

## **Help-seeking Behaviors and Treatment Preferences For Sleep Problems Among Persons With Arthritis**

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**Objectives:** Sleep disturbances, including difficulty initiating sleep, maintaining sleep, and/or early morning awakenings are prevalent among persons with inflammatory arthritis (IA) and have been shown to contribute to worsening of symptoms including fatigue, pain, and health related quality of life. Cognitive behavioral therapy for insomnia (CBTi) is considered first-line treatment for insomnia, but accessibility is limited. Internet delivered CBTi has the potential to overcome accessibility barriers. To guide the tailoring of an internet delivered CBTi for persons with arthritis experiencing insomnia, a needs assessment was conducted to identify help-seeking behaviors, insomnia management strategies and treatment preferences.

**Methods:** We conducted an on-line survey with 251 individuals with arthritis (mean age  $\pm$  standard deviation: 61.5 years  $\pm$  13.1) recruited through social media ads on Instagram, Twitter and Facebook and through the arthritis patient organizations Arthritis Consumer Experts, Arthritis Research Canada's Patient Advisory Board and Patients Intéressés par la Recherche en Arthrite. Participants completed self-report questions assessing insomnia symptoms (Insomnia Severity Index – ISI), help-seeking behaviors and barriers, and treatment preferences for sleep problems.

**Results:** Of the total sample in the past year, 65.7% had at least once used prescription medications and 36.7% had used over the counter medication to facilitate sleep. Among participants with probable insomnia (ISI score  $\geq$  8, n=210), 59.3% had ever discussed their sleep problem with a health care provider and 42.1% perceived a need to talk to a health care provider about their sleep problems in the past year but decided not to seek care. Most commonly endorsed reasons for not seeking treatment were having developed ways of coping (51.8%), perceptions of insomnia as an expected response to a stressful life situation (48.8%) and having previously spoken to their doctor about difficulty with sleep, but he/she was unable to help (45.2%). Among patients with probable insomnia, 25.1% rated medication treatment as very acceptable, while 43.5% rated nonmedication treatment as very acceptable, and 90.7% reported that they would be likely or very likely to try a nonmedication approach delivered over the internet and tailored to arthritis to improve sleep.

**Conclusion:** Given the prevalence, chronicity and adverse consequences associated with insomnia in individuals with arthritis, this study suggests that efforts designed to increase awareness of the effectiveness of behavioral treatments are needed. Behavioral interventions such as CBTi are acceptable to individuals with arthritis and these findings will guide the evaluation of an internet delivered CBTi program tailored to persons with arthritis experiencing insomnia. *Supported by a 2021 CIORA Grant entitled Adapting and Evaluating an Evidence-Based Online Behavioural Intervention to Manage Insomnia in Patients with Rheumatoid Arthritis.*

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## **Greater Preeclampsia Knowledge in SLE with a Specific Educational Tool: Interim Analyses**

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**Objectives:** Pregnant women with systemic lupus erythematosus (SLE) are at high risk of preeclampsia, leading to substantial maternal and fetal morbidity. Aspirin reduces preeclampsia risk, but recent studies suggest aspirin is used only in a minority of SLE pregnancies. It is necessary to improve preeclampsia counselling and management in this population.

Therefore, we are conducting the PREPARE (PREeclamPsia knowledge & Aspirin adheRence in lupus prEgnancies) trial, a randomized controlled trial (RCT), evaluating an educational tool on preeclampsia knowledge and aspirin adherence in SLE pregnancies. We present interim analyses of this tool's effect on preeclampsia knowledge.

**Methods:** We are recruiting consecutive pregnant SLE women up to the 16th gestational week at 5 Canadian SLICC centres (i.e., Montreal, Halifax, Quebec, Winnipeg, and Calgary) since May 2018. Participants are randomly assigned to receive either the specifically designed educational tool (intervention) or standard of care (control). At baseline (i.e., first trimester) and second trimester visits, the participants completed self-administered preeclampsia knowledge questionnaires (scored out of 30 by the research team blinded to the intervention). The current analyses include participants enrolled at the co-ordinating center, accounting for nearly half of the total planned sample size. We performed a univariate linear regression analysis to assess the effect of the educational tool on preeclampsia knowledge (i.e., mean score difference between the two groups from baseline to second trimester visit).

**Results:** Thirty-eight pregnant SLE women were included in the study, with 20 exposed to the intervention. Baseline characteristics were well-balanced between the two groups with similar mean maternal age between the intervention (32.9 years, standard deviation, SD, 4.6) and control group (34.2 years, SD 4.1) and proportion of participants with post-secondary education (Table 1). The difference in mean preeclampsia knowledge scores between second trimester and baseline visits in the intervention group was 5.3 points (95% CI 1.6, 8.9) and in the control group was 0.9 points (95% CI -2.9, 4.7). The mean difference in knowledge scores for those receiving the educational tool was 4.4 points higher (95% CI 0.6, 8.2) than those receiving standard of care.

**Conclusion:** Approximately midway into the trial, we observed an improvement in preeclampsia knowledge from baseline to second trimester visit in pregnant women with SLE who received the educational tool compared to those who did not. Our RCT is well-poised to provide a new evidence-based approach to improve preeclampsia knowledge in pregnant women with SLE, which could help to optimize aspirin use and outcomes in SLE pregnancies. *Supported by a 2017 CIORA Grant entitled Aspirin patterns of use and adherence for prevention of preeclampsia in SLE pregnancies.*

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### **Higher Prevalence of Aspirin Use with a Specific Educational Tool in SLE Pregnancies: Interim Results**

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**Objectives:** Pregnant women with SLE are at substantial risk of preeclampsia. International practice guidelines recommend aspirin (ASA) in this population as it has shown to halve preeclampsia risk in high-risk women. However, recent evidence shows that only a quarter of pregnant SLE women use ASA. It is therefore imperative to understand ASA use patterns to promote ASA adherence. To do so, we are conducting the PREPARE (PREeclamPsia knowledge & Aspirin adheRence in lupus prEgnancies) trial, a randomized controlled trial, evaluating a specifically designed educational tool. We present the tool's effect on ASA use and adherence as well as ASA dosages used at the 2nd trimester visit according to the intervention status.

**Methods:** We are recruiting consecutive pregnant SLE women up to the 16th gestational week at 5 Canadian SLICC centres. Participants were randomly assigned to receive the educational tool (intervention) or standard of care (control). At baseline (i.e., 1st trimester) and 2nd visits (i.e., 2nd trimester for ongoing pregnancies or 4-8 weeks after miscarriage), the participants completed self-reported ASA questionnaires and the modified Adherence to Refills and Medications Scale (ARMS). We measured the proportion of ASA users, mean ARMS scores, and dosage at both visits. We estimated a 95% CI for difference in proportion of ASA users between the groups using the Wilson procedure and mean ARMS score difference between the groups using the student's t test.

**Results:** Thirty-eight participants were included with 20 exposed to the intervention. Baseline characteristics, including maternal age and proportion of participants who had post-secondary education, were well-balanced (Table 1). Baseline ASA use prevalence was 65% and 44% in the intervention and control group, respectively. Proportion of ASA users at the 2nd visit were 100% in the intervention and 83% in the control group, with a difference of 17% (95% CI -2.7, 39.2). At the 2nd visit, mean ARMS score was not different between the two groups [difference of 0.3 points (95% CI -0.8, 1.4)]. Among ASA users who did not have miscarriage, 7% and 18% used 80-81mg, and 93% and 82% used 160-162mg in the intervention and control group, respectively.

**Conclusion:** Halfway into the trial, we observed a trend for higher ASA use in pregnant SLE women who received a specifically designed educational tool compared to those receiving standard of care. The PREPARE trial is on track to provide a new evidence-based approach to optimize aspirin use and potentially improve outcomes in this population. *Supported by a 2017 CIORA Grant entitled Aspirin patterns of use and adherence for prevention of preeclampsia in SLE pregnancies.*

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### **Formulation of an Interdisciplinary Care Pathway for Early Rheumatoid Arthritis**

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**Objectives:** A care pathway is a guide for the mutual decision-making and organization of care processes for a well-defined group of patients. It facilitates communication and care coordination among multidisciplinary team members, patients, and families. Our goal is to develop an interdisciplinary care pathway for patients with early rheumatoid arthritis (RA), including protocols for referral triage, diagnosis, and management, using input from members of our division.

**Methods:** The care pathway was developed in four main phases. In Phase 1, an anonymous survey consisting of 57 questions was electronically distributed to division rheumatologists. This provided data to a small interprofessional working group of rheumatology team members who drafted an initial care pathway informed by evidence-based practice in Phase 2. In Phase 3, an education day was held with approximately 40 physicians (including practicing rheumatologists and rheumatology residents), members of our interprofessional team (nursing, social work, physiotherapists, and pharmacists), and two clinic managers, to review the proposed care elements through presentations and small group discussions. The care pathway was revised for content and implementation considerations based on feedback received. The care pathway was summarized in a 20-page document outlining our team approach to early RA care. An accompanying 14-page document was also developed to support nurses in answering telephone calls from patients on common issues. Phase 4 consists of ongoing implementation efforts and evaluation of the care pathway across multiple practice sites.

**Results:** Our care pathway promotes an approach to patient-centered early RA care using an interdisciplinary approach. Care pathway elements include early workup, pre-treatment screening and vaccinations, choice of initial DMARDs, and use of steroids using shared decision-making strategies. Our triage system for stratifying the urgency of referrals for early inflammatory arthritis, as well as protocols for our nursing case manager roles, are also highlighted in this document, along with our interdisciplinary team roles to support optimal patient care. Pathway implementation has been facilitated by nursing protocols and evaluation, including continuous monitoring of key indicators.

**Conclusion:** The ‘Calgary Early RA Care Pathway’ emphasizes a patient-centered and interdisciplinary approach to early RA identification and treatment. Implementation and evaluation of this care pathway is ongoing to support optimal care for patients. *Supported by a 2019 CIORA Grant entitled Optimizing early treatment strategies in early RA through shared decision-making.*

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### **Mindfulness-Based Stress Reduction (MBSR) in Rheumatoid Arthritis (RA) Patients: A Patient-Related Outcomes (PRO)-Oriented Pilot Trial**

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**Objectives:** In a pragmatic pilot study, group sessions of Mindfulness-Based Stress Reduction (MBSR), an eight-week non-pharmacological approach, were offered to patients with clinically controlled RA but elevated negative Patient-Related Outcomes (PROs) and/or elevated Patient Global Disease Activity (PGA) scores.

**Methods:** During each 4-week period preceding the start of 4 successive MBSR groups held between November 2017 and June 2019, patients reported in clinical remission on stable treatment at last visit were reassessed at their regular follow up, and referred to research assistants if still clinically controlled and interested. Inclusion criteria were either elevated ( $\geq 16$ ) Center for Epidemiologic Studies Depression (CES-D) score or a difference  $\geq 2/10$  (Delta) between PGA and Physician General Assessment (EGA). Questionnaires on depression (CES-D and BDI), anxiety (GAD-7), sleep quality, function (M-HAQ), coping strategies (CHIP), mindfulness (FMMQ), and Simple Disease Activity index (SDAI) were evaluated at baseline and 6 and 12 months after the intervention. Scores were compared between baseline and 6 and 12 months. Differences were assessed with linear mixed regression models. p values were adjusted for multiple comparisons. Eleven participants were interviewed about their experience after the 6-month assessment using a semi-structured interview guide.

**Results:** Out of 306 tagged patients, 241 were not offered MBSR: 168 (69.7%) not eligible, 55 (22.8%) declined, 18 (7.5%) other reason. Of the 65 proposed MBSR, 39 (60%) consented, 31 took part to at least 1 meeting, and 28 (43%) completed both the baseline and the 6- and/or 12-month evaluation. Timing, site and frequency of the meetings, extremes of age and comorbidities were reported as barriers to participation. Results showed significant and progressive improvements from baseline to 12 months post-MBSR for depression, anxiety, emotional coping, sleep quality, mindfulness and function (Figure). PGA, Pain and SDAI did not change significantly. Emotional coping was the only strategy significantly modified by MBSR. Qualitative interviews at 6 months in 10 patients indicated persistent subjective patient benefits including integration of MBSR techniques and effective coping strategies into daily life.

**Conclusion:** Hurdles to offering MBSR to controlled RA patients with high negative PROs are numerous. Nonetheless, MBSR had lasting benefits on outcomes that are important to patients, particularly anxiety, depression, sleep and function. MBSR enabled patients to use fewer emotional coping strategies, a maladaptive approach to illness critical to quality of life. MBSR did not appear to improve PGA or pain and did not increase SDAI remission. The reasons for the apparent PGA / other PROs require further studies. *Supported by a 2017 CIORA Grant entitled Pilot study of Mindfulness-Based Stress Reduction (MBSR) in patients with rheumatoid arthritis (RA) that still screen depressed using the Centre for Epidemiologic Studies-Depression (CES-D) questionnaire, despite adequate control of systemic and joint inflammation.*

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### **Cost Impact of Switching to Biosimilar Infliximab and Etanercept in British Columbia**

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**Objectives:** Biosimilar medicines offer the potential for significant cost savings, but their uptake in North America has been relatively low. In 2019, the province of British Columbia (BC) became the first jurisdiction in North America to mandate switching from originator to biosimilar infliximab and etanercept in order to maintain coverage offered by the provincial government. We examined the impact of this policy on utilization and spending of the relevant

biosimilars in patients with inflammatory arthritis and inflammatory bowel disease.

**Methods:** We used administrative data for the entire population of BC. Individuals were eligible for inclusion if they (1) were  $\geq 18$  years (2) had rheumatic or inflammatory bowel disease, and (3) were eligible for public drug coverage during the study period (Jan 2013 - Dec 2020).

Individuals who ever received infliximab or etanercept and the number of switches were quantified. Using interrupted time series analysis, we examined the impact of the biosimilars policy on public and private payer spending on biosimilar infliximab and etanercept among individuals with diagnosis codes related rheumatic and inflammatory bowel disease.

**Results:** Over the entire study period, \$607 million and \$256 million was spent on infliximab and etanercept, respectively. Biosimilar spending was responsible for 9.9% and 12.9% of this expenditure on infliximab and etanercept, respectively. There was a sustained increase in the proportion of total spending on biosimilar etanercept and infliximab of 76.2% (95% CI 75.2, 77.2) and 80.9% (95% CI 77.7, 84.2), respectively, after the biosimilar policy was introduced, greater in the arthritis cohort than bowel disease. The overwhelming majority of switches to biosimilar infliximab (98.2%) and etanercept (94.4%) occurred post-policy.

**Conclusion:** There was a marked increase in biosimilar uptake, relative to the originator, after the introduction of a mandatory switching policy. The analysis is being updated with more recent data to understand the longer-term impact of the policy. It will also seek to understand patterns of those that switched compared to those that did not and potential impact on patients in terms of persistence on treatments and hospitalizations/physician visits. The results will help inform other provinces and jurisdictions in North America who are implementing or considering similar switching policies. *Supported by a 2020 CIORA Grant entitled Health Economic Evaluation of the Mandatory Switching Policy for Biosimilars in Patients with Rheumatoid Arthritis.*

### **POD03**

#### **Work Disability and Function in Systemic Lupus Erythematosus (SLE): Early Results of an Exploratory National Study**

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**Objectives:** As a potentially severe disease with high morbidity, systemic lupus erythematosus (SLE) is associated with disability and functional impairment. We hypothesize that the creation of a functional profile will enhance our understanding of the impact of SLE on patients' everyday functioning, allowing us to optimize interdisciplinary interventions. In this study, we focus on work disability and function. The objective of the study was to create a functional profile of patients with SLE. A functional profile is defined as activities of daily living and those related to work functioning (e.g., instrumental activities of daily living).

**Methods:** A self-administered questionnaire was used to collect data from patients at 10 Canadian centres (9 academic centres and one community centre). Patients who consented were asked to complete the Work Role Functioning Questionnaire v2.0 (WRFQ), World Health Organization – Disability Assessment Schedule 2.0 (WHO-DAS), and the Beck Depression Inventory (BDI-II). Descriptive statistics were obtained for demographic, clinical and functional outcomes. In this cross-sectional study, we report the results from the first 31 participants.

**Results:** Participants' mean age was  $41.3 \pm 12.0$  years. 90% were female, 51.6% Caucasian, 16.1% Black, 9.7% Chinese and 22.6% other races, with a mean SLE duration of  $15.5 \pm 10.9$  years. The total mean score for the WRFQ was  $73.8 \pm 24.8$ . The WRFQ subscale mean scores were also reported for work scheduling demands ( $66.4 \pm 36.0$ ), work output demands ( $75.7 \pm 26.5$ ), physical demands ( $71.6 \pm 29.5$ ), mental and social demands ( $73.5 \pm 25.2$ ) and flexibility demands ( $77.6 \pm 21.9$ ). The WHO-DAS 2.0 total mean score was  $27.5 \pm 12.2$ , representing approximately the 94.7th population percentile, meaning that only about 5.3% of the population score higher (more disabled) than our sample. Specifically, patients reported 'moderate to extreme' difficulty walking a long distance such as a kilometre (42.0%), getting dressed (22.6%) and taking care of household tasks (45.1%). The total score for the BDI-II was  $19.9 \pm 14.4$ , and 41.9% of patients reported scores  $\geq 22$ , suggesting moderate levels of depression.

**Conclusion:** The WRFQ total and subscale scores showed significant limitation among patients. Scores are comparable to a sample of patients diagnosed with cancer who returned to work for a least 12 hours per week. Quality of life was low, and rates of depression were high. We are actively recruiting patients at all 10 centres. It is anticipated that the creation of a first-ever functional profile of work disability will provide opportunities for a multidisciplinary team approach to deliver improved care and management of work disability and functional outcomes. *Supported by a 2020 CIORA Grant entitled Work disability and function in systematic lupus erythematosus: a national mixed-methods sequential explanatory study.*

## **TOUR28**

### **Development and Preliminary Acceptability of JIActiv, a Social Media-Based Program Promoting Engagement in Physical Activity among Young People Living with Juvenile Idiopathic Arthritis**

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**Objectives:** Young people with juvenile idiopathic arthritis (JIA) are at greater risk for adopting chronic sedentary behaviours and not meeting national physical activity (PA) guidelines compared to healthy peers, which can have an important impact on their health, daily function, and quality of life. To our knowledge few appealing, educational and interactive options exist to promote PA among young people living with JIA. We aimed to develop and evaluate the preliminary acceptability (i.e., how well the program is received by users, and how it meets their needs) of the JIActiv program, a 12-week educational and interactive social media-based program promoting PA from the perspectives of young people with JIA and parents, and to refine program format and content.

**Methods:** The JIActiv prototype was developed based on our earlier work which included three systematic reviews, as well as a needs assessment with key stakeholders. The JIActiv program aims to promote PA in young people with JIA through the delivery of evidence-based information and use of behavior-change strategies. A descriptive qualitative study design was used to assess the acceptability of the JIActiv prototype. Two adolescents 13 to 17 years of age, 13 young adults 18 to 26 years with JIA, and 2 parents were recruited from arthritis patient groups and a Canadian rehabilitation center. The individual virtual interviews were audiotaped, transcribed verbatim, coded, and categorised into emerging themes using simple content analysis. Findings reported on the format, content, and potential usefulness of the program.

**Results:** Most participants preferred Instagram as the platform for the program and appreciated the presented functionalities. All participants felt that the proposed length of the program and the number of activities per week were appropriate. The informational videos, individual educational and interactive group activities were thought to be pertinent and helpful to motivate young people to engage in physical activity. Participants found that the esthetics of the program could be improved by choosing one color scheme for all postings. Most participants thought that having a mentor and access to a HCP would be very helpful to help answer their questions and offer social support. The group format (size and age range of participants) was well accepted by participants.

**Conclusion:** The JIActiv program has good preliminary acceptability and is potentially useful for promoting engagement in PA among young people with JIA. Participants proposed ideas on how the program could be improved. Additional interview cycles will help to further refine the program. *Supported by a 2019 CIORA Grant entitled Promoting engagement in physical activity among adolescents with juvenile idiopathic arthritis: Development of a social network-based intervention.*