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RESEARCH ARTICLE

Yoga for the management of pain and sleep in rheumatoid arthritis: a pilot randomized controlled trial

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Abstract

Objective: The aim of the present study was to determine the feasibility of a relaxation-based yoga intervention for rheumatoid arthritis, designed and reported in accordance with Delphi recommendations for yoga interventions for musculoskeletal conditions.

Methods: Participants were recruited from a hospital database, and randomized to either eight weekly 75-min yoga classes or a usual care control. Feasibility was determined by recruitment rates, retention, protocol adherence, participant satisfaction and adverse events. Secondary physical and psychosocial outcomes were assessed using self-reported questionnaires at baseline (week 0), week 9 (primary time point) and week 12 (follow-up).

Results: Over a 3-month period, 26 participants with mild pain, mild to moderate functional disability and moderate disease activity were recruited into the study (25% recruitment rate). Retention rates were 100% for yoga participants and 92% for usual care participants at both weeks 9 and 12. Protocol adherence and participant satisfaction were high. Yoga participants attended a median of seven classes; additionally, seven of the yoga participants (54%) reported continuing yoga at home during the follow-up period. No serious adverse events were related to the study. Secondary outcomes showed no group effects of yoga compared with usual care.

Conclusions: A relaxation-based yoga programme was found to be feasible and safe for participants with rheumatoid arthritis-related pain and functional disability. Adverse events were minor, and not unexpected from an intervention including physical components. This pilot provides a framework for larger intervention studies, and supports further exploration of yoga as a complex intervention to assist with the management of rheumatoid arthritis.

KEYWORDS

complementary medicine, RCT, rheumatoid arthritis, yoga

1 | INTRODUCTION

Rheumatoid arthritis (RA) is a leading cause of pain and disability, associated with an increasing disease burden among our ageing population (Murray et al., 2013; Vos et al., 2013). The recommended management of RA includes an interdisciplinary approach (American College of Rheumatology, 2002), targeting both physical and psychological health through a combination of education, and pharmacological and non-pharmacological treatments.

Yoga presents as a promising non-pharmacological option for RA, combining physical, breathing and relaxation techniques to address the biopsychosocial impact of this chronic health condition (Evans, Tsao, Sternlieb, & Zeltzer, 2009; Ward, Treharne, & Stebbings, 2011). Evidence suggests that yoga has a moderate effect on improvement of pain and functional outcomes in a range of musculoskeletal conditions, including low back pain and osteoarthritis (Büssing, Ostermann, Lüdtke, & Michalsen, 2012; Cramer, Lauche, Haller, & Dobos, 2013; Ward, Stebbings, Cherkin, & Baxter, 2013).

To date, there have been few randomized controlled trials (RCTs) investigating the role of yoga for RA. A 6-week yoga intervention for young women with RA resulted in significant improvements in pain, disability and quality of life measures when compared with a usual care control (Evans et al., 2013). This supported findings from a convenience controlled study of 10 weeks' duration, involving 16 post-menopausal women. Significant improvements in perceived pain and perceived depression were reported in the yoga group compared

with the usual care control (Bosch, Traustadóttir, Howard, & Matt, 2009).

The primary objective of the current study was to investigate the feasibility and safety of a relaxation-focused yoga intervention for RA-related pain and sleep disturbance. The secondary objective was to estimate the effect of the yoga intervention on a range of functional and psychosocial outcomes. The content and focus of the yoga intervention were based on feedback from preliminary focus groups conducted with patients with RA, in which the preference for a relaxation-based yoga intervention targeting the improvement of pain and sleep outcomes was indicated (Ward et al., 2011). This study was designed according to Delphi recommendations for the components and reporting of yoga interventions for musculoskeletal conditions (Ward, Stebbings, Sherman, et al., 2014), and reported in accordance with CONsolidated Standards Of Reporting Trials (CONSORT) guidelines for non-pharmacological trials (Boutron, Moher, Altman, Schulz, & Ravaud, 2008), CONSORT guidelines for reporting of harms in randomized trials (Ioannidis et al., 2004) and CONSORT guidelines for reporting baseline data (CONSORT, 2013).

2 | METHODS

A detailed study protocol has been previously reported (Ward, Stebbings, Athens et al., 2014), and is summarized below. The study was registered with the Australian New Zealand Clinical Trials Registry (ACTRN12612001019897), received ethical approval from the Southern Health and Disability Ethics Committees (Ref 12/STH/24) and Health Research South (ID00837), and was conducted in accordance with the 1964 Declaration of Helsinki and its later amendments. All participants provided written informed consent prior to their inclusion in the study.

2.1 | Study design

The study was an assessor-blinded, two-arm, pilot RCT. The study duration was 13 weeks, inclusive of baseline and follow-up assessments. Participants were randomly assigned to either a standardized 8-week relaxation-based yoga programme or a usual care control group. Owing to the restricted availability of specialized equipment (electronic treatment tables), two separate cohorts participated.

The study, including yoga classes and outcomes assessments, was conducted at the School of Physiotherapy, University of Otago, New Zealand. All participants received a yoga pack (yoga mat, foam block, belt, relaxation CD) at study completion; no monetary incentives or reimbursements were provided.

2.2 | Participants

Sample size calculations are not required for feasibility studies (Leon, Davis, & Kraemer, 2011; Medical Research Council, 2012; Thabane et al., 2010); however, the number of participants considered appropriate for the present trial was 28, based on a 3-month recruitment period (Leon et al., 2011) and previous pilot studies of yoga for musculoskeletal conditions (Cox et al., 2010; Galantino et al., 2004; Saper et al., 2009). Potential participants were identified from a patient research database at a local hospital, and an invitation pack, including an information sheet and consent form, was posted to them. Those interested were screened for eligibility via a telephone assessment, and written informed consent was provided prior to the baseline assessment.

Eligibility criteria included age ≥ 18 years; physician-diagnosed RA according to American College of Rheumatology/European League Against Rheumatism 2010 classification criteria (Aletaha et al., 2010); average self-reported pain over the previous month ≥3 on a 10-point numerical rating scale; average self-reported sleep disturbance over the previous month greater than 30 min per night; and the ability to self-mobilize up and down from a chair. These criteria levels for pain and sleep, reflective of mild pain and mild sleep disturbance, are based on our previous focus group work, in which participants with RA indicated levels at which pain and sleep began to impact on their physical and psychosocial well-being (Ward et al., 2011). Specific exclusion criteria included current regular yoga practice (>1/week); major surgery within the past 6 months; planned surgery in the following 6 months; intra-articular steroid injections within the previous 4 weeks; serious co-morbidities; or inability to commit to the 13-week study period. Participants were requested to refrain from commencing complementary therapies or exercise programmes for the study duration.

2.3 | Randomization

Randomization and group allocation were conducted by an independent clinical study administrator. A block randomization sequence, generated using R statistical software (R, 2016), equally allocated participants from within each cohort into either the yoga (intervention) or usual care (control) group. Allocations were stored in a locked cabinet, in sealed, sequentially numbered, opaque envelopes, and then handed to participants in numerical order by the administrator after completion of their baseline assessments. Each envelope also contained a personal identification number (PIN), which participants used on all outcome assessments in place of their names.

2.4 | Interventions

2.4.1 | Yoga intervention

Participants allocated to the yoga group continued with their usual medical care provided by their rheumatologist and general practitioner. Additionally, they commenced an 8-week programme of group and home yoga practice (Ward, Stebbings, Athens, et al., 2014).

Group practice consisted of once-weekly 75-min yoga classes, conducted by a qualified yoga instructor and class assistant. Each class consisted of a 5-min check in, 5-min introduction to the class lesson and yoga philosophy theme, 7-min centring and breathing practice; 10-min warm-up practice (Pawanmuktasana 1) (Saraswati, 2008); 28-min session of supine, seated and standing yoga postures (5 − 10 postures per class); 15-min guided relaxation and 5-min closing discussion. Classes were progressive: new postures introduced every 2 weeks graduated from predominantly supine to predominantly standing. To accommodate functional limitations of participants, supine postures were practised on a 1.2-m-wide Metron Neuro electronic treatment table (Metron Neuro, manufactured by Metron Medical Australia),

accommodating self-mobilization up and down from the floor; standing postures had alternative seated versions for those who were uncomfortable with weight-bearing on their feet. Additionally, props (foam yoga block, belt, armless chair, pillows and blankets) were provided to support participants both in adopting postures and in resting comfortably in them.

Home practice consisted of a 20-min guided relaxation, based on the relaxation technique practised in the group sessions. A CD, recorded by the yoga instructor, was provided. Participants were asked to practise three times per week, at a time and day of their choice. Adherence to home practice in the previous week was verbally reported to the yoga instructor at the beginning of each session, and barriers and adherers to home practice were discussed among the group.

Instructors attended a training session before the classes began, and were provided with standardized class plans for each session. Any deviations from the plan were recorded at the end of class (Medical Research Council, 2012).

2.4.2 | Usual care intervention

Participants in the usual care group continued with their usual medical care provided by their rheumatologist and general practitioner for the management of their RA. This care included attending any prescheduled rheumatology or general practitioner appointments relating to their RA made prior to joining the study, and any changes in prescribed medication for their RA which may have resulted from these appointments. At the conclusion of the final follow-up assessment, participants in this group were offered a 2-day yoga course, consisting of a condensed version of the intervention classes.

2.5 | Outcome measures

Participant characteristics (including age, gender, ethnicity, RA duration, rheumatoid factor, anti-cyclic citrullinated peptide antibody and group preference) were collected at baseline. Outcome assessments were conducted by independent assessors, blinded to group allocation, at baseline (week 0), 1 week post-intervention (week 9; primary time point), and 4 weeks post-intervention (week 12). Primary feasibility outcomes included recruitment rates, retention (a priori level of 80% acceptable) and protocol adherence (a priori level of 6/8 group classes and 16/24 home classes acceptable). Participant satisfaction was assessed by a semi-structured questionnaire; all participants answered general questions regarding study satisfaction, and were encouraged to provide suggestions for improvements. Participants in the yoga group additionally answered questions regarding intervention content and home practice requirements. Primary safety outcomes included the type and frequency of adverse events (AEs) (Ioannidis et al., 2004).

Secondary outcomes were assessed using validated, self-reported questionnaires previously used in clinical RA trials. These included pain, measured on a 100-mm visual analogue scale (VAS) (Hawker, Mian, Kendzerska, & French, 2011); sleep quality, measured using the seven-item Insomnia Severity Index (ISI) (Bastien, Vallières, & Morin, 2001); functional disability, measured using the Health Assessment Questionnaire Disability Index (HAQ-DI) (Bruce & Fries, 2005); disease activity, assessed using the Clinical Disease Activity Index (CDAI) (Aletaha & Smolen, 2005); quality of life, assessed using the EuroQol EQ-5D-3 L (Carr, 2003; EuroQol Group, 2017); mood, assessed using the 14-item Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983); and fatigue, measured using the Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scales (BRAF-NRS) (Nicklin, Cramp, Kirwan, Greenwood, et al., 2010a; Nicklin, Cramp, Kirwan, Urban and Hewlett, 2010b).

2.6 | Statistical analysis

Participant PIN numbers ensured blinding of data analysis. Data were double-entered onto an Excel spreadsheet, and missing data replaced with group means (Williams et al., 2009). Composite scores were calculated and processed data transferred to R statistical software for analysis. Participant demographics and primary outcomes were classified as continuous or categorical, and appropriate descriptive statistics and percentages calculated.

Analysis of secondary outcomes was descriptive (Lancaster, Dodd, & Williamson, 2004); differences from baseline (week 0) to the primary time point (week 9) were calculated from individual participant differences. Group-by-time effects (week 0 to week 9) were calculated by univariate analysis of variance (UANOVA), using partial eta squared (PES). Levene's Test of Equality of Error Variances determined equal variance between the intervention and control groups for each outcome, which meant that log-transformation of data prior to analysis was unnecessary. In accordance with pilot study guidelines, *p*-values were not calculated for secondary outcomes (Leon et al., 2011).

3 | RESULTS

3.1 | Patient characteristics

Twenty-six individuals were recruited and randomized to the yoga ($N = 13$) or usual care ($N = 13$) group. Baseline demographic and clinical characteristics are reported in Table 1. Participants' ages ranged from 29 to 73 years (mean [standard deviation {SD}] 54 ± 11 years), with a duration of RA following diagnosis ranging from 1 to 31 years (mean [SD] 12 ± 10 years). Participants were predominantly female (96%), New Zealand European (85%), in a relationship (65%) and employed (73%). Yoga participants tended to be younger and had attained higher educational levels than usual care participants. Mean pain score at the telephone eligibility assessment was 6/10 (range 3–10). Medications taken by participants for RA included disease-modifying antirheumatic drugs (92%), glucocorticoids (46%) and bone-sparing therapies (31%). Prior to randomization, 12 of the 26 participants indicated a preference for allocation to the yoga group, and 12 participants indicated no preference.

3.2 | Primary outcome measures: Feasibility and safety

3.2.1 | Recruitment

Over a 3-month recruitment period, 103 RA patients were invited to join the study, of whom 77 (75%) expressed interest and were screened for eligibility (Figure 1). Fifty-one were subsequently excluded at the telephone eligibility assessment; the remaining 26

TABLE 1 Baseline demographics and clinical characteristics of study participants

Demographic	Group, *N* (%)		
	All (*N* = 26)	Yoga (*N* = 13)	Usual care (*N* = 13)
Age (years), mean ± SD	54 ± 11	50 ± 12	59 ± 8
RA duration (years), mean ± SD	12 ± 10	11 ± 10	12 ± 11
Female	25 (96)	13 (100)	12 (92)
Cultural origins			
New Zealand European	22 (85)	12 (92)	10 (77)
European	3 (12)	1 (8)	2 (15)
Asian	1 (4)	0 (0)	1 (8)
In a relationship/married	17 (65)	9 (69)	8 (62)
Employed	19 (73)	10 (77)	9 (69)
Tertiary education	12 (46)	8 (62)	4 (31)
BMI, mean ± SD	28 ± 4	27 ± 4	28 ± 4
Eligibility pain score (/10 on NRS)	6 ± 2	6 ± 2	5 ± 2
RF positive[a]	18 (90)	7 (88)	11 (92)
Anti-CCP positive[b]	14 (88)	6 (86)	8 (89)
RA medication			
DMARDs	24 (92)	12 (92)	12 (92)
NSAIDs	6 (23)	4 (31)	2 (15)
Biologics therapies	3 (12)	2 (15)	1 (8)
Bone-sparing therapies	8 (31)	4 (31)	4 (31)
Glucocorticoids	12 (46)	7 (54)	5 (38)
Analgesics	2 (8)	1 (8)	1 (8)
Previously practised yoga	8 (31)	4 (31)	4 (31)
Preferred group allocation			
Yoga intervention	12 (46)	6 (46)	6 (46)
Usual care	2 (8)	0 (0)	2 (15)
No preference	12 (46)	7 (54)	5 (39)

Anti-CCP, anti–cyclic citrullinated peptide; BMI, body mass index; CDAI, Clinical Disease Activity Index; DMARDs, disease-modifying anti-rheumatic drugs; NRS, numerical rating scale; NSAIDs, non-steroidal anti-inflammatory drugs; RA, rheumatoid arthritis; RF, rheumatoid factor; SD, standard deviation.

[a]Data available for seven yoga and 10 control participants.

[b]Data available for six yoga and eight control participants.

met all eligibility criteria, and were recruited into the study (93% of the targeted sample size of 28 participants). The overall recruitment rate was 25%; recruitment was higher among females (25/87; 29%) than males (1/16; 6%). The period between participant recruitment and baseline assessment ranged from 4 to 12 weeks (mean = 9.6 weeks).

3.2.2 | Retention

Participant retention exceeded the a priori feasibility level of 80% at baseline (100%), primary (96%) and follow-up (96%) periods (Figure 1). Following study completion, 11 of the 13 usual care participants (85%) attended the optional 2-day yoga workshop.

3.2.3 | Study adherence

No participants reporting commencing any additional exercise or therapy programmes during the study period. Two usual care participants had unplanned surgery; one yoga and two usual care participants received physiotherapy for pre-existing health reasons. As part of their usual medical care, 10 participants (six yoga, four usual care) received RA medication changes during the intervention period.

3.2.4 | Adherence to group yoga practice

Twelve yoga participants (92%) met a priori adherence levels, attending a median of seven of the eight group classes (IQR = 6,7). Weekly group adherence followed the same pattern for both cohorts, even though they started at different calendar points: attendance was lowest at Week 4, and highest in Weeks 7 and 8. Main reasons for non-attendance were pre-planned holidays, other commitments, and ill health.

3.2.5 | Adherence to home practice

Only five of the 13 yoga participants (38%) reached *a priori* adherence levels of at least 16/24 home practice sessions (median 14, interquartile range [IQR] 10–19). Adherence patterns mirrored those of group practice, and were lowest at week 4. Reasons given for not practising included time constraints (*N* = 3), illness (*N* = 3) or holidays (*N* = 2). Several yoga participants experienced difficulty in finding quiet time to use the CD provided for home practice, as the CD player was often located in a family space. One participant downloaded the CD to their mobile phone for easier use, and four participants reported memorizing the relaxation technique and practising most nights in bed without needing the CD.

3.2.6 | Participant satisfaction

Study satisfaction was high. All 25 participants who provided data at week 12 reported that they had been sufficiently informed about the study prior to giving consent, and 22 (88%) were very satisfied with being in the study. Of the 13 yoga participants, 11 (85%) reported that the yoga programme was not bothersome, and all (100%) preferred the instructor-led group classes over the self-directed home practice. The most favoured aspects of the classes were relaxation practices (54%), breathing practices (23%) and physical yoga postures (15%). Three participants (23%) indicated that they would have been physically unable to complete the supine postures without the electronic treatment tables. Seven of the 13 yoga participants (54%) indicated that they had continued to practise at home between the week 9 and week 12 assessments. Nine participants (64%) indicated that they would like to continue with yoga in the future, for the feelings of calmness and relaxation they experienced following practice. The main issues identified as preventing long-term practice were time pressure and lack of self-motivation.

3.2.7 | AEs

Thirteen yoga participants self-reported 25 AEs during the intervention period (weeks 1–8), and six yoga participants reported an AE during the follow-up period (weeks 9–12). No serious AEs were related to the yoga intervention (Table 2). The most common AE reported was increased musculoskeletal pain, which was generally mild, transient (of 24–48 h duration) and located in the upper body. Additionally, one participant reported six separate events of nausea when lying supine to practise relaxation.

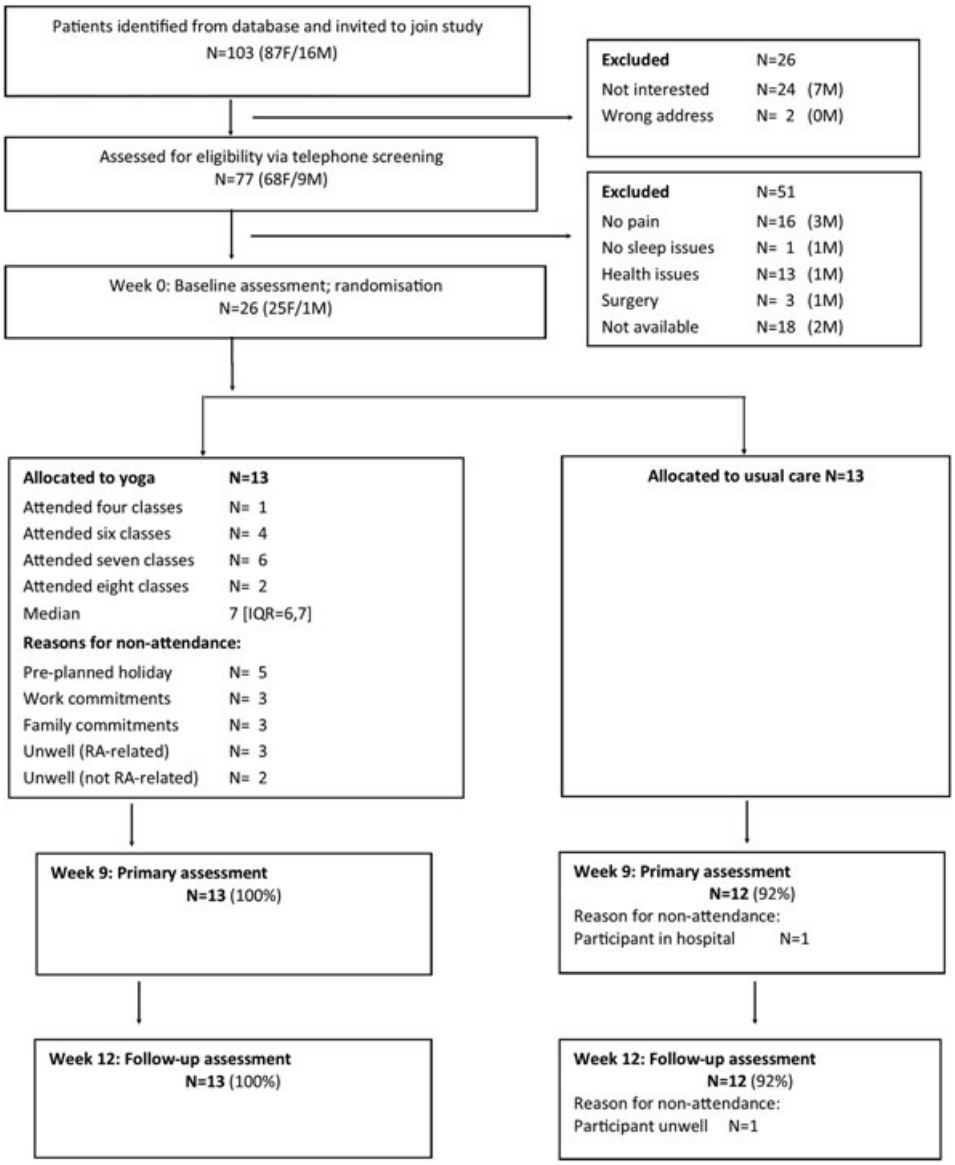

FIGURE 1 Flow of participants through the trial. F, Female; IQR, Interquartile range; M, Male

In the usual care group, nine participants each reported one AE during the intervention period, and seven participants each reported one AE during follow-up. These events included RA flares (*N* = 5), infections (*N* = 5) and unplanned surgery (*N* = 2).

3.3 | Secondary outcome measures

Descriptive statistics for secondary outcomes are reported in Table 3. Baseline scores were similar for both groups, indicating a clinical population with mild pain (Hawker et al., 2011) and sleep difficulties (Bastien et al., 2001). However, the pain (VAS) scores of 15 participants (yoga *N* = 7; usual care *N* = 8) and sleep (ISI) scores of two participants (yoga *N* = 1; usual care *N* = 1) were below the equivalent minimum eligibility criteria recorded at the telephone eligibility assessment.

Additional secondary outcomes indicated mild to moderate functional disability (HAQ-DI: yoga mean = 0.51 [SD 0.61]), usual care mean = 0.68 [SD 0.63]); moderate disease activity (CDAI: yoga: 14.2 [SD 6.2], usual care: 14.5 [SD 8.0]) and good psychosocial health (HADS: yoga: 6.5 [SD 2.8]), usual care: 4.9 [SD 3.0]; EuroQol EQ-5D-3 L: yoga: 0.77 [SD 0.17], usual care: 0.77 [0.24]) at baseline.

Scores remained comparatively stable for all secondary outcomes across all three time points. Accordingly, univariate analysis of variance, using PES, indicated no group-by-time effect of yoga for any secondary outcome measures. However, within-patient variability was high for all outcome measures, as noted by the broad 95% confidence intervals.

4 | DISCUSSION

The current pilot RCT investigated the feasibility of a relaxation-focused yoga intervention for RA, designed according to Delphi recommendations for the content and reporting of yoga interventions for musculoskeletal conditions (Ward, Stebbings, Sherman, et al., 2014).

Findings indicated that this relaxation-focused yoga programme was both feasible and safe for an RA population with mild pain, mild to moderate functional disability and moderate disease activity.

TABLE 2 Adverse events self-reported by participants during the intervention and follow-up periods

Event	Study period	Study related				
		Unrelated	Unlikely	Possible	Probable	Definite
Musculoskeletal pain	Intervention	YYYY C	YYY	YY	YYYYY	–
	Follow-up	Y	–	–	–	–
Nausea	Intervention	–	–	–	–	YYYYYY[a]
	Follow-up	–	–	–	–	–
RA flare-up	Intervention	Y CCC	–	–	–	–
	Follow-up	YYYY CC	–	–	–	–
Flu	Intervention	YY	–	–	–	–
	Follow-up	Y CC	–	–	–	–
Infection	Intervention	CCC	–	–	–	–
	Follow-up	CC	–	–	–	–
Neuralgia	Intervention	C	Y	–	–	–
	Follow-up		–	–	–	–
Surgery	Intervention	Y C	–	–	–	–
	Follow-up	C	–	–	–	–

C, control participant; RA, rheumatoid arthritis; Y, yoga participant.

[a]All six events of nausea were reported by one participant

Directly recruiting from an existing hospital patient database resulted in 93% of the targeted sample size being achieved within the pre-specified 3-month recruitment period, indicating high interest among local people in trialling yoga for the management of their RA. Recruitment rates compared favourably with those in previous yoga studies targeting patient databases (Cox et al., 2010; Sherman et al., 2011) and support further use of this recruitment method in future research.

Excellent retention of study participants was achieved, indicating satisfaction with the response cost of study involvement. Participant retention was comparable with previous non-randomized, wait-list control studies of yoga in an RA population. A 6-week pilot study of bi-weekly yoga involving posture and breathing techniques had 100% retention in both the yoga and control groups (Badsha, Chhabra, Leibman, Mofti, & Kong, 2009), and a 10-week programme of hatha yoga reported an average 80% retention rate among control and yoga participants (Bosch et al., 2009). The current study further demonstrates high retention rates among participants randomly allocated to the usual care group who had indicated a preference for the yoga group. This suggests that the provision of an optional yoga workshop on completion of the study was acceptable to usual care participants.

Excellent adherence (92%) of participants in the yoga group to the instructor-led group classes was indicative of participant satisfaction with the yoga programme. The use of electronic tables in the delivery of the yoga programme enabled recruitment of participants who may have struggled to self-mobilize to and from the floor when doing the supine yoga postures (Ward et al., 2011). The inclusion of these participants enhanced the ecological validity of the study (Schmuckler, 2001), by delivering the programme to a study population with functional limitations representative of a general RA population. The use of this specialized equipment also addressed previous reasons given for lack of physical activity in individuals with musculoskeletal conditions (Shih, Hootman, Kruger, & Helmick, 2006; Ward et al., 2011).

Comprehensive reporting of AEs indicated that the current protocol was low risk for individuals with RA, with no serious AEs attributed to the study. The most common AE associated with the yoga protocol was delayed onset of musculoskeletal pain, lasting 24–48 h after class. The majority of pain occurred in the upper body, notably the shoulder region, which participants attributed to the initial introduction of postures involving increased range of motion in the shoulder joint. These AEs reflect those commonly reported in previous yoga interventions for musculoskeletal conditions (Saper et al., 2009; Sherman et al., 2011; Taibi & Vitiello, 2011). Muscle soreness and discomfort is not uncommon in people with musculoskeletal conditions who are attempting new physical activities (Hagen et al., 2012) and usually decreases with continued practice (Garber et al., 2011).

Fourteen participants reported baseline levels of pain or sleep below equivalent minimum eligibility levels. This indicates the temporal variability of RA-associated symptoms (Schneider et al., 2012) and the associated difficulty of imposing minimum eligibility criteria when there may be a substantial delay between recruitment and baseline assessment. Verbal feedback from participants suggested that symptom variability was associated with the onset or remission of RA flares between assessment periods. Symptom variability is also reflected by the number of participants requiring medication changes to manage flares of their RA over the study period, a finding commonly observed in clinical trials in RA populations (Eversden, Maggs, Nightingale, & Jobanputra, 2007).

4.1 | Directions for future research

While high adherence to the instructor-led group classes suggests that participants are willing to commit to a regular instructor-led programme, adherence to home practice was poor. Complex interventions require high input from participants, and self-management components of these interventions may result in high attrition rates among people with arthritis (Newman, Steed, & Mulligan, 2004). As the guided relaxation CD developed for home practice involved a low response cost, and was based on preferences expressed in preliminary focus

TABLE 3 Descriptive statistics of secondary outcome measures

	Yoga			Usual care			
Outcome	**Week 0**	**Week 9**	**Change[a]**	**Week 0**	**Week 9**	**Change[a]**	PES
Pain VAS							
Mean (SD)	34 (18)	33 (21)	−1 (25)	31 (28)	33 (32)	2 (17)	0.001
95% CI	24, 44	21, 44	−15, 12	16, 46	15, 51	−7, 12	
ISI							
Mean (SD)	12.5 (7.1)	8.5 (4.7)	−4.1 (4.8)	10.4 (5.7)	8.8 (6.0)	−1.6 (3.8)	0.011
95% CI	8.7, 16.4	5.9, 11.0	−6.7, −1.5	7.3, 13.5	5.5, 12.0	−3.7, 0.5	
HAQ-di							
Mean (SD)	0.51 (0.61)	0.35 (0.35)	−0.16 (0.40)	0.68 (0.63)	0.83 (0.76)	0.14 (0.28)	0.017
95% CI	0.18, 0.84	0.16, 0.54	−0.38, 0.06	0.34, 1.023	0.41, 1.24	−0.01, 0.30	
CDAI							
Mean (SD)	14.2 (6.2)	11.5 (7.3)	−2.7 (9.7)	14.5 (8.0)	9.6 (7.6)	−4.8 (4.0)	0.010
95% CI	10.9, 17.6	7.6, 15.5	−8.0, 2.6	10.1, 18.8	5.5, 13.7	−7.0, −2.7	
EQ-5D-3 L							
Mean (SD)	0.77 (0.17)	0.76 (0.14)	−0.02 (0.18)	0.77 (0.24)	0.73 (0.26)	−0.04 (0.16)	0.001
95% CI	0.68, 0.86	0.68, 0.83	−0.12, 0.07	0.64, 0.90	0.59, 0.87	−0.13, 0.04	
EQ-5D-3 L vas							
Mean (SD)	76.5 (15.9)	75.8 (17.9)	−0.7 (23.3)	70.9 (19.8)	74.1 (21.0)	3.2 (10.2)	0.003
95% CI	67.9, 85.2	66.1, 85.6	−13.3, 12.0	60.2, 81.7	62.7, 85.5	−2.4, 8.7	
HADS Anxiety							
Mean (SD)	6.5 (2.8)	4.7 (3.8)	−2.0 (2.7)	4.9 (3.0)	4.9 (2.7)	0.0 (2.9)	0.023
95% CI	5.0, 8.1	2.6, 6.7	−3.5, −0.5	3.3, 6.6	3.4, 6.4	−1.6, 1.6	
HADS depression							
Mean (SD)	3.4 (2.3)	3.0 (1.9)	−0.4 (2.2)	2.9 (2.6)	3.1 (2.7)	0.2 (1.9)	
95% CI	2.2, 4.6	2.0, 4.0	−1.6, 0.8	1.5, 4.3	1.6, 4.5	−0.9, 1.2	0.003
BRAF-NRS level							
Median/IQR	5 (4, 8)	4 (2, 7)	−1 (−4, 1)	5 (2, 8)	3 (2, 5)	−1 (−3, 1)	0.002
Range	2 to 9	1 to 10	−6 to 6	1 to 10	1 to 7	−6 to 2	
BRAF-NRS effect							
Median/IQR	5 (2, 7)	3 (1, 5)	−1 (−4, 1)	3 (2, 6)	4 (1, 6)	−1 (−2, 2)	0.002
Range	0 to 9	0 to 10	−9 to 9	0 to 9	0 to 7	−5 to 3	
BRAF-NRS coping							
Median/IQR	7 (5, 9)	8 (7, 9)	0 (−1, 3)	8 (5, 9)	8 (4, 8)	−1 (−3, 2)	0.014
Range	4 to 10	4 to 10	−6.0 to 5.0	2 to 10	1 to 9	−7 to 6	

BRAF-NRS, Bristol Rheumatoid Arthritis Fatigue Numerical Rating Scales; CDAI, Clinical Disease Activity Index; CI, confidence interval; EQ-5D-3 L, EuroQol EQ-5D-3 L; HADS, Hospital Anxiety and Depression Scale; HAQ-DI, Health Assessment Questionnaire Disability Index; IQR, interquartile range; ISI, Insomnia Severity Index; PES, partial eta squared; SD, standard deviation; VAS, visual analogue scale.

[a]Difference in group means between baseline and primary time points.

group work (Ward et al., 2011), further investigation is required to determine barriers and facilitators to self-practice. Based on participant feedback from the current study, facilitators may include the provision of multiple audio-visual aids for home practice, varying in length and type of yoga practice. These resources would enable participants to choose a yoga practice best suited to their current time constraints and home environment.

Instructors play an important role in providing social support and motivation to participants in exercise-based programmes for arthritis (Schoster, Callahan, Meier, Mielenz, & DiMartino, 2005). Accordingly, providing participants with an initial one-on-one session with the instructor prior to the first group class may enhance adherence to group and home practice. This session would involve identifying any physical limitations or general concerns of the participant, providing variations of postures and prop use to accommodate these issues, and reducing the potential for AEs from the yoga practice. A home practice plan could also be devised, identifying optimal times and places for practice.

A substantial number of participants had limited pain and sleep issues at baseline, despite eligibility criteria imposing minimum levels for these outcomes. As the symptoms of RA may vary markedly within a patient over the course of a day, or a month (Stone, Broderick, Porter, & Kaell, 1997), to preclude individuals with primary clinical outcomes below minimum entry criteria from joining the study, a further eligibility screening of these outcomes at the baseline assessment is recommended. Additionally, it is recommended that a future trial targeting improvements in pain and sleep through the practice of relaxation-based yoga increases the eligibility criteria of these factors. We recommend a minimal score indicative of moderate, rather than mild,

pain over the previous month (Hawker et al., 2011), and a minimum score of 8 on the ISI, indicating sleep difficulties (Bastien et al., 2001). While these amendments to study design may necessitate a larger pool of potential participants, thus affecting costs and time schedules for recruitment, it will prevent a floor effect for these primary clinical outcome measures.

The descriptive statistics provided by the present study are supported as useful in determining sample size calculations for future larger clinical trials (Leon et al., 2011). Targeted sample sizes should incorporate attrition rates due to AEs. Rates of RA flares, infections and unplanned surgery in the current intervention ranged from 8% to 23%. As these events could potentially lead to participant withdrawal from a study, a conservative attrition rate of 20% is estimated for a future main trial.

The present pilot feasibility study had some limitations. The generalizability of pilot study results is limited to the eligibility criteria defining the study population (Leon et al., 2011). Additionally, it is noted that the inclusion of specialized equipment did not require participants to self-mobilize up and down from the floor. As many of the postures in the current protocol were conducted in a supine position, a lack of specialized equipment may prevent RA patients with similar levels of mild to moderate functional disability from performing these postures, limiting the replication of the present study in centres unable to provide this equipment.

In conclusion, an 8-week relaxation-focused yoga programme, designed with reference to Delphi recommendations of yoga interventions for musculoskeletal conditions, was feasible and safe to deliver in an RA population experiencing mild pain, mild to moderate functional disability and moderate disease activity. Some participants depended on the use of specialized equipment and props to achieve certain yoga postures within the constraints of their physical disability. AEs were minor, and not unexpected from an intervention including physical components. Additional eligibility assessments directly prior to the baseline assessment are recommended to accommodate the variable nature of RA symptoms, ensuring that all participants meet the minimum criteria for primary outcome measures.

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REFERENCES

Aletaha, D., Neogi, T., Silman, A. J., Funovits, J., Felson, D. T., Bingham, C. O., … Cohen, M. D. (2010). 2010 rheumatoid arthritis classification criteria: An American College of Rheumatology/European league against rheumatism collaborative initiative. *Arthritis and Rheumatism*, *62*(9), 2569–2581. https://doi.org/10.1002/art.27584.

Aletaha, D., & Smolen, J. (2005). The simplified disease Activity index (SDAI) and the clinical disease Activity index (CDAI): A review of their usefulness and validity in rheumatoid arthritis. *Clinical and Experimental Rheumatology*, *23*(Suppl. 39), S100–S108.

American College of Rheumatology (2002). Guidelines for the management of rheumatoid arthritis. 2002 update. *Arthritis and Rheumatism*, *46*(2), 328–346. https://doi.org/10.1002/art.10148.

Badsha, H., Chhabra, V., Leibman, C., Mofti, A., & Kong, K. (2009). The benefits of yoga for rheumatoid arthritis: Results of a preliminary, structured 8-week program. *Rheumatology International*, *29*(12), 1417–1421. https://doi.org/10.1007/s00296-009-0871-1.

Bastien, C. H., Vallières, A., & Morin, C. M. (2001). Validation of the insomnia Severity index as an outcome measure for insomnia research. *Sleep Medicine*, *2*(4), 297–307.

Bosch, P., Traustadóttir, T., Howard, P., & Matt, K. (2009). Functional and physiological effects of yoga in women with rheumatoid arthritis: A pilot study. *Alternative Therapies in Health and Medicine*, *15*(4), 24–31.

Boutron, I., Moher, D., Altman, D., Schulz, K., & Ravaud, P. (2008). Extending the CONSORT statement to randomised trials of nonpharmacologic treatment: Explanation and elaboration. *Annals of Internal Medicine*, *148*(4), 295–309.

Bruce, B., & Fries, J. F. (2005). The health assessment questionnaire (HAQ). *Clinical and Experimental Rheumatology*, *23*(Suppl. 39), S14–S18.

Büssing, A., Ostermann, T., Lüdtke, R., & Michalsen, A. (2012). Effects of yoga interventions on pain and pain-associated disability: A meta-analysis. *Journal of Pain*, *13*(1), 1–9. https://doi.org/10.1016/j.jpain.2011.10.001.

Carr, A. (2003). Adult measures of quality of life: The Arthritis impact measurement scales (AIMS/AIMS2), disease repercussion Profile (DRP), EuroQoL, Nottingham health Profile (NHP), patient generated index (PGI), quality of well-being scale (QWB), RAQoL, short form-36 (SF-36), sickness impact Profile (SIP), SIP-RA, and World Health Organization's quality of life instruments (WHOQoL, WHOQoL-100, WHOQoL-Bref). *Arthritis Care and Research*, *49*(S5), S113–S133. https://doi.org/10.1002/art.11414.

CONSORT. (2013). Transparent reporting of trials: Baseline data. Retrieved from http://www.consort-statement.org/consort-statement/13-19---results/item15_baseline-data/

Cox, H., Tilbrook, H., Aplin, J., Semlyen, A., Torgerson, D., Trewhela, A., & Watt, I. (2010). A randomised controlled trial of yoga for the treatment of chronic low back pain: Results of a pilot study. *Complementary Therapies in Clinical Practice*, *16*(4), 187–193. https://doi.org/10.1016/j.ctcp.2010.05.007.

Cramer, H., Lauche, R., Haller, H., & Dobos, G. (2013). A systematic review and meta-analysis of yoga for low back pain. *Clinical Journal of Pain*, *29*(5), 450–460. https://doi.org/10.1097/AJP.0b013e31825e1492.

EuroQol Group. (2017). EQ-5D. Retrieved from http://euroqol.org/home.html

Evans, S., Moieni, M., Lung, K., Tsao, J., Sternlieb, B., Taylor, M., & Zeltzer, L. (2013). Impact of Iyengar yoga on quality of life in young women with rheumatoid arthritis. *Clinical Journal of Pain*, *29*(11), 988–997. https://doi.org/10.1097/AJP.0b013e31827da381.

Evans, S., Tsao, J. C. I., Sternlieb, B., & Zeltzer, L. K. (2009). Using the biopsychosocial model to understand the health benefits of yoga. *Journal of Complementary and Integrative Medicine*, *6*(1), 15. https://doi.org/10.2202/1553-3840.1183.

Eversden, L., Maggs, F., Nightingale, P., & Jobanputra, P. (2007). A pragmatic randomised controlled trial of hydrotherapy and land exercises on overall well being and quality of life in rheumatoid arthritis. *BMC Musculoskeletal Disorders*, *8*, 23. https://doi.org/10.1186/1471-2474-8-23.

Galantino, M., Bzdewka, T., Eissler-Russo, J., Holbrook, M., Mogck, E., Geigle, P., & Farrar, J. (2004). The impact of modified hatha yoga on chronic low back pain: A pilot study. *Alternative Therapies in Health and Medicine*, *10*(2), 56–59.

Garber, C. E., Blissmer, B., Deschenes, M. R., Franklin, B., Lamonte, M. J., Lee, I.-M., … Swain, D. P. (2011). American College of Sports Medicine position stand. Quantity and quality of exercise for developing and maintaining cardiorespiratory, musculoskeletal, and neuromotor fitness in apparently healthy adults: Guidance for prescribing exercise. *Medicine and Science in Sports and Exercise*, *43*(7), 1334–1359. https://doi.org/10.1249/MSS.0b013e318213fefb.

Hagen, K. B., Dagfinrud, H., Moe, R. H., Østerås, N., Kjeken, I., Grotle, M., & Smedslund, G. (2012). Exercise therapy for bone and muscle health: An overview of systematic reviews. *BMC Medicine*, *10*(1), 167. https://doi.org/10.1186/1741-7015-10-167.

Hawker, G. A., Mian, S., Kendzerska, T., & French, M. (2011). Measures of adult pain. *Arthritis Care and Research*, *63*(Suppl.11), S240–S252. https://doi.org/10.1002/acr.20543.

Ioannidis, J. P., Evans, S. J., Gøtzsche, P. C., O'Neill, R. T., Altman, D. G., Schulz, K., & Moher, D. (2004). Better reporting of harms in randomised trials: An extension of the CONSORT statement. *Annals of Internal Medicine*, *141*(10), 781–788.

Lancaster, G. A., Dodd, S., & Williamson, P. R. (2004). Design and analysis of pilot studies: Recommendations for good practice. *Journal of Evaluation in Clinical Practice*, *10*(2), 307–312.

Leon, A. C., Davis, L. L., & Kraemer, H. C. (2011). The role and interpretation of pilot studies in clinical research. *Journal of Psychiatric Research*, *45*(5), 626–629. https://doi.org/10.1016/j.jpsychires.2010.10.008.

Medical Research Council. (2012). Developing and evaluating complex interventions: New guidance. Retrieved from http://mrc.ac.uk/documents/pdf/complex-interventions-guidance

Murray, C. J., Vos, T., Lozano, R., Naghavi, M., Flaxman, A. D., Michaud, C., … Abdalla, S. (2013). Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990–2010: A systematic analysis for the global Burden of disease study 2010. *Lancet*, *380*(9859), 2197–2223.

Newman, S., Steed, L., & Mulligan, K. (2004). Self-management interventions for chronic illness. *Lancet*, *364*(9444), 1523–1537.

Nicklin, J., Cramp, F., Kirwan, J., Greenwood, R., Urban, M., & Hewlett, S. (2010a). Measuring fatigue in rheumatoid arthritis: A cross-sectional study to evaluate the Bristol rheumatoid Arthritis fatigue multi-dimensional questionnaire, visual analog scales, and numerical rating scales. *Arthritis Care and Research*, *62*(11), 1559–1568. https://doi.org/10.1002/acr.20282.

Nicklin, J., Cramp, F., Kirwan, J., Urban, M., & Hewlett, S. (2010b). Collaboration with patients in the design of patient-reported outcome measures: Capturing the experience of fatigue in rheumatoid arthritis. *Arthritis Care and Research*, *62*(11), 1552–1558.

R. (2016). The R project for statistical computing. Retrieved from http://r-project.org/index.html

Saper, R. B., Sherman, K. J., Cullum-Dugan, D., Davis, R. B., Phillips, R. S., & Culpepper, L. (2009). Yoga for chronic low back pain in a predominantly minority population: A pilot randomised controlled trial. *Alternative Therapies in Health and Medicine*, *15*(6), 18–27.

Saraswati, S. (2008). *Asana Pranayama Mudra Bandha*. Munger, India: Yoga Publications Trust.

Schmuckler, M. A. (2001). What is ecological validity? A dimensional analysis. *Infancy*, *2*(4), 419–436.

Schneider, S., Junghaenel, D. U., Keefe, F. J., Schwartz, J. E., Stone, A. A., & Broderick, J. E. (2012). Individual differences in the day-to-day variability of pain, fatigue, and well-being in patients with rheumatic disease: Associations with psychological variables. *Pain*, *153*(4), 813–822. https://doi.org/10.1016/j.pain.2012.01.001.

Schoster, B., Callahan, L., Meier, A., Mielenz, T., & DiMartino, L. (2005). The people with Arthritis can exercise (PACE) program: A qualitative evaluation of participant satisfaction. *Preventing Chronic Disease*, *2*(3), A11.

Sherman, K. J., Cherkin, D. C., Wellman, R. D., Cook, A. J., Hawkes, R. J., Delaney, K., & Deyo, R. A. (2011). A randomized trial comparing yoga, stretching, and a self-care book for chronic low back pain. *Archives of Internal Medicine*, *171*(22), 2019–2026. https://doi.org/10.1001/archinternmed.2011.524.

Shih, M., Hootman, J., Kruger, J., & Helmick, C. (2006). Physical activity in men and women with arthritis: National Health Interview Survey, 2002. *American Journal of Preventive Medicine*, *30*(5), 385–393. https://doi.org/10.1016/j.amepre.2005.12.005.

Stone, A. A., Broderick, J. E., Porter, L. S., & Kaell, A. T. (1997). The experience of rheumatoid arthritis pain and fatigue: Examining momentary reports and correlates over one week. *Arthritis and Rheumatism*, *10*(3), 185–193.

Taibi, D. M., & Vitiello, M. V. (2011). A pilot study of gentle yoga for sleep disturbance in women with osteoarthritis. *Sleep Medicine*, *12*(5), 512–517. https://doi.org/10.1016/j.sleep.2010.09.016.

Thabane, L., Ma, J., Chu, R., Cheng, J., Ismaila, A., Rios, L., … Goldsmith, C. (2010). A tutorial on pilot studies: The what, why and how. *BMC Medical Research Methodology*, *10*(1), 1–10.

Vos, T., Flaxman, A. D., Naghavi, M., Lozano, R., Michaud, C., Ezzati, M., … Aboyans, V. (2013). Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990–2010: A systematic analysis for the global Burden of disease study 2010. *Lancet*, *380*(9859), 2163–2196.

Ward, L., Stebbings, S., Cherkin, D., & Baxter, G. D. (2013). Yoga for functional ability, pain, and psychosocial outcomes in musculoskeletal conditions: A systematic review and meta-analysis. *Musculoskeletal Care*, *11*(4), 203–217. https://doi.org/10.1002/msc.1042.

Ward, L., Stebbings, S., Sherman, K., Cherkin, D., & Baxter, G. (2014). Establishing key components of yoga interventions for musculoskeletal conditions: A Delphi survey. *BMC Complementary and Alternative Medicine*, *14*, 196. https://doi.org/10.1186/1472-6882-14-196.

Ward, L., Treharne, G. J., & Stebbings, S. (2011). The suitability of yoga as a potential therapeutic intervention for rheumatoid arthritis: A focus group approach. *Musculoskeletal Care*, *9*(4), 211–221. https://doi.org/10.1002/msc.217.

Ward, L. J., Stebbings, S., Athens, J., Cherkin, D., & Baxter, D. (2014). Yoga for pain and sleep quality in rheumatoid arthritis: Study protocol for a pilot randomized controlled trial. *Physical Therapy Review*, *19*(4), 266–276.

Williams, K., Abildso, C., Steinberg, L., Doyle, E., Epstein, B., Smith, D., … Cooper, L. (2009). Evaluation of the effectiveness and efficacy of Iyengar yoga therapy on chronic low back pain. *Spine*, *34*(19), 2066–2076.

Zigmond, A. S., & Snaith, R. (1983). The hospital anxiety and depression scale. *Acta Psychiatrica Scandinavica*, *67*(6), 361–370.

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