Yoga for Pain and Sleep Quality in RA

This is the protocol for a feasibility study on RA, or rheumatoid arthritis. "Feasibility" study simply means a small pilot study to determine if the protocol is safe and effective as the first step in the research process. A larger pilot study would be the next step.

RA is significantly more prevalant in New Zealand, where the study is taking place, than in other developed countries. The reason for this is unclear.

I became aware of this study because the lead investigator, Lesley Ward, included me in an extensive survey on conducting yoga research. (See "Survey Says" article.) Lesley used the survey to come up with 33 recommendations on how to conduct a yoga research study. 31 of those recommendations were included in this protocol.

One difficulty in yoga studies is compliance in home practice. In this study, the home practice was a 20-minute recorded relaxation practice – something the participants enjoyed in the group class. This was a brilliant way of enticing participants to do their homework. I look forward to seeing the results of this to learn how effective the protocol was in lessening disease symptoms, reducing pain and fatigue, enhancing mood and quality of life. These are all key reasons why students come to yoga therapy.

See the full protocol, "Yoga for pain and sleep quality in rheumatoid arthritis: study protocol for a pilot randomized controlled trial" for complete details.

Yoga for pain and sleep quality in rheumatoid arthritis: study protocol for a pilot randomized controlled trial

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Background: Yoga is a popular complementary and alternative medicine (CAM) therapy among people with rheumatoid arthritis (RA), perceived as offering self-management options for physical and psychosocial symptoms associated with RA.
Objectives: The primary aims of the current pilot study are (1) to assess the feasibility and safety of a relaxation-focused yoga intervention tailored for people with RA and (2) to estimate the effect of yoga on RA-related pain, sleep quality, functional disability, disease activity, quality of life, anxiety, depression, and fatigue.
Method: Twenty-eight participants with at least minimum levels of RA-related pain and sleep disturbance will be recruited from a local public hospital database. Participants meeting inclusion criteria will be randomized into either a yoga group (receiving an 8-week program of once-weekly 75-minute relaxation-based yoga classes and thrice-weekly home practice), or a usual care control group. Outcomes will be assessed at baseline, 9, and 12 weeks. Feasibility is operationalized as acceptability (recruitment, adherence, participant retention, and participant satisfaction) and safety of the yoga intervention. Effect sizes for changes in pain, sleep quality, functional disability, disease activity, quality of life, mental health, and fatigue will be estimated.
Discussion: Results of this pilot study will provide empirical data to determine if a larger, statistically powered main trial is feasible and safe in a national RA population. Additionally, participant feedback will provide information regarding further adaption and tailoring of the study protocol to a clinical RA population.
Trial registration: Australian New Zealand Clinical Trials Registry ACTRN12612001019897 (registered 20/09/2012).

Keywords: Complementary and alternative medicine, Musculoskeletal, Rheumatoid arthritis, Yoga

Background

Rheumatoid arthritis (RA) is a systemic, inflammatory musculoskeletal condition,[1] with an estimated prevalence of 0.3–1% in developed countries.[2] In New Zealand, these rates are considerably higher, with an average prevalence of 2.3%, increasing to over 7% in the 65+ years age group, and a significantly higher prevalence among women than men.[3] A leading cause of chronic pain and disability,[1] RA has also been shown to negatively impact upon the psychosocial health of those affected with the condition.[4]

Current best practice management of RA focuses on the pharmaceutical management of pain, joint function, and joint preservation; and on exercise.[5] However, despite strong evidence to suggest that exercise may improve symptoms in RA,[6] engagement in exercise amongst people with RA is significantly lower than in the general population.[7,8] Reasons for these lower levels of activity may include fatigue and decreased functional ability,[9] the perception of exercise programs as prescriptive and non-adaptable to the variable pain and fatigue levels of people with RA,[10] and a corresponding concern of exercise-induced pain.[8,10]

People with RA perceive that a focus on the biomedical management of their condition within the medical consultation fails to address the psychosocial aspect of living with RA.[10] Research suggests that people with RA are interested in self-management

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techniques both for the management of their pain and as a means of enhancing psychosocial well-being.[11] Self-management is perceived as providing an opportunity to reduce dependence on pharmaceutical management, adjust exercise routines to the current needs of this variable health condition, and address the management of the psychosocial aspects of the condition.[10,12] This interest in RA self-management is reflected in the high use of complementary and alternative medicine (CAM) therapies among people with RA,[13] either as an adjunct to biomedical treatment or as a preferred treatment option.[14]

One of the most popular forms of CAM therapy among people with RA is yoga.[15] A mind–body therapy, the practice of yoga generally features physical postures, breathing, and relaxation components,[16] thus promoting biopsychosocial health benefits beyond those of exercise.[17] Yoga is perceived by people with RA as adaptable to the variable nature of their condition, and as offering an opportunity to self-manage both the physical and psychosocial aspects of their health.[10] In previous clinical trials, yoga appears to be a safe and acceptable therapy, with moderate treatment effects on pain and functional outcomes in chronic musculoskeletal conditions.[18–20]

There is a paucity of randomized controlled trials (RCTs) of yoga in an adult RA population.[20,21] An RCT study from India reported that participation in a 40-day yoga intervention significantly decreased pain in an RA population, compared to an unspecified control group.[22] However, study findings are weakened by lack of reported data and poor methodological quality.[20] Findings from two convenience controlled studies of similar duration further suggest improvements in RA-associated symptoms following yoga practice. In a study of post-menopausal women with RA, yoga participants reported significant improvements in functional ability, perceived pain, and perceived depression following a 10-week yoga intervention compared to a usual care control.[23] Improved functional ability was also reported in women (mean age 44 years) with RA compared to usual care following 6 weeks of yoga.[24]

To date no clinical trials of yoga for RA have been conducted in a New Zealand population. Our previous qualitative research has identified RA-associated pain and sleep disturbance as patient-centered outcome priorities for a clinical trial, and indicated potential barriers and facilitators to class adherence.[10] Additionally, we have conducted an international Delphi survey to develop and define a core set of key components in the design and reporting of yoga interventions for musculoskeletal conditions.[25] The outcomes of these two studies, in conjunction with UK Medical Research Council guidelines,[26] have guided the development of the current study protocol, and informed the parameters of duration and frequency of the yoga classes.

The primary aim of the current study is to investigate the feasibility (operationalized as recruitment rates, participant retention, protocol adherence, and participant satisfaction) and safety (operationalized as frequency and severity of adverse events) of a relaxation-focused yoga intervention for the management of RA-related pain and sleep disturbance. A secondary aim is to estimate effect sizes for changes in outcomes of RA-related pain, sleep quality, functional disability, disease activity, quality of life, mood, and fatigue. This protocol is reported in accordance with CONSORT guidelines for nonpharmacologic trials.[27]

Methods

Trial design

The trial is an assessor-blinded, pilot RCT design, conducted over a 13-week period (inclusive of baseline assessment). The trial will be conducted in two cohorts, with a maximum of 14 participants per cohort. Outcome measures will be assessed at baseline (Week 0), 1-week post-intervention (Week 9; primary time point), and 4 weeks post-intervention (Week 12), resulting in a total time commitment of 13 weeks per participant. All assessments and yoga classes will be conducted in-person at the School of Physiotherapy, University of Otago, Dunedin. Ethical consent for the trial has been granted by the Southern Health and Disability Ethics Committees (12/STH/24), and Health Research South (ID00837); the trial is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12612001019897).

Study population

The targeted study population is people over the age of 18 years, with a clinical diagnosis of RA,[28] who self-report both pain and sleep disturbance associated with their condition. People who are not bothered by their RA symptoms, who already practice yoga, or who are currently involved in other research projects are not being sought for the study. Potential participants will be identified from an existing database of RA patients held by the Rheumatology Department, Dunedin Public Hospital, New Zealand. This method of database recruitment has previously been used in clinical yoga trials,[29] and enables focused targeting of potential participants within a small recruitment time frame.

Sample size

As this is a feasibility study, sample size calculations are not required.[26,30–32] We aim to recruit 28 participants for this feasibility study. Participants will be randomized equally between the intervention

and the control group, allowing two yoga classes of seven participants each to be conducted. This sample size reflects previous pilot studies of yoga for musculoskeletal conditions;[29,33,34] is considered to be a realistic target from the Rheumatology Department's database of approximately 3000 RA patients; and will provide sufficient data to assess feasibility, safety, and trends of outcome measures. Recruitment will be ongoing until 28 participants have been enrolled, and is estimated to take 3 months to complete.

Recruitment procedure and baseline assessment

The recruitment and study procedure is outlined in Fig. 1. Potential participants will be mailed a letter of invitation to the study, together with an information sheet explaining the study, a consent form indicating study commitments, and a postage-paid envelope. If potential participants are not interested in the study, they may either sign a tear-off form attached to the invitation letter and return it in the postage-paid envelope, or contact research staff by email or telephone. There will be no disadvantage to potential participants in declining to join the study, and they will not be further contacted.

Potential participants will be contacted by telephone approximately 10 days after receiving the letter of invitation (allowing them time to decline participation). If they indicate interest in the study, an eligibility screening interview will be conducted during the telephone call, with pre-defined inclusion and exclusion criteria questions based on previous yoga and musculoskeletal research (Table 1).[35–37] As pain and sleep disturbance are main secondary outcomes of interest, potential participants must verbally self-report average pain during the past month $\geq$3 on a 10-point numerical rating scale and sleep disturbance equivalent to >30 minutes at night. Participants will not be informed of these minimum inclusion levels before being asked to rate them. Additionally, the ability to self-mobilize up and down from a chair, but not from the floor, is required. This criterion ensures potential participants will not be excluded on the basis of functional limitation or variability of agility associated with active phases of RA.[38] If all criteria are met during the telephone screening interview, participants will be verbally enrolled into the study. A letter will subsequently be posted to them confirming their recruitment, and outlining the estimated timetable for the study.

When the first cohort has been recruited, individual appointments will be made for baseline assessment (Week 0). At this assessment, study procedures and commitments will again be explained to participants, written informed consent obtained, and baseline assessment of primary and secondary outcomes conducted. Baseline information will be collected on age, sex, ethnicity, height, weight, duration of RA, marital status, employment status, education level, rheumatoid factor, anti-CCP antibody status, current RA medication, current CAM treatments, current levels of activity, and knowledge of yoga. Immediately following collection of baseline data, participants will be randomized to the intervention/yoga group (Group A), or the control/usual care group (Group B). The 8-week yoga intervention will begin the following week (Week 1). An identical assessment and randomization procedure will be followed for the second cohort of 14 participants.

Randomization and treatment allocation

A randomization sequence will be generated by an independent researcher using the R statistical software package, version 2.14.2.[39] Randomization will be by random permuted blocks of 14, with each block randomizing seven participants to the intervention group and seven participants to the control group. The generated randomized numbers will be consecutively sealed in identical opaque envelopes, and stored in a locked cabinet by an independent study administrator, who will distribute envelopes to participants sequentially as they complete their baseline assessments. The independent researcher will also allocate each participant a personal identification number (PIN), which will be used in place of the participant's name on all assessment packs to ensure participant anonymity. This PIN will be known only to the participant and the independent researcher.

Study interventions

Yoga (Group A)

Participants in the yoga group will continue to receive their usual medical care under their Rheumatologist and General Practitioner, including prescribed concomitant medication (e.g. paracetamol and NSAIDs) for their RA. Additionally, they will receive an 8-week relaxation-focused yoga program consisting of group and home practice. This program duration conforms to Delphi recommendations for minimum parameter values of yoga interventions for musculoskeletal conditions;[40] and is of sufficient duration to indicate potential benefits of yoga in musculoskeletal populations.[37,41,42] The yoga program has been developed in consultation with a certified yoga therapist,[43] with reference to yoga practices and postures deemed safe and acceptable to participants in previous trials of yoga for musculoskeletal conditions.[22,34,37,43–45]

Group practice will consist of eight weekly 75-minute instructor-led classes, conducted at the School of Physiotherapy, University of Otago, Dunedin. Classes will be held in the early evenings, in a large, well-lit, carpeted room with stair and elevator access.

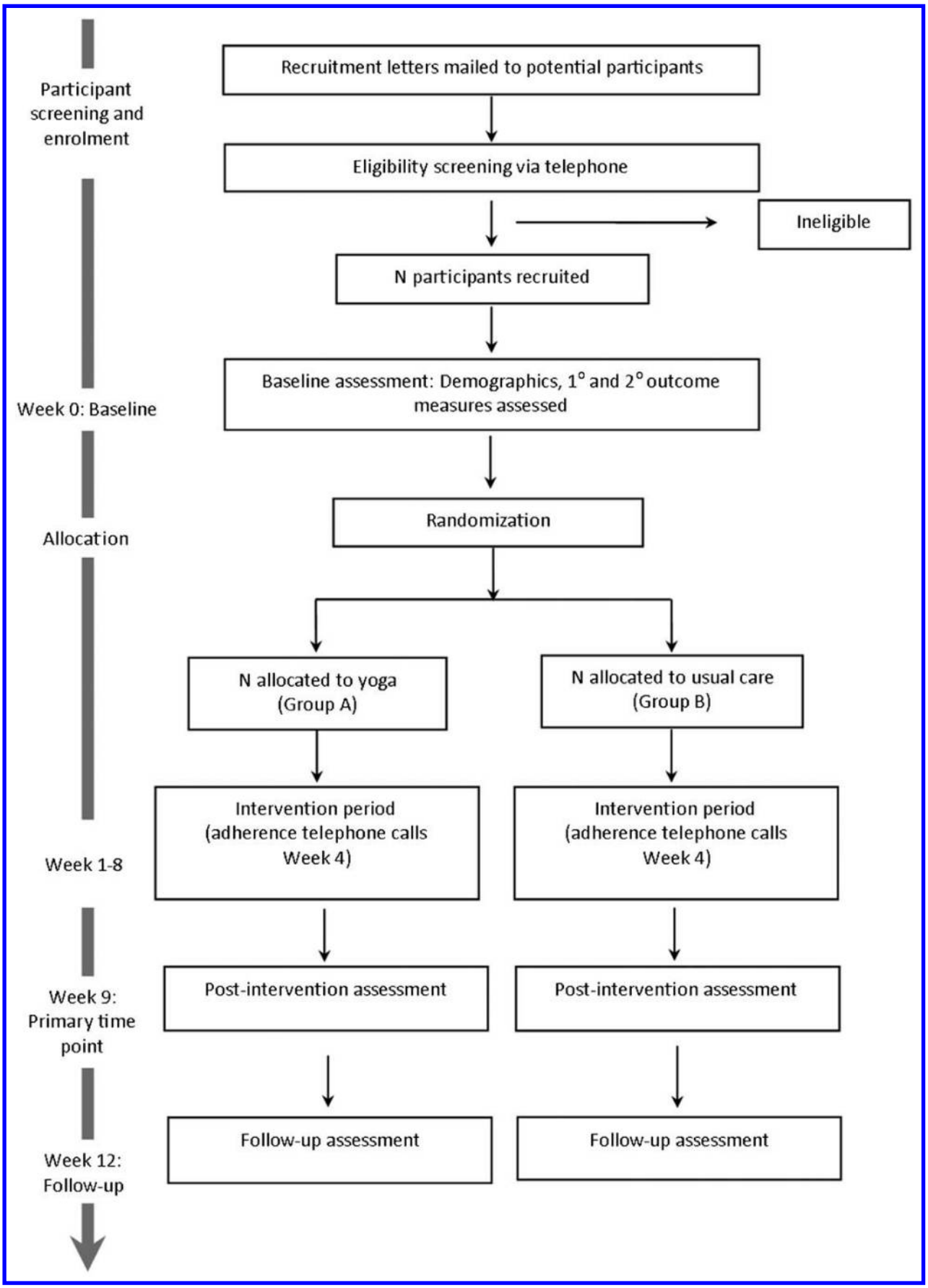

Figure 1 Flow chart of recruitment and study procedure.

A range of props will be provided, as suggested by RA participants in our previous focus group research.[10] Each participant will be provided with a standard set of a yoga mat, foam block, and yoga belt, which they may keep at the conclusion of the study. Additionally, each participant's practice space

Table 1 Inclusion and exclusion criteria

Inclusion	Exclusion
Clinical diagnosis of RA, according to American College of Rheumatology classification criteria	Regular (>1/week) practice of yoga within the past 6 months
Aged ≥18 years	Major surgery within past 6 months e.g. joint replacement; heart surgery
At telephone screening report RA-associated pain in the last month on average ≥3 on 10-point verbal rating scale	Surgery planned in the next 6 months
At telephone screening report RA-associated sleep disturbance in the last month equivalent to >30 minutes at night	Any medical condition or physical impairment apart from RA which the consultant rheumatologists advise would preclude safe participation in exercise/function-based assessments (e.g. uncontrolled hypertension, uncontrolled psychiatric disorder, chronic fatigue syndrome, morbid obesity)
Live within 45 minutes travel time from class location	Intra-articular steroid injections within 4 weeks of screening
Stable medication regime for the previous 8 weeks	Unable to commit to availability for the full course of the intervention
Able to self-mobilize in and out of a chair	
Agree to refrain from receiving or commencing other CAM treatments or exercise programs for the duration of the intervention	
Agree to notify researchers of any change in usual medications during the intervention, especially analgesics	
Able to understand written and spoken English	
Provide written informed consent, in accordance with the stipulations of the Treaty of Helsinki, and agree to comply with adherence to the study protocol	

will have an armless chair, and a 1.2 m wide electric plinth which is able to be electronically raised and lowered by foot pedal. Participants with limited mobility will be able to lie on these tables to carry out the supine postures in the program if they are not able to self-mobilize up and down from the floor. Seven tables are available for use, limiting class size to seven participants.

The 75-minute yoga classes taught during the 8-week yoga program will consist of yoga philosophy, warm-up exercises, yoga postures (asana), breathing (pranayama), and relaxation practices; with time for group discussion at the beginning and end of each class (Table 2). Sixteen yoga postures will be taught over the 8 weeks, with 5–10 postures taught per class (Table 3). Postures were chosen based on the following considerations: (1) they have been identified as safe and acceptable in previous yoga protocols for clinical musculoskeletal populations;[34,37,43–46] (2) they are able to be adapted to the functional limitations of a clinical RA population, while maintaining the integrity and purpose of the original posture; (3) they are not contraindicated for any potential concomitant medical conditions (e.g. hypertension; artificial joints). The names chosen for the included postures are based on previous protocols of yoga for musculoskeletal conditions,[34,37,41,43–45] and may differ from traditional English or Sanskrit naming of the postures.

Table 2 Structure of a 75-minute yoga class

Class component	Time (minutes)
Check in with participants	5
Lesson introduction and yoga philosophy	5
Centering and breathing	7
Warm-ups	10
Yoga postures	28
Guided relaxation	15
Closing	5
Total time	75

Class plans are progressive, with Weeks 1–2 focusing on the introduction of basic key yoga practices including a breathing technique, yoga warm-up routine (*Pawanmuktasana I*), basic supine yoga postures, and body awareness relaxation. Weeks 3–4 introduce the concept of alignment and engagement of core muscles, with the inclusion of seated yoga postures. Weeks 5–6 introduce balance, and basic standing yoga postures; finally, Weeks 7–8 introduce strength and stability in standing yoga postures. Postures progress from predominantly supine, to seated, to standing postures over the four class plans (Table 3). All standing postures have an alternative seated version. Sequencing of the postures within a class is based on the principles of stretching, then strengthening, then stretching a group of muscles, with asymmetrical postures sequenced between symmetrical postures.[43] Postures will be taught in a repetitive, flowing style, moving slowly in and out of the posture in time with the rhythm of the breath. We perceive this flowing style of delivery potentially less fatiguing for the yoga-naïve clinical population than statically holding an individual posture for several breaths.

Home practice will consist of a 20-minute guided relaxation practice, recorded by the primary investigator (LW), to be completed three times per week, at a time and non-class day of the participant's choice. A CD or audio file of the practice will be provided to

participants as per their preference; they may keep this at the conclusion of the study. An insert on the inside front cover of the CD will provide a home practice chart on which participants will record the days of the week they practiced the CD over the 8-week intervention period. Participants will be asked to bring this home practice chart with them to the Week 9 assessment, as a record of their self-reported adherence to home practice.

Usual care (Group B)

Participants in the usual care group will continue to receive their usual medical care under their consultant rheumatologist and general practitioner, including prescribed concomitant medication (e.g. paracetamol and NSAIDs) for their RA. At the completion of the Week 12 assessment, these participants will be given a yoga mat, foam yoga block, yoga belt, and relaxation CD to keep; and they will also be offered a weekend yoga workshop which teaches the group and home yoga practices received by Group A.

Class instructor

The yoga classes will be taught by the primary investigator, who is a qualified yoga teacher with 5 years' experience teaching yoga to people with chronic health conditions and limited mobility issues, and holds a current comprehensive first aid certificate. Additionally, two qualified physical therapists and a qualified yoga teacher will alternate as class assistants. The assistants will not have a teaching role, but will provide assistance to participants, such as handling props, as necessary.

Training and monitoring of the class instructor and assistants

The yoga instructor has a mentor for this study,[43] who is available to monitor progress and answer any concerns regarding the safe delivery of the yoga program to meet individual participant needs. A teaching manual for the instructor and assistants with specific weekly class plans has been developed by the primary investigator, in line with previous yoga teacher training manuals e.g. Taibi and Vitiello.[37] Any deviations to the class plan will be recorded by the primary investigator and the teaching assistant at the end of every class.[26]

Outcome measures

Assessments will be conducted at baseline (Week 0; 1-week pre-intervention); 1-week post-intervention (Week 9; primary time point); and 4 weeks post-intervention (Week 12). Outcome assessors will be independent to the study, and blinded to participant treatment allocation at every time point. Additionally, participants will be requested not to reveal their treatment allocation to the assessors. The schedule of independent blinded assessment of outcome measures is outlined in Table 4.

Primary and secondary outcome measures are detailed below. Primary acceptability and safety outcomes follow those of previous yoga intervention pilot studies.[37,47,48] A range of secondary outcomes is included to enable the estimation of effect sizes across both physiological and psychosocial domains.[26] The main secondary outcomes of interest are pain and sleep quality, as indicated by their use as inclusion criteria. Secondary outcome measures adhere to OMERACT (Outcome Measures in Rheumatology) outcome domains for short-term RA studies,[49] American College of Rheumatology disease activity measures,[50] Delphi guidelines for outcome domains in yoga interventions for musculoskeletal conditions,[25] and participant-identified health priorities.[10] The OMERACT-recommended outcome domain of acute-phase reactants has been excluded, in line with the provision of a non-invasive intervention protocol.[10] Specific questionnaires have been selected for appropriateness, clarity, ease of use, and minimum response cost in a clinical RA population. Each assessment pack will include a final page allowing participants the option of writing open comments regarding any aspect of their participation in the pilot study.

Table 3 Progression of yoga postures over the 8-week intervention

Yoga posture	Position	Week 1–2	Week 3–4	Week 5–6	Week 7–8
Shavasana	Supine	✓	✓	✓	✓
Knees to chest	Supine	✓	✓	✓	✓
Extended leg	Supine	✓	✓		
Hip circles	Supine	✓	✓		
Butterfly	Supine	✓	✓	✓	✓
Seated mountain	Seated		✓	✓	✓
Thunderbolt	Seated		✓	✓	✓
Cobra	Seated		✓		
Wheel/child's pose	Seated		✓		
Side bend	Seated			✓	
Seated twist	Seated				✓
Mountain	Standing			✓	✓
Half dog	Standing			✓	✓
Flowing warrior	Standing			✓	✓
Chair	Standing			✓	
Wide-leg forward bend	Standing				✓

1. Primary outcomes: feasibility and safety measures

1.1 Recruitment

Recruitment rates and time periods will be reported through a descriptive summary, and graphically presented using the CONSORT diagram of participant flow through a study.[51]

1.2 Retention

Retention will be assessed by the number of participants who complete measures at baseline, Week 9, and Week 12; and will be reported through descriptive summaries. A conservative retention rate of 80% is established *a priori* as acceptable for this study.[35–37]

1.3 Protocol adherence

Protocol adherence to group yoga classes will be assessed through class attendance rolls. If a yoga participant has missed two consecutive classes, they will be contacted by telephone to determine if any barriers to attending classes have arisen for them. *A priori* adherence levels are established as attending six of the eight group yoga classes.[37,41,45,52] Adherence to home practice will be assessed through self-completion of a home practice table included with the CD, which participants will bring to the Week 9 assessment. Additionally, weekly classes will begin by confirming with participants their frequency of home practice in the previous week, and potential solutions to any identified obstacles to practice will be discussed among the group. Acceptable adherence is established as completing 16 of the 24 requested home practice sessions.[20,34,44] Participants in both the yoga and the usual care groups will be telephoned by an independent outcome assessor during Week 4, to discuss any issues they may have with maintaining protocol adherence.

1.4 Participant satisfaction

Participant satisfaction will be assessed by a semi-structured questionnaire at the Week 12 assessment, and reported through a descriptive and qualitative summary. Questions will address information provided to participants regarding the study, response burden of assessment appointments, and suggestions for future improvements. Additionally, participants in the yoga group will complete a second questionnaire regarding satisfaction with the group and home yoga program.[48] This questionnaire will include rating of individual yoga postures for enjoyment and discomfort, to determine the suitability of the included postures for an RA population.

1.5 Safety

Safety will be assessed by participant self-report at the beginning and end of each yoga class, and by an independent outcome assessor at Week 4 (telephone interview), 9, and 12. Results will be reported through a descriptive summary. Additionally, participants will be asked to contact research staff immediately if they feel they have any adverse reactions they believe are a result of the yoga intervention, or which may prevent them from continuing the study. Accepted levels of safety will be based on the nature and frequency of reported adverse events.

2. Secondary outcomes

2.1 Pain

Pain will be measured with a visual analog scale (VAS), consisting of a 10 cm horizontal line anchored from 0 (no pain) to 10 (worst pain possible).[53] Participants will indicate their average pain associated with RA in the past week by marking a perpendicular line on the scale. Possible scores range from 0 to 10. The VAS is scored by measuring the distance from the 0 (no pain) anchor to the contact

Table 4 Schedule of independent blinded assessment of outcome measures

	Assessment period			
Outcome measure	Baseline/Week 0 (1-week pre-intervention)	Week 4	Week 9* (1-week post-intervention)	Week 12 (4 weeks post-intervention)
Demographics	x			
Pain VAS	x		x	x
ISI	x		x	x
HAQ-DI	x		x	x
CDAI	x		x	x
EQ-5D-Y	x		x	x
HADS	x		x	x
BRAF-NRS	x		x	x
Adherence		x	x	x
Safety		x	x	x
Satisfaction				x

* Primary time point.
BRAF-NRS: Bristol rheumatoid arthritis fatigue numerical rating scales; CDAI: clinical disease activity index; EQ-5D-Y: EuroQol-5D-Y; HADS: hospital anxiety and depression scale; HAQ-DI: health assessment questionnaire disability index; ISI: insomnia severity index; VAS: visual analog scale.

point with the participant's mark. The VAS has good reliability and validity, and is sensitive to detecting changes in pain in inflammatory health conditions.[53]

2.2 Sleep quality

Sleep quality will be measured with the insomnia severity index (ISI), a 7-item self-report questionnaire assessing severity of insomnia and symptom-associated distress in the previous 2-week period.[54,55] Items are rated on a 5-point Likert scale, with possible scores ranging from 0 to 28, and a higher score indicating greater severity of insomnia. The ISI has acceptable to good reliability and good validity,[56] and has been previously used in RA[56,57] and yoga research.[37]

2.3 Functional disability

Functional disability will be measured with the anglicized version of the health assessment questionnaire disability index (HAQ-DI), a 20-item self-report measure which assesses difficulty of carrying out activities of daily living over the period of the past week.[58,59] Items are grouped into eight categories, individual items scored from 0 to 3, and the highest individual scores from each of the eight categories summed and averaged. Possible overall HAQ-DI scores range from 0 to 3, with higher scores indicating higher levels of functional disability.[58] The HAQ is the most commonly used measure of functional disability in RA,[60] and has good to excellent reliability and validity.[58]

2.4 Disease activity

Disease activity will be assessed using the clinical disease activity index (CDAI).[61] The CDAI is a non-invasive assessment comprising four independent measures: (1) swollen joint count (possible score ranging from 0 to 28), (2) tender joint count (possible score ranging from 0 to 28), (3) participant assessment of global disease activity over the past week (11-point numerical rating scale, possible scores ranging from 0 to 10), and (4) an evaluator assessment of the participant's global disease activity (11-point numerical rating scale, possible scores ranging from 0 to 10). A composite score of the four measures has a possible range of 0 to 76, with a higher score indicative of higher disease activity. The CDAI is well validated in rheumatology research, and shows good correlation with the HAQ.[62]

2.5 Quality of life

Quality of life will be assessed with the generic English (New Zealand) version of the EQ-5D-3L.[63,64] The EQ-5D-3L consists of six items. Five items address the domains of current mobility, self-care, activities, pain or discomfort, and anxiety or depression; these are individually scored from 1 to 3. The sixth item rates current health state on a numeric rating scale from 0 to 100. Composite scores have a possible range of 0–1, with a higher score indicative of a better health state. The EQ-5D-3L is a valid measure of QOL in an RA population;[65,66] has comparable discrimination to larger-itemed disease-specific QOL measures across a range of RA severity;[67] and has previously been used in yoga research.[68]

2.6 Mood

Mood is operationalized as anxiety and depression for the purpose of this study, and will be measured with the hospital anxiety and depression scale (HADS).[69] The 14-item HADS consists of a 7-item anxiety subscale and a 7-item depression subscale, referring to mood over the previous 1 week. A composite score is calculated for each subscale, ranging from 0 to 21, where higher scores are indicative of more severe symptoms of anxiety or depression. An *a priori* score of 10 or higher will be used to indicate possible anxiety or depression, in line with previous research.[69,70] Both subscales have discriminant validity,[69] and good internal consistency.[71]

2.7 Fatigue

Fatigue will be measured by the Bristol rheumatoid arthritis fatigue numerical rating scales (BRAF-NRS).[72] The BRAF-NRS measures the impact of fatigue for people with RA, but is not disease-specific. The questionnaire consists of three anchored numerical rating scales assessing a person's experience of fatigue during the previous 7 days: (1) the level of fatigue, from 0, 'No fatigue', to 10, 'Totally exhausted'; (2) the effect of fatigue, from 0, 'No effect', to 10, 'A great deal of effect'; and (3) coping with fatigue, from 0, 'Not at all well', to 10, 'Very well'. The BRAF-NRS has acceptable to good convergent validity.[72]

Statistical analysis

The current study is a pilot study primarily investigating the feasibility and safety of a relaxation-based yoga intervention for an RA population. Raw data will be double-entered into an Excel spreadsheet, by research staff blinded to group allocation. Composite scores of outcome measures will be calculated where necessary, and processed data will be transferred to a statistical software package, SPSS software 20.0[73] for analysis.

Data will be classified as continuous or categorical, according to each specific demographic or outcome measure (outcome measures which produce a composite score will be treated as continuous variables for analysis). Data will be analyzed descriptively and graphically to determine the distribution pattern, and appropriate statistical tests for central tendency and variability of each measure will be conducted.

Differences between baseline and Week 9 (primary time point) data will be calculated for each secondary outcome measure, and effect sizes calculated by univariate analysis of variance (UANOVA). As previously mentioned, in accordance with guidelines for pilot feasibility studies sample size calculations for outcome measures are not required;[26,30–32] and *P*-values will not be reported for secondary outcome measures.[30,31]

Adverse event recording

Owing to the pilot nature of this study, an adverse event is operationalized as any level of physical or mental discomfort reported by participants in either group during the course of their involvement in the study. The severity of an adverse event will be rated as mild, moderate, or serious, in line with international classification of serious adverse events.[74,75]

Any adverse event will, in the first instance, be recorded on a *pro forma* which details a description of the event, duration, severity, action taken by the participant, medications involved, and likelihood of the event being related to participation in the yoga study. Any serious adverse event will be immediately referred to an independent internal data safety monitoring committee at Dunedin Public Hospital. The study investigators reserve the right to contact a participant's General Practitioner or Rheumatologist, or request a participant to withdraw from the study if they feel the yoga intervention is adversely affecting the physical or mental health of the participant, or are otherwise concerned for the health of the participant.

Discussion

The current pilot study is designed to provide data to assess the feasibility and safety of a relaxation-focused yoga intervention for a clinical RA population, and to estimate effect sizes of secondary physical and psychosocial outcomes measures.[26] A fully-powered future trial may be considered feasible based on acceptable levels of participant retention, acceptable adherence to the study protocol, low risk of safety issues, and participant satisfaction with the design and content of the clinical trial. Additionally, participant feedback will provide information for future adaption of the study protocol to this clinical population.[26]

This pilot study will add to the current evidence for the role of yoga in the management of musculoskeletal conditions.[76] The current study is the first to be designed and reported based on the Delphi recommendations of expert researchers and consultants in the field of yoga for musculoskeletal conditions.[40] Furthermore, this is the first reported trial of yoga for a clinical population in New Zealand; and will determine if international trial guidelines are pragmatic in a national research environment.

Strengths of the current study include the use of chairs and electronic massage tables to provide an alternative for participants who are not able to get up and down from the floor to carry out the yoga postures. This design feature addresses potential barriers to participation previously raised by people with RA,[10] and allows the potential inclusion of a more functionally disabled RA population to be recruited for the study. The provision of a yoga workshop for participants in the usual care group at the conclusion allows all participants to experience yoga, and is intended to reduce the risk of attrition bias among this control group. Finally, the inclusion of various health professionals from the local community (rheumatologists, physical therapists, and yoga teachers) and the support of established international yoga researchers have enabled this RCT to be designed and conducted at minimal cost.

The primary limitations of this pilot feasibility study are the small sample size, lack of statistical power, and lack of an active or attention control group. However, the study design, sample size, and use of a usual care control reflects previous good quality pilot studies in the field of yoga for musculoskeletal conditions.[34,37,41,68] Additionally, this study uses reliable and validated outcome measures which incorporate both participant preference[10] and clinical standards.[49,50] Results of the current study will provide empirical data to determine if a larger, statistically powered main trial is feasible in a national clinical RA population, and to support grant applications for the funding of a future study.

Disclaimer Statements

Contributors All authors contributed to the conception and design of the study, and the development of the research protocol. LW developed the yoga program. All authors were involved in the revision of all drafts of the manuscript, and the approval of the final manuscript for publication.

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