Paris backslab and collar and cuff sling over clothing with elbow flexion at 50 degrees for supra-condylar humeral fracture	Collar and cuff sling under clothing with elbow flexion at 120 degrees	Pain (faces pain scale-revised and the face, legs, activity, cry, consol-ability pain scale)	180	Princess Margaret Hospital for Children, WA	Princess Margaret Hospital for Children, WA	Nil	Princess Margaret Hospital for Children, WA	NYR

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ACTRN12612000463875	26/04/2012	P	To evaluate the clinical efficacy of in-shoe orthotic devices and flip-flops in the management of heel pain	Heel pain	RCT-O	Contoured flip-flops; contoured in-shoe orthoses	Flat flip-flops	Global rating of change scale	150	NHMRC program grant; Vasyli International USA	University of Queensland, QLD; Regis University USA; University of Colorado USA	Nil	University OF Queensland, QLD	NYR
ACTRN12612000446864	19/04/2012	P	In individuals with both periodontal disease and rheumatoid arthritis does periodontal treatment influence clinical features of rheumatoid arthritis compared with no periodontal treatment?	Periodontal disease and Rheumatoid arthritis	RCT-O	Conventional periodontal examination, treatment and follow-up	No examination, treatment or follow-up	Change in Disease Activity Score	90	National Health & Medical Research Council of Australia	University of Adelaide, SA	Royal Adelaide Hospital, SA	University of Adelaide, SA	NYR
ACTRN12612000442808	18/04/2012	P	Modified conservative management with external rotation bracing versus early arthroscopic surgical intervention amongst 16 to 30 year olds with primary anterior shoulder dislocation: a randomised controlled trial to compare shoulder stability, clinical efficacy and quality of life	Anterior shoulder dislocations	RCT-O	External rotation brace	Arthroscopic stabilisation surgery	Shoulder instability index	50	Princess Alexandra Hospital, QLD	Princess Alexandra Hospital, QLD; Queen Elizabeth II Hospital, QLD	Nil	Princess Alexandra Hospital, QLD	NYR
ACTRN12612000426886	16/04/2012	P	A randomised controlled trial of Strain-Counterstrain treatment for people with neck pain selected using a treatment based classification system with the Neck Disability Index as primary outcome measure	Non-specific acute neck pain	RCT-PB	Passive positioning of the participant	Sham positioning	Neck disability index	85	Self funded/ Unfunded	Stanthorpe Health Service, QLD	Professor Michele Sterling RBWH, QLD	Stanthorpe Health Services, QLD	OTR

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ACTRN12612000401853	10/04/2012	R	Does the addition of hyaluronidase to ultrasound-guided fascia iliaca compartment block improve the time to onset and extent of anaesthesia in patients undergoing unilateral knee arthroplasty?	Knee osteoarthritis	RCT-PB	Hyaluron-idase powder	No hyaluron-idase powder	Anaesth-esia	180	Department of Anaesthesia, Royal Prince Alfred Hospital, NSW; Australian and New Zealand College of Anaesthetists	Department of Anaesthesia, Royal Prince Alfred Hospital, NSW	Nil	Department of Anaesthesia, Royal Prince Alfred Hospital, NSW	NYR
ACTRN12612000383864	4/04/2012	P	Patients with gluteal tendinopathy who undergo autologous tenocyte implantation will have improved clinical and radiological outcomes at 3,6,12 and 24 months post injection	Gluteal tendinopathy	SCT	Autologous tenocyte implantation	Uncontrolled	Pain (visual analogue pain scores)	20	Orthocell Australia	Orthocell Australia	Nil	Perth Orthopaedic and Sports Medicine Centre, WA	NYR
ACTRN12612000374864	2/04/2012	P	For young male jockeys, will 6-month calcium and vitamin D supplementation compared to a placebo increase tibial and radial bone strength and density	Low bone density	RCT-PB	Calcium + vitamin D	Placebo	Strength strain index	60	Australian Catholic University, NSW	Australian Catholic University, NSW	Nil	Australian Catholic University, NSW	NYR
ACTRN12612000366853	29/03/2012	P	The effect of full versus partial immobilisation on functional outcomes and redislocation rates in individuals with acute first time patella dislocations	Patella dislocation	RCT-O	Partial immobilis-ation	Full immobilis-ation	Pain and functional outcomes	60	Self funded/ Unfunded	Southern Health, VIC; Monash University, VIC	Nil	Monash University, VIC	NYR
ACTRN12612000354886	28/03/2012	P	In patients presenting to the emergency department with acute non-traumatic neck pain, does benztropine compared to placebo relieve pain	Acute non-traumatic neck pain	RTC-PB	Benztropine	Saline	Pain (visual analogue pain scores)	30	Self funded/ Unfunded	St George Hospital, NSW	Nil	St George Hospital, NSW	NYR

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ACTRN12612000343808	26/03/2012	P	A retrospective/ prospective study of patients who had undergone total knee arthroplasty during 2011 and 2012 with a specific pain protocol, analysing outcomes in the post operative period	Knee arthroplasty	SCT	Multi-modal analgesic pathway	Uncontrolled	Quad-riceps weakness and mobility	100	Self funded/ Unfunded	Cairns Base Hospital, QLD	Nil	Cairns Base Hospital, QLD	NYR
ACTRN12612000347864	26/03/2012	P	Randomised placebo controlled cross-over trial of airway humidification, in patients with pSS(Primary Sjogrens Syndrome) and to study its effect on sleep architecture	Sjogrens Syndrome	RCT-O	High intensity humidifier machine(AIRVO)	Look alike machine	Improvement in apnoea-hypopnea index	20	Adelaide Institute for Sleep Health, Repatriation General Hospital, SA	Adelaide Institute for Sleep Health, Repatriation General Hospital, SA	Nil	Adelaide Institute for Sleep Health, Repatriation General Hospital, SA	NYR
ACTRN12612000340831	23/03/2012	P	A randomised controlled trial of Ivabradine and Atorvastatin in emergent orthopaedic lower limb surgery for neck of femur fracture in elderly patients: a mechanistic study of peri-operative myocardial injury and its prevention using computed tomography coronary plaque imaging and novel biomarkers of cardiovascular stress and lipid metabolism	Neck of femur fracture	RCT-O	Atorvastatin, Ivabradine	No treatment	New myocardial injury	200	Northern Hospital, VIC	Northern Hospital, VIC	Nil	Northern Hospital, VIC	NYR
ACTRN12612000322831	21/03/2012	P	Effectiveness of off-the-shelf footwear in reducing foot pain in Australian Department of Veterans' Affairs recipients not eligible for medical grade footwear: a	Foot pain	RCT-O	Low cost, off-the-shelf footwear	Usual treatment	Pain	120	Australian Department of Veterans' Affairs	La Trobe University, VIC; Australian Department of Veterans' Affairs	Nil	La Trobe University, VIC	NYR

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			randomised controlled trial											
ACTRN1261200030889 7	19/03/2012	P	The effect of telephone coaching in addition to physiotherapy compared with physiotherapy alone on pain and physical function for people with knee osteoarthritis	Knee osteoarthritis	RCT-O	Physical activity program + health coaching via telephone	Physical activity program	Pain	168	NHMRC program grant	The University of Melbourne, VIC	Nil	The University of Melbourne, VIC	NYR
(A) ACTRN1261200029881 9	15/03/2012	R	A phase 3, multicentre, open-label, extension study to assess the safety and tolerability of epratuzumab treatment in systemic lupus erythematosus subjects (EMBODY 4)	Systemic lupus erythematosus	SCT	Epratuzumab	Uncontrolled	Treatment response criteria	1400	UCB Inc, USA	UCB Inc, USA	Nil	UCB BioSciences, Inc, USA	OTR
ACTRN1261200027982 0	9/03/2012	P	Validation of a clinical questionnaire for the diagnosis of Plantar Fasciitis in patient with a painful condition affecting the foot and ankle	Plantar Fasciitis	SCT	Question-naire	Uncontrolled	Develop-ment of a validated, scored, self-administ-ered patient question-naire	150	Epworth Foundation - Foot and Ankle Research Fund, VIC	Epworth Foundation - Foot and Ankle Research Fund, VIC	Nil	Epworth Healthcare, VIC	NYR
ACTRN1261200026280 8	5/03/2012	P	For people with neck pain receiving manual therapy treatment, how does their segmental mobility alter in relation to improvements in active range of movement?	Neck Pain	SCT	Manual therapy treatment	Uncontrolled	Segmental cervical mobility	20	Self-funded/ Unfunded	Griffith University, QLD	University of Canberra, ACT	Griffith University, QLD	NYR

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ACTRN12612000260820	2/03/2012	P	Randomised controlled trial comparing ultrasound-guided to patient-guided extracorporeal shock wave therapy (ESWT) for calcific soft tissue pathologies (including tendinopathy) when assessing patient outcomes of decreased pain, improved function and reduced calcification size.	Painful calcified soft tissue pathologies including tendinopathy.	RCT-O	Ultrasound-guided shockwave treatment	Patient-guided shockwave treatment	Pain	120	DJO International Australia	The Sports Clinic at Sydney University, NSW	Dr Tim Driscoll (University of Sydney, NSW); Jessica Orchard (NSW Cancer Council)	The Sports Clinic at Sydney University, NSW	NYR
ACTRN12612000112864	24/01/2012	P	SACRED - Southern Adelaide Co-ordinated Regional Hip and Debility Rehabilitation Programme to Improve Quality of Life,	Hip replacement	RTC-O	Medical assessment; Review of medications and co-morbidities; physio-therapy	Standard care	Quality of life	236	NHMRC project grant	NHMRC; Flinders University, SA; University of Sydney, NSW	Nil	Flinders University, SA	NYR
ACTRN12612000082808	17/01/2012	P	The Effect of Whole-Body Vibration Treatment on Bone Metabolism in Prostate Cancer Survivors who are undergoing Androgen Suppression Therapy	Bone metabolism in prostate cancer undergoing Androgen therapy	RCT-O	Whole body vibration therapy	No treatment	Marker of bone formation - Serum Type 1 Pro-collagen N-terminal Pro-peptide	50	Australian Unity Foundation Heritage Fellowship	Edith Cowan University, WA; Dr. Carolyn Peddle-McIntyre (Edith Cowan University, WA)	Dr. Michael Baker (Edith Cowan University, WA); A/Prof Daniel Galvao (Edith Cowan University, WA)	Edith Cowan University, WA	NYR
ACTRN12612000080820	16/01/2012	P	To determine the efficacy of the use of multimedia patient education technology when obtaining informed consent in an orthopaedic foot and ankle practice	Foot and ankle surgery	SCT	Multimedia patient education module	Uncontrolled	Knowledge transfer and patient learning	500	Epworth Foundation - Foot and Ankle Research Fund, VIC	Epworth Foundation - Foot and Ankle Research Fund, VIC	Nil	Epworth Hospital, VIC	NYR

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ACTRN12612000648 8	12/01/2012	P	Radiostereometric assessment of the rotational stability of Collarless Polished Tapered (CPT) stems inserted for primary hip arthroplasty	Hip arthroplasty	SCT	CPT stem	Uncontrolled	Rotational movement of CPT stem	50	Fremantle Hospital, WA	Fremantle Hospital, WA	Nil	Fremantle Hospital, WA	NYR
ACTRN12612000148 53	4/01/2012	R	The effect of an evidence based bowel protocol on time taken to return to normal bowel function in post operative major joint replacement patients	Post operative constipation in major joint replacement patients	RCT-O	Polyethylene glycol with electrolytes (Movicol)	Usual care	Time taken (in days) to return to baseline bowel function	320	St John of God Health Care, VIC	St John of God Health Care, VIC	University of Notre Dame Australia, WA	St John of God Hospital, VIC	OTR
ACTRN12612000128 75	4/01/2012	P	A dose-finding study assessing the effectiveness of sub-dissociative doses of intranasal ketamine in the treatment of moderate to severe acute pain in the emergency department in children. Part One of a two-part study protocol.	Analgesic medication for MSK injuries	SCT	Intranasal ketamine	Uncontrolled	Visual Analog Scale pain	60	Monash Medical Centre, Clayton, VIC	Southern Health, VIC	Nil	Monash Medical Centre, Clayton, VIC	R
ACTRN12611001202954	23/11/2012	R	A comparison of arthroscopic synovial biopsy based targeted biologic therapy versus conventional therapy on the time to achieve remission in adults with rheumatoid arthritis (RA)	Rheumatoid arthritis	RCT-O	Biologic disease modifying anti-rheumatic drug (bDMARD)	Conventional DMARD therapy	Time to achieve remission	104	Self-funded/ Unfunded	Repatriation General Hospital, SA; Royal Adelaide Hospital, SA; Flinders Medical Centre, SA	Nil	Repatriation General Hospital, SA	OTR

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ACTRN1261100118397 6	15/11/2011	P	A randomised controlled trial on the effect of Physiotherapy and an external rotation brace on re-dislocation rate and shoulder function in patients aged 15-40 years with a first time anterior shoulder dislocation.	Primary anterior shoulder dislocation	RCT-O	Supervised physio-therapy program + pulsed ultrasound and massage	Supervised physio-therapy program	Re-dislocation	200	Gold Coast Hospital; Gold Coast Hospital Foundation and Griffith University Research Grant; Queensland Health - Health Practitioner Research Grant	Gold Coast Hospital, QLD	Nil	Gold Coast Hospital, QLD	NYR
ACTRN1261100118496 5	15/11/2011	P	Mindfulness, cognitive processes and coping in chronic illness: a randomised controlled trial to evaluate the effect of mindfulness training prior to total joint arthroplasty on post-operative pain and physical function	Total hip or knee replacement	RCT-O	Mindfulness training	Total hip or knee replacement alone	Pain and physical function	150	Australian Research Council	St. Vincent's Hospital, VIC; Swinburne University of Technology VIC	Nil	St. Vincent's Hospital, VIC	NYR
ACTRN1261100118397 6	15/11/2011	P	A randomised controlled trial on the effect of Physiotherapy and an external rotation brace on re-dislocation rate and shoulder function in patients aged 15-40 years with a first time anterior shoulder dislocation	Anterior shoulder dislocation	RCT-O	Nine physio-therapy sessions	Seven physio-therapy sessions	Re-dislocation	200	Gold Coast Hospital, QLD; Queensland Health, QLD	Gold Coast Hospital, QLD	Nil	Gold Coast Hospital, QLD	NYR

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ACTRN12611001178932	14/11/2011	P	The Arthroplasty and Bariatric Surgery (ABS) study: a randomised controlled trial to determine the efficacy of laparoscopic adjustable gastric banding prior to total knee arthroplasty in obese patients with osteoarthritis	Knee osteoarthritis	RCT-O	Laparoscopic adjustable gastric banding +total knee arthroplasty	Total knee arthroplasty	Death from any cause; peri or post-operative comp-lications; wound comp-lications; joint infections and unplanned pro-cedures and/or re-admissions	120	NHMRC project grant	St. Vincent's Hospital, VIC; Monash Medical School, VIC; Royal Melbourne Hospital, VIC	Nil	St. Vincent's Hospital, VIC	OTR
ACTRN12611001166965	8/11/2011	P	Comparison of dexamethasone route of administration on ankle block duration and analgesia for foot and ankle surgery	Foot or ankle surgery	RCT-PB	Dexa-methasone intravenously and saline added to the ropivacaine ankle block; dexa-methasone added into the ropivacaine ankle block and saline intravenously	No dexa-methasone	Duration before analgesic effect of block wears off	90	Burnside War Memorial Hospital, SA; The Memorial Hospital, WA	Flinders Medical School, SA	Nil	Flinders Medical School, SA	OTR
ACTRN12611001163998	8/11/2011	R	A pilot study of mindfulness based stress reduction in total joint arthroplasty patients	Joint arthroplasty	SCT	Mindfulness training	Uncontrolled	Pain and physical function	30	Self funded/ Unfunded	St Vincent's Hospital, VIC	Nil	St Vincent's Hospital, VIC	C
ACTRN12611001096943	21/10/2011	R	A prospective randomised study comparing functional outcomes in patients' weight bearing at two weeks versus six weeks following surgical fixation of ankle fracture.	Ankle fractures	RCT-O	Weight-bearing mobilising	Non weight-bearing mobilising	Ankle Score measures	50	Self funded/ Unfunded	Flinders Medical Centre, SA	Nil	Flinders Medical Centre, SA	OTR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
ACTRN1261100109496 5	20/10/2011	P	The Effect of Whole-Body Vibration Treatment on Bone Metabolism in Breast Cancer Survivors who are undergoing Aromatase Inhibitor Therapy	Bone metabolism in Breast cancer patients undergoing Aromatase Inhibitor Therapy	RCT-O	Whole body vibration therapy	No treatment	Marker of bone formation - Serum Type 1 Pro-collagen N-terminal Propeptide	50	Cancer Council Western Australia	Edith Cowan University ECU Health and Wellness Institute, WA	A/Prof Daniel Galvao and Prof Robert Newton (Edith Cowan University ECU Health and Wellness Institute, WA)	Edith Cowan University ECU Health and Wellness Institute, WA	OTR
(A) ACTRN1261100108299 8	19/10/2011	P	Study to determine if the addition of a collagen scaffold device will increase tendon thickness with comparable clinical outcomes over subacromial decompression and/or repair alone in patients with a supraspinatus tear.	Partial thickness or larger partial thickness or small full thickness Supraspinatus tendon tears	RCT-O	Addition of an implanted collagen scaffold	No collagen scaffold; standard subacromial de-compression and/or repair alone	Supra-spinatus tendon thickness	36	Rotation Medical, Inc. USA	Rotation Medical, Inc. USA	Nil	Rotation Medical, Inc. USA	OTR
ACTRN1261100104996 5	6/10/2011	P	The effectiveness of Bodyflow therapy post Total Knee Replacement surgery: post-operation hospitalisation duration and patient recovery.	Total knee replacement	RCT-PB	Low voltage electrical stimulation of muscles	Sham stimulation	Reduction of post-surgery hospital stay duration	72	Self funded/ Unfunded	Bodyflow International Pty Ltd	Sportsmed, SA	Sportsmed, SA	OTR
ACTRN1261100104699 8	5/10/2011	R	A Randomised Double Blind, Placebo Controlled Study Of The Efficacy And Safety Of Autologous Non-Expanded Adipose Derived Stem Cells In The Treatment Of Knee Osteoarthritis	Knee osteoarthritis	RCT-PB	Autologous adipose derived stem cells injection into the knee	Placebo	Change in ICOAP pain scale	40	Regeneus Pty Ltd, NSW	Regeneus Pty Ltd, NSW	Nil	Royal North Shore Hospital, NSW	C: FUCont
ACTRN1261100102097 6	22/09/2011	P	The Effect of a Single Dose Intravenous Dexamethasone Compared to Placebo on Visual Analogue Pain Scores in Patients with Low	Low back pain and lumbosacral radiculopathy	RCT-PB	Dexa-methasone	Placebo	Pain scores	100	Gold Coast Health Service District, QLD	Gold Coast Hospital, QLD	Gold Coast Hospital, QLD	Gold Coast Hospital, QLD	OTR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
			Back Pain and Radiculopathy Presenting to the Emergency Department											
ACTRN12611000971932	12/09/2011	R	A comparison of Mechanical Diagnosis & Therapy and Motor Control Exercises on the thickness of the trunk muscle in patients with chronic low back pain.	Chronic low back pain	RCT-O	McKenzie method exercises	Motor control exercises	Thickness of the trunk muscles	70	International MDT Research Foundation, USA	International MDT Research Foundation, USA	Nil	Concord Repatriation General Hospital, NSW	OTR
ACTRN12611000972921	12/09/2011	P	An Investigator-Initiated Phase 2, Single Centre, Double-Blind, Randomised, Controlled Trial of the Effect of Adalimumab Upon Endothelial Function in Patients with Early and Established Anti-CCP Antibody Positive Rheumatoid Arthritis.	Rheumatoid arthritis	RCT-PB	Adalimumab + usual care	Placebo + usual care	En-dothelial function	60	Abbott Pharm-aceuticals, USA	Royal Newcastle Centre, NSW	Royal Newcastle Centre, NSW; Georgetown Arthritis	Royal Newcastle Centre, NSW	NYR
ACTRN12611000954921	5/09/2011	P	A prospective, non-randomised Roentgen Stereo-photogrammetric Analysis study to determine the migration pattern of the Stryker Accolade II(R) Hip Stem in patients undergoing total hip arthroplasty	Hip osteoarthritis	SCT	radiopaue tantalum bead markers	Uncontrolled	Migration pattern	35	Stryker Australia, NSW	Stryker Australia, NSW	Nil	Stryker Australia, NSW	OTR
ACTRN12611000950965	5/09/2011	P	A randomised, double-blind, placebo controlled cohort study of the benefits of sufficient levels of vitamin D3 as defined by decreasing the number of fractures, acute illnesses and	Number of fractures, acute illnesses and exacerbation of chronic conditions	RCT-O	Vitamin D3	No treatment	Frequency of unplanned hospital and GP visits	250	Private Practice Fund Admin-istration, Canberra Hospital, ACT	ACT Government Health Directorate, Canberra Hospital, ACT	Nil	Canberra Hospital, ACT	NYR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
			exacerbation of chronic conditions, the need for hospitalisation as well as the mortality rate for permanent residents of residential care facilities											
(A) ACTRN1261100094097 6	1/09/2011	R	A Randomised, Controlled, Double-Blind Study of a Single Intra-Articular Injection of the less than 5,000 MW Fraction of Human Albumin 5% (Ampion-Trademark) in Adults with Osteoarthritis of the Knee for the Reduction of Pain	Knee osteoarthritis	RCT-PB	Ampion +lignocaine + beta-methasone; Ampion + beta-methasone	Placebo + lignocaine + beta-methasone	Reduction in pain	60	Ampio Pharma-ceuticals Inc. USA	Ampio Pharma-ceuticals Inc. USA; CPR Pharma Services SA	Nil	Ampio Pharma-ceuticals, Inc. USA	OTR
ACTRN1261100091199 8	25/08/2011	R	The effectiveness of additional interpreter sessions post total knee surgery on impairment, self management and quality of life in Greek speaking patients versus usual care: A pilot randomised controlled trial	Total knee replacement	RCT-O	Additional interpreter sessions	Usual care	Inter-national knee scores	44	St Vincent's Health Melbourne, VIC	St Vincent's Health Melbourne, VIC	Nil	St Vincent's Health Melbourne, VIC	OTR
ACTRN1261100089192 1	22/08/2011	P	A multicentre, randomised, double-blind phase II study of crystalline glucosamine sulphate versus placebo in the management of aromatase inhibitor induced arthralgia in post menopausal women with early breast cancer on letrozole	Letrozole induced Arthralgia in breast cancer patients	RCT-PB	Crystalline glucosamine sulphate	Placebo	Dis-continua-tion rate of letrozole	143	Australia and New Zealand Breast Cancer Trial Group, NSW	Australia and New Zealand Breast Cancer Trial Group, NSW	Nil	Australia and New Zealand Breast Cancer Trial Group, NSW	NYR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
ACTRN12611000798965	29/07/2011	P	Pharmacokinetics and measurement of drug levels of Enteric Coated Mycophenolic sodium in Lupus Nephritis Patients	Lupus Nephritis	SCT	Therapeutic drug monitoring(TDM) guided dosing of EC-MPS	Uncontrolled	Establish-ed targets of MPA exposure	32	Royal Brisbane Hospital Research Foundation, QLD; Novartis Pharma-ceuticals Australia, NSW	Royal Brisbane Hospital, QLD; Novartis Pharma-ceuticals Australia, NSW	Nil	Royal Brisbane Hospital, QLD	OTR
ACTRN12611000757910	20/07/2011	R	Does addition of visceral manipulation improve pain, disability and functional outcomes for low back pain patients, compared to standard physiotherapy management?	Low back pain	RCT-PB	Manipulation of the thoracic, abdominal and pelvic organs and their associated supportive ligaments, connective tissue and fascia	Sham manipulation	Low back pain intensity	64	Self funded/ Unfunded	University of Sydney, NSW	Nil	University of Sydney, NSW	OTR
ACTRN12611000748910	18/07/2011	R	Comparison of the efficacy of cortisone injection with cortisone injection plus hydrodilatation for treatment of stiff painful shoulders.	Stiff painful shoulder	RCT-PB	Cortisone injection + hydro-dilatation	Cortisone injection	Increased global pain free movement of the shoulder	80	Self funded/ Unfunded	Monash University, VIC; MIA Diagnostic Imaging, VIC; Melbourne Shoulder and Elbow Centre, VIC	Nil	Melbourne Shoulder and Elbow Centre, VIC	C:FUCont
ACTRN12611000743965	15/07/2011	R	Understanding the dose-response relationship of allopurinol in patients with gout.	Gout	SCT	Various dosages of Allopurinol	Uncontrolled	Plasma urate concentra-tions	30	NHMRC Safety Grant; Lexy Davies Bequest	St Vincent's Hospital, NSW	Nil	St Vincent's Hospital, NSW	C: FUComp
ACTRN12611000691943	7/07/2011	R	The effect of nerve and tendon gliding exercises on carpal tunnel pressure in patients with carpal tunnel syndrome	Carpal tunnel syndrome	RCT-O	Nerve and tendon gliding exercises	No treatment	Carpal tunnel pressure	30	NHMRC project grant	The University of Queensland, QLD	Nil	The University of Queensland, QLD	OTR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
ACTRN1261100069095 4	7/07/2011	R	The effect of nerve and tendon gliding exercises and splinting on median nerve oedema in patients with carpal tunnel syndrome	Carpal tunnel syndrome	RCT-O	Nerve and tendon gliding exercises	Splinting	Median nerve signal intensity	30	Queensland Health Practitioner Research Scheme; National Health and Medical Research Council	The University of Queensland, St Lucia, QLD	Nil	The University of Queensland, QLD	C:FUCont
ACTRN1261100069897 6	7/07/2011	P	Alignment in Total Knee Replacement: A Randomised Controlled Study Comparing Intramedullary Alignment Systems with Patient Specific Instrumentation	Total knee replacement	RCT-O	Patient matched Instru-mentation	Standard intra-medullary alignment systems	Overall alignment of the prosthesis	200	Smith & Nephew Pty Limited, Australia	Smith & Nephew Pty Limited, Australia	Nil	Hollywood Medical Centre, WA	NYR
ACTRN1261100069798 7	7/07/2012	P	For people waiting for hip and knee joint replacement surgery, does a pre-operative program of education, self-management and exercise provide benefit before joint replacement?	Hip and knee replacement	SCT	Pre-operative Education and Exercise program	Uncontrolled	Functional Independ-ence Measure mobility scale	40	Self funded/ Unfunded	Box Hill Hospital Physio-therapy Department, Box Hill, VIC	Nil	Box Hill Hospital Physio-therapy Department, Box Hill, VIC	NYR
ACTRN1261100068195 4	6/07/2011	R	Chiropractic manipulation for osteoarthritic hip pain for changes in pain, range of motion, quality of life, cost, and risk for falls in subjects with hip osteoarthritis	Hip OA	RCT-O	Adjustments to the entire kinetic chain (five areas)	Adjustments to one area	Western Ontario and McMaster Universit-ies Osteo-arthritis Index	60	Self funded/ Unfunded	Cronulla Chiropractic & Sports Injury Centre, NSW; Cleveland College of Chiropractic, USA	Nil	Cronulla Chiropractic & Sports Injury Centre, NSW	C
ACTRN1261100068096 5	5/07/2011	R	The rehabilitation of glenohumeral Range of Motion in Patients with Frozen Shoulder: A Comparison Between Conventional Therapy, Placebo and 'SCENAR' Electrical	Frozen Shoulder	RCT-PB	Electrical stimulation therapy	Placebo stimulation therapy	Shoulder range of motion	40	University of the Sunshine Coast, QLD	University of the Sunshine Coast, QLD	Nil	University of the Sunshine Coast, QLD	OTR

ACTRN	Registration Date	Registration Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
			Stimulation Therapy											
ACTRN12611000658910	28/06/2011	P	A Phase-I Randomised, Comparison Pilot Trial Evaluating the Efficacy of Nutraceutical Compounds in patients with Osteoarthritis of the Knee – Therapeutic Outcome Measures Correlated to Gastrointestinal Integrity	Knee osteoarthritis	RCT-O	Green-Lipped Mussel extract	Glucosamine sulphate	Faecal Microbial Analysis; Western Ontario and McMaster Universities Arthritis Index; Gastrointestinal Symptom Rating Score	40	Self funded/ Unfunded	The University of Queensland; Aroma NZ, NZ	Bio21 Molecular Science & Biotechnology Institute, VIC	Princess Alexandra Hospital, QLD	OTR
ACTRN12611000651987	24/06/2011	R	The effects of intra-articular injection of platelet rich plasma on pain and function in patients with knee osteoarthritis: A randomised controlled trial.	Knee Osteoarthritis	RCT-PB	Platelet-rich plasma injections into the knee	Hylan G-F 20 injections	Pain	30	Self funded/ Unfunded	Australian Catholic University, VIC; Lakeside Sports Medicine Centre, VIC	Nil	Australian Catholic University, VIC	OTR
ACTRN12611000614998	15/06/2011	P	Does acupuncture/dry needling applied as a sensory discrimination training tool decrease pain in chronic low back pain patients more than acupuncture alone?	Chronic nonspecific lower back pain	RCT-PB	Acupuncture of lumbar spine with sensory discrimination	Acupuncture of Lumbar spine without sensory discrimination	Lower back pain	25	Curtin University, WA	Curtin University, WA	University of Notre Dame WA	Curtin University, WA	NYR
ACTRN12611000542998	25/05/2011	P	A randomised sham-controlled trial examining the efficacy of short term usual chiropractic care for non-specific spinal pain and associated adverse events	Non-specific spinal pain	RCT-PB	Usual Chiropractic Care	De-tuned ultrasound and random spinal de-tuned activator treatment	Adverse event	180	Chiropractors Registration Board of Victoria	Murdoch University, WA	Nil	Murdoch University, WA	NYR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
ACTRN12611000539932	25/05/2011	P	For people waiting for hip and knee joint replacement surgery, does a pre-operative program of education, self-management and exercise provide benefit before joint replacement?	Hip and knee replacement	SCT	Pre-operative Education and Exercise program	Uncontrolled	Self efficacy	20	Self funded/ Unfunded	Box Hill Hospital Physio-therapy Department, VIC	Nil	Box Hill Hospital Physio-therapy Department, VIC	NYR
ACTRN12611000510943	16/05/2011	R	To determine the efficacy of the pre-admission education in fulfilling the total joint replacement patients' educational requirements and preparedness for surgery, pain management and the post operative period from the patients' perspective.	Total hip or knee joint replacement	SCT	Pre-admission education program	Uncontrolled	Effective-ness	200	Epworth HealthCare, VIC	Epworth HealthCare, VIC	Nil	Epworth HealthCare, VIC	OTR
ACTRN12611000507987	16/05/2011	P	A randomised, double-blind, one-year controlled trial comparing bone mineral density following treatment with Aclasta (zoledronic acid 5mg i/v) versus placebo infusion in patients with AED-induced bone loss	Anti-epilepsy drug induced bone loss	RCT-PB	Zoledronic acid	Placebo	Lumbar spine and/or total hip bone mineral density	60	Novartis Pharma-ceuticals Australia Pty Limited	Melbourne Health, VIC	Nil	Royal Melbourne Hospital, VIC	NYR
ACTRN12611000492954	11/05/2011	R	In patients with anterior knee pain, are prefabricated in-shoe foot orthoses as good or better than a wait-and-see control group for physiological adaptation and relief of symptoms in the short-term?	Anterior knee pain	RCT-O	Prefabricated commercially available, full length in-shoe orthoses	Standard treatment	Patient perceived improve-ment	40	Australian Research Council	University of Queensland, QLD; Australian Institute of Sport, ACT	Nil	University of Queensland, QLD	C:FUComp

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
(A) ACTRN12611000464965	5/05/2011	R	A phase 3, randomised, double-blind, placebo-controlled, multicentre study of the efficacy and safety of four 12-week treatment cycles (48 weeks total) of Epratuzumab in systemic lupus erythematosus subjects with moderate to severe disease (EMBODY 1)	Systemic lupus erythematosus	RCT-PB	Epratuzumab	Placebo	Response criteria	1053	UCB, Inc., USA	UCB, Inc., USA	Nil	UCB, Inc., USA	OTR
ACTRN12611000447954	3/05/2011	R	The effect of postural re-education and/or progressive resisted strengthening on dynamic thoracic kyphosis measurements in people with and without stroke.	Thoracic kyphosis	RCT-O	Postural re-education; progressive resisted back extension exercise; both	No intervention	Mean kyphosis angle in standard static positions and over a day	160	NHMRC PhD Scholarship; The Canberra Hospital, ACT; AOSpine Asia Pacific, China	Australian National University ACT; The Canberra Hospital, ACT	Nil	The Canberra Hospital, ACT	C
ACTRN12611000433909	27/04/2011	P	Effect of altering ropivacaine concentration on interscalene block duration for arthroscopic shoulder surgery	Shoulder surgery	RCT-PB	Varying does of ropivacaine	Dose control	Duration before analgesic effect of block wears off	120	Southern Adelaide Health Service, SA	Flinders Medical Centre, SA	Nil	Flinders Medical Centre, SA	NYR
ACTRN12611000374965	11/04/2011	P	In patients with chronic non-specific neck pain, is a high force mobilisation better than a low force mobilisation or laser for immediate improvement in pressure pain threshold scores?	Chronic non-specific neck pain	RCT-O	High force mobilisation	Low force mobilisation; Laser	Pressure pain threshold	66	Physio-therapy Research Foundation, Australia	The University of Newcastle, NSW	Nil	The University of Newcastle, NSW	OTR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
ACTRN12611000291987	21/03/2011	P	A Prospective Randomised Controlled Trial comparing standard rehabilitation versus additional exercises using the Nintendo Wii-Fit following Total Knee Replacement in patients who have undergone a primary unilateral total knee replacement.	Total knee replacement	RCT-O	Nintendo Wii-Fit exercises	Standard treatment	Pain	128	Self-funded/ Unfunded; Sydney Orthopaedic Research Institute NSW; North Shore Hospital NSW	Sydney Orthopaedic Research Institute NSW	Nil	Sydney Orthopaedic Research Institute NSW	OTR
ACTRN12611000289910	18/03/2011	P	A multicentre, prospective, consecutive clinical study of the anthropometric dimensions of the Genesis II and Genesis II Slim Total Knee Prostheses in patients with degenerative joint disease requiring knee replacement.	Knee replacement	RCT-O	Modified Genesis II Slim	Genesis II	Anthropo metric dimen-sions of the pre- and post-cut knee joint	1060	Smith & Nephew, NSW	Smith & Nephew, NSW	Nil	John Flynn Hospital, QLD	OTR
ACTRN12611000284965	17/03/2011	P	The effect of the Genutrain knee brace on joint pain and activity limitation when compared with a generic neoprene knee brace in the treatment of knee osteoarthritis: a randomised controlled trial	Knee osteoarthritis	RCT-O	Genutrain knee brace	Neoprene knee orthosis	Pain	90	Melbourne Orthotics Pty Ltd, VIC; MAS Medical Pty Ltd, VIC	Melbourne Orthotics Pty Ltd, VIC; MAS Medical Pty Ltd, VIC	The University of Melbourne, VIC	Melbourne Orthotics Pty Ltd, VIC	NYR
ACTRN12611000274976	15/03/2011	P	Adipose-derived stem cells in patients with knee osteoarthritis: A randomised controlled trial evaluating pain, function and cartilage repair	Knee osteoarthritis	RCT-PB	Stromal vascular fraction containing adipose-derived stem cells injection into the knee	Hylan G-F 20 injections	Pain	60	Australian Catholic University, VIC	Australian Catholic University, VIC; Lakeside Sports Medicine Centre, Melbourne Sports and	Nil	Australian Catholic University, VIC	NYR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
											Aquatic Centre, VIC			
ACTRN12611000229976	3/03/2011	P	In patients with chronic non-specific low back pain, are core stability exercise programs as good or better than general exercise for relief of pain	Chronic non-specific low back pain	RCT-O	Exercise rehabilitation program	General exercise	Low back pain (Visual Analogue Pain Scale)	52	University of Western Sydney, NSW	University of Western Sydney, NSW	Nil	University of Western Sydney, NSW	NYR
ACTRN12611000227998	2/03/2011	P	A randomised trial to determine whether anaesthetist-performed preoperative transthoracic echocardiography (intervention) improves the quality of recovery of patients (PQRS assessment) aged over 65 years who undergo fractured neck of femur surgery	Femur Surgery	RCT-O	limited transthoracic echo cardiography	standard clinical assessment of cardio-vascular function	Post-operative quality of recovery score	180	The University of Melbourne, VIC	The University of Melbourne, VIC; Australian and New Zealand College of Anaesthetists VIC	Nil	The University of Melbourne, VIC	NYR
ACTRN12611000199910	21/02/2011	R	A randomised placebo controlled trial to assess the effects of therapy with cholecalciferol on biochemical, bone and patient-level outcomes in patients undergoing haemodialysis (chronic kidney disease stage 5D; CKD 5D)	Bone loss in chronic kidney disease	RCT-PB	Cholecal-ciferol liquid	Placebo	Muscle strength	62	Roche Pharmaceuticals Pty Ltd, Australia	Westmead Hospital, NSW; University of Sydney, NSW	Nil	Westmead Hospital, NSW	C:FUComp
ACTRN12611000168954	11/02/2011	P	In young adults experiencing mild, undiagnosed knee pain, is oral Glucosamine sulphate more effective than a placebo in reducing	Undiagnosed knee pain	RCT-PB	Glucosamine sulphate	Placebo	Knee injury and osteo-arthritis outcome score	60	Victoria University, VIC; Pharmafoods Australia	Victoria University, VIC	Nil	Victoria University, VIC	OTR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
			joint pain and improving function?											
ACTRN1261100016796 5	11/02/2011	R	Comparison of structured physiotherapy rehabilitation with an unsupervised home exercise program after elective total hip replacement surgery for optimal patient recovery.	Total hip replacement	RCT-O	Independent home exercise program	Supervised exercise class	Quality of life	120	Australian National University, ACT	Canberra Hospital, ACT; Australian National University, ACT	Canberra Hospital, ACT	Canberra Hospital, ACT	OTR
ACTRN1261100015292 1	9/02/2011	R	Do patients aged 50 years or over who have post-acute phase lower limb orthopaedic surgery who are in-patient in rehabilitation; that have a combined one-on-one/group-circuit physiotherapy format, compared with traditional one-on-one physiotherapy format show "cost-saving" as measured by length-of-stay and required physiotherapist contact hours?	Lower limb orthopaedic surgery	RCT-O	One-on-one and group physio-therapy sessions	One-on-one sessions only	Cost-saving	89	John Flynn Private Hospital, QLD	John Flynn Private Hospital, QLD; Bond University, QLD	Nil	John Flynn Private Hospital, QLD	C
ACTRN1261100014996 5	8/02/2011	R	Feasibility of use of acupuncture for treatment of arthralgia secondary to aromatase inhibitor therapy in women with early breast cancer	Arthralgia secondary to aromatase inhibitor therapy in breast cancer patients	RCT-PB	Acupuncture	Sham Acupuncture	Severity of pain; impact of pain on quality of life; social and emotional well being.	30	Cancer Institute NSW Innovation Grant	Royal Prince Alfred Hospital, NSW	Nil	Royal Prince Alfred Hospital NSW	OTR
ACTRN1261100013898 7	7/02/2011	P	In persons with moderate to severe knee osteoarthritis, is McConnell patella taping more effective than a placebo in decreasing pain and	Knee Osteoarthritis	RCT-O	McConnell taping	Vitamin E cream	Knee pain	30	Self funded/ Unfunded	University of South Australia, SA	Nil	University of South Australia, SA	NYR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
			improving knee kinematics during a steep descent task?											
ACTRN12611001159332	1/02/2011	P	Assessing the accuracy of bone cuts in total knee arthroplasty using Smith & Nephew Visionaire custom patient specific cutting blocks	Total knee arthroscopy	SCT	Patient matched instrument-ation	Uncontrolled	Intra-operative alignment of cutting blocks as assessed with computer navigation	30	Smith & Nephew, Australia	Gold Coast Hospital, QLD; Smith & Nephew, Australia	Nil	Gold Coast Hospital, QLD	OTR
ACTRN12611001029766	31/01/2011	P	In adults with primary osteoarthritis of the small joints of the hand, is a 12 week program of forearm strengthening exercises more effective than no exercises for improving pain and function?	Osteoarthritis of small joints of the hand	RCT-O	Forearm strengthen-ing exercises	No exercises	Pain in hands	66	Self funded/ Unfunded	Westmead Hospital, NSW	Nil	Westmead Hospital, NSW	NYR
ACTRN12611000959655	28/01/2011	P	In patients with non-inflammatory joint disease who qualify for total hip replacement (THR) surgery, does insertion of the Nanos short stem femoral component enhance clinical outcomes?	Hip replacement	SCT	Short stem femoral components	Uncontrolled	Migration patterns and rotational stability	25	Sir Charles Gairdner Hospital, WA	Smith & Nephew Pty Limited, NSW	Nil	Sir Charles Gairdner Hospital WA	NYR
ACTRN12611000829029	21/01/2011	P	A double blind randomised controlled trial assessing the effect of zoledronate on marrow fat in older osteoporotic persons after suffering a minimal trauma fracture	Osteoporotic persons with minimal trauma fracture	RCT-PB	Intravenous zoledronic acid	Placebo	Changes in marrow fat in femur and vertebrae	60	Novartis Pharma-ceuticals, Australia	Westmead Hospital, NSW; University of Sydney, NSW	Queensland University of Technology, QLD	University of Sydney, NSW	NYR

ACTRN	Registration Date	Registra-tion Type	Research Question	MSK Condition Studied	Trial Design	Intervention (s)	Comparator (s)	Primary Outcome	Sample Size	Funding Source(s)	Sponsor(s)	Collaborator (s)	Contact Location	Recruiting Status
ACTRN12611000669867	19/01/2011	R	Effect of a progressive resisted exercise program on shoulder pain and function following accessory nerve neurapraxia after neck dissection surgery for cancer	Shoulder pain resulting from accessory nerve injury after surgery	RCT-O	Supervised exercise program	Usual care	Shoulder pain and disability index	60	Calvary Mater Newcastle Hospital, NSW	Calvary Mater Newcastle Hospital, NSW; University of Newcastle, NSW	Calvary Mater Newcastle Hospital, NSW	University of Newcastle, NSW	OTR
ACTRN12611000739099	19/01/2011	R	The identification and treatment with manual therapy of patients with cervicogenic dizziness and pain	Dizziness and pain from cervical spine problems	RCT-PB	Sustained Natural Apophyseal Glides (SNAGs)	Detuned machine	Severity of dizziness	90	Mulligan Concept Teachers Association, NZ	University of Newcastle, NSW	Nil	University of Newcastle, NSW	OTR
ACTRN12611000539211	17/01/2011	P	Evaluation of the effectiveness (improving beliefs about LBP and minimising fear avoidance behaviours related to LBP) of a consumer pamphlet for the self management of low back pain.	Low back pain	RCT-O	Pamphlet only; Pamphlet with education	Usual care	Back pain beliefs questionnaire	360	Department of Health WA	Curtin University, WA; Musculo-skeletal Health Network, WA	Pharma-ceutical Society of WA	Curtin University, WA	NYR

Legend: P - prospectively registered; R - retrospectively registered; RCT-PB - Randomised controlled trial – participant-blinded; RCT-O - randomised controlled trial - open; SCT - single arm clinical trial; NYR - Not yet recruiting; C - Completed; OTR - Open to recruitment; C -FUComp: Closed Follow-up complete; C:FUCont: Closed, Follow-up continuing, (A) - trials not initiated in Australia, Funding source(s): Major source(s) of monetary or material or infrastructure support for the trial and sponsors, Sponsor(s): Individuals, organisations, groups or other legal persons taking on responsibility for securing the arrangements to initiate and/or manage a study, including arrangements to ensure that the design of the study meets appropriate standards and to ensure appropriate conduct and reporting ,Collaborator(s): additional individuals, organisations or other legal persons, if any, that have agreed with the primary sponsor to jointly take on responsibilities of sponsorship

* included due to likelihood of orthopaedic surgeries including knee/hip replacement for OA patients

Appendix 3

WHO Registered MSK Trials

Trial ID	Registration Date	Scientific Title	MSK Condition Studied	Trial Design	Target Sample Size	Intervention(s)	Comparator(s)	Primary Outcome	Main Sponsor	Recruitment Status
EUCTR2012-003644-71-ES	21/12/2012	A Randomised, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Etanercept in Subjects with Rheumatoid Arthritis Who Have Had and Inadequate Response to Adalimumab or Infliximab Plus Methotrexate	Rheumatoid Arthritis	RCT-PB	168	Enbrel	Placebo	Efficacy	Pfizer Inc.	ND
EUCTR2012-002323-15-PL	19/12/2012	Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have Had an Inadequate Response to Tumor Necrosis Factor Inhibitors - RA - BEACON	Rheumatoid Arthritis	RCT-PB	525	Baricitinib	Placebo	Efficacy	Eli Lilly and Company	ND
EUCTR2012-002322-73-HU	27/11/2012	A Randomised, Double-Blind, Placebo- and Active Controlled, Phase 3 Study Evaluating the Efficacy and Safety of Baricitinib in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have Had an Inadequate Response to Methotrexate Therapy. - RA-BEAM	Rheumatoid Arthritis	RCT-PB	1280	Baricitinib; Humira	Placebo	Proportion of patients achieving ACR20 at Week 12	Eli Lilly and Company	ND
EUCTR2012-004090-16-DE	6/11/2012	A randomised, double-blind, placebo-controlled trial for establishing safety, tolerability, pharmacokinetics, pharmacodynamics and clinical efficacy of multiple subcutaneous doses of BI 655064 in healthy volunteers and in rheumatoid arthritis patients with prior inadequate response to methotrexate therapy	Rheumatoid Arthritis	RCT-PB	130	BI 655064	Placebo	Pharma-cokinetics	Boehringer Ingelheim Pharma GmbH & Co. KG	ND
EUCTR2012-004091-19-GB	5/11/2012	A Phase 3b open-label, historically-controlled study to assess the safety and efficacy of two concurrent injections of AA4500 in adult subjects with multiple Dupuytren's contractures with palpable cords - AA4500 Multicord Study	Multiple Dupuytren's contractures with palpable cords	SCT	600	Xiapex	Uncontrolled	Safety and effectiveness of Xiapex	Auxilium UK Limited	ND
EUCTR2011-003538-16-LT	5/11/2012	A Randomised, Double-blind, Parallel, Placebo-controlled Study Assessing The Efficacy and Safety of Sarilumab Added To non-biologic DMARD Therapy In Patients With Rheumatoid Arthritis Who Are Inadequate Responders To Or Intolerant Of TNF-a Antagonists - SARIL-RA-TARGET	Rheumatoid Arthritis	RCT-PB	522	Sarilumab	Placebo	Efficacy	Sanofi-aventis recherche & développement	ND

Trial ID	Registration Date	Scientific Title	MSK Condition Studied	Trial Design	Target Sample Size	Intervention(s)	Comparator(s)	Primary Outcome	Main Sponsor	Recruitment Status
NCT01721044	1/11/2012	A Randomised, Double-Blind, Placebo-Controlled, Phase 3 Study Evaluating the Efficacy and Safety of Baricitinib (LY3009104) in Patients With Moderately to Severely Active Rheumatoid Arthritis Who Have Had an Inadequate Response to Tumor Necrosis Factor Inhibitors	Rheumatoid Arthritis	RCT-PB	525	Baricitinib	Placebo	20% improvement in the American College of Rheumatology (ACR) criteria	Eli Lilly and Company	R
NCT01721057	1/11/2012	A Randomised, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients With Inadequate Response to Conventional Disease-Modifying Antirheumatic Drugs With Moderately to Severely Active Rheumatoid Arthritis	Rheumatoid Arthritis	RCT-PB	660	Baricitinib	Placebo	20% improvement in the American College of Rheumatology (ACR) criteria	Eli Lilly and Company	R
NCT01714817	24/10/2012	A Phase 3 Randomised, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of BMS-188667 (Abatacept) or Placebo on a Background of Mycophenolate Mofetil and Corticosteroids in the Treatment of Subjects With Active Class III or IV Lupus Nephritis	Lupus Nephritis	RCT-PB	400	BMS-188667 + Mycophenolate mofetil; BMS-188667 + Prednisone	Placebo + Mycophenolate mofetil; Placebo + Prednisone	Complete Response of renal disease	Bristol-Myers Squibb	R
EUCTR2011-002353-57-DE	23/10/2012	A randomised, multi-centre, double-blind, active-controlled, parallel group study to assess the efficacy and safety of modified release prednisone (Lodotra®) compared to immediate release prednisone (prednisone IR) in subjects suffering from polymyalgia rheumatica (PMR).	Polymyalgia rheumatica	RCT-PB	400	Lodotra	Placebo	Efficacy	Mundipharma Research Limited	ND
NCT01709578	15/10/2012	A Randomised, Double-blind, Parallel, Placebo-controlled Study Assessing the Efficacy and Safety of Sarilumab Added to Non-biologic DMARD Therapy in Patients With Rheumatoid Arthritis Who Are Inadequate Responders to or Intolerant of TNF-a Antagonists	Rheumatoid Arthritis	RCT-PB	522	Sarilumab SAR153191 (REGN88)	Placebo	20% improvement in the American College of Rheumatology (ACR) criteria	Sanofi	R
EUCTR2012-001821-28-ES	2/10/2012	A Randomised Double-blind Study to Evaluate the Safety and Efficacy of Denosumab Compared With Zoledronic Acid in Postmenopausal Women With Osteoporosis Previously Treated With Oral Bisphosphonates	Osteoporosis	RCT-PB	620	Denosumab; Zoledronic acid	Placebo	Efficacy	Amgen, Inc.	ND
NCT01690299	19/09/2012	A Phase 3b, Multicenter, Randomised, Placebo-Controlled, Double Blind, Double-Dummy, Study of the Efficacy and Safety of Apremilast (CC-10004), Etanercept, and Placebo, in Subjects With Moderate to Severe Plaque Psoriasis	Psoriasis; Psoriatic Arthritis	RCT-PB	240	Apremilast; Etanercept	Placebo	Apremilast Psoriasis Area and Severity Index-75	Celgene Corporation	R
EUCTR2012-000444-10-GB	21/08/2012	A Phase IV study to evaluate decreased dosing frequency in patients with active systemic juvenile idiopathic arthritis who experience laboratory abnormalities during treatment with Tocilizumab	Systemic juvenile idiopathic arthritis	SCT	20	Tocilizumab	Uncontrolled	Efficacy of TCZ	F. Hoffmann-La Roche Ltd.	ND

Trial ID	Registration Date	Scientific Title	MSK Condition Studied	Trial Design	Target Sample Size	Intervention(s)	Comparator(s)	Primary Outcome	Main Sponsor	Recruitment Status
NCT01651936	25/07/2012	A Phase IIa, Randomised, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Worldwide, Proof-of-Concept Clinical Trial to Evaluate the Safety, Tolerability, and Efficacy of MK-8457 in Subjects With Active Rheumatoid Arthritis and an Inadequate Response or Intolerance for Anti-TNF-a Therapy	Rheumatoid Arthritis	RCT-PB	178	Methotrexate (MTX); MK-8457	Placebo	Proportion of Participants Achieving American College of Rheumatology 20	Merck Sharp & Dohme Corp.	R
NCT01650246	24/07/2012	A Long-Term Open-Label Extension Study for Subjects Completing a Phase 3 Efficacy and Safety Study of Lesinurad Monotherapy in Subjects With Gout	Gout	SCT	200	Lesinurad	Uncontrolled	Incidence of TEAE	Ardea Biosciences, Inc. USA	R
NCT01643928	06/07.2012	Extension Study Evaluating Treatment With PF-05280586 Versus Rituximab In Subjects With Active Rheumatoid Arthritis Who Have Participated In Other PF-05280586 Trials	Rheumatoid Arthritis	RCT-PB	157	Rituximab-EU+ Rituximab-Pfizer	Rituximab-Pfizer (PF-05280586); Rituximab-US + Rituximab-Pfizer	American College of Rheumatology (ACR) response	Pfizer	R
EUCTR2011-002896-40-GB	11/06/2012	A randomised, double-blind, study comparing the pharmacokinetics and pharmacodynamics and assessing the safety of PF-05280586 and Rituximab in subjects with active Rheumatoid Arthritis on a background of Methotrexate who have had an inadequate response to one or more TNF antagonist therapies	Rheumatoid Arthritis	RCT-PB	195	PF-05280586;	MabThera®; Rituxan®	Pharmacokinetics	Pfizer Inc	ND
NCT01606761	24/05/2012	A Multicenter, Randomised, Double-blind, Placebo-controlled, Parallel Group Study of CNTO 136 (Sirukumab), a Human Anti-IL-6 Monoclonal Antibody, Administered Subcutaneously, in Subjects With Active Rheumatoid Arthritis Despite Anti-TNF-Alpha Therapy	Rheumatoid Arthritis	RCT-PB	990	Sirukumab	Placebo	Proportion of patients with an ACR 20 response	Janssen Research & Development, LLC	R
NCT01583153	19/04/2012	Randomised Controlled Trial Comparing Hospital Inpatient vs. Home Rehabilitation After Total Knee	Knee replacement	RCT-O	220	Hospital Inpatient Rehabilitation	Hybrid Home Programme	Gait speed	Mark Buhagiar, NSW; HammondCare, NSW	R
EUCTR2011-001555-37-GB	16/04/2012	A phase 3, multicenter, randomised, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of apremilast (CC-10004) in the treatment of active ankylosing spondylitis	Ankylosing spondylitis (AS)	RCT-PB	456	Apremilast	Placebo	Reduction of signs and symptoms	Celgene Corporation	ND
EUCTR2010-022101-18-AT	11/04/2012	A Phase 3b, Multicenter, Open-Label Study to Evaluate the Long-Term Safety and Efficacy of Subcutaneous LY2127399 in Patients with Systemic Lupus Erythematosus (SLE) (ILLUMINATE-X) - ILLUMINATE-X	Systemic Lupus Erythematosus (SLE)	SCT	1276	LY2127399	Uncontrolled	Safety and tolerability	Eli Lilly and Company	ND

Trial ID	Registration Date	Scientific Title	MSK Condition Studied	Trial Design	Target Sample Size	Intervention(s)	Comparator(s)	Primary Outcome	Main Sponsor	Recruitment Status
EUCTR2011-003142-41-IT	5/03/2012	A Multicenter, International, Randomised, Double-blind, Alendronate-controlled Study to Determine the Efficacy and Safety of AMG 785 in the Treatment of Postmenopausal Women With Osteoporosis	Postmenopausal osteoporosis	RCT-PB	4000	AMG 785; AMG 785 + Fosamax	Fosmax alone	Incidence of clinical fracture	Amgen Inc.	ND
EUCTR2011-001456-11-HU	1/03/2012	A Multicenter, International, Randomised, Double-blind, Placebo controlled, Parallel-group Study to Assess the Efficacy and Safety of AMG 785 Treatment in Postmenopausal Women With Osteoporosis	Postmenopausal osteoporosis	RCT-PB	5600	Romosozumab + Denosumab	placebo + Denosumab	Incidence of new vertebral fracture	Amgen Inc.	ND
EUCTR2011-001456-11-HU	1/03/2012	A Multicenter, International, Randomised, Double-blind, Placebo controlled, Parallel-group Study to Assess the Efficacy and Safety of Romosozumab Treatment in Postmenopausal Women With Osteoporosis	Osteoporosis	RCT-PB	6000	Romosozumab; Denosumab	Placebo + Denosumab	Incidence of new vertebral fracture	Amgen Inc	ND
NCT01541670	20/02/2012	A Study to Assess the Safety and Tolerability of Anti-MIF Antibody in Subjects With Lupus Nephritis	Systemic Lupus Erythematosus	SCT	4	Anti-Macrophage Migration Inhibitory Factor Antibody	Uncontrolled	Serious adverse events; adverse events	Baxter Healthcare Corporation	Terminated
NCT01550562	15/02/2012	Precision™ High-Rate Sub-perception Spinal Cord Stimulation for the Treatment of Chronic Intractable Pain	Low back pain	RCT-PB	1	Boston Scientific Precision Plus spinal cord stimulation therapy	Not described	Pain relief	Boston Scientific Corporation	Terminated
NCT01526057	1/02/2012	A Randomised, Double-Blind, Study Comparing The Pharmacokinetics And Pharmacodynamics, And Assessing The Safety Of PF-05280586 And Rituximab In Subjects With Active Rheumatoid Arthritis On A Background Of Methotrexate Who Have Had An Inadequate Response To One Or More TNF Antagonist Therapies	Rheumatoid Arthritis	RCT-PB	210	MabThera	PF-05280586; Rituxan	Pharma-cokinetics	Pfizer	R
EUCTR2011-004046-18-CZ	19/01/2012	Knee joint replacement over 5 years in patients with knee osteoarthritis. A long term follow up study in patients of the CL3-12911-018 study	Osteoarthritis	RCT-PB	1206	Strontium ranelate	Placebo	Knee joint replacement procedures or procedures practiced in the knee	Institut de Recherches Internationales Servier	ND
NCT01510769	12/01/2012	A Phase 3 Randomised, Double-Blind, Multicenter, Placebo- Controlled, Combination Study to Evaluate the Efficacy and Safety of Lesinurad and Febuxostat Compared to Febuxostat Alone at Lowering Serum Uric Acid and Resolving Tophi in Subjects With Tophaceous Gout	Gout	RCT-PB	315	Lesinurad	Placebo	Efficacy	Ardea Biosciences, Inc. USA	R

Trial ID	Registration Date	Scientific Title	MSK Condition Studied	Trial Design	Target Sample Size	Intervention(s)	Comparator(s)	Primary Outcome	Main Sponsor	Recruitment Status
EUCTR2011-001729-25-DE	10/01/2012	A multi-centre, randomised, double-blind, placebo-controlled study to evaluate the efficacy and safety of certolizumab pegol in combination with methotrexate for inducing and sustaining clinical response in the treatment of DMARD-naïve adults with early active rheumatoid arthritis.	Early active rheumatoid arthritis	RCT-PB	800	Cimzia + Trexan	Placebo + Trexan	Sustained remission by Week 52	UCB Pharma SA	ND
NCT01508702	10/01/2012	A Phase 3 Randomised, Double-Blind, Multicenter, Placebo- Controlled Study to Assess the Efficacy and Safety of Lesinurad Monotherapy Compared to Placebo in Subjects With Gout and an Intolerance or Contraindication to a Xanthine Oxidase Inhibitor	Gout	RCT-PB	200	Lesinurad	Placebo	Proportion of subjects with an sUA level that is < 6.0 mg/dL	Ardea Biosciences, Inc. USA	R
EUCTR2011-005514-10-LT	28/12/2011	A Blinded Extension to 5 Years of a Phase III Randomised, Placebo-Controlled Clinical Trial to Assess the Safety and Efficacy of Odanacatib (MK-0822) to Reduce the Risk of Fracture in Osteoporotic Postmenopausal Women Treated With Vitamin D and Calcium	Postmenopausal Osteoporosis	RCT-PB	16300	MK-0822	Placebo	Risk of morphometrically assessed vertebral fractures	Merck Sharp & Dohme Corp.	ND
NCT01500278	22/12/2011	A Multicenter, Single-blind, Randomised Parallel-group Study to Assess the Short- and Long-term Efficacy of Certolizumab Pegol Plus Methotrexate Compared to Adalimumab Plus Methotrexate in Subjects With Moderate to Severe Rheumatoid Arthritis Responding Inadequately to Methotrexate	Rheumatoid Arthritis	RCT-O	892	Adalimumab + Methotrexate	Certolizumab Pegol + Methotrexate	Disease Activity Score 28	UCB Pharma SA	R
EUCTR2011-002143-95-PL	20/12/2011	A Multicenter, Randomised, Double-blind, Placebo- and Active-Controlled Study Comparing the Safety and Analgesic Efficacy of ABT-110 to Placebo in Subjects with Chronic Low Back Pain	Chronic Low Back Pain	RCT-PB	390	ABT-110 + Naprosyn®	Placebo + Naprosyn®	Safety, tolerability and the analgesic efficacy	Abbott GmbH & Co. KG	ND
NCT01493531	13/12/2011	A Phase 3 Randomised, Double-Blind, Multicenter, Placebo- Controlled, Combination Study to Evaluate the Efficacy and Safety of Lesinurad and Allopurinol Compared to Allopurinol Alone in Subjects With Gout Who Have Had an Inadequate Hypouricemic Response to Standard of Care Allopurinol	Gout	RCT-PB	600	Lesinurad	Placebo	Efficacy	Ardea Biosciences, Inc. USA	R
EUCTR2010-023047-15-DE	8/12/2011	A Phase 2 Proof-of-Concept, Multicenter, Randomised, Double-blind, Placebo-controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Efficacy of Pomalidomide (CC-4047) In Subjects with Systemic Sclerosis with Interstitial Lung Disease	Systemic Sclerosis	RCT-PB	88	Pomalidomide	Placebo	Safety and tolerability	Celgene Corporation	ND

Trial ID	Registration Date	Scientific Title	MSK Condition Studied	Trial Design	Target Sample Size	Intervention(s)	Comparator(s)	Primary Outcome	Main Sponsor	Recruitment Status
NCT01487161	5/12/2011	A Double-Blind, Randomised, Parallel Group, Dose-Ranging Study Comparing FX006 to Commercially Available Triamcinolone Acetonide Injectable Suspension in Patients With Osteoarthritis of the Knee	Knee osteoporosis	RCT-PB	152	FX006	Triamcinolone acetonide	Pain intensity score	Flexion Therapeutics, Inc, USA	R
NCT01487200	5/12/2011	A Double-Blind, Randomised, Parallel Group, Active Comparator Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamic Effects (HPA Axis) of FX006 in Patients With Osteoarthritis of the Knee	Knee osteoporosis	RCT-PB	24	FX006	Triamcinolone acetonide	Pharma-cokinetic	Flexion Therapeutics, Inc, USA	R
NCT01502423	1/12/2011	A Multicenter, Randomised, Single-Blind Crossover Study of the Safety and Tolerability of Two Adalimumab Formulations in Adult Subjects With Rheumatoid Arthritis	Rheumatoid Arthritis	RCT-PB	61	Adalimumab (high levels)	Adalimumab (current levels)	Adverse Events	AbbVie (prior sponsor, Abbott)	Completed
NCT01499355	23/11/2011	A Multicenter, Randomised, Double Blind, Placebo Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of BIIB023 in Subjects With Lupus Nephritis	Lupus Nephritis	RCT-PB	300	BIIB023	Placebo	Proportion of subjects with complete and partial renal response	Biogen Idec	R
EUCTR2011-001116-65-HU	22/11/2011	Second study on the Effect of Teriparatide on Femoral Neck Fracture Healing - GHDQ	Low trauma femoral neck fracture	RCT-PB	1220	Forsteo	Placebo	Low trauma femoral neck fracture	Eli Lilly and Company	ND
EUCTR2010-021395-28-SE	21/11/2011	Effect of Teriparatide on Femoral Neck Fracture Healing - GHDN	Low trauma femoral neck fracture	RCT-PB	1220	Forsteo	Placebo	Low trauma femoral neck fracture	Eli Lilly and Company	ND
ISRCTN75076749	18/11/2011	A prospective imaging study of cruciate retaining and substituting knee replacement, in osteoarthritis and healthy aging: a randomised controlled trial	Knee osteoporosis	RCT-PB	120	Posterior stabilised knee implant	Posterior cruciate retaining knee implant	Knee kinematics	Canberra Hospital Private Practice Fund, ACT	R
NCT01473589	14/11/2011	Effect of Teriparatide on Femoral Neck Fracture Healing	Femur Neck Fracture	RCT-PB	122	Teriparatide; Vitamin D; Calcium	Placebo	Participants with No Revision Surgery	Eli Lilly and Company	Active, Not recruiting
NCT01490450	14/11/2011	A Phase 2b, Randomised, Double-Blind, Placebo-Controlled, Dose Ranging, Multi-Centre Study to Evaluate the Efficacy and Safety of BMS-945429 Subcutaneous Injection in Adults With Active Psoriatic Arthritis	Psoriatic Arthritis	RCT-PB	150	BMS-945429	Placebo	American College of Rheumatology criteria	Bristol-Myers Squibb	R
EUCTR2011-002144-27-NL	19/10/2011	A Multicenter, Randomised, Double-Blind, Placebo and Active-Controlled Study Comparing the Safety and Analgesic Efficacy of ABT-110 to Placebo in Subjects with Pain from Osteoarthritis of the Knee	Pain from Osteoarthritis of the Knee	RCT-PB	390	ABT-110 + Naprosyn®	Placebo + Naprosyn®	Safety, tolerability and analgesic efficacy	Abbott GmbH & Co. KG	ND

Trial ID	Registration Date	Scientific Title	MSK Condition Studied	Trial Design	Target Sample Size	Intervention(s)	Comparator(s)	Primary Outcome	Main Sponsor	Recruitment Status
CTRI/2011/09/001986	6/09/2011	Fixation using Alternative Implants for the Treatment of Hip Fracture (FAITH):A Multi-Centre Randomised Trial Comparing Sliding Hip Screws and Cancellous Screws on Revision Surgery Rates and Quality of Life in the Treatment of Femoral Neck Fractures - FAITH	Hip Fractures	RCT-PB	100	Multiple cancellous screws fixation	Sliding hip screw	Rates of revision surgery	McMaster University, Canada	R
NCT01421069	18/08/2011	An Open-label Extension Study to Assess the Long-term Safety and Clinical Benefit of Etanercept in Children and Adolescents With Extended Oligoarticular Juvenile Idiopathic Arthritis, Enthesitis-related Arthritis, Or Psoriatic Arthritis Who Were Previously Enrolled in Protocol 0881A1-3338-ww	Juvenile Idiopathic Arthritis, Enthesitis-related Arthritis, Or Psoriatic Arthritis	SCT	100	Etanercept	Uncontrolled	Occurrence of malignancy	Pfizer, USA	Active, Not recruiting
NCT01470989	16/08/2011	An Open-label Extension Study of CACZ885H2356E2 and CACZ885H2357E2 on the Treatment and Prevention of Gout Flares in Patients With Frequent Flares for Whom NSAIDs and/or Colchicine Are Contraindicated, Not Tolerated or Ineffective	Gout	SCT	200	Canakinumab	Uncontrolled	Immunogenicity of canakinumab	Novartis Pharmaceuticals	R
NCT01407068	29/07/2011	An Open-label Study to Assess the Safety and Efficacy of Concurrent Administration of Two Injections of AA4500 0.58 mg Into the Same Hand of Subjects With Multiple Dupuytren's Contractures	Dupuytren's Contractures	SCT	60	AA4500 collagenase clostridium histolyticum	Uncontrolled	Percent change from baseline in total fixed flexion	Auxilium Pharmaceuticals, USA	Completed
NCT01391325	7/07/2011	Long-term Allopurinol Safety Study Evaluating Outcomes in Gout Patients (LASSO)	Gout	SCT	1743	Allopurinol	Uncontrolled	Safety	Ardea Biosciences, Inc. USA	Completed
NCT01389895	23/06/2011	A Randomised, Double-blind, Placebo-controlled, Multiple Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics and Clinical Effect of AMG 557 in Subjects With Subacute Cutaneous Lupus Erythematosus	Lupus Erythematosus	RCT-PB	32	AMG 557	Placebo	Adverse events, vital signs, physical examinations, clinical laboratory safety tests, ECGs, and the incidence of binding and neutralizing antibodies to AMG 557	Amgen	R
NCT01414764	23/06/2011	Does Autologous Conditioned Plasma Enhance Rotator Cuff Tendon Healing After Surgery?	Rotator Cuff injury	RCT-PB	60	Autologous conditioned plasma	Placebo	Magnetic resonance imaging	The University of Western Australia, WA; Arthrex, Inc, USA	R

Trial ID	Registration Date	Scientific Title	MSK Condition Studied	Trial Design	Target Sample Size	Intervention(s)	Comparator(s)	Primary Outcome	Main Sponsor	Recruitment Status
EUCTR2011-000276-34-CZ	21/06/2011	A randomised, double-blind, placebo-controlled, multicenter study of secukinumab to demonstrate the efficacy at 24 weeks and to assess the long term safety, tolerability and efficacy up to 2 years in patients with active psoriatic arthritis	Psoriatic arthritis	RCT-PB	600	Secukinumab	Placebo	ACR20 response	Novartis Pharma AG	ND
EUCTR2010-023802-10-HU	8/06/2011	An open label extension study to assess the long term safety of Etanercept in children and adolescents with extended Oligoarticular Juvenile Idiopathic Arthritis, Enthesitis-related Arthritis or Psoriatic Arthritis who were previously enrolled in protocol 0881A1 3338 WW(B1801014) - Clipper 2	Oligoarticular Juvenile Idiopathic Arthritis, Enthesitis-related Arthritis or Psoriatic Arthritis	SCT	123	Enbrel®	Uncontrolled	Incidence of malignancy	Pfizer Inc	ND
NCT01572779	7/06/2011	A Multicentre, Cluster Randomised, Placebo-controlled, Open-label Pilot Study of Back Strain Monitor (BSM) With Feedback Compared With the BSM Without Feedback in Subjects With Moderate Lower Back Pain.	Low Back Pain	RCT-O	96	Back Strain Monitor device with bio-feedback	Back Strain Monitor device with no bio-feedback	Patient Specific Functional ; Quadruple Visual Analogue Scale; Roland Morris Disability Questionnaire	Pro-Active Medical Pty Ltd	Active, Not recruiting
EUCTR2010-023396-25-GB	11/04/2011	Phase IIa, 2:2:1 randomised, double-blind, placebo-controlled, parallel group, multi-centre clinical trial to investigate the safety, efficacy and pharmacokinetics of recombinant human soluble Fc-gamma receptor IIb (SM101) for intravenous application in the treatment of systemic lupus erythematosus (SLE) patients with or without a history of lupus nephritis - SMILE	Systemic lupus erythematosus	RCT-PB	50	Soluble Fc-gamma receptor IIb	Placebo	Safety	SuppreMol GmbH	ND
EUCTR2010-022710-77-DE	31/01/2011	Prospective, randomised, placebo-controlled, double-blind, multicenter, parallel group study to assess the efficacy, safety and tolerability of macitentan in patients with ischemic digital ulcers associated with systemic sclerosis - DUAL-1: Digital Ulcers with mAcitentan in systemic scLerosis	Ischemic digital ulcers associated with systemic sclerosis	RCT-PB	285	Macitentan	Placebo	Reduction of the cumulative number of new digital ulcers	Actelion Pharmaceuticals Ltd	ND

Legend: RCT-PB - Randomised controlled trial – participant-blinded; RCT-O - randomised controlled trial - open; SCT - single arm clinical trial; ND - Not determined, (Authorised-recruitment may be ongoing or finished); R - recruiting

Appendix 4

Australian Investigator-initiated Publications

Journal Area	Journal	Article Title	First Author	Condition	Trial Design	Trial Size	Intervention(s)	Comparator(s)	Funding	Corresponding Author	Study Location(s)
General Medicine	**New England Journal of Medicine**	Fracture Risk and Zoledronic Acid Therapy in Men with Osteoporosis	Boonen, S	Osteoporosis	RCT-PB	1199	Zoledronic acid	Placebo	Novartis Pharma	Dr. Boonen, University Hospitals Leuven, Belgium	International including Australia
		Tofacitinib or Adalimumab versus Placebo in Rheumatoid Arthritis	Van Vollenhoven, RF	Rheumatoid arthritis	RCT-PB	717	Tofacitinib (two different dosages); Adalimumab	Placebo	Pfizer	Dr. Wilkinson at Pfizer Inc., USA	International including Australia
	The Lancet	Efficacy and safety of belimumbab with active systemic lupus erythematosus: a randomised, placebo-controlled, phase 3 trial	Navarra, SV	Systemic Lupus Erythe-matosus	RCT-PB	867	Belimumbab	Placebo	Human genome Services and GlaxoSmithKline	Dr Michelle A Petri, Johns Hopkins University School of Medicine, Division of Rheumatology, MD, USA	International including Australia
	British Medical Journal	Ultrasound guided corticosteroid injection for plantar fasciitis: randomised controlled trial	McMillan, A	Plantar fasciitis	RCT-PB (A)	82	Ultrasound-guided injection of the plantar fascia with corticosteroid	Saline injection	Australian Podiatry Education and Research Foundation; Briggate Medical (supplied consumables)	A McMillan, La Trobe University, VIC, Australia	Vic, Australia
		Lateral wedge insoles for medial knee osteoarthritis: 12 month randomised controlled trial	Bennell, KL	Knee osteoarthritis	RCT-O (A)	200	Wedge insoles	Flat insoles	NHMRC project grant	KL Bennell, University of Melbourne, VIC, Australia	Vic, Australia
Rheumatology	**Annals of the Rheumatic Diseases**	Effectiveness of intra-articular hyaluronan (Synvisc, hylan G-F 20) for the treatment of first metatarsophalangeal joint osteoarthritis: a randomised placebo-controlled trial	Munteanu, SE	Joint osteoarthritis	RCT-PB (A)	151	Hylan G-F 20	Placebo	Australian Podiatry Education and Research Foundation (APERF) and the La Trobe University Faculty of Health Sciences; Genzyme Australasia Pty. Ltd. (North Ryde, NSW, Australia)	Dr Shannon Munteanu, La Trobe University, Vic, Australia	Vic, Australia

Journal Area	Journal	Article Title	First Author	Condition	Trial Design	Trial Size	Intervention(s)	Comparator(s)	Funding	Corresponding Author	Study Location(s)
Rheumatology	**Annals of the Rheumatic Diseases**	Zoledronic acid reduces knee pain and bone marrow lesions over 1 year: a randomised controlled trial	Laslett, LL	Knee osteoarthritis	RCT-PB (A)	59	Zoledronic acid	Placebo	Novartis Pharmaceuticals Australia; Australian Government; National Health and Medical Research Council; and Osteoporosis Australia	LL Laslett, University of Tasmania, Menzies Research Institute Tasmania, Australia	Tasmania, Australia
		Efficacy and safety of adalimumab in patients with non-radiographic axial spondyloarthritis: results of a randomised placebo-controlled trial (ABILITY-1)	Sieper, J	Axial spondylo-arthritis	RCT-PB	185	Adalimumab	Placebo	Abbott Laboratories	Professor Joachim Sieper, Charité Universitätsmedizin, Berlin	International including Australia
		Efficacy and safety of strontium ranelate in the treatment of knee osteoarthritis: results of a double-blind, randomised placebo-controlled trial	Reginster, J-Y	Knee osteoarthritis	RCT-PB	1683	Strontium ranelate (two different dosages)	Placebo	Servier, France	Professor Jean-Yves Reginster, University of Liege, Belgium	International including Australia
		A 2-year randomised, double-blind, placebo-controlled, multicentre study of oral selective iNOS inhibitor, cindunistat (SD-6010), in patients with symptomatic osteoarthritis of the knee	Hellio le Graverand, M-P	Knee osteoarthritis	RCT-PB	1457	Cindunistat (two different dosages)	Placebo	Pfizer	Dr Marie-Pierre Hellio Le Graverand, Medicines Development Group, Primary Care Business Unit, Pfizer Inc., USA	International including Australia
		Intravenous golimumab is effective in patients with active rheumatoid arthritis despite methotrexate therapy with responses as early as week 2: results of the phase 3, randomised, multicentre, double-blind, placebo-controlled GO-FURTHER trial	Weinblatt, ME	Rheumatoid arthritis	RCT-PB	592	Golimumab + Methotrexate	Placebo + Methotrexate	Janssen Research & Development LLC, and Merck/Schering-Plough	Dr Michael E Weinblatt, Department of Rheumatology, Brigham and Women's Hospital, 75 Francis St, Boston, USA	International including Australia

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Rheumatology	**Annals of the Rheumatic Diseases**	Ofatumumab, a fully human anti-CD20 monoclonal antibody, in biological-naive, rheumatoid arthritis patients with an inadequate response to methotrexate: a randomised, double-blind, placebo-controlled clinical trial	Taylor, PC	Rheumatoid arthritis	RCT-PB	260	Ofatumumab + Methotrexate	Placebo + Methotrexate	Genmab and GlaxoSmithKline	Professor Peter Taylor, Kennedy Institute of Rheumatology Division, Imperial College, London, UK	International including Australia
		Assessment by MRI of inflammation and damage in rheumatoid arthritis patients with methotrexate inadequate response receiving golimumab: results of the GO-FORWARD trial	Conaghan, PG	Rheumatoid arthritis	RCT-PB	444	Golimumab (two different dosages) + Methotrexate	Placebo + MTX; Placebo + Golimumab	Centocor Research and Development, Inc. and Schering Plough Research Institute, Inc.	Philip G Conaghan, Leeds Institute of Molecular Medicine, University of Leeds, UK	International including Australia
		Inhibition of joint damage and improved clinical outcomes with rituximab plus methotrexate in early active rheumatoid arthritis: the IMAGE trial	Tak, PP	Rheumatoid arthritis	RCT-PB	748	Rituximab (two different dosages) + Methotrexate	Methotrexate	Hoffmann-La Roche Ltd, Genentech Inc and Biogen Idec; NIH	Professor Paul P Tak, Academic Medical Centre/University of Amsterdam, The Netherlands	International including Australia
Rheumatology	**Arthritis & Rheumatism**	Significant improvement in synovitis, osteitis, and bone erosion following golimumab and methotrexate combination therapy as compared with methotrexate alone: A magnetic resonance imaging study of 318 methotrexate-naive rheumatoid arthritis patients	Østergaard, M	Rheumatoid arthritis	RCT-PB	318	Golimumab (two different dosages) + Methotrexate	Placebo + Methotrexate; Placebo + golimumab	Centocor Research & Development; Schering-Plough/Merck Research Institute, Inc	Mikkel Østergaard, Department of Rheumatology, Copenhagen University Hospital, Denmark	International including Australia

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Rheumatology	**Arthritis & Rheumatism**	Subcutaneous abatacept versus intravenous abatacept: A phase IIIb non-inferiority study in patients with an inadequate response to methotrexate	Genovese, MC	Rheumatoid arthritis	RCT-PB	1457	Abatacept subcutaneously	Abatacept intravenously	Bristol-Myers Squibb.	M. C. Genovese, Stanford University, USA	International including Australia
		Clinical efficacy and safety of etanercept versus sulfasalazine in patients with ankylosing spondylitis: A randomised, double-blind trial	Braun, J	Ankylosing spondylitis	RCT-PB	566	Etanercept	Sulfasalazine	Wyeth Pharmaceuticals	Andrew S. Koenig, Pfizer Specialty Care Business Unit, Pfizer Inc., USA	International including Australia
		The effectiveness of pulsed electrical stimulation in the management of osteoarthritis of the knee: Results of a double-blind, randomised, placebo-controlled, repeated-measures trial	Fary, RE	Knee osteoarthritis	RCT-PB (A)	70	Pulsed electrical stimulation	Sham electro stimulation	Arthritis Australia and State & Territory Affiliate Grant and a Physiotherapy Research Foundation Research Seeding grant	Robyn E. Fary, Curtin University, WA, Australia	Curtin University, WA
		Abatacept in the treatment of patients with psoriatic arthritis: Results of a six-month, multicenter, randomised, double-blind, placebo-controlled, phase II trial	Mease, P	Psoriatic arthritis	RCT-PB	170	Abatacept (three different dosages	Placebo	Bristol-Myers Squibb	Philip Mease, MD, Seattle Rheumatology Associates, Seattle, USA	International including Australia
		Tocilizumab inhibits structural joint damage in rheumatoid arthritis patients with inadequate responses to methotrexate: Results from the double-blind treatment phase of a randomised placebo-controlled trial of (No Suggestions) safety and prevention of structural joint damage at one year	Kremer, JM	Rheumatoid arthritis	RCT-PB	1196	Tocilizumab (two different dosages)	Placebo	Roche	Joel L. Kremer, Albany Medical College, USA	International including Australia

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Rheumatology	**Arthritis Care Research**	Tai Chi exercise for treatment of pain and disability in people with persistent low back pain: A randomised controlled trial	Hall, AM	Low back pain	RCT-O (A)	160	Tai Chi	no treatment	Arthritis Foundation of Australia; Arthritis Care of the UK	Amanda Hall, The George Institute for Global Health and University of Sydney, NSW, Australia	NSW, Australia
		American College of Rheumatology hybrid analysis of certolizumab pegol plus methotrexate in patients with active rheumatoid arthritis: Data from a 52-week phase III trial	Van Vollenhoven, RF	Rheumatoid arthritis	RCT-PB	784	Certolizumab (two different dosages) + Methotrexate	placebo + methotrexate	UCB, Inc.	R. F. van Vollenhoven, Karolinska Institute, Stockholm, Sweden	International including Australia
	Rheuma-tology	Improvements in health-related quality of life after treatment with Tocilizumab in patients with rheumatoid arthritis refractory to tumour necrosis factor inhibitors: results from the 24 week randomised controlled RADIATE study	Strand, V	Rheumatoid arthritis	RCT-PB	489	Tocilizumab	Placebo	Hoffman-La Roche	Vibeke Strand, Division of Immunology/Rheumatology, Stanford University, CA, USA	International including Australia
	Osteo-arthritis and Cartilage	Treatment with 4Jointz reduces knee pain over 12 weeks of treatment in patients with clinical knee osteoarthritis: a randomised controlled trial	Laslett, LL	Knee osteoarthritis	RCT-PB (A)	133	4Jointz cream	Placebo cream	Arthritis Relief Plus Ltd	L. Laslett, Menzies Research Institute Tasmania, University of Tasmania, Australia	Tasmania and New South Wales in Australia
		Medial arch supports do not significantly alter the knee adduction moment in people with knee osteoarthritis	Hinman, RS	Knee osteoarthritis	RCT-O (A)	21	Standardised athletic shoes wearing prefabricated medial arch support	Standardised athletic shoes wearing no medial arch supports	ARC	R.S. Hinman, The University of Melbourne, Vic, Australia	Vic, Australia

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Rheumatology	**Journal of Rheuma-tology**	Challenges in Evaluating an Arthritis Self-management Program for People with Hip and Knee Osteoarthritis in Real-world Clinical Settings	Ackerman, IN	Hip or knee osteoarthritis	RCT-O (A)	120	Stanford Arthritis Self Management Program + self-help book	Self-help book	NHMRC	RH Osborne, Melbourne EpiCentre, Department of Medicine (Royal Melbourne Hospital), The University of Melbourne, VIC, Australia	Vic, Australia
		Health-related Quality of Life Outcomes of Adalimumab for Patients with Early Rheumatoid Arthritis: Results from a Randomised Multicentre Study	Strand, V	Rheumatoid arthritis	RCT-PB	799	Adalimumab + Methotrexate; Adalimumab	Methotrexate	Abbott Laboratories	V Strand, Division of Immunology/Rheumatology, Stanford University School of Medicine, USA	International including Australia
		An International, Randomised, Double-blind, Placebo-controlled, Phase III Trial of Pregabalin Monotherapy in Treatment of Patients with Fibromyalgia	Pauer, L	Fibromyalgia	RCT-PB	747	Pregabalin (three different dosages)	Placebo	Pfizer	Pfizer Global Research and Development, USA	International including Australia
Orthopaedics	**Journal of Bone & Joint Surgery (American)**	Large Femoral Heads Decrease the Incidence of Dislocation After Total Hip Arthroplasty: A Randomised Controlled Trial.	Howie, D	Hip Arthroscopy	RCT-PB (A)	644	36 mm metal femoral head on highly cross-linked polyethylene	28-mm metal femoral head on highly cross-linked polyethylene	NHMRC; Zimmer Pty Ltd USA	Donald W. Howie, Royal Adelaide Hospital, SA, Australia	SA, VIC and NSW, Australia and UK
		Internet-Based Outpatient Tele-rehabilitation for Patients Following Total Knee Arthroplasty: A Randomised Controlled Trial	Russell, T	Knee Arthroplasty	RCT-O (A)	65	Internet-based tele-rehabilitation physical therapy program	Standard physical therapy	Self funded/ Unfunded	T Russell, University of Queensland, Brisbane, Australia	QLD, Australia
	Journal of Bone & Joint Surgery (British)	Joint line position correlates with function after primary total knee replacement	Babazadeh, S	Knee replacement	RCT-PB (A)	115	Computer-assisted total knee replacement	Conventional total knee replacement	Not Specified	PFM Choong, St. Vincent's Hospital, Melbourne, VIC Melbourne, Australia	Vic, Australia

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Orthopaedics	**Journal of Bone & Joint Surgery (British)**	Joint line position correlates with function after primary total knee replacement	Ward, TR	Knee replacement	RCT-PB (A)	28	Bicruciate stabilised design for total knee replacement	traditional posterior-stabilised design TKR	Smith and Nephew	TR Ward, Canberra Hospital, ACT, Australia	ACT, Australia
	Journal of Orthopaedic Research	Effect of Splinting and Exercise on Intraneural Edema of the Median Nerve in Carpal Tunnel Syndrome—An MRI Study to Reveal Therapeutic Mechanisms	Schmid, A	Carpal tunnel	RCT-O (A)	21	Night splinting	Nerve and tendon gliding exercises	Queensland Health; NHMRC	Michel W. Coppieters, University of Queensland, QLD, Australia	QLD, Australia
	Journal of Arthroplasty	Magnetic Resonance Imaging Features of Preserved vs. Divided and Repaired Piriformis During Total Hip Arthroplasty: A Randomised Controlled Trial	Khan, RJK	Hip arthroplasty	RCT-PB (A)	22	Single-incision mini-posterior approach	Standard posterior approach	Smith and Nephew Surgical Pty. Ltd.	RJ Khan, The Joint Studio Suite 1 the Hollywood Medical Centre, WA	WA, Australia
		Comparing Outcomes of Medial Parapatellar and Subvastus Approaches in Total Knee Arthroplasty: A Randomised Controlled Trial	Bourke, MG	Knee arthroplasty	RCT-PB (A)	90	Subvastus approach for knee arthroplasty	Medial parapatellar approach	No external sources of funding	MG Bourke, QEII Jubilee Hospital, QLD, Australia	QLD, Australia
		Three-Dimensional Component Alignment and Functional Outcome in Computer-Navigated Total Knee Arthroplasty	Harvie, P	Knee arthroplasty	RCT-PB (A)	40	TKA with Stryker Full Navigation	TKA with Stryker Articular Surface Mounted system Surface Mounted system	Novartis Pharma	P Harvie, Royal Perth Hospital, Western Australia	WA, Australia
Sports Sciences	**Medicine & Science in Sports & Exercise**	Clinical Pilates versus General Exercise for Chronic Low Back Pain: Randomised Trial.	Wajswelner, H	Low back pain	RCT-O (A)	87	Pilates	General exercise	Mr. Craig Phillips, DMA Clinical Pilates Physiotherapy and Mr. Marcus Pain, Back in Motion Physiotherapy, VIC, Australia	Dr Henry Wajswelner, DMA Clinical Pilates, Vic, Australia	Vic, Australia
Sports Sciences	**British Journal of Sports Medicine**	Prolotherapy injections and eccentric loading exercises for painful Achilles tendinosis: a randomised trial	Yelland, MJ	Achilles tendinosis	RCT-O (A)	40	Prolotherapy injections of hypertonic glucose + lignocaine	Eccentric loading exercises	Musculoskeletal Research Foundation of Australia; Australian Podiatry Education and Research Foundation; Griffith University	Professor Michael J Yelland, Griffith University, QLD	Australia (across five centres)

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		A randomised control trial of short term efficacy of in-shoe foot orthoses compared with a wait and see policy for anterior knee pain and the role of foot mobility	Mills, K	Anterior knee pain	RCT-O (A)	40	Prefabricated orthoses	No orthoses	Australian Research Council	Professor Bill Vicenzino, University of Queensland	Australian Institute of Sport (Canberra, Australia)
		Treatment of refractory anterior knee pain using botulinum toxin type A (Dysport) injection to the distal vastus lateralis muscle: a randomised placebo-controlled crossover trial	Singer, BJ	Refractory anterior knee pain	RCT-PB (A)	24	Botulinum toxin type A injection	Saline injection	Raine Medical research foundation at University of WA; Ipsen	Dr Barbara J Singer, University of WA, Australia	WA, Australia
		Effectiveness of once-weekly gym-based exercise programmes for older adults post discharge from day rehabilitation: a randomised controlled trial	Foley, A	Spinal or lower limb MSK impairment disability or surgery or reduced functional mobility or falls	RCT-O (A)	106	Gym-based exercise programmes once or twice a week	Usual Care	Arthritis Australia; Royal Adelaide Hospital	Dr Amanda L Foley, Physical Activity in Ageing, Hampstead Rehabilitation Centre, Royal Adelaide Hospital	SA, Australia
	Journal of Science and Medicine in Sports	Effects of exercise on bone density and falls risk in post-menopausal women with osteopenia: A randomised controlled trial	Bolton, KL	Osteopenia	RCT-O (A)	39	Exercise	Usual Care	Swisse Vitamins Pty Ltd.	KL Bennell, University of Melbourne, VIC, Australia	Vic, Australia
Spine	**Spine**	A Randomised Trial Comparing Acupuncture and Simulated Acupuncture for Subacute and Chronic Whiplash.	Cameron, ID	Whiplash	RCT-PB (A)	124	electro acupuncture treatment	simulated electro acupuncture treatment	Government funds not described	ID Cameron, Sydney Medical School, University of Sydney, NSW, Australia	NSW, Australia
	Journal of Bone and Mineral Research	Ronacaleret, a calcium-sensing receptor antagonist, increases trabecular not cortical bone in post-menopausal women	Fitzpatrick, LA	Post-menopausal osteoporosis	RCT-PB	569	Ronacaleret (various dosages)	Alderonate; placebo	GlaxoSmithKline	Lorraine A Fitzpatrick, MD, GlaxoSmithKline, USA	International including Australia

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		Effect of alendronate and vitamin D3 on fractional calcium absorption in a double-blind, randomised, placebo-controlled trial in postmenopausal osteoporotic women	Shapses, SA	Post-menopausal osteoporosis	RCT-PB	56	Alendronate	Placebo	Trans-Antarctic Association and the Austin Hospital Medical Research Foundation	Sue A Shapses, PhD, Department of Nutritional Sciences, Rutgers University, USA	International including Australia
	Osteoporosis International	The effect of teriparatide compared with risedronate on reduction of back pain in postmenopausal women with osteoporotic vertebral fractures	Hadji, P	Back pain in post-menopausal osteoporosis	RCT-PB	712	Teriparatide	Risedronate	Warner Chilcott; Sanofi	Klinik für Gynäkologie, Gynäkologische Endokrinologie und Onkologie, Germany	International including Australia
		Treatment with acetaminophen/paracetamol or ibuprofen alleviates post-dose symptoms related to intravenous infusion with zoledronic acid 5 mg	Wark, JD	Osteoporosis	RCT-PB	481	Zoledronic acid IV + acetaminophen/paracetamol; Zoledronic acid IV + ibuprofen	Zoledronic acid IV + placebo; Placebo IV + placebo	Servier	JD Wark, University of Melbourne Department of Medicine and Bone & Mineral Service, The Royal Melbourne Hospital, VIC, Australia	International including Australia
		Effects of strontium ranelate and alendronate on bone microstructure in women with osteoporosis	Rizzoli, R	Post-menopausal osteoporosis	RCT-PB	83	Strontium ranelate	Alendronate	Pfizer	R Rizzoli, Division of Bone Diseases, Department of Medical Specialties,Geneva University Hospitals, Switzerland	International including Australia
Spine	**Osteoporosis International**	Arzoxifene versus raloxifene: effect on bone and safety parameters in postmenopausal women with osteoporosis	Kendler, DL	Post-menopausal osteoporosis	RCT-PB	320	Arzoxifene	Raloxifene	Eli Lilly and Company	DL Kendler, University of British Columbia, Vancouver, Canada	International including Australia
	Bone	Bisphosphonates and glucocorticoid osteoporosis in men: results of a randomised controlled trial comparing zoledronic acid with risedronate	Sambrook, PN	Osteoporosis in men	RCT-PB	265	Zoledronic acid + Calcium + Vitamin D	Risedronate + Calcium + Vitamin D	Sanofi	PN Sambrook, Sydney Medical School, Royal North Shore Hospital, NSW, Australia	International including Australia

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	Calcified Tissue International	Randomised Trial of Alendronate Plus Vitamin D3 Versus Standard Care in Osteoporotic Postmenopausal Women with Vitamin D Insufficiency	Ralston, SH	Osteoporosis	RCT-O	515	Alendronate + Vitamin D	Usual care	NHMRC; Zimmer Pty Ltd USA; University of Adelaide; Royal Adelaide Hospital; Australian Orthopaedic Association	SH Ralston, Western General Hospital, Edinburgh, UK	International including Australia
Rehabilitation	**Journal of Physio-therapy**	Neural tissue management provides immediate clinically relevant benefits without harmful effects for patients with nerve-related neck and arm pain: a randomised trial.	Nee, R	Nerve-related neck and arm pain	RCT-O (A)	60	Education + manual therapy + nerve gliding exercise	Usual activity	University of Queensland	Professor Bill Vicenzino, University of Queensland	QLD, Australia
		Telephone coaching can increase activity levels for people with non-chronic low back pain: a randomised trial	Iles, R	Low back pain	RCT-O (A)	30	Telephone coaching + physiotherapy care	Physiotherapy care	Not Specified	Ross Ilses, La Trobe University, Vic, Australia	Vic, Australia
		Strain-Counterstrain therapy combined with exercise is not more effective than exercise alone on pain and disability in people with acute low back pain: a randomised trial.	Lewis, C	Low back pain	RCT-O (A)	99	Strain-counterstrain treatment + Standard exercises	Standard exercises	Self funded/ unfunded	Cyan Lewis, Stanthorpe Health Services, QLD, Australia	QLD, Australia
Rehabilitation	**Physio-therapy**	Effect of Motor Control Exercises Versus Graded Activity in Patients With Chronic Nonspecific Low Back Pain: A Randomised Controlled Trial	Macedo, LG	Chronic Nonspecific Low Back Pain	RCT-O (A)	172	Motor control exercises	Graded activity	NHMRC	R. Stafford, University of Queensland	NSW and QLD, Australia

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		Does Passive Mobilisation of Shoulder Region Joints Provide Additional Benefit Over Advice and Exercise Alone for People Who Have Shoulder Pain and Minimal Movement Restriction? A Randomised Controlled Trial	Yiasemides, R	Shoulder Pain	RCT-O (A)	98	Passive mobilisation of shoulder region + exercise + advice	Exercise + advice	Physiotherapy Research Foundation	Associate Professor Ginn, Sydney Medical School,The University of Sydney	NSW, Australia
	Archives of Physical Medicine and Re-habilitation	Training mode-dependent changes in motor performance in neck pain	O'Leary, S	Neck pain	RCT-O (A)	60	Endurance training	Coordination training; Active mobility training	NHMRC development grant	S O'Leary, Women's Royal Hospital, QLD, Australia	QLD, Australia

Legend: (A) - Australian investigator-initiated trial; RCT-PB - Randomised controlled trial – participant-blinded, RCT-O - randomised controlled trial – open, ND - not determined.

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