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The effect of mindfulness training prior to total joint arthroplasty on post-operative pain and physical function: a randomised controlled trial

Running Title: Mindfulness in total joint arthroplasty

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Highlights:

- Total joint arthroplasty (TJA) is the only definitive surgical intervention for treating advanced osteoarthritis of the hip or knee and is one of the highest volume elective surgeries
- Pre-surgery psychological distress is an important predictor of sub-optimal patient outcomes following TJA
- According to this study pre-surgery MBSR improves pain and function in people with psychological distress undergoing TJA.
- A potential causal mechanism to explain these findings is yet to be identified

ABSTRACT

Objective: To evaluate the efficacy of Mindfulness-Based Stress Reduction (MBSR) in improving pain and physical function following total joint arthroplasty (TJA).

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Design: Two-group, parallel-group, randomised controlled trial, conducted between September 2012 and May 2017.

Setting: Single centre study conducted at a University-affiliated, tertiary hospital.

Intervention: People with arthritis scheduled for TJA, with a well-being score <40 (Short Form-12 Survey) were randomly allocated to a pre-surgery eight-week MBSR program or treatment as usual (TAU).

Outcome Measures: Self-reported joint pain and function at 12 months post-surgery, assessed using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Secondary outcomes were knee stiffness and global improvement (WOMAC); physical and psychological well-being (Veterans RAND 12-item Health Survey); self-efficacy (Arthritis Self-Efficacy Scale); and mindfulness (5-Factor Mindfulness Questionnaire).

Results: 127 participants were randomised; 65 to MBSR and 62 to TAU, of which 45 participants allocated to the intervention and 56 participants allocated to usual care proceeded to surgery and 100 (99%) completed primary outcome measures. Greater improvements in knee pain (mean difference, -10.3 points, 95% CI -19.0 to -1.6; *P*=0.021) and function (mean difference, -10.2 points, 95% CI -19.2 to -1.3; *P*=0.025) at 12 months post-surgery were observed in the MBSR group compared to the TAU group. A between group difference in global scores (-9.5 points, 95% CI -17.9 to -1.1; *P*=0.027) was also observed. No other differences in secondary outcomes were observed.

Conclusion: MBSR improves post-surgery pain and function in people with psychological distress undergoing TJA. Further research is required to examine potential barriers to broader implementation and uptake.

Key Words: Hip and knee arthroplasty, Mindfulness-Based Stress Reduction, Randomised controlled trial, Pain and function

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1. INTRODUCTION

Osteoarthritis is a leading cause of pain and disability, affecting an estimated 10% percent of the population.[1] Total joint arthroplasty (TJA) is the only definitive surgical intervention for treating advanced osteoarthritis of the hip or knee and is one of the highest volume elective surgeries performed, exceeding 100,000 procedures each year in Australia.[2] While most people report substantial improvements in symptoms after TJA, there is a subset of patients who report ongoing pain, poor function and dissatisfaction after surgery[3], with an estimated 15% failing to achieve a clinically meaningful improvement at 12 months.[4, 5]

Pre-surgery psychological distress is an important predictor of patient outcomes following TJA and co-morbidities including depression, anxiety, neuroticism, catastrophizing, poor self-esteem, and low self-efficacy, are consistently associated with less than expected symptom improvement, in both the short and longer term.[6-11] Up to 40% of people presenting for TJA self-report moderate to severe psychological distress,[12] suggesting that a substantial proportion of patients undergoing TJA is at risk of poor response to surgery. Coinciding with rising TJA numbers, it is likely therefore, that the absolute number of dissatisfied patients will grow unless therapies that effectively target psychological well-being are implemented.

The efficacy of pre-surgery mind-body based interventions on post-surgery outcomes have been examined in a recent systematic review.[13] The review which included 20 studies evaluating relaxation, guided imagery and hypnosis, demonstrated that the quality of evidence for the efficacy of mind-body therapies in improving post-surgical outcomes was limited. Most studies were limited by small sample sizes, short-term follow-up and a majority of interventions were initiated the day prior to surgery, without sufficient time to apply and practice learned techniques. Further appropriately conducted studies were recommended to address these limitations.

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It has been postulated that therapies such as mindfulness training, whereby acceptance rather than avoidance of pain is promoted, may be more effective than therapies that aim to alter the context of the negative pain experience.[14] A systematic review of randomised controlled trials in Mindfulness Based-Stress Reduction (MBSR) and Mindfulness Based Cognitive Therapy (MBCT) found evidence for the efficacy of MBSR in improving mental health.[15] Mindfulness training has been shown to be efficacious for patients with fibromyalgia,[16] arthritis[17] and chronic pain,[18] but its efficacy for improving post-surgical outcomes has not been established.

Given the established link between pre-operative psychological distress and sub optimal symptom improvement following TJA surgery, we sought to test whether pre-surgery mindfulness training would improve pain and function outcomes in distressed individuals post TJA. The aim of this study therefore, was to determine whether post-surgery pain and physical function could be improved in patients with psychological distress undergoing TJA, if surgery was preceded by a mindfulness-based intervention. We hypothesized that in patients with self-reported psychological distress, improvement in knee pain and function at 12 months post-surgery would be greater when TJA was preceded by an 8-week group-based Mindfulness-Based Stress Reduction (MBSR) program, compared with TJA surgery alone.

2. METHODS

2.1 Trial Design

The trial was a single-centre 2-group, parallel RCT conducted between September 2012 and May 2017. The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (ANZCTRN12611001184965). The trial protocol has been published [12], and the full protocol is provided in Supplement 1. Protocol changes are summarized in Supplement 2 (s2-Methods 1). The

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trial was approved by the St. Vincent's Hospital Human Research Ethics Committee (HREC-A 143/11) and participants gave written informed consent before taking part.

2.2 Setting and Recruitment

Participants were recruited from an orthopaedic outpatient clinic at St Vincent's Hospital in Melbourne, Australia (SVHM) between September 2012 and December 2014. Patients were approached by the study co-ordinator during their attendance at the orthopaedic outpatient clinic following surgeon assessment for TJA and assessed for eligibility and willingness to participate. Written informed consent was obtained from all participants. Eligibility criteria included; 18+ years with hip or knee arthritis; base-line Short Form-12 survey mental component summary score <40 points; and consented to undergo TJA by an orthopaedic surgeon. Exclusion criteria were; revision surgery or surgery for neoplastic disease; inability to provide informed consent due to mental incompetence; active drug or alcohol use disorder; and limited English language proficiency.

2.3 Randomisation and Blinding

Participants were randomly assigned using computer-generated random permuted blocks of six to 12, prepared in advance by an independent biostatistician in Excel© which were then concealed in opaque, sequentially numbered, tamperproof envelopes and locked and stored in a centrally accessible location. Immediately following written informed consent, an independent researcher was contacted to open the lowest numbered envelope and reveal group allocation to the study coordinator. A research co-ordinator was responsible for participant recruitment, consent, co-ordination of appointments, and travel assistance. A separate researcher blinded to group allocation was responsible for collection of primary outcome measures. MBSR facilitators were blinded to outcome data and a blinded statistician not involved in the randomisation process performed the final analysis.

2.4 Interventions

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Participants in both intervention and treatment as usual (TAU) groups underwent surgery and post-operative care as per SVHM's routine TJA program, which has been standardised through the use of clinical pathway protocols.[19] As part of routine post-surgical follow-up all patients attended the same outpatient clinic at 6-weeks and 12 months post TJA for review by their treating surgeon.

In additional to usual care, participants in the intervention arm completed an eight-session group-based MBSR intervention prior to surgery. The intervention, previously described,[12] consisted of weekly 2.5 hour sessions, a 7-hour full day session held in week six and a 'booster' day-long workshop three months post-surgery. Sessions were conducted at SVHM and each 8-week program was administered by one of three qualified MBSR facilitators whose primary professions were psychiatry, orthopaedic surgery and nursing. Patients in the study were given a manual covering specific, predetermined MBSR exercises, topics covered in the weekly sessions, instructions for home practice and CDs with recorded meditation instructions (Supplement 3).

All three facilitators had completed the same MBSR course and were qualified to teach through Openground, the authorised body for training MBSR teachers in Australia, which was endorsed by the Centre for Mindfulness in Boston. Prior to the study, the MBSR facilitators had; i) at least twelve months of regular meditation practice ii) had attended a silent seven-day insight meditation teacher led retreat on at least one occasion in the prior twelve months, and iii) had completed teacher training intensives run by Openground which included hands on practice sessions and supervision. In line with international standards, after completing training facilitators were supervised for at least two full rounds of MBSR teaching and had attended regular MBSR Teacher development intensives. To ensure treatment fidelity, the intervention was manualised (see Supplement 3 – MBSR manual) and a single independent observer attended all sessions to monitor that delivery of the MBSR program was as intended. In addition, during delivery of each 8-week

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program, MBSR facilitators received weekly external supervision from an MBSR trained and accredited supervisor.

2.5 Follow-up Assessments

Participants completed outcome measures at baseline, 3- and 12 months, using paper-based questionnaires. Baseline questionnaires were distributed to participants during attendance at pre-admission clinics for completion and return in a reply-paid envelope. Post-surgery questionnaires were mailed to participants for completion and return to a blinded researcher who entered responses onto a dedicated database for future extraction and blinded analyses. Participants received a phone-call reminder if surveys were not returned with 4-weeks of the initial mail out.

2.6 Primary Outcome

Primary outcomes were self-reported pain and physical function at 12-months measured using the Western Ontario and McMaster Universities (WOMAC) Osteoarthritis Index.[20, 21] The WOMAC consists of 24 items covering three subscales: knee pain (range 0-20), stiffness (range 0-8), and physical function (0-68). The pain and physical function subscales were transformed to a score ranging from 0 to 100; a higher score indicates greater pain and worse physical function.

2.7 Secondary Outcomes

Secondary outcomes included joint stiffness and global change (assessed using the transformed WOMAC); physical and psychological health status using the Veterans RAND 12-item Health Survey[22], self-efficacy in managing ones pain using the Arthritis Self-Efficacy Scale[23] and mindfulness skills using the Five Facet Mindfulness Questionnaire.[24] Full details on secondary outcome measures are detailed in Supplement 2 (s2-Methods 2). Primary and secondary outcome measures were also collected at an interim time-point of 3 months.

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2.8 Post-Hoc Outcomes

The proportion of patients who achieved the minimum clinically important improvement in pain or physical function scores between baseline and one year 1-year following TJA was determined from the WOMAC using pre-defined cut-points; 25 points for hip TJA[25] and 15 points for knee TJA.[26]

Additional measures included attendance at MBSR sessions and a health services utilisation survey for use in a proposed future health economic evaluation [12]. A range of additional psychological measures were also collected [12]. These are for analyses of hypotheses concerning mechanisms that may predict change in WOMAC pain and function and are not reported here. Exploration of interactions with these parameters is outside the scope of this paper and will be discussed separately elsewhere.

2.9 Statistical Analysis

Treatment efficacy was evaluated by comparing change in primary outcome measures between groups. We aimed to detect the minimum clinically important difference (MCID) in pain and physical function. In the absence of prior MBSR trials in surgery, the MCIDs for pain and physical function were drawn from prior studies of nonsurgical interventions for lower extremity osteoarthritis.[27-29] Based on these studies the MCID for WOMAC Pain was 10.0 and the MCID for WOMAC function was 9.1 normalised points (0–100 scale). We therefore powered our study to detect a minimum difference of 10.0 points for WOMAC pain and 9.1 points in WOMAC function scores at 12 months. The sample size calculation was based on an analysis of covariance adjusting for baseline scores, estimating between-patient SDs of 18.0 points for pain and 16.1 points for function,[28] baseline to 12-month follow-up correlations of 0.5 an alpha value = 0.05, 2-sided test and power= 90%. To demonstrate a difference in pain of at least 10.0 points, a total of 104 participants were required, whereas to demonstrate a difference in function scores of 9.1 points 100 participants were required. We aimed to recruit 126 participants to allow for a 20% drop-out rate.

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Analyses were conducted on a modified intention-to-treat basis by a blinded statistician using Stata, version 14.0 (StataCorp, College Station, Texas) utilizing data from all 45 (MBSR) and 56 (TAU) subjects who underwent surgery. All participants who underwent TJA were analysed according to group allocation, irrespective of attendance at MBSR sessions for the intervention group. For continuous outcomes the mean difference (95% CI) in 12-month outcome scores was estimated using an analysis of covariance, adjusting for baseline scores. Statistical significance was set at p =.05 for all analyses. In keeping with recommendations for analysing multiple endpoints in clinical trials [30] we did not lower the Type 1 error threshold to adjust for co-primary endpoints. We established *a priori* that adjustment for confounding variables would be performed as secondary analyses if we identified imbalances in baseline patient characteristics hypothesised to influence the main outcomes. We also established *a priori* that if there were more than 5% missing data, sensitivity analyses, would be reported for the main outcomes of the study.

For our post-hoc analyses, the $\chi 2$ test was used to compare the proportion of participants who achieved the MCII in WOMAC pain or function following TJA.

3. RESULTS

Between September 2012 and December 2014, 139 individuals awaiting hip or knee arthroplasty were enrolled, of whom 12 subsequently withdrew prior to treatment allocation (Figure 1). Of the 65 participants allocated to the intervention, 45 proceeded to arthroplasty. Reasons for not proceeding with surgery included: symptom improvement (n=14), change of mind (n=3), deceased (n=2) and clinically unfit (n=1). Of the 62 participants allocated to treatment as usual, six did not proceed with surgery due to; change of mind (n=5) and clinically unfit (n=1). The characteristics of the intervention and treatment as usual groups were similar at baseline (Table 1).

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From November 2012 to February 2015 a total of eight MBSR programs with group sizes between seven and 10 participants were run by one of three facilitators. There was no difference in mean (SD) attendance at MBSR sessions for the 45 participants who proceeded to surgery [7.8 (2.1) sessions] and the 20 participants who did not proceed with surgery [7.4 (2.0)]. Time from study enrolment to surgery was 25.7 weeks, 95% CI: 18.4 to 32.9 for the MBSR group and 19.5 weeks 95% CI: 14.0 to 24.9, (p=0.165). All surgeries were completed by April 2016, with final follow-up completed in May 2017. Retention at 12 months post-surgery was near complete, with one participant in the MBSR group lost 10 months post-arthroplasty due to death unrelated to the study or surgery. No adverse events occurred throughout the conduct of the MBSR program. Peri-operative complications occurred in 10 participants in the MBSR group and 15 participants in the usual care group (p=0.526). A complete list of peri-operative complications by group allocation are available in Supplement 2 (s2-Table 1)

3.1 Outcomes

For the primary outcome at 12 months there was a significant between-group difference in WOMAC pain, mean difference of -10.3 (95% CI, -19.0 to -1.60; *P*=0.021) and WOMAC function, mean difference of -10.3 points (95% CI, -19.2 to -1.3; *P*=0.025), (Table 2). For secondary outcomes there was a significant between group difference in WOMAC global of -9.5 (95% CI, -17.8 to -1.1; *P*=0.027). No other between group differences in any other secondary outcomes were observed at 12 months and no between group differences were observed at 3-months for any outcome (Table 2). While there was no statistically significant between group difference in the time that elapsed from consent to surgery, for completeness we performed a secondary analysis with time to surgery included as a covariate and this did not significantly alter our findings, Supplement 2 (s2-Table 2).

Main outcomes were collected and analysed in 100 of 101 (99%) of study participants who underwent TJA, however 26 participants did not proceed to surgery after randomisation and as such had missing

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outcome data at 1-year. We identified no imbalance in baseline characteristics between participants who were randomised (Table 1) and participants who were analysed, Supplement 2 (s2-Table 3). An assessment of missingness (Supplement 2, s2-Table 4) suggested differential loss to follow-up in the MBSR group with a higher proportion of those who did not proceed to surgery being from a lower socioeconomic background (SEIFA score) and for the TAU group baseline WOMAC scores were lower and VR12 physical component scores (PCS) were higher in those who did not proceed to surgery. To assess the sensitivity of our primary analysis we conducted a full intention to treat analysis using linear mixed-models analysis including those with no follow-up measures and adjusting for covariates associated with the missingness[31]. Consistent with a likelihood-based and non-biased estimation, missing data was imputed based on information contained in the observed data. Models were adjusted for all baseline variables that were imbalanced across groups in those cases with 1-year follow-up, Supplement 2 (s2-Table 4).

The sensitivity analyses returned effects of similar size and significance as our primary analyses for WOMAC pain, function and global, Supplement 2 (s2-Table 5).

3.2 Post Hoc Outcomes

A higher proportion of patients who underwent MBSR achieved the MCII threshold for pain improvement at 12 months [n=40/44 (91%)] compared to the control group [n=42/56 (75%), *P*=0.040], as well as for function improvement at 12 months [n=40/44 (91%)], compared to the control group [n=37/56 (66%), *P*=0.003] (Table 3).

4. DISCUSSION

In patients with moderate to severe psychological distress, improvements in pain and function 12-months post-TJA were significantly greater for those in whom surgery was preceded by an 8-week

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MBSR program, compared to a treatment as usual group. While overall, substantial improvements in pain and function were achieved by both groups, a higher proportion of patients who underwent MBSR training prior to TJA experienced a clinically meaningful improvement in pain and function, compared to the treatment as usual group. Unexpectedly, a higher proportion of patients withdrew from TJA surgery following MBSR, a majority citing symptom improvement as the reason.

To our knowledge there have been no prior trials testing the efficacy of mental health enhancement programs in patients awaiting TJA to which we can compare our results. Overall there is a paucity of trials targeting distressed patients that examine psychological therapies for improving pain and function after TJA or indeed, other elective surgical procedures. A single pilot study assessing the efficacy of pain coping skills training prior to knee arthroplasty for patients with elevated pain catastrophizing, reported greater reductions in pain severity, and greater improvements in function as compared to a usual care cohort at 2-months post-surgery.[32] A number of trial protocols have been recently published in this population [29, 33] suggesting an identified need for effective strategies to improve surgical outcomes for this high risk sub-group of patients.

In contrast, numerous studies of pre-surgery education and physiotherapy have been conducted, with little evidence for their effectiveness in improving post-TJA outcomes. A systematic review and meta-analysis of non-surgical and non-pharmacological interventions for patients with OA awaiting TJA, found no evidence of pre-surgery programs for improving outcomes after TKA and low quality evidence for exercise and education programs improving outcomes after THA.[34] A major point of difference between the systematic review and our trial, is that our intervention specifically targeted patients with a predefined risk factor associated with poor pain and function outcomes, whereas interventions in the systematic review were more broadly applied. The strength of our study was the *a priori* decision to target our intervention to patients with psychological distress. Patients who present for TJA are a heterogeneous group. Measuring the average treatment efficacy in

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heterogeneous populations fails to account for variation in individual responses to a treatment. Targeted treatment is more likely to demonstrate treatment-related benefit and increase health care efficacy.[35] For low back pain patients, emerging evidence suggests better response to treatments are achieved when physical and psychological interventions focus on modifiable prognostic risk factors.[36, 37]

There are a number of limitations in this study. Most notably, a significant proportion of patients randomised to the intervention, decided not to proceed with surgery based on symptom improvement, creating an imbalance in the numbers between our study arms and diminishing the power of our tests. This was an unexpected finding, given that enrolled patients had advanced OA and were deemed suitable candidates for TJA. We found no difference between those who proceeded to surgery and those who did not in terms of baseline characteristics and program attendance that might explain this finding, suggesting that even people with advanced OA may benefit from non-surgery interventions as a definitive treatment. That said, we did not collect pain and function questionnaires post completion of the MBSR program, so we have no basis from which to compare those who withdrew from surgery due to symptom improvement to those who proceeded to surgery, other than patient declaration. While we cannot rule out that systematic differences between participants who did and did not proceed to surgery may account for our findings, we believe the likelihood of this is low, given the similar size and significance of the treatment effect estimates under our primary and sensitivity analyses.

We chose to compare our intervention to a treatment as usual group which may call into question the effect of the intervention over and above any potential effect related to differential contact time. Differential contact time is problematic in therapy trials and there is no way to overcome this through statistical adjustment. Recognizing this issue, we chose a pragmatic approach in comparing our

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intervention to a control that represents current practice rather than non-credible sham time, that would more likely result in poor compliance and a differential dropout rate. For that reason, our primary end-point was measured at 12 months, whereby any potential bias arising from differential contact time is unlikely to be retained.

We encountered challenges with recruitment whereby more than half of eligible patients declined to participate and this prolonged the duration of the study. The main reasons for declining included a lack of interest in the study and logistical barriers to participating. Logistical barriers related to family commitments including being a carer for a dependent spouse or family member and responsibilities of caring for children and grandchildren. A portion of patients reported they were not physically well enough to commit to the travel required for attending the 8-week program, even after the offer of travel assistance. The timing of the MBSR program created logistical barriers for patients currently employed. For patients undergoing TJA, return to work can be delayed for up to six weeks after surgery. For working patients, it was difficult to motivate time off work pre-operatively that was required to attend weekly sessions.

A further logistical barrier was the time commitment of the course with some patients expressing concern about the potential of an 8-week course to delay surgery. Strategies that might help enhance participation in future trials include running abbreviated mindfulness-based courses to increase accessibility. Traditionally MBSR courses involve an 8-week format, however recent evidence supports the efficacy of shorter courses that incorporate a mindfulness-based intervention over a 4-week period in patients with low back pain. Further strategies include offering an MBSR program to patients with end-stage OA before they are waitlisted for TJA, upon initial presentation to the orthopaedic clinic. This would not only reduce the anxiety faced by patients over potentially delaying time to surgery but may also defer or even prevent patients proceeding with surgery.

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5. CONCLUSIONS

In patients with moderate to severe psychological distress, participating in a pre-surgery MBSR program resulted in greater improvements in pain and function after TJA. As up to 40% of people presenting for TJA report psychological distress[12] and this is associated with an increased risk of ongoing pain and poor function following TJA,[38, 39] substantial reductions in the number of patients who report a poor response to TJA could be achieved if this program was more broadly implemented. What remains unanswered and warrants further investigation, is a potential causal mechanism that would explain our main findings, and this is the subject of future research. We also acknowledged a number of limitations and logistical issues which may pose challenges for broader implementation and detract from the generalizability of our findings to other settings and surgical procedures. Despite this, the findings of our study represent an important advancement in the management of the sub-group of patients who exhibit psychological risk factors but are otherwise candidates for arthroplasty surgery.

Contributions: MD was a chief investigator, designed the trial, provided management oversight of the whole trial, wrote the statistical analysis plan, monitored data collection for the whole trial, and drafted and revised the paper. DC was a chief investigator, initiated the collaborative project, designed the trial, provided management oversight of the whole trial, drafted and revised the paper, SK was a chief investigator, designed the trial, provided management oversight of the whole trial, drafted and revised the paper, KM was a chief investigator, designed the trial, delivered the intervention, drafted and revised the paper, MS was a chief investigator, designed the trial, provided management oversight of the whole trial, drafted and revised the paper, EN was the trial co-ordinator, was responsible for participant recruitment, provided technical telephone support to trial participants, drafted and revised the paper, AD, JD, delivered the intervention and drafted and revised the paper, TS was the trial statistician, conducted all statistical analyses and drafted and revised the paper, PC was the lead investigator, initiated the collaborative project, designed the trial, provided management oversight of

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the whole trial, drafted and revised the paper. All authors had full access to all of the study data and take responsibility for the integrity of the data and the accuracy of the data. MD (mmdowsey@unimelb.edu.au) and PC (pchoong@unimelb.edu.au) take responsibility for the integrity of the work as a whole, from inception to finished article

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Data sharing: Reasonable requests for patient level data should be made to the corresponding author and will be considered by the trial Chief Investigators. Consent for data sharing was not obtained and ethics approval would be required from the study institution for future use of patient level data.

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FIGURE LEGEND

Figure 1: Consort Diagram of Screening, Randomisation, and Follow-up of Study Participants

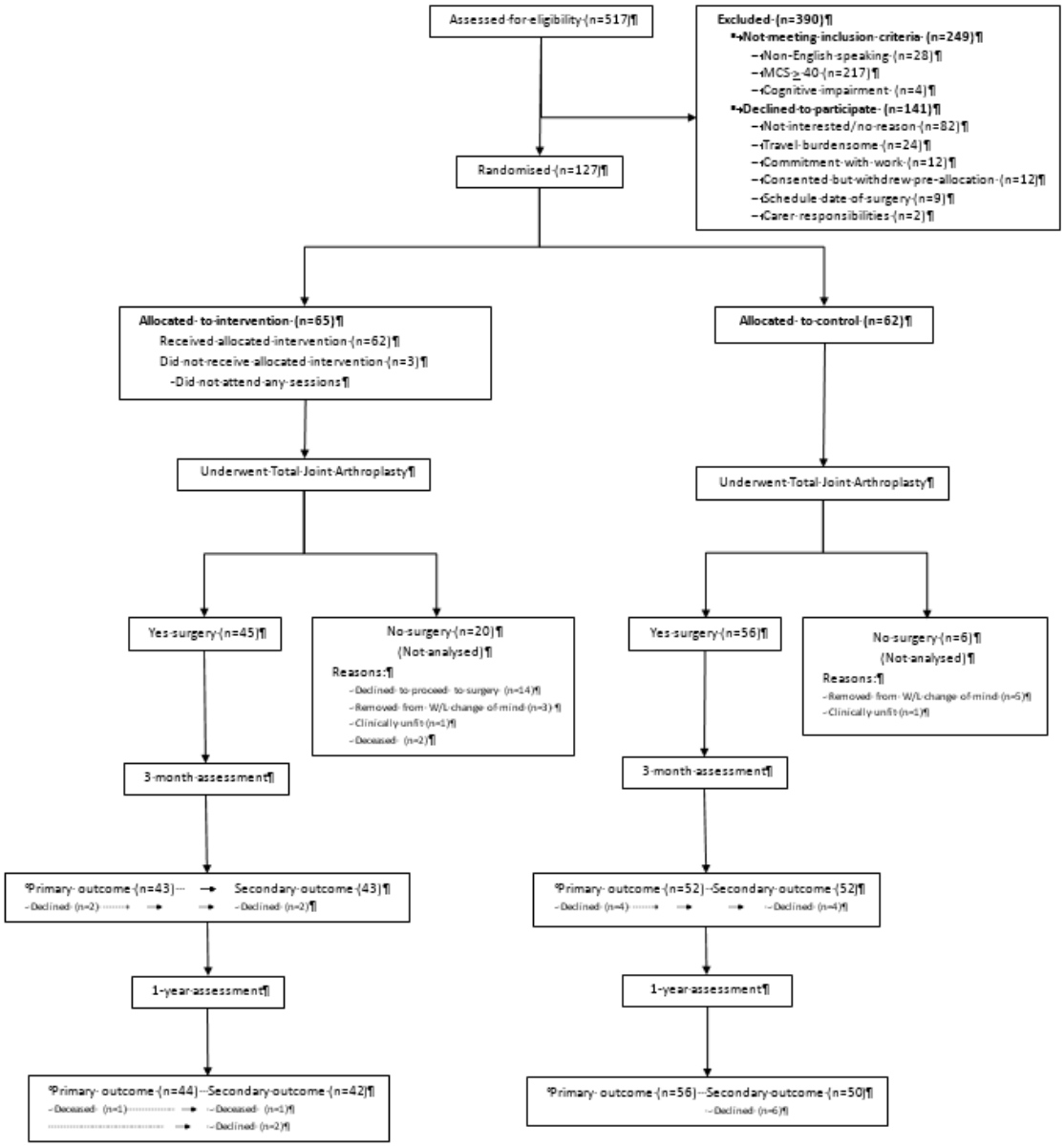

Figure 1: CONSORT Flow Diagram

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Table

Table 1: Baseline characteristics of randomised participants, by group

Measure*	TAU Group (n=62)	MBSR Group (n=65)	p-value
Age, *y*	65.1 (9.2)	65.8 (9.4)	.700
Female sex, *n, (%)*	41 (66.1)	51 (78.5)	.120
Body Mass Index, kg/m^2	33.0 (6.9)	33.1 (8.4)	.956
Socio-economic status, *n (%)*			
≤ 5	23 (37.1)	21 (32.3)	
> 5	39 (62.9)	44 (67.7)	.571
Aetiology, *n (%)*			
Osteoarthritis	58 (93.5)	61 (93.8)	
Rheumatoid Arthritis	4 (6.5)	4 (6.2)	.945
Kellgren Lawrence Grade, *n* (%)			
≤3	19 (28.8)	21 (32.3)	
4	43 (71.2)	44 (67.7)	.840
Charlson Comorbidity Index, *n (%)*			
0	40 (64.5)	36 (55.4)	
1	14 (22.6)	15 (23.1)	
>2	8 (12.9)	14 (21.5)	.404
**WOMAC, Pain	63.3 (21.2)	62.2 (16.2)	.748
WOMAC, Function	63.6 (19.4)	62.5 (14.2)	.719
WOMAC, Stiffness	66.5 (22.8)	64.8 (19.0)	.647
WOMAC, Global	66.7 (19.0)	62.5 (13.8)	.697
VR12, Physical Component Score	24.0 (7.1)	24.5 (7.6)	.734
VR12, Mental Component Score	40.2 (17.6)	41.6 (15.9)	.637
Arthritis Self Efficacy Scale, Pain	20.8 (12.0)	22.2 (11.0)	.497
Arthritis Self Efficacy Scale, Function	58.7 (14.4)	56.7 (18.9)	.505
Arthritis Self Efficacy Scale, Other	29.8 (14.7)	32.3 (13.6)	.335

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Mindfulness Questionnaire, Total	133.4 (18.2)	129.8 (20.6)	.317

*Presented as mean (SD) unless otherwise stated; **WOMAC - Western Ontario & McMaster Universities Arthritis Index

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Table 2. Mean Scores on Continuous Outcome Measures, by Group

Primary Outcomes	TAU Group		MBSR Group		Mean difference in outcome
	Number	Mean (SD)	Number	Mean (SD)	Mean (95% CI)
WOMAC*, Pain					
Baseline	56	66.3 (19.6)	45	63.0 (14.7)	
3 Months	52	26.3 (22.2)	43	21.6 (18.4)	-4.1 (-12.6 to 4.3)
12 Months	56	24.8 (25.1)	44	14.2 (16.4)	**-10.3 (-19.0 to -1.6)‡**
WOMAC, Function					
Baseline	56	66.1 (18.5)	45	64.3 (12.8)	
3 Months	52	30.0 (21.1)	43	23.8 (15.6)	-5.5 (-13.0 to 2.0)
12 Months	56	31.7 (26.4)	44	20.9 (17.8)	**-10.3 (-19.2 to -1.3)‡**
Secondary Outcomes					
WOMAC, Stiffness					
Baseline	56	69.4 (21.3)	45	67.5 (17.4)	
3 Months	52	34.6 (19.2)	43	32.6 (19.5)	-1.8 (-9.7 to 6.2)
12 Months	56	29.8 (27.6)	44	26.6 (24.6)	-3.0 (-13.5 to 7.6)
WOMAC, Global					
Baseline	56	66.3 (17.8)	45	64.1 (12.1)	
3 Months	52	29.5 (19.9)	43	24.0 (14.7)	-4.9 (-12.1 to 2.3)
12 Months	56	30.1 (24.7)	44	20.0 (16.3)	**-9.5 (-17.9 to -1.1)‡**
VR12* – Physical Component Summary					
Baseline	56	23.4 (6.5)	45	23.4 (7.2)	
3 Months	52	35.2 (11.5)	43	36.3 (11.5)	1.1 (-3.4 to 5.7)

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12 Months	56	37.6 (13.4)	44	38.8 (11.5)	1.2 (-3.9 to 6.2)
VR12 – Mental Component Summary					
Baseline	56	40.3 (18.1)	45	43.8 (17.0)	
3 Months	52	49.1 (14.6)	43	47.3 (15.9)	-3.5 (-8.5 to 1.5)
12 Months	56	47.1 (14.9)	44	48.0 (12.7)	-0.5 (-5.5 to 4.4)
Arthritis Self Efficacy, Pain					
Baseline	52	20.3 (12.0)	43	23.4 (9.7)	
3 Months	52	32.8 (12.2)	43	35.7 (10.1)	1.7 (-2.7 to 6.0)
12 Months	50	34.4 (12.8)	42	37.4 (10.0)	1.7 (-2.8 to 6.1)
Arthritis Self Efficacy, Function					
Baseline	52	57.7 (14.6)	43	58.7 (17.2)	
3 Months	52	70.4 (17.8)	43	71.7 (17.4)	-0.6 (-4.9 to 6.0)
12 Months	50	69.0 (18.3)	42	74.3 (17.1)	4.9 (-1.0 to 10.9)
Arthritis Self Efficacy, Other					
Baseline	52	29.8 (15.3)	43	33.9 (12.5)	
3 Months	52	42.9 (14.7)	43	47.1 (10.3)	2.1 (-2.4 to 6.6)
12 Months	50	42.6 (17.0)	42	47.0 (11.2)	2.3 (-3.0 to 7.6)
Mindfulness, Total					
Baseline	52	133.0 (18.6)	43	131.6 (21.1)	
3 Months	52	135.9 (19.4)	43	138.1 (14.5)	3.2 (-1.0 to 10.9)
12 Months	50	137.8 (21.2)	42	134.6 (22.8)	1.1 (-9.0 to 11.1)

ǂ **p=<0.05; WOMAC=** Western Ontario and McMaster Universities Osteoarthritis Index; VR12= Veterans Rand 12 item Health Questionnaire

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Table 3. Proportion of TJR recipients who achieved the minimum clinically important difference in WOMAC pain and function at 1 year, by Group

Outcome	TAU Group (n=56)	Group (n=44)	*p*
MCII Pain, *n* (%)	42 (75%)	40 (91%)	0.040
MCII Function, n (%)	37 (66%)	40 (91%)	0.003

*MCII = Minimum clinically important improvement

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