


# BMJ Open Randomised controlled trial of cognitive behaviour therapy versus mindfulness for people with rheumatoid arthritis with and without a history of recurrent depression: study protocol and design

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## ABSTRACT

**Introduction** Psychosocial treatments have been shown to benefit people with rheumatoid arthritis (RA) on various outcomes. Two evidence-based interventions are cognitive behavioural therapy (CBT) and mindfulness-based stress reduction (MBSR). However, these interventions have been compared only once. Results showed that CBT outperformed MBSR on some outcomes, but MBSR was more effective for people with RA with a history of recurrent depression, with efficacy being moderated by history of depressive episodes. However, this was a post-hoc finding based on a small subsample. We aim to examine whether a history of recurrent depression will moderate the relative efficacy of these treatments when delivered online.

**Methods and analysis** This study is a randomised controlled trial comparing CBT and MBSR delivered online with a waitlist control condition. History of recurrent depressive episodes will be assessed at baseline. The primary outcome will be pain interference. Secondary outcomes will include pain intensity, RA symptoms, depressive symptoms and anxiety symptoms. Outcome measures will be administered at baseline, post-treatment and at 6 months follow-up. We aim to recruit 300 participants, and an intention-to-treat analysis will be used. Linear mixed models will be used, with baseline levels of treatment outcomes as the covariate, and group and depressive status as fixed factors. The results will demonstrate whether online CBT and MBSR effectively improve outcomes among people with RA. Importantly, this trial will determine whether one intervention is more efficacious, and whether prior history of depression moderates this effect.

**Ethics and dissemination** The trial has been approved by the Human Research Ethics Committee of the University of Sydney (2021/516). The findings will be subject to publication irrespective of the final results of the study, and based on the outcomes presented in this protocol.

**Trial registration number** Australian New Zealand Clinical Trials Registry (ACTRN12621000997853p).

## Strengths and limitations of this study

- ⇒ This randomised controlled trial will examine whether cognitive behavioural therapy or mindfulness-based stress reduction is more efficacious for people with rheumatoid arthritis, and whether efficacy is moderated by prior history of depression.
- ⇒ The treatments have been designed with the involvement of individuals with lived experience of rheumatoid arthritis.
- ⇒ The study includes comprehensive outcome measures assessed at multiple timepoints.
- ⇒ Participants will not be screened for psychopathology for inclusion in the trial, which may reduce the chance of significant effects on secondary outcomes.

## INTRODUCTION

Rheumatoid arthritis (RA) is an autoimmune disorder which causes pain and swelling in the joints. RA affects approximately 1% of the population.<sup>1</sup> Although there are effective disease-modifying anti-rheumatic drugs, especially if used in the early stages of the disease, there is no cure. Most people will experience a course of disease marked by symptom flare ups, and then periods of remission, with increasing disability. Physical limitations and uncontrolled pain can serve as stressors, potentially triggering anxiety or depressive symptoms. In line with this, approximately 16% of people with RA report clinically significant depressive symptoms, a figure substantially higher than that found in the general population.<sup>2</sup> It has also recently been proposed that the relationship between RA and depression may be bidirectional, in that the increased inflammation associated with depression may contribute to autoimmune diseases including RA.<sup>3</sup>



For this reason, there has been a long history of psychosocial treatments for people living with RA that have typically focused on improving coping strategies in people with RA. Meta-analyses suggest that psychological treatments are effective in improving pain, disability and psychological symptoms, with a reduction in swollen joints also evident at follow-up.<sup>4,5</sup> In fact, the importance of psychological treatments is reflected in the European League Against Rheumatism guidelines for the management of early arthritis. These guidelines recommend that programmes which help people better cope with the pain and disability associated with RA should be used as an adjunct to medical treatment.<sup>6</sup>

Cognitive behavioural therapy (CBT), which centres on addressing unhelpful beliefs and behaviours, is the most widely evaluated psychological therapy for people with RA.<sup>7</sup> In the context of RA, CBT may involve helping the patient develop more realistic and balanced attitudes to their disease, and a more effective balance of activity and rest.<sup>7</sup> Meta-analyses confirm that CBT results in reductions in pain, disability and depression.<sup>8</sup> There are relatively fewer studies of mindfulness in RA. In contrast to CBT, mindfulness interventions focus on cultivating non-judgmental awareness of the present moment.<sup>9</sup> In relation to chronic illnesses, mindfulness focuses on noticing physical symptoms, thoughts and feelings about the illness, without judging or challenging them, to reduce emotional reactivity.<sup>9</sup> Two recent meta-analyses identified five<sup>9</sup> and six studies,<sup>10</sup> which found preliminary evidence to support the efficacy of mindfulness for pain, depression and disability. Available data show that both CBT and mindfulness-based stress reduction (MBSR), a mindfulness intervention which involves a combination of meditation and body awareness, are likely to be efficacious for RA. However, only one study has directly compared these treatments.<sup>11</sup> Zautra and colleagues found that, in comparison to an education only condition, both CBT and MBSR were efficacious on a range of outcomes. Specifically, CBT was more effective for pain and inflammation compared with MBSR. However, for patients with a history of recurrent depression (ie, at least two depressive episodes), MBSR resulted in better outcomes across several measures, particularly measures of psychological functioning. These results suggest that a history of recurrent depression may moderate the relative effectiveness of CBT versus MBSR.

While both CBT and MBSR appear to be effective for people with RA, access to psychological interventions is problematic.<sup>7</sup> For this reason, it has been suggested that Internet-delivered interventions would be a useful way to increase access to effective treatments.<sup>7,10</sup> Online interventions have been proposed to address issues such as lengthy treatment waitlists, the high cost of standard therapy, lack of services in remote areas and physical mobility issues which may affect in-person treatment attendance.<sup>12,13</sup> The adoption of Internet-delivered interventions for pain has become increasingly advocated for pain conditions over recent years.<sup>14</sup> While a range of

self-help and behaviour change programmes have been delivered online for people with RA,<sup>15–17</sup> we could identify only one online trial of Internet-delivered CBT for RA. Ferwerda *et al* demonstrated that Internet-delivered CBT was efficacious for people with RA on measures of disability, depression and pain.<sup>18</sup> This is consistent with meta-analytic findings suggesting that guided self-help Internet-based interventions are just as effective as face-to-face interventions for mental health problems,<sup>19</sup> and that web-based CBT is effective for chronic pain more generally.<sup>20</sup> However, Internet-delivered MBSR programmes are yet to be adapted or evaluated for those with RA.

Hence, the aim of the current study is twofold. First, we aim to evaluate the efficacy of an online CBT programme, and an online MBSR, compared with a waitlist control group. It was hypothesised that the online CBT and MBSR interventions will produce significant improvements in pain interference (primary outcome), pain, disability, depressive symptoms and anxiety, at post-treatment and 6 months follow-up, compared with waitlist controls. Second, we aimed to determine whether a history of recurrent depression would moderate the relative efficacy of CBT and MBSR. On the basis of Zautra *et al's* study,<sup>11</sup> we hypothesised that those with recurrent depression would benefit significantly more from the MBSR programme whereas the reverse would be true for CBT.

## METHODS AND ANALYSIS

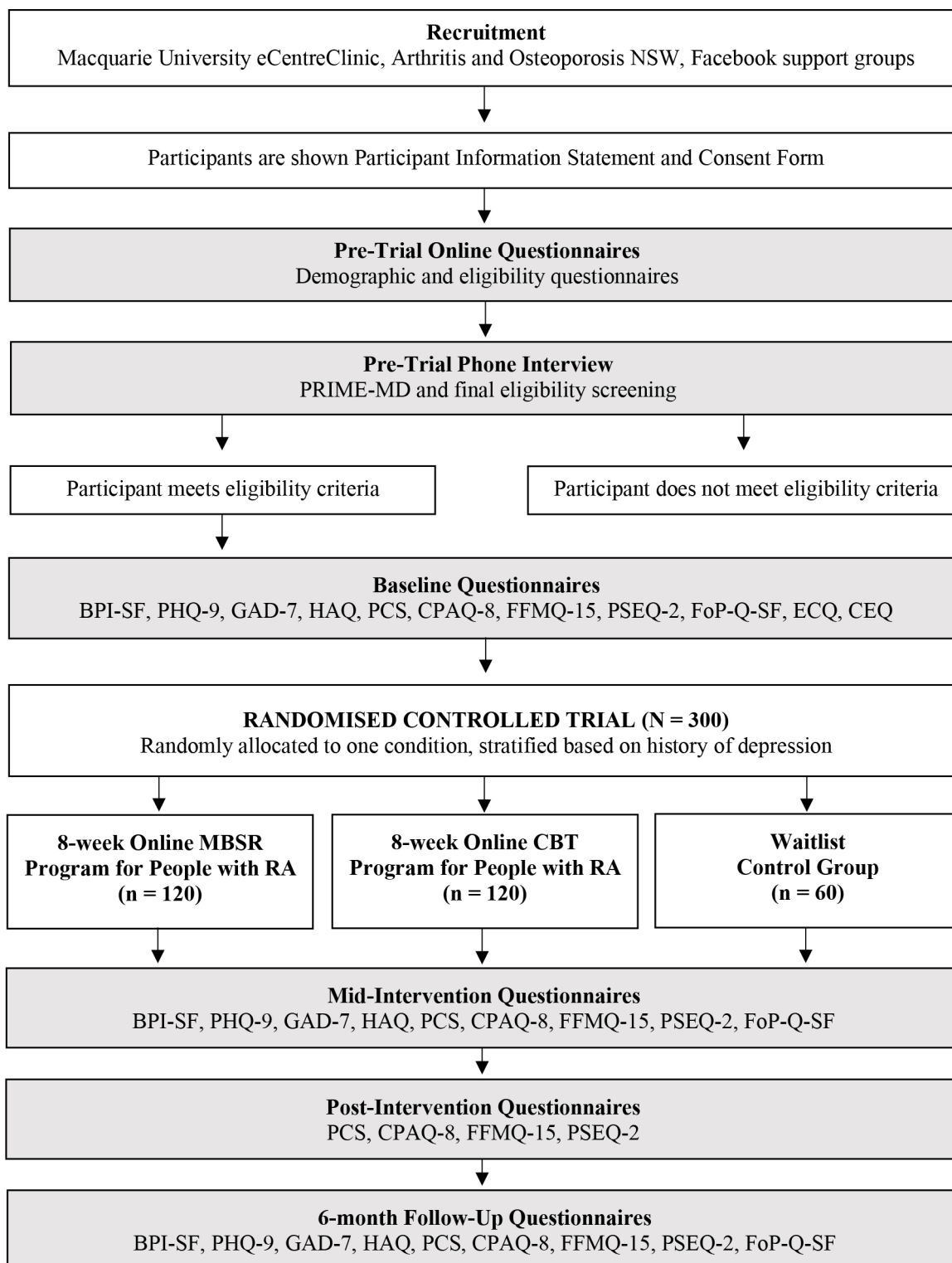
The current study has been prospectively registered with the Australian New Zealand Clinical Trials Registry and is a CONSORT-Revised compliant randomised controlled trial (RCT). The current protocol has been approved by the University of Sydney Human Research Ethics Committee (2021/516). An overview of the trial design is outlined in [figure 1](#).

### Participants

Participants will be eligible to participate if they (1) report a confirmed diagnosis of RA, (2) are more than 18 years old, (3) currently live in Australia, (4) have regular access to the Internet, (5) have functional written and spoken English, (6) if receiving RA treatment, have been on a consistent RA treatment regime for more than 1 month (ie, on a stable dose of the same medication, with no current plan to increase this dose) and (7) if taking antidepressant medication, have been on a stable dose for more than 8 weeks. Exclusion criteria include having: (1) suicidal intent requiring emergency care, (2) substance abuse (including alcohol) or dependence, (3) a psychotic illness or (4) received consistent psychotherapy within the last 6 months.

### Patient and public involvement

Patient and public involvement took place in the preliminary development of the two interventions and the design of the trial. We engaged and interviewed 10 individuals



**Figure 1** Outline of trial design. BPI-SF, pain intensity and interference from the Brief Pain Inventory—Short Form; CBT, cognitive behavioural therapy; CEQ, Credibility/Expectancy Questionnaire; CPAQ-8, Chronic Pain Acceptance Questionnaire; ECQ, Existential Concerns Questionnaire; FFMQ-15, Five Facet Mindfulness Questionnaire; FoP-Q-SF, Fear of Progression Questionnaire—Short Form; GAD-7, Generalized Anxiety Disorder Scale; HAQ-DI, Health Assessment Questionnaire-Disability Index; MBSR, mindfulness-based stress reduction; PCS, Pain Catastrophizing Scale; PHQ-9, Patient Health Questionnaire; PRIME-MD, Primary Care Evaluation of Mental Disorders—Major Depression Module; PSEQ-2, Pain Self-Efficacy Questionnaire; RA, rheumatoid arthritis.

with RA to ensure that the two treatments were relevant, and that the study design appeared acceptable.

### Procedure

The trial will be advertised via the eCentreClinic website ([www.ecentreclinic.org](http://www.ecentreclinic.org)) and other relevant avenues of advertisement, including but not limited to, social media (eg, RA Facebook support groups, eCentreClinic Facebook accounts), and through relevant patient organisations (eg, Arthritis Australia). The Participant Information and Consent Form will be made available online on the eCentreClinic website (The consent form is available in online supplemental material 1). Once participants have provided consent, they will be directed to an online questionnaire assessing demographic details and initial eligibility (eg, age, country of residence, time since RA diagnosis, previous treatment history).

Next, participants will be contacted by a researcher, who will conduct a phone assessment in order to confirm eligibility for the study. As part of the assessment, the researcher will administer the Major Depression Module of the Primary Care Evaluation of Mental Disorders (PRIME-MD) to establish a lifetime history of depression.<sup>21</sup> The PRIME-MD is structured interview and is a valid and reliable diagnostic tool,<sup>21 22</sup> which has high accuracy, sensitivity and specificity.<sup>21</sup> Suicidal intent will also be assessed, and at-risk individuals will be referred to appropriate services. Further, details regarding RA treatment and course (eg, disease duration, comorbidities and current medication) will be assessed at baseline, and each following timepoint.

On completion of initial measures and eligibility screening, participants will be randomised to one of the three trial conditions in a 2:2:1 ratio (CBT:MBSR:wait list control (WLC)). Randomisation will be conducted using computer-generated random numbers and will be done by an independent researcher and concealed until allocation. Random allocation will be stratified based on depression history (ie, recurrent vs non-recurrent depression), as established by the PRIME-MD. Participants will also be asked their treatment preference prior to commencing the programme, in order to control for treatment expectancy effects. Finally, a member of the research team will contact participants to inform them of their trial condition and the course start date (for those in the treatment arms). At this point, baseline pre-treatment measures will be administered.

Participants in the CBT and MBSR treatment arms will then begin their respective 8-week intervention. Participants in the waitlist control group will be asked to continue with treatment as usual. Each week throughout the trial, all participants will be asked to complete the Patient Health Questionnaire (PHQ-9), to monitor mood and suicide risk. Further, participants in both the online CBT and MBSR programmes will be guided by a registered clinical psychologist, given previous evidence that therapist guidance significantly improves outcomes compared with unguided online interventions.<sup>23</sup>

Guidance will consist of telephone calls and/or email support, to provide encouragement and ensure understanding of key programme concepts. However, this therapist support will not be used to provide additional therapy. Immediately following the intervention, post-intervention questionnaires will be administered to all participants. Follow-up questionnaires will then be administered at 6 months.

Finally, the waitlist group will be allowed to commence one of the two treatments, as per their preference. Prior to commencing the online interventions, we will assess any changes in treatment in the waitlist group during the trial (eg, whether they accessed psychological care). Intention-to-treat analyses will be used, such that all randomised participants will be represented in the final analysis, irrespective of whether they have accessed psychological treatment prior to commencing the online intervention. The waitlist group will again be administered questionnaires after completing the online intervention.

### Measures

#### The Brief Pain Inventory-Short Form (BPI-SF)

The BPI-SF<sup>24</sup> is an 11-item scale, which is comprised of two subscales that assess pain severity and pain interference. For each item, participants must rate their pain severity and interference from 0 ('No pain/Does not interfere') to 10 ('Pain as bad as you can imagine/Completely interferes'). As such, higher scores on the BPI-SF are indicative of greater pain severity and interference. The BPI-SF has been validated among chronic non-malignant pain samples and both subscales have acceptable reliability.<sup>25 26</sup>

#### The Patient Health Questionnaire (PHQ-9)

The PHQ-9<sup>27</sup> is a 9-item self-report measure of depressive symptoms and severity. Each item encompasses one of the Criterion A symptoms of major depression as outlined in the Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV). Participants must indicate how often in the last 2 weeks they have been affected by each symptom, from 0 ('Not at all') to 3 ('Nearly every day'). Scores range from 0 to 27, with higher scores signifying more severe depression symptomatology. Scores of  $\geq 10$  have been used as a cut-off for clinically significant depression.<sup>27 28</sup> The PHQ-9 has good psychometric properties.<sup>27 28</sup>

#### The Generalized Anxiety Disorder Scale (GAD-7)

The GAD-7<sup>29</sup> is a 7-item anxiety measure, which was derived from the DSM-IV criteria for generalised anxiety disorder. Each item describes a symptom of anxiety and participants must indicate how often they have experienced it in the previous 2 weeks, from 0 ('Not at all') to 3 ('Nearly every day'). Scores range from 0 to 21, with higher scores indicating greater anxiety symptoms. Scores of  $\geq 10$  have been used as a cut-off for clinically significant anxiety.<sup>28-31</sup> The GAD-7 is a well-validated and reliable measure.<sup>29 30</sup>

### The Health Assessment Questionnaire Disability Index (HAQ-DI)

The HAQ-DI<sup>32</sup> is a 20-item scale, which assesses self-reported functional ability when performing eight key activities: dressing, rising, eating, walking, hygiene, reach, grip and usual activities. For each item, participants must report on whether they were able to perform the task: without difficulty (0), with some difficulty (1), with much difficulty (2) or unable to do (3). An index score is then calculated by averaging responses across the number of items. Index scores range from 0 (no functional disability) to 3 (severe functional disability). The HAQ-DI has consistently demonstrated sound validity and reliability.<sup>33 34</sup>

### The ambiguous cues task

The ambiguous cues task<sup>35</sup> consists of 14 ambiguous words which participants must respond to with the first word which comes to their mind. Responses are then coded as either being pain-related or neutral. The ambiguous cues task has been shown to be sensitive to interpretation biases in chronic pain populations.<sup>35</sup>

### The Pain Catastrophizing Scale (PCS)

The PCS<sup>36</sup> is a 13-item scale which measures pain catastrophising across three subscales: rumination, magnification and helplessness. Each item describes a specific thought or feeling, and participants must indicate whether they have experienced it while in pain. Responses range from 0 ('Not at all') to 4 ('Always'), with higher scores on the PCS signalling a greater tendency to catastrophise pain. The PCS is a well-validated and reliable measure.<sup>36–38</sup>

### The Fear of Progression Questionnaire—Short Form (FoP-Q-SF)

The FoP-Q-SF<sup>39</sup> is a 12-item short form version of the well-validated Fear of Progression Questionnaire.<sup>40</sup> The FoP-Q-SF measures concerns about illness progression in those with chronic illness. For each item participants are asked to indicate how often they have experienced concerns about the progression of their illness in relation to four areas: affective reactions, partnership/family, occupation and loss of autonomy. Responses range from 1 ('Never') to 5 ('Very often'). Total scores range from 12 to 60, with scores of  $\geq 34$  indicating that fear of progression is high.<sup>41</sup> The FoP-Q-SF has been validated among cancer populations,<sup>39 42 43</sup> and those with systemic sclerosis.<sup>44</sup>

### The Chronic Pain Acceptance Questionnaire—Short Form (CPAQ-8)

The CPAQ-8<sup>45</sup> is an 8-item scale, comprised of two subscales which assess the capacity to engage in activities while experiencing pain (Activity Engagement) and the ability to disengage from attempts to control or avoid pain (Pain Willingness). For each item, participants respond on a 7-point scale from 0 ('Never') to 6 ('Always true'). Scores range from 0 to 48, where higher scores represent greater pain acceptance. The CPAQ-8 has been shown to be a valid and reliable measure in chronic pain samples.<sup>45 46</sup>

### The Five Facet Mindfulness Questionnaire—Short Form (FFMQ-15)

The FFMQ-15<sup>47</sup> is a 15-item short form version of the original 39-item FFMQ.<sup>48</sup> The FFMQ-15 measures mindfulness across five facets: Observing, Describing, Acting with awareness, Non-judging of inner experience and Non-reactivity to inner experience. The FFMQ-15 requires participants to report on how frequently they have engaged in mindful practices, from 1 ('Never or Very rarely true') to 5 ('Very often or Always true'). Higher FFMQ-15 total scores indicate greater mindfulness. The FFMQ-15 has good psychometric properties ( $\alpha=0.80-0.85$ ).<sup>47 49</sup>

### The Existential Concerns Questionnaire (ECQ)

The ECQ<sup>50</sup> is a 22-item scale which measures concerns around death, meaninglessness, guilt, social isolation and identity. The ECQ is comprised of three subscales: general existential anxiety, death anxiety and avoidance. Each ECQ item is responded to on a 5-point scale, ranging from 1 ('Never') to 5 ('Always'). Higher scores on the ECQ are suggestive of greater existential concerns. The ECQ has been shown to be a valid and reliable measure.<sup>50</sup>

### The 2-item Pain Self-Efficacy Questionnaire (PSEQ-2)

The PSEQ-2<sup>51</sup> is a short form of the original 10-item Pain Self-Efficacy Questionnaire.<sup>52</sup> Consisting of two items, the PSEQ-2 assesses the extent to which those living with chronic pain feel capable and confident in participating in activities, despite their pain. Each item is scored from 0 ('Not at all confident') to 6 ('Completely confident'). Higher scores on the PSEQ-2 indicate greater pain self-efficacy. The PSEQ-2 is a valid and reliable measure of pain self-efficacy ( $\alpha=0.90-0.91$ ).<sup>51 53</sup>

### The Credibility/Expectancy Questionnaire (CEQ)

The CEQ<sup>54</sup> is a 6-item questionnaire assessing treatment credibility and expectancy. Four items are rated on a 9-point scale, while two items are rated as a percentage, assessing estimate of symptom improvement (eg, 0% improvement to 100% improvement). The CEQ has been shown to have high internal consistency and good test-retest reliability.<sup>54</sup>

### CBT intervention

The online CBT intervention, the Pain Course, was developed by members of the research team.<sup>12</sup> It has been shown to be efficacious through large scale RCTs at improving disability, anxiety, depression and pain intensity, with outcomes maintained at 12-month and 24-month follow-ups.<sup>55</sup> Prior studies have reported on the intervention in detail;<sup>12</sup> however, in brief: The Pain Course contains five modules, which cover the following topics: (1) pain education; (2) cognitive therapy (thought monitoring and challenging); (3) controlled breathing and pleasant activity scheduling; (4) pacing and graded exposure and (5) relapse prevention and goal setting. Importantly, these include all the strategies deemed necessary in the gold standard pain management approaches in a recent Delphi study.<sup>56</sup> Each module spans approximately 15 min in length, with one module being delivered every

1–2 weeks. The overall intervention will span 8 weeks. There are also additional resources on topics (eg, sleep hygiene, problem solving, assertiveness), which can be accessed at participants will. Participants will be given home-based practice tasks to complete for each of the skills introduced in the programme. The Pain Course materials have been adapted to be relevant for RA, and to include fictional characters living with RA, which vary in important demographic variables.

### MBSR intervention

The online MBSR intervention has been tailored to the needs and difficulties found among people with RA. The proposed programme has been adapted from a previous MBSR online intervention for multiple sclerosis, created by members of the research team.<sup>57 58</sup> This programme was found to be efficacious for people with multiple sclerosis (MS), particularly those with a history of recurrent depression.<sup>58</sup> The proposed MBSR programme includes fictional case examples of characters living with RA. The MBSR programme consists of five modules, which cover the following topics: (1) An Introduction to Mindfulness Meditation, (2) Dealing with Stress, (3) Dealing with Difficult Sensations and Emotions, (4) Dealing with Difficult Thoughts and (5) Mindful Communication, Compassion and Relapse Prevention. Each module spans approximately 15 min in length, with one module being delivered every 1–2 weeks. The overall intervention will span 8 weeks. Alongside each module, participants will be directed to guided meditation audio recordings. These have been adapted from meditation scripts of Jon Kabat-Zinn, and recorded by the research team. Lastly, participants will be encouraged to attempt informal mindfulness practice each week, and to complete weekly logs of their frequency and duration of mindfulness practice.

### Piloting of intervention materials

For the purpose of reviewing the adaptations to the CBT and MBSR interventions, interviews were conducted with 10 people with RA (The demographic details of these participants are presented as a supplemental file (see online supplemental material 2)). The first author met with each participant individually over an online video call. They reviewed sections of the treatment materials which had been tailored for RA, and qualitative feedback was elicited. Overall, the feedback on the two interventions was positive. After the completion of these 10 interviews, the feedback was compiled, and a meeting with the investigator team was conducted to decide what changes to implement. As a result, changes were made to some sections of the case stories, including the description of characters and their illness progression. Additional illness-related stressors raised by participants were also added to the treatment materials.

### Outcome measures

The primary outcome will be pain interference, as measured by the BPI-SF. Secondary outcomes will

include depressive symptoms (PHQ-9), anxiety symptoms (GAD-7) and RA functionality (HAQ-DI). Outcomes will be measured at baseline, post-intervention and 6 months follow-up. The ambiguous cues task will also be administered at baseline and post-intervention.

To explore potential treatment mechanisms, we will also be measuring several process outcomes. These include pain catastrophising (PCS), pain acceptance (CPAQ-8), pain self-efficacy (PSEQ-2) and mindfulness (FFMQ-15). These measures will also be administered at baseline, mid-treatment (ie, week 5), post-intervention (ie, immediately after completion of the final module) and 6 months follow-up. At post-intervention, all participants will be asked to rate their treatment satisfaction using three questions, each rated on a 5-point Likert scale.<sup>12</sup> Therapy adherence, operationalised by number of modules completed, will be recorded.

Additional measures will be administered at baseline only. Participants in the two treatment groups will also be asked to rate their expectancy of improvement and treatment credibility using the CEQ, prior to commencing the intervention. Lastly, in order to explore potential differences between those with and without recurrent depression, fear of illness progression (FoP-Q-SF), and existential concerns (ECQ) will be measured at baseline and post-treatment.

### Statistical analyses

A power analysis revealed that a total of 203 participants would be needed in the two treatment arms to have sufficient power (80%) to test the moderation effect. Thus, overall, we will aim to recruit 300 participants, with 120 participants in each treatment arm, and 60 in the waitlist control condition. This will allow for a drop-out rate of approximately 20%.

An intention-to-treat analysis will be used to analyse the data. To examine treatment efficacy, linear mixed models will be used, with baseline levels of treatment outcomes as the covariate, and group and depressive status as the fixed factors. Prior history of depressive disorder will also be analysed as a moderator of clinical outcomes for the two treatments.

Analyses of clinical significance will also be conducted, in line with guidelines by Dworkin *et al.*<sup>59</sup> The proportion of participants improving by  $\geq 30\%$  (reflecting moderate improvement) and  $\geq 50\%$  (reflecting substantial improvement) will be reported for post-treatment and 6 months follow-up. To examine whether process outcomes (eg, pain acceptance, self-efficacy) may significantly moderate the effect of treatment, structural equation modelling will be used.

## DISCUSSION

RA is a chronic and progressive autoimmune disease, which carries a significant burden for both the individual and broader society. Symptoms such as pain and fatigue, as well as comorbid conditions such as anxiety or depression,

can significantly impact functioning.<sup>60</sup> Estimates of the annual economic burden of RA in Australia range from \$234 million to \$550 million.<sup>60–62</sup> With a forecasted estimate of 579 915 Australians living with RA by 2030, the impact of the condition on the healthcare system is expected to increase even further.<sup>60</sup> Given this, research which establishes effective and accessible treatments for RA, and its related psychosocial symptoms, is essential.

The proposed trial will be the first to examine and compare the efficacy of Internet-delivered CBT and MBSR for people with RA. CBT is currently the most widely studied psychological treatment for RA.<sup>7</sup> Meta-analytic findings indicate that CBT can effectively reduce pain, disability and depressive symptoms among people with RA,<sup>4</sup> and offers long-term benefits, including reduced reliance on healthcare services when administered early in the course of disease.<sup>63</sup> Growing evidence also suggests that MBSR may significantly improve psychosocial outcomes in RA.<sup>64</sup> However, studies comparing CBT and MBSR for RA have found differing efficacy depending on outcome measures and history of depressive episodes.<sup>11</sup> This suggests that the optimal therapy may differ between individuals with RA.

Despite the evidence that CBT and MBSR are effective for ameliorating symptoms in RA, there is only a single study that we could find which had used an online format.<sup>18</sup> In the proposed trial, the CBT and MBSR treatments are delivered via the Internet and are specifically tailored for people with RA. Treatments are also matched on important variables (eg, five lessons over 8 weeks, the inclusion of patient stories, similar styles of presentation and so on). Notably, the online interventions are likely to be significantly more accessible and cost-effective than standard face-to-face therapies. Unlike traditional therapy, online interventions, such as those under investigation in the proposed trial, require minimal therapist input,<sup>12</sup> and rely on a manualised and scalable format. This makes them particularly advantageous for individuals who are unable to access face-to-face therapy, due to living remotely, long waitlists, costly treatment expenses or illness-related mobility issues. Further, the need for online interventions has never been more pressing, as evidenced by the rapid shift in how healthcare has been delivered over the past year due to COVID-19.<sup>14</sup> Online interventions are particularly valuable given that they appear to be just as effective as face-to-face therapies for a number of conditions,<sup>65 66</sup> including pain.<sup>20</sup> Thus, the proposed examination of online treatments for RA is likely to have a significant impact on clinical practice, potentially offering an accessible, evidence-based and effective supplement to usual care.

## ETHICS AND DISSEMINATION

The trial has received ethical approval from The University of Sydney Human Research Ethics Committee (2021/516). In addition, the current protocol will adhere to the ethical principles of the Declaration of Helsinki. All participants will be fully informed about the aims of the research prior to taking part. Written informed consent will be obtained

from each participant. Data will be anonymised and aggregated for all statistical analyses, such that individual participants will not be identifiable in the final publication. The findings from this study will be submitted to high-impact peer-reviewed journals, in line with the outcomes presented in this protocol, and irrespective of the final results. The findings will also be disseminated at national and international scientific conferences.

**Contributors** LS led the conception and design of the study. REM, JD, JT, MS, A-LS and BD contributed to and provided feedback on the study design. REM, BR and LS drafted and edited the manuscript. All authors contributed to the revision of the draft and have read and approved the final version.

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**Competing interests** BD is part of a team funded by the Australian Federal Department of Health to develop and operate a national digital mental health service, the MindSpot Clinic. He has developed several digital psychological interventions, but derives no royalties or financial benefits from them.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

**Patient consent for publication** Not applicable.

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