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Support for a non-therapist assisted, Internet-based cognitive-behavioral therapy (iCBT) intervention for mental health in rheumatoid arthritis patients

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ABSTRACT

Background: Anxiety is common in patients with rheumatoid arthritis (RA) and associated with worse RA outcomes. This study assessed the feasibility and preliminary health impacts (mental and physical) of a non-therapist assisted, online mental health intervention targeting anxiety in this population.
Methods: Participants with confirmed RA and elevated anxiety symptoms were enrolled into the Worry and Sadness program, an Internet-based cognitive-behavioral therapy (iCBT) intervention for anxiety and depression shown to be effective in the general population. Validated self-report measures of anxiety, depression, pain interference, fatigue, physical health-related quality of life, functional status, and patient-reported disease severity were collected at baseline, post-intervention, and at three-month follow-up. Emotional distress scores were tracked between lessons. Participants provided qualitative feedback in writing post-intervention.
Results: We analyzed the responses of 34 participants; the majority was female (86%) and the mean age was 57 (SD = 13). Of these, 80% ($n = 28$) completed the study in its entirety. Among these completers, 94.1% described the program as worthwhile. We found statistically significant improvements in anxiety, depression and fatigue from baseline to three-month follow-up, with small to large effect sizes ($d = 0.39$–0.81). Post-hoc analyses revealed that statistically significant change occurred between baseline and post-intervention for anxiety and depression and was maintained at three-month follow-up, whereas statistically significant change occurred between baseline and three-month follow-up for fatigue. Statistically significant reductions in emotional distress occurred across the program, with a large effect size ($d = 1.16$) between the first and last lesson.
Conclusion: The Worry and Sadness program shows promise as a feasible resource for improving mental health in RA.

1. Introduction

Rheumatoid arthritis (RA) is an autoimmune disease producing chronic joint inflammation and pain. For those with this condition, psychological symptoms are frequent (Astin et al., 2002). Approximately 20–40% of RA patients meet criteria for major depressive disorder (Margaretten et al., 2011; Matcham et al., 2013), 25–70% of RA patients present with an anxiety disorder (El-Miedany and El Rasheed, 2002; Matcham et al., 2018), and the vast majority exhibit symptoms of both (Covic et al., 2012). Research has consistently supported adverse outcomes in terms of both disease severity (Kojima et al., 2009) and activity (Edwards et al., 2011) for co-occurring depression and RA, and more recent literature confirms comorbid anxiety is also associated with worsened pain (Jamshidi et al., 2016), fatigue (Geenen and Dures, 2019), functional impairment (Soósová et al., 2017), and quality of life (Beşirli et al., 2020). Yet while interest rises in the use of

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pharmacotherapy in RA (Vallerand et al., 2019), investment in psychological approaches remains limited (Fiest et al., 2017).

The most widely studied and frequently implemented psychological interventions for anxiety and depression employ cognitive-behavioral therapy (CBT) (Kaczkurkin, 2015; Thase et al., 2018). CBT refers to a family of effective mental health treatments, which share techniques yet vary depending on target outcomes. CBT interventions demonstrate immediate and sustained effects when targeting both anxiety (Olatunji et al., 2010) and mood symptoms (Driessen and Hollon, 2010) in the general population. Similar effects have been found in samples of patients with chronic diseases, such as inflammatory bowel disease (Evertsz et al., 2017) and multiple sclerosis (Askey-Jones et al., 2013).

CBT has also proven effective in the management of chronic pain (Knoerl et al., 2015). With the explosion of Internet-based CBT (iCBT) and its removal of barriers such as physical accessibility, the number of validated programs for use with pain populations has increased dramatically (Dear et al., 2013). In RA specifically, CBT programs have targeted self-reliance (Trudeau et al., 2015), quality of life (Shigaki et al., 2013), and pain (Sharpe, 2016), with depression and anxiety often framed as peripheral considerations; as such, iCBT programming targeting mood and anxiety in RA represents an unmet need. An appropriate program candidate would balance feasibility for the patient (e.g., six to 10 total hours over six to 10 weeks) (Edhe et al., 2014) and the health care system (e.g., not requiring the costly ongoing engagement of a therapist) (Knoerl et al., 2015).

Given the predominance of anxiety relative to depression in RA, our primary outcome of interest for this study was anxiety. Our aims were to: (1) assess the feasibility of a non-therapist assisted iCBT intervention for anxiety (i.e., The Worry and Sadness program) in people with RA, as determined by rates of recruitment, treatment adherence and participants' experience during treatment; (2) assess program efficacy for anxiety reduction in people with RA; and (3) assess program efficacy in terms of additional facets of mental health (i.e., depression and emotional distress) and well as physical health (i.e., pain interference, fatigue, physical health-related quality of life, functional status, and patient-reported disease severity).

2. Methods

2.1. Participants

We recruited participants with confirmed RA (Aletaha et al., 2010) through email, letter, or in-person (by a research assistant) from ongoing study cohorts and the Arthritis Centre in Winnipeg, MB. We assessed study eligibility and participants gave verbal consent by phone. Inclusion criteria required: (1) elevated levels of anxiety (as determined by an anxiety screener measure T-score $\geq$ 56.0); (2) ability to communicate in English; and (3) access to a computer/tablet/smart phone and the Internet. We used anxiety as our screener given that anxiety was our primary outcome. An a priori sample size calculation was not conducted given recommendations and standard practice in the context of feasibility studies (Cocks and Torgerson, 2013; Teare et al., 2014).

2.2. Measures

2.2.1. Recruitment and treatment adherence

We recorded the number of participants who were eligible for enrollment, completed baseline measures, enrolled in the program, and completed the program. We also recorded time intervals between data collection points and asked two questions regarding homework completion: (1) did you practice the homework outside of the lessons; and (2) if so, approximately how many hours were dedicated to homework in total (select most appropriate answer between <1 and >6; a total of 7 response options).

2.2.2. Treatment experience

We evaluated treatment experience with the following free text response questions: (1) did you find this program a worthwhile experience; (2) would you recommend the program to a friend with a similar experience as you; (3) did you think the program spoke to your personal experience/if not, how would you have improved it; (4) what was your favourite aspect of the program; (5) what was your least favourite aspect of the program; and (6) how would you rank the modules (1 = favourite, 6 = least favourite).

2.2.3. Anxiety and depression

The National Institutes of Health Patient-Reported Outcomes Measurement Information System (PROMIS) is a collection of self-report outcome measures proven to be valid and reliable across a range of populations (Cella et al., 2010), with the 4 to 8-item measures found valid and reliable for use in RA (Bartlett et al., 2015; Hitchon et al., 2020). We assessed anxiety symptoms using the 4-item Anxiety Short Form during screening. Study inclusion required a score higher than 8 (T-score $\geq$ 56.0), indicating anxiety symptoms elevated above the population mean. For treatment response, we assessed anxiety symptoms using the extended 6-item PROMIS Anxiety Short Form. The internal consistency (i.e., Cronbach's alpha) for this Anxiety Short Form at baseline in the current study was $\alpha = 0.88$. We also assessed depressive symptoms using the 6-item PROMIS Depression Short Form. The internal consistency for the Depression Short Form at baseline in the current study was $\alpha = 0.94$.

2.2.4. Emotional distress

The Kessler Psychological Distress Scale (*K*-10) is a widely used, 10-item self-report measure of global emotional distress. There is strong psychometric support for its use in the general population (Furuakawa et al., 2003), and evidence for its reliability in RA (Hitchon et al., 2020).

2.2.5. Pain interference

We assessed the functional impact of pain using the 6-item PROMIS Pain Interference Short Form. The internal consistency for the Pain Interference Short Form at baseline was $\alpha = 0.95$.

2.2.6. Fatigue

We assessed the experience (frequency, duration, and intensity) and impact of fatigue using the 6-item PROMIS Fatigue Short Form. Construct validity has been established (Bartlett et al., 2018). The internal consistency for the Fatigue Short Form at baseline was $\alpha = 0.94$.

2.2.7. Physical health-related quality of life

We assessed physical health-related quality of life using the 2-item PROMIS Global Health-Physical, which demonstrates good internal consistency in other health populations such as stroke (Katzan and Lapin, 2018). The internal consistency for the Global Health Short Form at baseline was $\alpha = 0.65$.

2.2.8. Functional status

We used the 8-item modified Health Assessment Questionnaire (mHAQ) to assess functional status (Maska et al., 2011). The internal consistency for the mHAQ at baseline was $\alpha = 0.90$.

2.2.9. Patient-reported disease severity

We used the Patient Global Visual Analogue Scale (PG-VAS) to assess disease severity. Patients were verbally asked: considering all the ways your condition affects you, how active has your disease been (0 = Not active, 10 = Severely active). This and several other phrasing variations of the PG-VAS are routinely used in both clinical practice and research (Ferreira et al., 2018).

2.3. Treatment

The Worry and Sadness Program is a mixed mental health intervention, targeting anxiety and depressive symptomology in the general adult population (Newby et al., 2013; Newby et al., 2014). The program was originally designed to treat comorbid generalized anxiety disorder and major depressive disorder, as these conditions often co-occur in the general population and this co-occurrence is rarely addressed in CBT protocols (Newby et al., 2013; Brown et al., 2001). Adherence to this treatment was high in a past RCT (89%), with large effect sizes (>0.8) reported in reducing anxiety and depressive symptoms and emotional distress (Newby et al., 2013). Although this program had yet to be investigated in a chronic disease population, a similar intervention developed by the same research group (iCBT for major depressive disorder; iCBT-MDD) improved symptoms of depression, anxiety and emotional distress for people with diabetes (Newby et al., 2017). Aside from program efficacy, we chose this program because it allowed us to target our primary outcome of anxiety without neglecting the high co-occurrence of depression in RA.

The treatment includes six modules (see Table 1 for a detailed description). Modules must be completed in order (there is no skip option) and they take approximately 15 min to complete. Material is provided in the form of illustrated stories in a slideshow presentation, with both male and female characters overcoming their difficulties with anxiety and depression. Interaction is not required during the lesson; however, a lesson summary is provided at the end that involves responses from the participant. This lesson summary must be downloaded and submitted (i.e., click to submit) to gain access to the next lesson, five days later. The lesson summaries involve tasks that require immediate completion (e.g., provide examples of personal thoughts) as well as optional homework worksheets (e.g., activity planning, thought challenging). The purpose of requiring a submission at the end is to confirm full completion of the lesson; there is no marking/response from a therapist. The purpose of the wait time is to mimic weekly attendance with a live therapist and allow practice of the learned material throughout the week. Additional materials are also provided in the program, including frequently asked questions about each lesson, patient success stories, and resources on topics such as sleep, medications, and worry stories (i.e., imaginal worry exposure).

Table 1
Details of the Worry and Sadness Program.

Lesson	Description	Homework Practice Tasks
I: About anxiety and depression	Psychoeducation on anxiety and depression, including the fight or flight response, controlled breathing, and the benefits of physical exercise.	Controlled breathing, physical exercise
II: Identifying thoughts and tackling low activity	Cognitive therapy components, including education about the cognitive model and introductions to cognitive distortions and thought monitoring. Activity planning is also introduced.	Thought monitoring, activity planning
III: Tackling thoughts	Thought challenging/cognitive restructuring, including challenging positive and negative meta-cognitive beliefs about repetitive thinking, shifting attention, and hunting for positives.	Thought challenging, hunting for positives
IV: Tackling avoidance	Education about avoidance and safety behaviors, as well as graded exposure and structured problem solving.	Graded exposure and structured problem solving
V: Mastering your skills	Advanced graded exposure understanding (addressing activities such as imaginal exposure and interoceptive exposure) and troubleshooting difficulties with graded exposure.	Graded exposure
VI: Staying well	Relapse prevention.	Relapse prevention plan

Note: Adapted from Newby et al., 2013.

2.4. Procedure

This feasibility study used a single-arm, open-label design i.e., all consenting participants gained access to the iCBT program. At baseline, participants were mailed a package containing a written consent form, a post-marked envelope, and questionnaires, including a demographics form and self-report symptom measures of mental and physical health (i.e., anxiety, depression, pain interference, fatigue, and physical health-related quality of life). Upon receipt of the returned package, research personnel administered measures (i.e., functional status and patient-reported disease severity) by telephone. At this time participants were provided a code to enroll in the online program. Four weeks later, participants who received a code were contacted by telephone for a "check-in," with the primary purpose being troubleshooting any technical difficulties and reminding participants of the deadline (the intended program duration was 10 weeks, but a two-week "cushion" period was available). Unlike all other measures, the measure of emotional distress was embedded into the program at the start of each lesson to track mental health experience across the duration of treatment.

Upon completion of the program or at the 12 week mark, whichever came first, research personnel administered the measures of functional status and patient-reported disease severity by telephone a second time. The post-intervention package included baseline measures, a post-marked envelope, and qualitative feedback measures (i.e., treatment experience, homework completion). Participants also completed the mailed baseline measures and telephone measures at three-month follow-up (see Fig. 1 for further details). In summary: measures of anxiety, depression, pain interference, fatigue, physical health-related quality of life, functional status, and patient-reported disease severity were administered at baseline, post-intervention, and three-month follow-up; a measure of emotional distress was administered between lessons; and measures of treatment experience and homework completion were administered at post-intervention. The Health Research Ethics Board approved this study.

2.5. Analytic strategy

We used descriptive statistics to characterize the sample. We used an intention-to-treat (ITT) approach, complemented by a per-protocol approach for our primary health outcome (i.e., anxiety). Specifically, we used a modified ITT approach (Gupta, 2011), in which one participant was excluded from the ITT analysis because they enrolled in the program then immediately requested removal from the study due to time constraints. An ITT approach was used to capitalize on data given the sample size, and to avoid bias in the estimate of treatment effect; a per-protocol approach was implemented to assess any potential differences between completers and non-completers on the primary health outcome, and to gather a less conservative estimate of treatment effect. To understand the characteristics of those who completed the study for the purpose of future study design, we used chi-squares/one-way ANOVAs to compare the three sub-groups within the sample of participants eligible for enrollment (i.e., per-protocol completers, non-completers, and non-enrollers) on baseline characteristics.

We used descriptive statistics to describe most other facets of feasibility. A summative content qualitative analysis, where the focus is uncovering meanings of content for the purpose of preliminary insight (Hsieh and Shannon, 2005), was performed on appropriate treatment experience responses. There were two independent coders, and any disagreement in coding was resolved through consensus. Final themes, number/percentage of participants who endorsed each theme, and

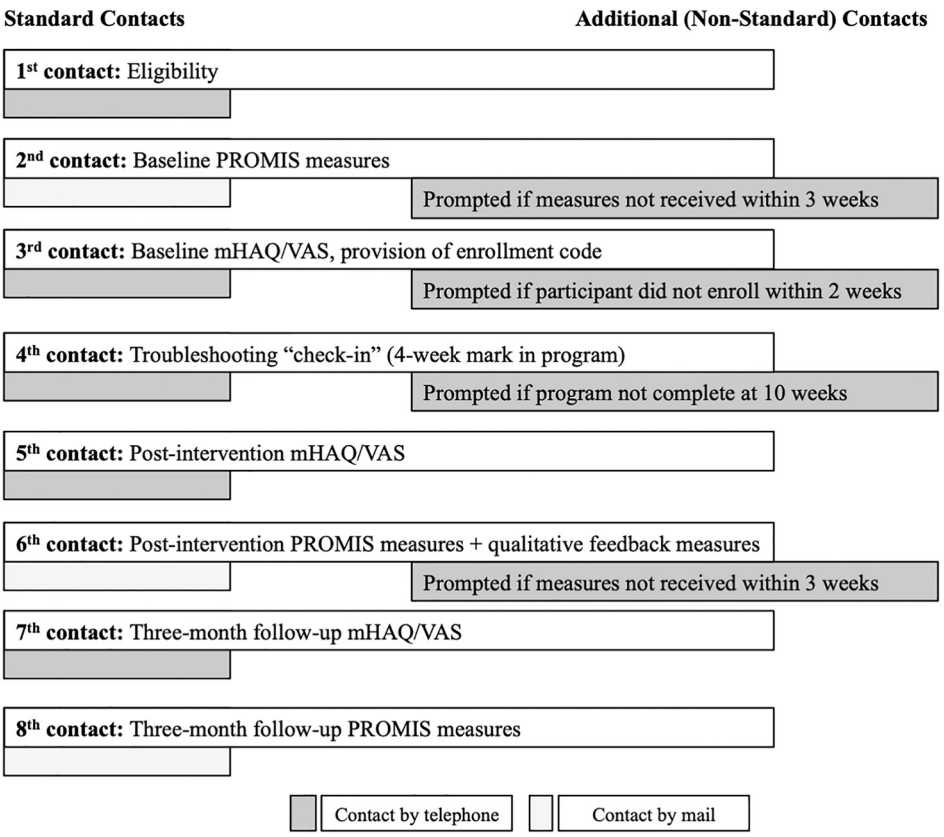

Fig. 1. The standard and additional (non-standard) contacts participants received as per study protocol.

examples are presented in table format.

All PROMIS summary scores were transformed into T-scores using HealthMeasures Scoring Service powered by Assessment Center[SM] (Evans et al., 2018). The missing data rate was less than 5%. Missing data in the mailed measures (i.e., anxiety, depression, pain interference, fatigue, and physical health-related quality of life) were managed with imputation, using an expected a priori pattern response scoring method through the HealthMeasures Scoring Service (the Assessment Center[SM] protocol for scoring PROMIS measures). Missing data in the telephone measures (i.e., functional status, patient-reported disease severity) were managed with the last observation carried forward (LOCF) imputation method, common to small sample ITT analyses (Gupta, 2011). This was only required for one participant, who could not be reached by telephone for three-month follow-up. We used a one-way repeated measures analysis of variance (ANOVA) to assess the effect of time (baseline, post-intervention, and three-month follow-up) on each symptom measure, separately. We also conducted a one-way repeated measures ANOVA to assess the effect of time (pre-lesson one through six) on emotional distress. We used univariate analyses for each mental and physical health outcome given the exploratory nature of this work and to allow comparison of outcomes with the many other feasibility studies using univariate methods (Saccenti et al., 2013). This is appropriate for feasibility studies when the assumption of sphericity is met and there is an overall absence of missing data. Of note, for one of the seven health outcomes (i.e., functional status) that former was not met, and therefore the Greenhouse-Geisser correction was used. Significance was set to $p \leq 0.05$. We did not perform a correction for multiple tests because of the exploratory nature of the study (Armstrong, 2014). We conducted post-hoc analyses on significant results to determine where significant changes occurred. We then used Cohen's *d* comparison of means (T1-T3/pooled standard deviation [SD]; T1-T6/pooled SD in the case of emotional distress) to assess effect sizes as means of better understanding meaningful change. Effect sizes are considered small if $d > 0.20$, medium is $d > 0.5$, and large if $d \geq 0.8$ (Cohen, 1988). Finally, to address clinical significance for our primary mental health outcome (i.e., anxiety), we determined the percentage of participants who completed follow-up measures and no longer demonstrated elevated levels. Analyses were performed using SPSS version 26 (IBM SPSS Statistics, Armonk, NY: IBM Corp).

3. Results

3.1. Participant characteristics

The ITT sample consisted of 34 participants. Of these, 28 (68%) completed the program, producing the per-protocol sample (see Fig. 2). Baseline participant characteristics are presented in Table 2. Most of the ITT sample was female, White, and had moderate (T score $\geq$ 60 to <70) levels of anxiety and mild (T -score $\geq$ 55 to <60) levels of depression at baseline. Nearly three-quarters of the ITT sample was recruited through email or letter. The per-protocol sample demonstrated similar demographics. At baseline, there were no significant differences between participants eligible for enrollment (i.e., per-protocol completers, non-completers, and non-enrollers), except for race and recruitment method; specifically the per-protocol completers were more commonly White and recruited through email or mail.

All ITT results from baseline/post-intervention/three-month follow-up comparisons are reported in Table 4; the results for changes in anxiety, depression, pain interference, fatigue and physical health-related quality of life are illustrated in Fig. 3.

3.2. Feasibility outcomes

3.2.1. Recruitment

Of 70 candidates approached, 47 (67%) were eligible for participation. Of those, 41 (87%) returned completed baseline measures and were

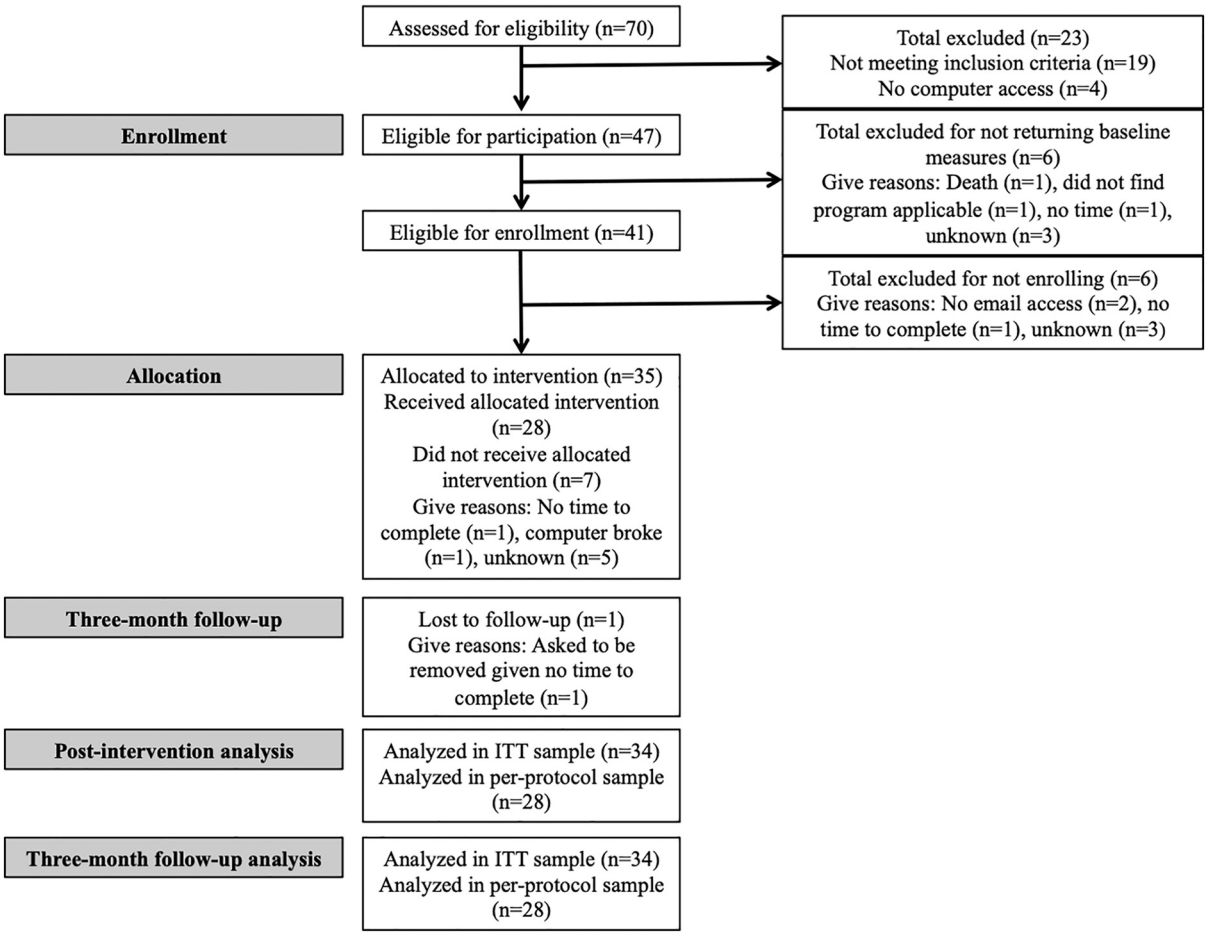

Fig. 2. CONSORT flowchart.

therefore considered eligible for enrollment. Of this group, 35 (85%) enrolled in the program, 34 (83%) began the program and completed post-intervention measures, and 28 participants (80% of the enrollers) completed the program per-protocol (see Fig. 1).

3.2.2. Treatment adherence

Baseline measures (n = 41) were completed, on average, 42.7 days (SD = 18.3; range = 4.0–92.0) before engagement with the program. For completers, the average program completion time was 61.3 days (SD = 18.7; range = 32.0–98.0). Post-intervention measures were completed, on average, 17.4 days (SD = 18.9; range = 26–83) after program completion and 83.5 days (SD = 26.9; range = 41.0–120.0) after last completed lesson for non-completers. Three-month follow-up measures were completed, on average, 115.1 days (SD = 25.7; range = 93.0–227.0) after program completion and 172.2 (SD = 17.3; range = 151.0–194.0) days after last completed lesson for non-completers. Of those who completed the full program, 96.4% completed supplementary homework. On average, completers engaged in 2.9 (SD = 1.7; range = 0–6.0) hours of homework total ().

3.2.3. Treatment experience

There had been some confusion among non-completers on how to describe their treatment experience. For that reason, non-completers were excluded from this analysis. Of those who completed the program (n = 28), (1) 94.1% described the program as a worthwhile experience; (2) 88.2% would recommend the program to a friend with a similar experience; and (3) 54.8% indicated the program spoke to their personal experience. In contrast, 9.7% felt the program did not speak to their experience, and 35.5% indicated the program needed improvement. Of those who called for improvement, the most common suggestion (15% of responders) was to incorporate disease-relevant content. The provision of self-management tools was cited as the (4) favourite aspect of the program (45% of responders); and the structure of the course (e.g., issues with homework) was cited as the (5) least favourite aspect of the program (39% of responders). Among those who endorsed a favourite/least favourite module (n = 19), (6) the most common favourite (37% of responders) was Lesson 1: About anxiety and depression and the two least favourite lessons (26% of responders, respectively) were Lesson 5: Mastering your skills and Lesson 6: Staying well. Full details of the summative content qualitative analysis are presented in Table 3. Mean agreement between coders was 84%.

3.3. Mental health outcomes

3.3.1. Statistical changes from baseline

In the ITT analysis (n = 34), there was a statistically significant difference in anxiety and depression scores from baseline to three-month follow-up. Additionally, there was a statistically significant difference in emotional distress across the duration of the program [F (5,21)=9.78, p < 0.001]. Pairwise comparisons determined significant change occurred between baseline and post-intervention for anxiety and depression, and these reductions were maintained at three-month follow-up. For emotional distress, there was a significant reduction across all time points yet pairwise comparisons of means demonstrated some change between consecutive modules was significant and some change was not (see Table 4).

Table 2
Characteristics of the study sample.

Variable	Eligible for enrollment (n = 41)	ITT sample (n = 34)	Per-protocol sample (n = 28)	Non-completers (n = 7)	Non-enrollers (n = 6)	Chi-square/ ANOVA
Gender: (%)						
Female	87.8	85.7	85.7	85.7	100.0	
Male	12.2	14.3	14.3	14.3	0	
Age (years):						
Mean	57.3	57.0	58.4	52.0	58.5	
(SD)	(12.8)	(13.0)	(12.9)	(12.9)	(13.3)	
Race: (%)						**
White	78.0	85.7	89.3	71.4	33.3	
Other	22.0	14.3	10.7	28.6	66.7	
Marital status: (%)						
Married/common law	70.7	71.4	71.4	71.4	66.7	
Divorced/separated	14.6	11.4	10.7	14.3	33.3	
Widowed	4.9	5.7	3.6	14.3	0	
Never married	9.8	11.4	14.3	0	0	
Education: (%)						
<Highschool	19.5	17.1	17.9	14.3	33.3	
Highschool/GED	17.1	17.1	14.3	28.6	16.7	
College/Tech/trade school	39.0	40.0	42.9	28.6	33.3	
Undergraduate degree	17.1	20.0	17.9	28.6	0	
Graduate degree	7.3	5.7	7.1	0	16.7	
Annual income: (%)						
<$15,000	23.1	17.6	14.8	28.6	60.0	
$15,000-$29,999	20.5	23.5	25.9	14.3	0	
$30,000-$49,999	17.9	17.6	22.2	0	20.0	
$50,000-$100,000	38.5	41.2	37.0	57.1	20.0	
Anxiety screener						
Raw score						
Mean	11.5	11.6	11.7	10.6	11.5	
(SD)	(2.4)	(2.5)	(2.4)	(2.8)	(2.2)	
T-score						
Mean	62.8	63.0	63.2	60.9	63.0	
(SD)	(4.9)	(5.0)	(4.9)	(5.4)	(4.8)	
Baseline anxiety						
Raw Score						
Mean	16.3	16.0	15.8	17.1	17.7	
(SD)	(4.3)	(4.4)	(4.8)	(1.9)	(3.4)	
T-score						
Mean	61.2	60.8	60.5	62.2	63.2	
(SD)	(5.9)	(6.0)	(6.6)	(2.5)	(4.5)	
Baseline depression						
Raw score						
Mean	15.5	15.4	15.0	17.0	15.8	
(SD)	(5.5)	(5.6)	(5.9)	(3.9)	(5.3)	
T-score						
Mean	58.0	58.0	57.4	60.7	57.7	
(SD)	(8.4)	(8.3)	(8.9)	(4.7)	(9.9)	
Recruitment method: (%)						**
Email/mail	73.2	82.9	89.3	57.1	16.7	
Baseline mHAQ score						
Mean (SD)	0.67 (0.5)	0.64 (0.5)	0.73 (0.5)	0.27 (0.3)	0.83 (0.3)	
Descriptor	Mild	Mild	Mild	Normal	Mild	
Baseline VAS						
Mean (SD)	5.0 (2.5)	4.8 (2.4)	5.0 (2.4)	4.1 (2.5)	6.2 (2.6)	

Note: ITT = intention to treat, mHAQ = modified health assessment questionnaire (indicator of functional status), VAS = visual analogue scale (indicator of patient-reported disease severity). Descriptor refers to severity of functional disability.
** $p \leq 0.01$.

3.3.2. Meaningful changes from baseline

From baseline to three-month follow-up, the reduction in anxiety was deemed a medium effect size and the reduction in depression was deemed a small effect size. From lesson one to lesson six, reduction in emotional distress was deemed a large effect size ($d = 1.16$).

3.3.3. Clinical change from baseline

Fifteen participants (44.1%) scored in the normal range (T-score < 55) for anxiety at three-month follow-up.

3.3.4. Changes in anxiety for completers only

In the per-protocol analysis ($n = 28$), there was a similar statistically significant difference in anxiety [F (2,26)=16.13, p < 0.001] from baseline to three-month follow-up, evident post-intervention and maintained at three-month follow-up. From baseline to three-month follow-up, reduction in anxiety was deemed a large effect size (d = 0.81) and again 15 participants (53.6% of the per-protocol sample) scored in the normal range for anxiety at three-month follow-up.

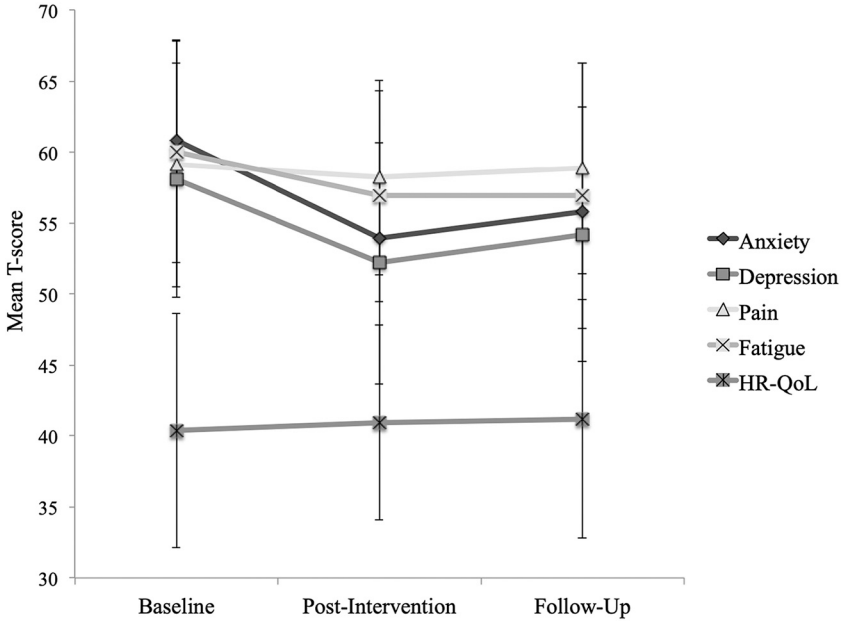

Fig. 3. Baseline, post-intervention, and three-month follow-up mean scores for the five PROMIS measures (anxiety, depression, pain interference, fatigue and physical health-related quality of life; $n = 34$).

3.4. Physical health outcomes

3.4.1. Statistical changes from baseline

In the ITT analysis (n = 34), there was only a statistically significant difference in fatigue across the three time points. Pairwise comparisons demonstrated non-significant effects between consecutive time points. There was no significant effect of time for pain interference, physical health-related quality of life, functional status, and patient-reported disease severity (see Table 4).

3.4.2. Meaningful changes from baseline

From baseline to three-month follow-up, reduction in fatigue was deemed a small effect size.

4. Discussion

This project is novel in several respects, given that psychological approaches to mental health are heavily reliant on therapist involvement in chronic pain (Knoerl et al., 2015) and rare to non-existent in RA. We established the feasibility of a non-therapist assisted iCBT program for anxiety among those with RA and provided preliminary evidence of clinical benefit. We had a completion rate of 80%, with an average completion time just under nine weeks. Most participants found the program worthwhile and would recommend it to a friend. Over half indicated that the program spoke directly to their personal experience. We found improvements at three-month follow-up for anxiety, depression, and fatigue, with the improvements in anxiety and depression demonstrating significant change immediately post-treatment. Changes in emotional distress between lessons suggested mental health improvements are greater with greater treatment progression. Effect sizes indicated meaningful change similar to that found in the general population (Newby et al., 2013), and change scores indicated clinically significant reductions in anxiety symptoms.

This study suggests that the Worry and Sadness program is a feasible treatment option for anxiety in RA. Outcomes were largely positive; the completion rate nearly replicated that from the original paper evaluating the Worry and Sadness Program in the general population (Newby et al., 2013) and most participants described the program favourably. This aligns with literature suggesting that most patients desire emotional support when living with RA (Sharpe, 2016). Many hypothesized concerns regarding online psychological treatment with an RA sample, such as difficulty with ongoing computer engagement due to hand deformity and resistance towards psychological approaches to managing illness experience, did not appear to be obstacles to treatment adherence/success. Importantly, the absence of therapist engagement (a treatment factor traditionally associated with online program success) (Andersson and Cuijpers, 2008) also did not appear to hinder efficacy.

Our results also hinted at a possible explanation for the documented correlation between therapist involvement and online treatment success. In our study, self-identifying mental health difficulties appeared to be a factor in initial engagement and treatment adherence (i.e., almost 90% of completers responded to a received email or letter). This aligns with past research (Newby et al., 2013) where program adherence was better among individuals with expressed interest in iCBT (i.e., those self-seeking supports) versus those from primary care (i.e., those not self-seeking supports). This suggests that establishing readiness to change might be an important step missing from non-therapist assisted programs. If true, for RA patients specifically, this supports routine psychoeducation (e.g., pamphlets in Rheumatology waiting rooms) as part of any pragmatic mental health initiative, promoting psychological readiness without therapist involvement.

Potential limitations of the program in terms of feasibility for this population were also highlighted. For example, the material in the Worry and Sadness Program is not specific to a disease population and, while only endorsed by 15% of responders, our qualitative analysis revealed the most commonly suggested area for improvement was to add RA-related content. Another factor in adherence might be participants' reactions to homework (cited as the least enjoyed aspect of participation), which might improve with modification of homework materials or advance notice prior to enrollment. The importance of adherence to the program in its entirety was highlighted by the fact that completers experienced greater benefit (e.g., only completers moved into the normal range for anxiety following treatment).

The intervention had the largest impact on mental health, with some benefit also seen for fatigue. The largest effect at three-month follow-up was for anxiety, despite elevations for both anxiety and depressive symptoms at baseline. The simplest explanation for this differential is baseline anxiety was higher than baseline depression because it was

Table 3
Results from the summative content qualitative analysis of per-protocol participants' feedback on the intervention.

Theme	n (%) who endorsed	Quote support
Question: Did you think the program spoke to your personal experience? If not, how would you have improved it?		
Positive endorsement, no suggestions	23 (70%)	"Yes. It mostly did. Thank you."
Incorporate disease-relevant content	5 (15%)	"Have incidents that would happen for a person with disabilities and their particular issues."
Incorporate content unrelated to disease experience	3 (9%)	"For me more family situations (with kids, etc.,) would be better."
Logistical issues (no computer involvement, more structure)	2 (6%)	"I would have preferred mailed packages. I have no use for computers. If it was easily accessible, than I would have been a better participant."
Speak to location	2 (6%)	"However, in Canada-weather and inability to go outside (when you have disability and mobility issues and the snow and cold are severe) makes it a difficulty situation…seasonal aspects are more of a challenge for me living in Winnipeg-so that is one thing that stood out to me… (the course) does not speak to our locational aspects of depression here in the cold."
Negative endorsement, no suggestions	1 (3%)	"No, I don't really feel the depression and anxiety applied to me."
Question: What was your favourite aspect of the program?		
Provides self-management tools	15 (45%)	"Learning the tools and strategies to recognize and deal with anxiety and depression."
User-friendly/convenient	13 (39%)	"That I could work on it when and where I wanted to. Also, that I have a year to go back and review the program as I need to."
Appealing/interesting platform/ content	11 (33%)	"I like how they had two characters who gave examples of how anxiety and depression affected them."
Promotes self-awareness	9 (27%)	"Made me stop and 'think'… your attitude is everything! I am in control of my attitude, no one else. There is no 'pill' to fix how you think. I actually have control over quite a bit, which is directly related to how I feel most of the time (I learned that here!)"
Promotes sense of unity with others	3 (9%)	"I am not unique in how I feel."
Question: What was your least favourite aspect of the program?		
Structure of course (length, timing of lessons, amount of content, design/organization of content, issues with homework, no therapist involvement)	13 (39%)	"The homework took considerable time."
Content of course (not easy to understand, not engaging/ interesting, issues with specific content)	4 (12%)	"The lessons seemed repetitive sometimes."
Issue unrelated to program/ participation	4 (12%)	"Trying to incorporate these lessons in my life- habits are hard to break (old habits)."
Not relatable to a pain population	3 (9%)	"…Another aspect (that) was lacking was the importance of exercise for people with some form of arthritis. Yes, they did say exercise but such exercises as shown would be out of the realm of someone with severe RA. Check The Arthritis Help Book by Drs. Kate Lorig and James Fries. Pages are devoted to exercise we can do-how encouraging and motivating!.."
Specific timing of study	2 (6%)	"I think for me it was the timing, i.e., the cold and dreary weather, where you stay at home and a million and one thoughts go through your mind (mostly negative). I think that having to redo these exercises (during summer and fall) would (have) had different results. More positive than negative."
Discomfort with technology/ technological issues	5 (3%)	"Getting onto the computer with (the password) was challenging. Not very user friendly. After having the same problems every time I just gave up and left the program."

Note: Mean agreement between coders was 84%.

specifically targeted for inclusion criteria. However, another interpretation of these results is that anxiety in the context of RA is more amenable to online treatment, relative to depression. If true, implementation of anxiety interventions may be particularly worthwhile. The reduction in fatigue may be a result of reducing mental-health contributions to fatigue, or an outcome of common mechanistic pathways (Nerurkar et al. (2019)). We did not find a significant impact on pain interference, physical health-related quality of life, functional status, or patient-reported disease severity, which may be because the intervention was not intended to directly target these outcomes. Alternatively, reductions in these aspects may have become evident over a greater length of time.

With this small sample, there was potential for Type II error (e.g., missing characteristic differences between completers, non-completers, and non-enrollers) and the potential for a cohort effect related to the impact of seasonal change (all baseline measures were collected in winter and follow-up measures in spring). Caution in the interpretation of secondary outcomes should be applied. We did not control for changes in medication, other non-pharmacologic interventions or time engaged with the program. Our sample also lacked diversity in terms of gender, race and baseline disease status. Some participants required prompting, and despite no clinical involvement, this may have impacted program outcomes. Additionally, there is potential for bias when using patient-report measures.

5. Conclusions

The Worry and Sadness program may be an appropriate psychological intervention for RA patients presenting with elevated anxiety symptoms. While RCTs enrolling a larger, more diverse sample are needed, establishing feasibility was a critical starting point. Minor program modifications such as integrating RA specific content may further enhance efficacy. This online iCBT program is a potentially useful initial step in an integrated care approach for addressing mental health symptoms in people with RA, as it appears to combine ease of access and cost-efficiency with efficacy.

Table 4
Results from the ITT analysis.

Outcome	Baseline	Post-intervention	Three-month follow-up	*F*-value	*p*-value	Cohen's *d*
	Mean (SD)	Mean (SD)	Mean (SD)			
Anxiety	60.82 (6.13)[a]	53.92 (7.65)[b]	55.75 (7.04)[b]	15.74	<0.001	0.77
Depression	58.08 (8.40)[a]	52.17 (8.51)[b]	54.20 (8.94)[b]	10.07	<0.001	0.45
Quality of life	39.91 (7.92)[a]	40.94 (6.89)[a]	41.19 (8.38)[a]	1.47	0.245	0.15
Pain interference	59.67 (8.19)[a]	58.21 (6.87)[a]	58.85 (7.43)[a]	1.16	0.326	0.11
Fatigue	60.29 (7.79)[a]	56.90 (7.44)[ab]	56.91 (9.33)[b]	3.83	<0.05	0.39
Functional impairment	5.26 (4.25)[a]	4.79 (3.81)[a]	4.82 (4.03)[a]	0.73	0.44	0.11
Patient-reported disease severity	4.91 (2.42)[a]	4.65 (2.30)[a]	4.50 (2.35)[a]	0.63	0.538	0.17

Note: Quality of life = physical health-related quality of life. [ab]Post-hoc analyses: Means in a row without a common superscript letter significantly differ ($p < 0.05$). For example, in the case of fatigue, baseline significantly differed from three-month follow-up only.

Declaration of competing interest

None.

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