Creation and Testing of the Rheumatoid Arthritis Splint Adherence Measure (RA-SAM)

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ABSTRACT

A working hand splint is a treatment modality used in occupational therapy to address pain and to prevent joint destruction in individuals with Rheumatoid Arthritis. Despite positive properties of splints such as decrease of pain and inflammation of the wrist joint, they are often abandoned for various reasons. Given the evidence that joint deterioration progresses rapidly and is associated with pain and loss of productive use of the hands in people with RA, improving splint adherence is crucial. Therefore, it was deemed important to develop a measure that enables clinicians to identify readiness to adhere to the use of a functional hand splint. For individuals who appear to be unwilling or not ready to make use of a splint, the clinician can then address the client's concerns and hesitations in the domain(s) highlighted by the measure in order to enhance the splint adherence. While a number of tools have been created to assess readiness to adhere to treatment, there currently exists no "gold standard" to evaluate adherence readiness for splint usage.

The first manuscript of this thesis explores the content development of the Rheumatoid Arthritis Splint Adherence Measure (RA-SAM). More specifically, the process of theme identification and generation of items specific to splint use readiness and refinement of the items are described in detail. To provide a framework for assessing readiness to adopt a new behaviour, the *Transtheoretical Model* (TTM) (Prochaska & DiClemente, 2005) was used. This model describes the change of the health behaviour through six stages: *pre-contemplation, contemplation, preparation, action, maintenance,* and *termination*. The identification of an individual's "stage" can facilitate in adapting the intervention to the individual's needs in the most appropriate way.

The objectives of the second manuscript were twofold: development and refinement of the measure and, assessment of the measure's psychometric properties including content and construct validity.

In the first phase described in the first manuscript the themes and potential items were identified using an extensive review of the literature. Item generation continued with input from two focus groups: one consisting of individuals diagnosed with RA (n=5); the other with health care professionals working in the field of rheumatology and experts with knowledge regarding adherence issues (n=9). During the focus groups the topics discussed were structured to include: factors contributing to the use or non-use of splints, client's expectations of splints, the role of the therapist in enhancing adherence, etc. Based on the literature review and the focus group input, the initial version of the measure was created by the two researchers using question design strategies and was then reviewed for content, clarity, and pertinence of items by 3 expert clinicians and a small (n=5) representative sample of individuals with RA. The preliminary version was then reviewed by the research team: it consisted of 38 items tentatively grouped around four domains that potentially effect adherence: *health-care context, motivation/locus of control, social context, and perceived splint value.* Once the English preliminary version was finalized, the items were forward-translated into French by three bilingual translators independently, and then back-translated into English. Next, the English and French 38 item versions were pilot-tested on 82 participants (French speakers, n=39; English speaking, n=43) including individuals with RA as well as those familiar with RA.

Participants were recruited using two strategies including social media – specifically the *Facebook* page of the Quebec's Arthritis Society and the Quebec's Juvenile Arthritis Group –

and clinicians working in the rheumatology departments of two University affiliated teaching sites. For those recruited through the Arthritis Society it was assumed that they had a diagnosis of RA but there may have been some individuals who were interested in learning about RA who had not been formally diagnosed. Participants were asked to read the 38 items twice (Table 6.9): the first time while reflecting on the clarity of each item so that we could identify redundancies, omissions, unclear questions; the second time by responding to each question using a 0 to 10 scale. As we analyzed the data we worked under the assumption that those without RA would answer "not applicable" to all questions specific to RA during this second round. The cultural differences of English and French versions were assessed by having bilingual individuals review both versions to compare similarity in meaning of the items. The average scores on the English and French versions were compared item-per-item. Then, using only the answers of those who indicated having RA (n=76) factor analysis was performed using answers in both languages simultaneously. The objective was to further substantiate whether the items hypothesized to group into four factors related to adherence (*health-care context, motivation/locus of control, Social context, perceived splint value)* were indeed grouping together to represent each domain. Based on the accumulated information (comments of participants, review of the meaning of the measure items in English and in French, comparison of average scores of English and French items, and factor analysis) items with questionable measure integrity were identified and tagged for possible rephrasing or removal. Finally, we made use of comments posted on an Arthritis-specific social network discussion on *"Arthritis Is Unacceptable because_____?"* that appeared during the study period offering an excellent opportunity to understand more about the impact of RA and variables that would be important to capture in an adherence measure.

Through a multistep process 10 items were eliminated, two were added, and several were rephrased. The results of the exploratory factor analysis indicated 35 items with a factor loading equal to or greater than .25, corresponding to 4 factors, and, explaining 44.8% of the total variance. In light of these results, we concluded that our theoretical groupings (*health-care context*, *motivation/locus of control*, *social context*, and *perceived splint value)* were too broad, and there are more than four underlying factors. Nevertheless, the exploratory factor analysis provided evidence of content validity of the RA-SAM. The final version consists of 30 items grouping under 4 new domains with the domain of *Preparedness for splint use* incorporating 12 items, *Nuisance* – 7 items *Commitment* - 7 items, and *Social support* – 4 items. In a future study, investigation of the measure's criterion-related validity and test-retest reliability; along with its ability to predict adherence, is planned.

RÉSUMÉ

Les orthèses fonctionnelles pour la main sont des appareils utilisés en ergothérapie pour réduire les sensations douloureuses et pour prévenir la destruction graduelle des articulations chez les personnes souffrant de polyarthrite rhumatoïde. Bien que leur efficacité ait été prouvée, les orthèses sont souvent abandonnées pour différentes raisons. Il existe des preuves scientifiques à l'effet que, chez les personnes souffrant de polyarthrite rhumatoïde, les articulations se détériorent rapidement, ce qui cause des sensations douloureuses et la perte de l'usage des mains. Il est donc crucial d'améliorer l'adhérence aux orthèses prescrites. C'est dans ce but qu'il a été jugé important de développer un outil qui permet aux professionnels de la santé d'évaluer la propension des patients à utiliser une orthèse de fonction. Au cas où le professionnel de la santé trouve un risque élevé d'abandon de l'orthèse ou qu'il juge que la personne n'est pas prête à l'utiliser, il peut engager une discussion avec le patient sur le fonds de ses inquiétudes et de ses hésitations en se laissant guider par les points identifiés par l'outil. Même s'il existe une panoplie d'outils servant à évaluer la propension des personnes à adhérer à un traitement médical donné, il n'existe de « étalons de référence » pour évaluer la propension à utiliser les orthèses de fonction.

Le premier papier de ce mémoire traite de développement du contenu du « *Rheumatoid Arthritis Splint Adherence Measure (RA-SAM)* ». Plus précisément, il s'agit d'une description détaillée du processus de synthèse de questions relatives à la propension à utiliser les orthèses de fonction. Nous avons choisi le *Modèle Transthéorique de Changement* (Prochaska & DiClemente, 2005) pour évaluer la propension à adopter de nouvelles habitudes. Ce modèle décrit en six phases le changement des habitudes en matière de santé : *pré-contemplation, contemplation, préparation/détermination, action, maintien* et *rechute.* Le dépistage de la phase précise dans

laquelle se trouve une personne permet une intervention mieux ciblée adaptée aux besoins de la personne.

Le deuxième papier a un double objectif: 1) le développement et le raffinement de l'outil et 2) l'évaluation des caractéristiques psychométrique de l'outil incluant la validation du contenu et des dimensions.

Dans un premier temps, nous avons identifié les questions potentielles en recourant à une profonde revue de la littérature existante. Nous avons aussi recueilli les propos et opinions des participants de deux groupes de discussion. Le premier groupe consistait de personnes souffrant de polyarthrite rhumatoïde (n=5) alors que le deuxième groupe était composé de professionnels de la santé en rhumatologie ainsi que d'experts ayant eu affaire avec des problèmes d'adhésion aux prescriptions (n=9). Les sujets couverts dans les groupes de discussions touchent aux facteurs contribuant à l'utilisation ou au refus d'utiliser les orthèses, les attentes des patients par rapport aux orthèses, le rôle des thérapeutes dans l'amélioration de la conformité aux prescriptions, etc. Les deux chercheurs prenant part à cette étude ont créé un premier jet en utilisant différentes stratégies de création de questions. Par la suite, cette première version a été revue et révisée par trois experts cliniciens pour en évaluer le contenu, la clarté et la pertinence ainsi que par un petit échantillon de personnes (n=5) souffrant de polyarthrite rhumatoïde. L'équipe de recherche a de nouveau revu et révisé la version finale, qui était constituée de 38 questions regroupées de façon temporaire en quatre domaines : *contexte des services de la santé, motivation/ locus de contrôle, contexte social et l'utilité perçue des orthèses.* A cette étape, l'outil a été jugé satisfaisant et propice à la phase pilote. Une fois l'analyse de la version anglaise terminée, les questions ont été traduites en français canadien et de nouveau du français à l'anglais par trois cliniciens bilingues

de façon complètement indépendante les uns des autres. Suite à cet exercice, les deux versions, franco-canadienne et anglaise, ont été jugées propices à être utilisées dans la phase pilote.

Nous avons ensuite fourni l'outil à 82 personnes souffrant de polyarthrite rhumatoïde ou familières avec cette maladie, dont trente-neuf (n=39) francophones et quarante-deux (n=43) anglophones. Nous avons testé les deux versions, française et anglaise de façon simultanée. Nous avons dispensé la version comprenant les 38 questions à 82 participants (39 francophones, n=39 et 43 anglophones, n=43). Etant donné que sur le site web de la Société d'Arthrite il y avait le risque d'avoir des répondants qui ne souffraient pas ou n'avaient pas souffert de polyarthrite rhumatoïde, nous avons posé comme hypothèse que ces participants répondraient par « non applicable » aux questions relatives à cette maladie. Nous avons par la suite éliminé ce genre de réponses durant l'analyse factorielle. Les réponses des participants ont permis d'éliminer les questions redondantes, d'identifier les omissions et de mieux formuler les questions qui n'étaient pas claires. Nous avons également analysé les différences linguistiques et culturelles des versions française et anglaise par le biais d'une comparaison entre les scores obtenus à chaque question. Afin de déterminer si les questions supposées mesurer les quatre facteurs relatifs à la conformité remplissaient vraiment cet objectif, nous avons procédé à l'analyse factorielle. Sur la base de l'information recueillie (commentaires de participants, analyse lexicale du questionnaire en français et en anglais, comparaison des scores moyens obtenus en anglais et en français, analyse factorielle, et revue des commentaires affichés dans les médias sociaux dans des discussions sur l'arthrite - *"Arthritis Is Unacceptable because_____?"*), nous avons identifié les questions dont la pertinence dans le questionnaire laissait planer un doute afin de les reformuler ou de les éliminer ultérieurement.

Au bout de plusieurs itérations, nous avons éliminé 10 questions et en avons rajouté deux tout en en reformulant plusieurs. Les résultats de l'analyse factorielle exploratoire ont donné 35 questions avec un «*factor loading* » équivalent ou supérieur à .25, ce qui correspond à 4 facteurs, soit 44.8% de la variance totale. A la lumière de ces résultats, nous avons conclu que le regroupement théorique que nous avions préalablement effectué (*contexte des services de la santé, motivation/ locus de contrôle, contexte social et l'utilité perçue des orthèses*) était trop large et qu'il devait y avoir plus de quatre facteurs sous-jacents. Nonobstant ce constat, l'analyse factorielle exploratoire nous a permis de prouver la justesse du contenu du RA-SAM. La version finale du RA-SAM qui devra être soumise à d'autres tests comprend 30 questions regroupées en 4 nouveaux domaines. Le domaine de « é*tat de préparation à utiliser une orthèse*» comprend 12 questions, celui de «*nuisance*» – 7 questions, «*engagemen* » - 7 items et « *soutien social* » – 4.

Il est à noter que, afin de valider les résultats obtenus dans cette étude, une nouvelle étude sur la capacité de cet outil de prédire la conformité, «*criterion related validity*» et répétabilité (*test-retest reliability*) seront nécessaires. Afin de tester notre outil, nous sommes présentement à la recherche de personnes souffrant de polyarthrite rhumatoïde à qui on a récemment prescrit une orthèse fonctionnelles de la main mais qui ne l'ont pas encore reçu. La réduction finale du nombre de question se fera une fois le test terminé.

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through all this long process; and finally, Annie-Laurine, who is always cheerful, loving, and faithful in me. We made it…

CONTRIBUTION OF AUTHORS

The first manuscript of this thesis entitled, *"Content Development of the Rheumatoid Arthritis Splint Adherence Measure (RA-SAM): Item Generation, Development, and Refinement"* was submitted for publication in the Canadian Journal of Occupational Therapy. It is in process of being reviewed. It was mainly written by me with suggestions and guidance by Dr. Nicol Korner-Bitensky. As a co-author, Dr. Sara Ahmed provided us with insightful suggestions and helped with the content and structure of the manuscript.

The second manuscript entitled, *"Content Validation of the Rheumatoid Arthritis Splint Adherence Measure (RA-SAM)"* was mainly written by me with guidance from Dr. Nicol Korner-Bitensky. It is being prepared for journal submission. Co-authors Dr. Sara Ahmed and Dr. Jeffrey Jutai gave us valuable insights into the content and presentation of the manuscript. Two questionnaires developed by Dr. Nicol Korner-Bitensky and Ada Pagnotta were used in this study to collect information on daily activities, which the individuals with Rheumatoid arthritis perform. Under Dr. Nicol Korner-Bitensky's guidance I created the socio-demographic questionnaire to collect information about explanatory variables and the secondary outcome. I developed the consent forms, submitted the study for ethics approval and developed the content for the measure to assess the splint readiness. I recruited participants with the help of Karyn Dion and the research assistants at the Constance Lethbridge Rehabilitation Hospital, collected all data, and analyzed the data under the supervision of Dr. Korner-Bitensky. The Rheumatoid Arthritis Splint Adherence measure (RA-SAM) was created and offered to the Occupational Therapists at the Juwish general Hospital, Jewish Rehabilitation Hospital and Constance Lethbridge Rehabilitation Center, by the first author, Marina Voznyak, with help from Dr. Korner-Bitensky, Isabelle Hamel-Hebert, Marilyn Miller, and Julie Elissade.

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PREFACE

This thesis consists of a collection of two manuscripts. As per McGill University requirements, these papers have a cohesive, unitary character making them a report of a single program of research. The first manuscript has been submitted for publication to the *Canadian Journal of Occupational Therapy*. The second manuscript, presenting the results of a two phase study completed by the candidate, is being prepared for submission to a scientific journal. The Graduate and Postgraduate Studies at McGill University require that the thesis incorporates a literature review and a conclusion that is separate from that included in the manuscripts. Thus, it is unavoidable to have material duplication in this report.

This thesis contains 8 chapters. Chapter 1 addresses the epidemiology of the Rheumatoid Arthritis (RA), and the use of hand splints in people living with this condition. Chapter 2 is a review of the pertinent literature covering the following areas: 1. signs, symptoms, and treatment of RA; 2. economic burden related to RA; 3. loss of productive work due to RA-induced disability; 4. introduction to the purpose of splints and splint adherence issues; and 5. a brief introduction to the *Transtheoretical* Model as it relates to an individual's readiness to adopt a new behavior. Chapter 3 describes the thesis objectives. Chapter 4 consists of the first manuscript entitled: *Content Development of the Rheumatoid Arthritis Splint Adherence Measure (RA-SAM): Item Generation, Development, and Refinement*. Here the reader is shown the process of theme identification and item generation through an extensive literature review and two focus groups, creation of the initial version of the measure, refinement through experts' review for content, clarity, and pertinence of items, and translation into French. Chapter 5 provides a link between the first and second manuscripts. It is followed by Chapter 6 which contains the second manuscript that describes the multi-phased second study entitled: *Refinement and Content*

Validation of the Rheumatoid Arthritis Splint Adherence Measure (RA-SAM). The manuscript details the process of pilot testing of the preliminary version, the assessment of the English and French version comparability, and the establishment of content validity through analysis of the participants' responses, with the final version being grouped under four domains, using the results of the exploratory factor analysis. Chapter 7 summarizes the findings of both manuscripts and Chapter 8 consists of a conclusion incorporating the content from both manuscripts.

1. INTRODUCTION

Rheumatoid arthritis (RA) is an autoimmune chronic, typically progressive disease that causes pain, swelling, destruction, and functional disability in the joints[1]. It is considered to be the most frequent and the most disabling among inflammatory conditions[2]. RA has been shown to have an adverse effect on quality of life[3]. This disease has a negative impact on psychological and social functions, contributing to low self-esteem, mental distress, depression, and generalized fatigue[1]. It affects approximately 1% of Canadian adults or 300 000 individuals and twice as many women as men[4]. The annual incidence rates of RA are estimated to be between 20 and 50 cases per 100,000 inhabitants in North American and North European countries[5]. In a cross-sectional study of 1333 of individuals with RA, Kvien et al. (1997) estimated that about 50% experience considerable physical limitations as determined by the Modified Health Assessment Questionnaire[1,6.] The rates of the work disability in individuals with RA presented in a systematic review in 2006 varied from 20 to 70% by 7-10 years in individuals working at the time of disease onset[7]. However, since the 1970s there is a significant decrease in prevalence of RA-related work disability, which is mostly explained by the decrease in physically demanding work with less heavy manual tasks[7,8].

Currently, there is no cure for RA[9]. Regardless of the progress in the medical and pharmaceutical fields since the 1990's, the impact of this disease remains substantial both in terms of mortality and morbidity[1]. For instance, Young (2000) found that of 746 subjects with RA followed over 5 years, 40% (142/353) of those who worked at baseline had retired by the 5-year follow up: with 69% of these indicating that the RA was the main or contributing reason[10].

A working hand splint is a treatment modality used in the management of individuals with RA to address pain and to prevent joint destruction[11,12,13,14]. It is thought that when the wrist joint is not supported, intra-articular temperature increases with joint motion, exacerbating inflammation[15]. Typically, a functional hand splint stabilizes the wrist joint in a slightly extended position ensuring a mechanically advantageous position of the hand and allowing normal range of motion of the fingers[15]. Thus, given the negative impact of RA over time it would be important that hand splints be used to preserve joint integrity and function for as long as possible.

Unfortunately, it has been shown that very often assistive devices, including wrist splints, are prescribed to patients who are not ready to adhere to their use[9] Therefore it would be important to quantitatively measure a patient's readiness to adhere to wrist splint use[9]. It would then be possible to plan interventions to increase the potential for adherence in those at risk for non-adherence. Indeed, Bradley (1989) suggests that adherence to treatment regimens among individuals with RA is higher in those who receive an intervention that is specifically focused on adherence enhancement[16]. This intervention can involve behavioural approach strategies[16,17], problem-solving strategies based on a self-regulation model[18], or cognitive-behavioural regimens[16,19,20]. In addition, interventions to improve adherence have been shown to be more effective when they are adapted to the individual and his/her family, and, when they relate to an individual's personal circumstances and personal barriers to use[16,21,22].

While a number of tools have been created to assess readiness to adhere to treatment in general, (ex. University of Rhode Island Change Assessment (URICA); Readiness to Change Questionnaire (RTCQ); Circumstances, Motivation, Readiness, and Suitability Scale (CMRS);

Texas Chistian University (TCU) Motivational Assessment)[23], there currently exists no "gold standard" to evaluate adherence behaviour for splint usage specific to RA. However, as previously mentioned, there are numerous factors that have been linked to use/abandon of technical aids, including splints specifically suggesting that a general measure would not be adequate[21,24]. Keeping this in mind, it was deemed important to develop an objective, valid and reliable measure to address readiness for wrist splint use in individuals with RA of the hand and wrist. By definition, treatment readiness or motivation for treatment includes personal considerations, commitments, reasons, and intentions that lead to the performance of certain behaviours[25]. Here, we are referring to readiness to adhere to use of a prescribed hand splint.

2. REVIEW OF LITERATURE

2.1 Rheumatoid Arthritis: signs, symptoms, and treatment strategies

Rheumatoid arthritis (RA) is an idiopathic, autoimmune, long-term condition that leads to the inflammation of the joints and surrounding tissues[1,26]. The onset of the disease can occur at any age, but it is more prevalent in middle age. RA usually affects joints on both sides of the body equally. Wrists, fingers, knees, feet, and ankles are the most commonly affected. The main symptoms of the RA include the morning stiffness lasting for about one hour, joint tenderness and stiffness. In some cases RA leads to joint deformities[26,27]. For instance, Johnsson et al.(2009) who followed 183 people with RA over 10 years, found that 108 (59%) developed at least one hand deformity, according to radiographic evidence using the Larsen scoring method, and goniometric evaluation[28].

The management of RA typically involves a combination of treatment modalities including medications, exercise, physiotherapy and occupational therapy, education, and in some cases surgery[26,27,29]. The evidence suggests that an early aggressive intervention for RA can delay joint destruction[28].

2.2 Economic Burden

RA is a costly disease both in terms of direct costs in health services and indirect costs caused by work disability, and loss of income[1,2]. In a 1994 study in Canada, the yearly health care expenditure on arthritis and rheumatic diseases using prevalence based analysis was estimated to be $5.9 billion[30]. These costs included hospitals, institutions, medical services, and drugs. The

cost of the splinting materials usually varies from $20 to $100, depending on the needs of the person (thermoplastic vs. leather splints)[63]. Based to the discussion with 8 clinicians[62], on average, 2 individual sessions with a client is required to fabricate and make the necessary adjustments to the custom made splint. In a cross-sectional study of 144 subjects with RA, Fautrel et al. (2002) determined using a willingness to pay analysis (the maximum amount that could be paid for a disease), that the total economic burden per individual with RA in Canada was $26,717 and $36,817 per year in the context of public and private programs, respectively. These costs were determined using the Cost Assessment Questionnaire, which inquires about the use of health care resources and time lost in work or in household activities during the preceding month[2]. In a cross-sectional study of 2262 patients with varying chronic diseases Dekker et al. (2003) found that severity of disability was a major determinant of possession of technical aids[31] and in those with RA technical aids accounted for a substantial portion of expenses incurred. Furthermore, people with RA were four times more likely to possess technical aids and adaptations than people with other chronic diseases[31].

2.3 **Loss of Productive Work due to RA-induced Disability**

A structured literature review by Scott et al. (2000) including 60 reports on progression of joint damage and disability revealed a causal relationship between joint damage and disability[32]. In most of the reviewed studies, disability was assessed with the Health Assessment Questionnaire (HAQ), which measures a person's perceived disability in dressing and grooming, arising, eating, walking, hygiene, reach, grip, and common daily activities[32,33]. For example, in a prospective study of 103 people with RA followed for 8 years, a moderately strong correlation ($r = 0.68$) was found between radiographic joint damage and disability measured by the HAQ[34]. Wolfe et al.

(1998) followed 823 subjects with RA over an 18-year period and established that prevalence of work disability was positively associated with pain scores, measured on a visual analogue scale (VAS)[35]. In a cross-sectional study of 119 participants identified as having paid employment in Holland (Doeglas et al. 1995), 62% reported having a work disability 1.8 years after disease onset: 7.5% were working less and 55% were either on sick leave or had stopped working due to their RA[36]. Albers et al. (1999) investigated the socio-economic consequences of RA in an inception cohort of 186 individuals with mean disease duration of 3 years. The relative risk (RR) of registered work disability was 6.9 (95% CI= 5-9) compared to the general Dutch working population (statistics were based on demographic and socioeconomic data from the Netherlands Central Bureau of Statistics for 1990)[37]. In terms of leisure activities, 57% needed to change or abandon their leisure activities in favour of activities that required less impact on upper extremities joints[37]. Similarly, Young (2000) found that of 746 individuals with RA followed over 5 years, 40% (142 /353) of those who worked at baseline had retired by the 5-year follow up: 69% indicated that the RA was the main or contributing reason[10]. Studies by Doeglas et al (1995) and Barrett et al. (2000) demonstrated that manual workers were at higher risk of work disability[36,38]. For instance, Doeglas et al. (1995), established that 80% of those (37/46) with a manual job were no longer able to work because of their RA[36]. Similarly, Barrett et al. (2000), recruited 110 individuals with an onset of RA between 1989 and 1992, and followed them for an average of 8.6 years from symptom onset. It was found that 40% (19/47) of those with RA who worked in manual jobs were no longer working at paid employment due to their health in 1995 versus 2.6% of a cohort matched on age, gender and employment status at baseline[38].

Most commonly RA affects hand joints symmetrically on both sides of the body[26,27]. For example, approximately 75% of individuals with RA have inflammatory involvement of both

wrist joints[11,32,39] that must be addressed early to avoid rapid deterioration. Four studies {Brook et al. (1977) (n=94), Paimela (1991) (n=40), Van Der Heijde (1992) (n=147), and Plant (1998) (n=126)}– where individuals with early RA were followed prospectively for 3 to 8 years from onset, showed that 60% to 73% developed one or more erosions and destruction of the articular cartilage in the joints of the hands and wrists[32,40,41,42,43]. Furthermore, Möttönen (1988), who followed 58 individuals with early RA over a 24-month period, observed significantly more ($p<0.001$) joint destruction in the dominant versus non-dominant hand as measured using radiographic methods and scores according to the method of Larsen[44]. In addition, in a cross-sectional study of 20 subjects with RA, Owsianik et al. (1980) found a statistically significant difference in joint damage in the dominant hand compared to the non-dominant ($p<0.0026$)[45] strongly suggesting that mechanical stress is an important factor in the development of joint erosion. Similarly in a prospective study of 183 subjects followed annually for 10 years, 43% developed hand deformities within the first year, and 56% within 2 years[28]. In patients who developed a hand deformity within the first 5 years, the disease activity was generally more severe, suggesting that a treatment has to be offered early post-diagnosis, in order to better control disease progression[28]. Given that RA is often characterized by a rapid progression[29,32], and that early destruction of joints results in a serious change in life and work, it is critical to initiate early intervention focusing on reducing pain and inflammation, and on preventing excessive stress on joints in order to retard disease progression and control symptoms.

2.4 Functional Hand Splints and Splint Adherence

The provision of a wrist splint is an important component of RA management[46]. Splints have been shown to be effective in reducing joint pain and oedema of the surrounding tissue and in

minimizing the workload of the affected joint, with the added benefit of allowing the affected joint to rest[11,12,13,14]. Working splints are usually recommended to be worn during daily activities[13].

There are several types of functional hand splints and they can be either custom-made or prefabricated[14,15]. A crossover study by Pagnotta et al. (2005) including 30 individuals with wrist involvement found that for 13 of 14 simulated functional tasks (such as vacuuming, driving, chopping with knife, etc.) splint use either improved or did not change pain severity and endurance, and did not interfere with work performance during these functional tasks[11]. For instance, in the randomised controlled study by Kjeken et al. (1995), the group of 36 participants who used wrist splints for six months demonstrated statistically significant improvements in grip strength (as measured by spyghmomanometer connected to a 20 mmHg inflated bag) and in wrist pain during activity (as measured by the visual analogue scale)[64]. However, the control group (n = 33) which did not use splints over the 6 month period demonstrated statistically significant improvements in wrist range of motion, which were not evident in the splinted group[64]. Two studies by Backman and Deitz (1988)[65] and Nordenskiold, (1990)[66] showed that functional splints improve power hand grip up to 29% in individuals with moderate to severe RA.

In several studies by Backman and Deitz (1988)[65] and Stern et al. (1994, 1996)[67,68] participants have reported an increased sense of security during the functional tasks. However no improvements were notices in terms of hand dexterity, fine finger movement and speed of hand activity. The Chocrane review by Egan et al. (2003) based on 10 studies concluded however that there is insufficient evidence to drive conclusions regarding the effectiveness of functional splints in decreasing pain or increasing function for individuals with RA[69].

Although there is some evidence of the usefulness of splints in reducing pain and joint destruction, clinicians frequently cite poor adherence to splint wear[11,12,17,46,47] with studies showing adherence ranging from 25% to 60-70% in others[12,16].

In general, adherence can be defined as a patient's acceptance and follow-through with treatment recommendations[13,48]. Adherence is a key component of effectiveness of most interventions[9,49]. According to the WHO, in developed world countries such as Canada, adherence to long-term therapy for chronic conditions is about 50%[9]. Poor adherence to treatment contributes to the waste and misuse of already limited treatment resources[9]. Numerous factors are associated with poor adherence to treatment. These are potentially classifiable into five main categories: *social- and economic-related factors* (ex. long distance from treatment setting); *health system/health care team-related factors* (ex. lack of knowledge of health professionals about pain management; poor delivery of care education to the patient or to the family, etc); *therapy-related factors (*ex. complex treatment regimens, misunderstanding instructions, adverse effects of treatment*)*; *condition-related factors (*ex. nature of the patient's illness; poor understanding of the disease and its symptoms*)*; and *patient-related factors/interventions (*ex. forgetfulness, misconceptions about pain, anxieties about possible adverse effects, no self-perceived need for treatment, psychological stress, etc.*)*[9]. Factors that have been associated with abandoning hand splints and other assistive devices are related to psychological perspectives of the patient, socio-cultural and economic background, as well as factors related to the device (such as poor adjustment, aesthetics, etc.) [46,50,51]. For instance, the level of acceptance of one's own condition and denying the need for assistance are two examples of psychosocial factors[50,52,53]. Other common reasons that have been cited include discomfort or difficulty wearing the splint while doing activities; easy to get dirty and poor appearance, Veehof and Taal (2008)[53]. Splint adherence has also been

shown to be directly related to the patient's and therapist's perceptions regarding the perceived benefit of splinting[16,46,47] with an increased rate of adherence if the patient's anticipates that the splint will be beneficial[16,46]. Adding complexity to the understanding of wrist splint adherence is the fact that the perceived benefit may vary from one activity to another[11]. In other words, a splint may be useful or perceived as useful for activities such as gripping the car steering wheel, but not for cooking where there is a need for hand washing and frequent removal of the splint. In addition, Callinan & Mathiowetz (1996) reported that splint adherence was linked to comfort (hard splints were less used than soft ones)[70].

2.5 Transtheoretical Model (TTM)

A useful model in understanding readiness to accept a new aid or adaptation is the TTM which was developed in 1977 by J. O. Prochaska and colleagues [54]. This is a model of intentional change that focuses on the individual's decision making. It involves emotions, cognitions, behavior, and a reliance on self-report[55]. According to the model, health behaviour change involves progress through six stages of change: *pre-contemplation, contemplation, preparation, action, maintenance*, and *termination* (Appendix 1). In the field of health psychology, this model provides a framework for assessment of an individual's readiness to adopt a new behavior. It also provides a framework to develop strategies to guide the individual through the "stages of change" to *action* and *maintenance* of the new behavior[55,56.]

Since splints are often provided to an individual who is newly diagnosed with RA and has never used a splint before, we anticipate that this individual will be at the stage of *pre-contemplation, contemplation,* or *preparation*. For example, at the *pre-contemplation (not ready)* stage an

individual with RA does not intend to integrate the new behavior – i.e. wearing the splint for daily activities – in the near future – given multiple reasons including that he or she may not be aware of the impact of RA on physical function. If this stage is properly identified, this individual could then be encouraged to become more mindful of their decision making and more conscious of the multiple benefits of early and consistent splint use. In the *contemplation (getting ready)* stage an individual with RA is intending to start using the splint in the near future. At this stage an individual might be encouraged to work at reducing the barriers to splint use (ex. perception of poor appearance of splints; strategies to reduce the nuisance factor etc.). Individuals with RA identified as being in the *preparation (ready)* stage are of a mind to begin using the splint. For example, they might tell family and friends about the intention to use splint and explain its purpose. At this stage, the individual is encouraged to engage family and friends as a means of supporting the new behavior. Overall, the TTM, by identifying the individual's "stage of change", enables planning of an adherence intervention that is congruent with the individual's readiness level and adapted to their specific needs.

Rapid initiation of intervention is critical given that when RA affects the wrist and hand in it leads to substantial disability and loss of productive work and daily life. In order to slow down the disease progression and to control symptoms, intervention should be focused on pain and inflammation reduction, and on prevention of excessive stress on the joints. Despite the beneficial effects of functional hand splints in reducing pain and wrist joint destruction, adherence to splint wear remains low, ranging from 25% to 60-70%[12,16]. Therefore, it would be important to develop a valid and reliable measure addressing readiness for wrist splint use in individuals with RA of the hand and wrist.

Development of the new measure requires a multistep process involving content development, item analysis and reduction, item scaling, and assessment of the measure's psychometric properties including content, construct validity, criterion-related validity and test-retest reliability[57]. In this manuscript, the process of item generation, development and refinement of the preliminary measure in two languages - English and French, as well as the assessment of content validity, are addressed.

3. THESIS OBJECTIVES

PHASE 1

- To generate themes and items specific to wrist splint use, using input from expert-clinicians in the field of rheumatology, and individuals with rheumatoid arthritis, thus permitting content development and preliminary refinement of a new measure - *the Rheumatoid Arthritis Splint Adherence Measure (RA-SAM*);

- To translate the preliminary English version of the new measure into French, aiming for linguistic and cultural similarity

PHASE 2

- To refine and finalise the new measure - using the results of pre-testing of the preliminary version of the measure, on individuals with RA or who are familiar with RA;

- To establish the measure's content validity using the results of pre-testing of the preliminary version of the measure, on individuals with RA or who are familiar with RA;

4. MANUSCRIPT 1: CONTENT DEVELOPMENT OF THE RHEUMATOID ARTHRITIS SPLINT ADHERENCE MEASURE (RA-SAM): ITEM GENERATION, DEVELOPMENT, AND REFINEMENT

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ABSTRACT

Objectives: The global objective was to create a predictive measure, the *Rheumatoid Arthritis Splint Adherence Measure (RA-SAM)* that evaluates readiness of individuals with rheumatoid arthritis (RA) to use a newly prescribed working splint. The specific objectives addressed here are: 1-identifying themes specific to splint use readiness; 2-generating items, developing, and refining the measure; and 3- translating the preliminary English version of the new measure into French, aiming for linguistic and cultural similarity.

Methods: This qualitative study was conducted as part of item generation for the purpose of RA-SAM creation. Items were generated through an extensive literature review and two focus groups, one with health professionals and another with individuals with RA. Once the initial version was created by the research team, it was then reviewed by three experts in rheumatology and five individuals with RA for content, clarity, and pertinence of items. Next, the RA-SAM was translated into French, spoken in Canada.

Results: Based on the multi-modal stepwise process, key themes were identified and tentatively grouped around four domains: *health-care context, motivation/locus of control, social context, and perceived splint value*. The initial version of the measure included 45 items. All reviewers indicated that the purpose of the measure was important and that this measure would be relevant for use in clinical settings. Following further validation, seven (7) questions were eliminated leading to a 38-item version each scored on an 11 point scale. Once the English preliminary version was finalized, the items were forward-translated into French and then back-translated into English using standardized forward and backward

translation methodology. The comparability of the English and French versions was evaluated and corrections made to insure linguistic and cultural similarity.

Conclusion: Adherence to splint use is a key component of self-management in RA. Identifying and addressing patient concerns at the time of splint prescription may potentially improve adherence. The RA-SAM has been shown to be usable and acceptable to patients. It is now undergoing further psychometric testing.

Key words: Rheumatoid arthritis, wrist, functional hand splint, readiness to adhere, adherence, occupational therapy, occupational therapists

INTRODUCTION

Rheumatoid arthritis (RA) is an autoimmune, typically progressive disease that causes pain, swelling, destruction, and functional disability in the joints[1,2]. It affects approximately 300000 Canadian adults[3]. Currently, there is no cure[4].

Approximately 75% of individuals with RA have inflammatory involvement of the wrist joint[5,6,7] that must be addressed early to avoid joint deterioration and loss of function. Four studies where subjects with early RA of the hands and wrists were followed prospectively from onset for 3-8 years showed that 60-73% developed one or more erosions and destruction of the articular cartilage[7,8,9,10,11]. Given that RA is often characterized by rapid progression[7,12] and that joint destruction impacts on daily life and work, early intervention is critical.

A working hand splint is a treatment modality used in occupational therapy to address pain and to prevent joint destruction[6]. Working hand splints have been shown to be effective in reducing joint pain and oedema of the surrounding tissue and in minimizing the workload of the affected joint, with the added benefit of allowing the affected joint to rest [6,13,18,37,38,43]. Despite strong evidence indicating the usefulness of splints, studies frequently cite poor adherence[6,13,14,15,16] ranging from 25% to 70%[13,17]. Adherence is defined as a patient's acceptance and follow-through with treatment recommendations[18,19]; it is key to intervention effectiveness[4,20]. Bradley (1989) suggests that adherence to treatment among adults with RA is higher in clients who receive an intervention focused on adherence enhancement (eg. behavioral approach involving visual displays, or problem-solving interventions)[17]. Several studies have shown that interventions aimed at improving adherence to treatment regimens (exercise, rest, splint usage, medication) in

RA population are more effective when they are adapted to the individual's personal circumstances[14,17,21,23,24,44]. For example, the personal circumstances may include beliefs in personal ability to manage the environment and one's behavior, personal range of problem-solving responses and beliefs in one's ability to effectively use them, and one's methods for testing the effectiveness of problem-solving responses[17,44].

Despite the existence of tools that assess readiness to adhere (ex. University of Rhode Island Change Assessment (URICA); Readiness to Change Questionnaire (RTCQ); Circumstances, Motivation, Readiness, and Suitability Scale (CMRS); Texas Christian University (TCU) Motivational Assessment), no "gold standard" exists for assessing readiness for splint use in individuals with RA. Readiness refers to the intention to acquire and use assistive devices, and is affected by the degree to which potential users are aware of devices and their benefits, and their feelings about how well devices fit with their lifestyle and image[25]. In context of public services, it is wasteful to prescribe splints without knowledge regarding the patient's readiness to use the splint. Therefore, it was deemed important to develop an objective and reliable measure that would predict readiness for splint use – ultimately enabling clinicians to identify individuals who will require intervention earmarked at enhancing readiness. The identification of barriers to use hand splints could enable clinicians to better target their intervention in splint adherence. The specific objectives were to generate themes and items specific to wrist splint use thus permitting content development and preliminary refinement of a new measure - *the Rheumatoid Arthritis Splint Adherence Measure (RA-SAM)*.

Transtheoretical Model (TTM)

The TTM[26] was used to provide a framework for assessing readiness to adopt new behaviors. This model has been used in explaining health related behavior changes, such as quitting smoking[45,46], weight management and exercising[48], adhering to the recommendations for home modifications in elderly[49], and to recommendations for treatment in chronic pain patients[50,51], as well as self-management in arthritis[52]. This is a model of intentional change that focuses on the individual's decision making. It involves emotions, cognitions, and behavior, and a reliance on self-report[46]. According to this model, health behavior change involves six stages: *pre-contemplation, contemplation, preparation, action, maintenance,* and *termination*. In the field of health psychology, this model provides a framework for assessment of an individual's readiness to adopt a new behavior. It also provides strategies to guide the individual through the "stages of change" to *action* and *maintenance* of the new behavior[26,49]. Since splints are often provided to an individual who is newly diagnosed with RA and has never used a splint before, we anticipate that this individual will be at the stage of *pre-contemplation (not ready), contemplation (getting ready),* or *preparation*[26]. Overall, the TTM was chosen because it can be used for developing predictive measures[50,51]. The identification of the individual's "stage of change" enables planning of an adherence intervention that is congruent with the individual's readiness level and adapted to their specific needs[26,50,51].

METHODS

Overview of the study design

Stage 1, theme identification, was performed used an extensive literature review as well as input from two focus groups, one consisting of health care professionals, the other, individuals

diagnosed with RA. In Stage 2, items were generated the initial version of the RA-SAM and were reviewed for content, clarity, and pertinence. The initial version was again reviewed by three clinicians working in the domain of rheumatology and by five individuals with RA, for readability and to verify that the items covered all important domains. Next, a French language version was created and tested (Table 4.1). The study was approved by the Institutional Review Board of the Faculty of Medicine, McGill University, Canada.

Stage 1- Protocol for Theme Identification

Literature Review

The literature review was performed to identify relevant items from existing studies on adherence as well from assessment tools that aim at predicting use or abandonment of assistive devices, and adherence to treatment. Specifically the search included perusal of PsycINFO, HaPI, Cinahl, MEDLINE, Mental Measurements Yearbook, ERIC publications from 1950 to June 2009 to identify English language studies with adult subjects. The following terms were combined and also were run independently to insure inclusion of items useful to measure adherence outside of the realm of RA: splint, hand splint, orthotic devices, technical aids, assistive technology, assistive devices, predictive assessment, and predisposition assessment, readiness, motivation, and adherence. Retrieved items were grouped into factors that have been identified to be associated with adherence: appearance, comfort, ease of use, acceptance/perception of own condition, willpower, self-efficacy, complexity of treatment, and social support[15,25,27,28].

The search identified several domains important to adherence to splint wear. These were reviewed in light of potential predictors for splint use including: *socio-economic, health system, health care team, therapy*, *condition* and *patient-related factors and interventions*[4]. Other

domains included in some tools are motivation, treatment readiness, circumstances, problem recognition, and desire for help[34,35]. Factors associated with the abandonment of splints and other assistive devices included: clients' psychological perspective (such as importance of splints, splint related stigma), socio-cultural and economic background, perceptions of benefit (ex. while driving, cleaning activities)[13,16,17], and splint properties such as discomfort, hygiene, adjustment, aesthetics[20,27,36]. The acceptance level of one's own condition and denial of the need for assistance are examples of psychosocial factors contributing to splint abandonment[28,37,38]. Adding complexity to the understanding of wrist splint adherence is the fact that perceived splint benefit may vary from one activity to another[6]. For instance, clients may see the hand splint being useful for driving, but not for cooking, and they will use the splint according to their perception.

Focus groups

Two focus groups were conducted to confirm that the literature search had identified the key domains of interest to measuring adherence readiness and to identify missing themes. To ensure structured discussions, two sets of open-ended questions were generated; one for health professionals, the other for the layperson group (Appendix 1).

Focus group of health professionals: The target participants were health professionals with expertise related to RA or to adherence issues. Participants were recruited from the disciplines of rheumatology, occupational therapy, physiotherapy, and psychology. Eligibility criteria included: working with clients with RA who have hand involvement for a minimum of two years or, for those in psychology, - working with clients with chronic pain experiencing adherence issues with treatment regimens. Health professionals were recruited among clinicians known to work in rheumatology based on the lists that are used for student placements at McGill and by snowball

sampling – that is by asking those who were contacted whether they had colleagues in the disciplines of interest that worked with this clientele.

Focus group of individuals with RA: Participants with a range of age, education, hand/wrist disability due to RA, and job types were recruited. Participants were eligible if they had received a hand splint even if they never used it, so that issues related to adherence could be investigated for splint users and non-users. Recruitment took place in acute care and rehabilitation hospitals, and aqua-arthritis programs in Greater Montreal. Participants were recruited through clinicians and through group mentors of the pool programs, who approached individuals to ask about their willingness to be contacted by the primary researcher. Those who agreed to be contacted were phoned by the primary researcher who explained the focus group purpose. Upon agreement, participants were invited to the 2 to 2.5 hour focus group. The participation in the focus group was on voluntary bases and no monetary remuneration was provided to participants.

Focus Group Sample Size

In determining the sample size the goal was to accrue a sufficient number of participants so that major themes of interest could be elicited and saturation in themes would occur. A sample size of six to ten participants in each group was deemed sufficient to attain a variety of viewpoints and to make sure that everyone had a chance to participate[29]. Additional groups were to be held if saturation did not occur or if the themes were very different from those already identified through the extensive literature review.

Focus Group Procedures

Each group was structured using focus group methodology[29] and was run by the principal investigator who acted as the moderator, along with two trained assistants. Each participant completed a brief socio-demographic questionnaire and provided written consent agreeing to participate in the study, to be audio-taped, and to have the information from the focus group used, without personal identifiers, in presentations and publications. The consent form was approved by the Institutional Review Board of the Faculty of Medicine, McGill University, Canada. Each participant received a copy of the consent for their personal record. The facilitator explained the discussion format and proceeded with prepared questions covering: factors contributing to use or non-use of splints identified through the literature review[28]; reasons for not wearing splints; common characteristics of individuals who do not use splints; client's expectations; topics commonly discussed when splints are provided; perception of today's health care system in the context of splint prescription and adherence; and, the role of therapists in enhancing adherence. As the participants spoke, an assistant recorded comments on a flipchart, viewable by all. Following completion of each question, participants were asked to review the recorded comments to confirm accuracy. After clarifications, additions and corrections were made, the moderator proceeded to the next question.

Focus Group Data Analysis

The information collected (tape-recorded discussion, and notes recorded on a flipchart) was examined by two study investigators (MV&NKB). Content-based analysis techniques were used to identify emerging themes and key points relating to each question[30]. Specifically, our assumption was that words and key points mentioned most often are those reflecting important concerns that are deemed to be associated with adherence. Relevant quotes and statements that

depicted themes were categorized according to topic areas and conclusions were drawn based on the content. Finally, salient quotes were identified to help illustrate themes[29] and the data were organized by themes[31].

Stage 2- Protocol for Item Generation, Development and Refinement of the Measure

Based on the results of the literature review and focus groups we created the preliminary version of the measure using question design strategies[31] that outline the necessary attributes of a question. The factors identified in the literature review and the themes and relevant quotes from the two focus groups were analyzed and discussed by two research team members (MV&NKB). Then, they were thematically grouped into four domains that appeared logical.

RESULTS

Stage 1- Theme Identification - Focus Group Findings

The aim of holding the two focus groups was twofold: to confirm that the literature search had identified the key domains of interest to measuring adherence readiness and to identify missing themes not yet present in the existing literature.

Focus Group 1- Health Professionals

Nine health professionals (7 females) participated in the health professional focus group including seven occupational therapists, one psychologist (working with clients with chronic pain), and one physical therapist. Two OTs were also certified hand therapists (CHT). Seven were females. The majority (7/9) indicated being very familiar with clients' concerns and expectations regarding splint wear. The work setting of participants varied and included:

rehabilitation hospitals/centers (n=4); outpatient clinic in acute hospital (n=2.5), private practice (n=1.5) and university (n=1). Six had more than 10 years of clinical experience in rheumatology.

Key discussed topics

Splint adherence is related to symptom severity: Several questions elicited the health professionals' perception of the problem of splint abandonment (Appendix 1). One recurrent point was the perceived ability of the splint to relieve pain and symptoms of instability. The majority believed that individuals are more likely to wear splints when they see "*functional gain and symptom reduction*". Furthermore, most felt that adherence depended on severity of symptoms - adherence being higher during acute periods when the benefits are most noticeable. It was also noted that "*Some individuals do not feel the need for splints because their symptoms are adequately controlled by medication*".

Client education is a crucial element for splint adherence enhancement: Most participants believed that education about the splint is an essential prerequisite for splint adherence: "*to increase the compliance clients have to understand what splints are supposed to do*".

The majority agreed that education is a key element and that at least two "one-on-one sessions" with a client are required to fabricate a splint and to provide education. Several expressed a strong conviction that splint use has to be personalized –"*activity needs have to be assessed and the therapeutic goals of each client considered*". Topics that healthcare professionals discuss with their clients include wearing schedule, the danger of "*pressure points*", and explanation about how to recognize when splint use should be stopped, splint care, contact phone numbers,

and the necessity for clients not to make adjustments by themselves. Several mentioned the importance of informing clients about harmful effects of splints if worn for prolonged periods.

Some clinicians encourage clients to come prepared with questions. Others provide a "*list of nearly all home activities*" and ask clients to think about problems experienced with any. Due to lack of time, some prefer providing take-home material or refer clients to websites.

All perceived that the approach to client education and services received varies greatly in the current healthcare system. In addition, health professionals remarked that they are often confronted with lack of time to provide information and to practice activities with the client.

Comfort and functionality are major contributors to splint wear: According to several participants, comfortable and "*soft*" splints are more likely to be worn - "*thick, heavy splints, that are rubbing on skin are less likely to be used*" whereas "*adding extra padding to make a rigid splint soft*" increases adherence. Overall, custom-made splints respecting individual pathology and morphology were said to provide better symptom relief than "*off-the-shelf*" splints.

Participants suggested that an important variable is the splint's convenience or lack thereof during activities. Several noted that some of the reasons given by clients for non-use are that they *"cannot work with a splint*" or that it "*gets in the way"*, difficulty grasping objects, fear of hurting children, or overall low perceived benefit. Situations requiring alternating wet and dry (child care, nursing, etc.); the wearing of gloves; or, frequent on and off lead to poor adherence. It was noted that severe hand deformities increase the difficulty of removing the splint repeatedly and that inefficiency in completing a task is a negative factor because of the extra time and the feeling of diminished performance.

Hygiene was cited as a contributing factor as, over time, splints become "*dirty looking*" and "*smelly*". The complaint by patients that splints or Velcro fastenings damage clothing was another reason for poor adherence.

Role of the Healthcare system and therapist in encouraging splint use: A number of participants felt that satisfaction with the health care services and the relationship with the therapist contributed to adherence. The therapist's role within the healthcare system was discussed along with the need to educate doctors about referring clients for splints as quickly as possible after disease onset. Participants suggested the need for good communication between the client and therapist through regular follow-up. Other suggestions included: increasing budgets for splinting materials, creating "arthritis centers" where individuals could consult with professionals; participate in education and self-management groups.

Client's Expectations to splint use: The majority of experts felt that most clients did not have clear expectations. One health professional mentioned that adherence is higher when individuals are "*not looking for magic but rather adjust their expectations*". Clients' expectations include relief of pain and increased hand function. Some anticipated prevention or correction of deformity.

Other discussed factors contributing to splint adherence

Among other adherence factors, professionals suggested family support and the feeling of "*being understood*". Furthermore, some individuals are more likely to adhere to a splint when it is prescribed by a doctor.

Nonverbal cues found to be predictive of poor adherence included "*staring at the splint like if a person cannot imagine wearing it*", and, difficulty putting the splint on during practice. Some clients clearly stated that they were not going to wear the splint.

Conversely, personal and cultural perspectives, language barriers, and cognitive problems were cited as contributors to non-adherence. Individual economic status, age and gender were thought to be "weak" determinants of adherence. One participant stated, "*a combination of gender and cultural background could be a factor:* "*macho style men*" *cannot see themselves wearing a splint"*. Several participants cited aesthetics and embarrassment of wearing a splint in public as contributors to abandonment.

Focus Group-2 – Individuals with RA

Five female individuals with RA participated in the focus group conducted in English: four were over 60 years of age. Three were married, one was single, one widowed. Three had been diagnosed with RA for more than nine years; the other two - less than three. All had used a splint in the past and were taking medication to relieve symptoms. The topics discussed during the focus group: reasons the hand splint was prescribed; expectations; difficulties encountered; reasons for use or non-use; noticed improvements; side effects; perception of the role of the clinician in reinforcing use.

Key discussed topics

Splint adherence is related to symptoms: Participants who had pain did indicate that they noticed improvement in pain symptoms and diminished discomfort of the hand, improved hand flexibility, and reduction of uncomfortable sensation. While some had persistent hope that the

splint would slow down or reduce hand deformity, others found the splint useless because they felt no pain currently and thus thought the splint was of no use.

Nevertheless, the majority agreed that splints are helpful in reducing the feeling of discomfort in the hand, as distinguished from pain: "*without a splint, the hand is not aligned properly*"; a splint helps to have the hand "*well placed; it feels more comfortable with it on*". Other reasons for using splints included: decreased hand numbness, improved sleep thanks to pain reduction, and, reduced swelling. A motivation for use expressed by the majority was an improvement in function and increased ability to complete daily activities.

Comfort and functionality as major contributors to splint wear: Individuals shared their first impression of the splint as being heavy, awkward, and uncomfortable. Most felt that activities became more difficult to perform and that it took time to get used to the splint. The situation was considered worse when splints are prescribed for both hands. These negative aspects generally improved over time. The majority declared that the splint interfered with their sleep because the hand becomes itchy and sweaty after extended wear. When talking about splint fit, most suggested that it can take several attempts before a splint is well fitted. Only when a splint is perceived to be comfortable does it gradually get incorporated into daily activities. Participants also indicated that the splinting material is important with a preference for smaller, lighter splints made of flexible materials.

With regards to side effects - irritability and frustration were identified as key issues. Several described themselves as being "very *impatient to get used to it*" and "*feeling restricted*". Other

common complaints included difficulty positioning the hand, especially at night. Discomfort associated with sweating, skin rashes, itchiness and increased wrist joint stiffness were noted.

In terms of function, all agreed that they did not see improvements in individual tasks, but in general. Mention was made that during the periods when the wrist and hand are swollen the splint was helpful in gaining function. When asked about the reasons for not using splints all indicated that most household chores are more difficult with the splint on.

Participants mentioned having difficulties in specific daily activities including driving, holding objects, etc. However most found that over time, they got more used to completing activities with the splint on.

Role of the therapist in encouraging splint use: Lastly, participants shared their perceptions about the role that a therapist should play in encouraging and enabling clients to use splints. One individual stated that, prior to providing a hand splint, the therapist should be aware of the type of arthritis, the severity, pain level, and the client's daily activities. All agreed that a splint should be custom-made, and be appropriate for activities that a person performs regularly. The participants generally thought that the relationship with the therapist was important because a good relationship with the therapist "*induced harder work*".

Interestingly, most participants could not recall the details that they had discussed with the occupational therapist when they first received the splint. Those who could recall the discussion had recollections including "*fascination*" about how the therapist described the splint and how it was supposed to help. However, none remembered specific instructions about splint care or wearing schedules other than the fact that the splint had to be worn at night or for all activities.

Client's Expectations: Concerning expectations and difficulties when a splint was first provided, all agreed that they looked forward to pain reduction and improvement of hand function. Participants also anticipated "*resting the hand"* and slowing the deformity.

Other discussed factors contributing to splint adherence

Participants suggested that family support was one of the essential factors encouraging them to adhere to splint wear. Individual economic situation, other peoples' opinions and the splint look were deemed not to be important in adherence. One individual affirmed that thanks to splint use, she was able to take less medication, thus reducing expenses. Several participants shared the feeling of being an active player in improving their condition by wearing a splint. Acceptance of one's condition was identified as a weak factor influencing splint wear.

Comparison of themes according to patient versus professional focus group discussion

Overall, both groups placed equal importance on the theme of symptom severity being related to splint adherence. The splint comfort was discussed more in depth by the individuals with RA. The group of experts emphasised the importance of education in adherence enhancement. On the other hand, the RA group valued the relationship with therapist and family support as important motivational factors to wear their splints. Interestingly, factors identified in the literature[4,13,17,27,28,37,38] such as individual's psychological perspective (level of acceptance of own condition, perception of illness, etc), economic background, and, factors related to the device (adjustment, aesthetics, etc.) were not extensively discussed.

Focus group conclusions

The main factors that emerged were the perceived relief of symptoms, comfort with splints, perceived nuisance of splints, splint appearance, acceptance of own condition, hygiene, ability to function with splints and job requirements of the person, severity of the deformity, family support, and personal expectations. Participants of both groups indicated that individuals with RA are more likely to use a splint when they clearly see its beneficial effects; in other words when the individual notes a relief of pain and wrist instability, or improvement in activity performance.

Stage 2- Item Generation, Development and Refinement of measure

The objectives of the stage 2 were: 1- to generate items specific to splint use readiness, and to develop and refine the preliminary measure; 2- to translate the preliminary English version into French, aiming for linguistic and cultural similarity.

For ease of reading, the methods for each of the following sections will be presented with corresponding results.

Item generation

Methods

To generate items for the preliminary version of the RA-SAM, the research team (MV &NKB) reviewed and then used the focus group and the literature review content (themes, salient comments, etc.). A questionnaire design process using the Total Design Method Approach[31] that describes how to maximize the clarity and format of items and the overall questionnaire format, flow etc. was used. An attempt was made to formulate items in a short and concise manner, while avoiding the use of jargon, negative wording, double-barreled, vague, and ambiguous

formulation[31]. The TTM was used to provide a framework for formulating the items, according to the stages of change defined in this model[26,51,52].

Results

In total, 45 items were generated based on the identified themes: *health-care context*, *motivation/locus of control, social context,* and *perceived splint value.* For instance, the majority of health professionals who participated in the focus group confirmed that the adherence to splint use often depends on an individual's symptoms, such as pain or wrist joint instability. This finding was coherent with a "*disease severity*" factor identified in the literature. Based on this information, several items related to symptoms of RA were created; for example: "*I am confident that wearing a splint will help with my pain*".

Assessment of content validity through consultation with expert and individuals with RA

Methods

The initial version of the measure, consisting of 45 items, was independently reviewed by two experienced occupational therapists, one physiotherapist; and five individuals with RA who had previously used hand splints. Each was instructed to: 1- review the items; 2- confirm the appropriateness of items chosen to predict an individual's readiness to wear a splint; 3- identify omissions; redundancies; 4- assess the clarity of instructions and suggest changes; and, 5- give their opinion about the usefulness of the measure in clinical practice.

The feedback was collated, each comment was scrutinized, and suggested changes were discussed by the research team who reflected on the relevance and appropriateness of each recommendation based on the measure's global goals and the literature. Based on the feedback,

items were eliminated and new items generated to add domains or additional items under a domain where items appeared to be lacking.

Results

All 8 respondents indicated that a measure that evaluates readiness of individuals with RA to use a newly prescribed working splint was important and relevant for clinical use. Numerous comments and suggestions were made about the items or domains that resulted in the reordering of some items; rephrasing of questions and instructions; and, adjusting terms for clarity or to prevent potentially biased responses. For instance, following one expert's suggestion, a question about previous exposure to splints was added to the final version of the measure. In the initial version, although the phrase "*hand, wrist and fingers*" was used in many items of the original version, we changed to the word "*hand*" to allow for shorter sentences. This was noted at the beginning of the measure in the instructions. Overall, participants indicated that the statements were easy to understand.

After the first round of feedback a few clarifying sentences were added to the introduction regarding the purpose of the measure and 7 questions deemed redundant were eliminated, resulting in 38-item version.

Translation of Measure

Method

Once the English preliminary version was finalized, the items were forward-translated into French and then back-translated into English using standardized forward and backward translation methodology[32,33]. The methods employed for translation were adapted based on the

process of translation and adaptation of instruments described by the World Health Organization, 2010[32]. These include: 1-forward translation by English/French translators; 2-review of the translations by the research team and creation of the French version; 3-review of English and French version by experts in rheumatology; 4-back translation of the French version.

Results

First, the 38-item English version of the RA-SAM was translated into French by 3 independent bilingual English/French translators using standardized methodology[32,33]. These individuals were selected on the basis of professional qualifications and experience in the health care. Conceptual rather than literal equivalence of specific words and phrases was emphasized to reflect the French language spoken in Canada given that we anticipated using it in Canada immediately.

When the three translations were ready, two study investigators (MV&NKB), both bilingual health care professionals, met to review the first draft of the French version. We then created a forward translation of the French version without consulting the original English version. Then by comparing the French to the original English version, we were able to identify "difficult items", that is those that were challenging to translate conveying the original meaning of the English version. Several original questions were lexically modified to be as close as possible to the French version without affecting the original meaning. By comparing the original version to the forward translation, eight items either did not match the 1st English version, or contained words that were translated correctly but without conveying cultural nuances. For example the original wording "*the look of my splint...*" became "*the appearance of my splint...*". Lexical changes were made in the original English or in French items while preserving the original meaning. For instance, "*l'apparence de mon orthèse...*" was changed to "*l'allure de mon*

orthèse..." to match the original expression - "*the look of my splint...*". In another example the original item "*I am confident that wearing a splint will help with my pain"* was translated *"Je suis confiant que le port d'orthèse diminuera ma douleur*". To match the French version, the original item was changed: "*I am confident that wearing a splint will diminish my pain".*

Then, the research team, in consultation with clinicians working in the field of rehabilitation, were queried to ensure that the English and French language health terms were being used appropriately and similarly in the two versions. Once the clean versions (English and French) were ready, two additional bilingual occupational therapists who were accustomed to working in the area of RA were asked to review the English and French language version to: evaluate the items for clarity of phrasing; and, to identify any apparent differences in the cultural aspects of the wording. These health care professionals did not have prior knowledge of the RA-SAM. Based on this feedback, several items were rephrased to reflect perceived divergence in the cultural aspects of the items' phrasing. Based on the comments from two bilingual occupational therapists, several items were rephrased again in English or in French.

The reconciled French version was sent to one English translator to backward translate it into English. Her translation was reviewed and compared to the English version by the study investigators in terms of conceptual equivalence (the degree to which the concept and intent of the original version was captured). This backward translation was judged by the research team to be sufficiently acceptable in terms of cultural similarity, and in that the phrasing captured the intent of the item to act as the preliminary version for testing.

Final version of the Measure readied for testing

Of the 38 items we hypothesized that 6 were related to the domain *health-care context*, 14 to *motivation/locus of control*, 8 to *social context*, and 10 to *perceived splint value*. For example, under *health-care context* were grouped factors related to clients' attitude towards health care professionals, instructions provided and willingness to follow prescriptive information *(e.g. I believe that education about arthritis will influence my splint wear).* Factors associated with a client's enthusiasm (or lack thereof) regarding splint wear were grouped under *motivation/locus of control (e.g. I feel ready to wear a splint).* *Social context* encompasses factors related to the attitude towards wearing a splint in public and the psychological and physical support provided by family and friends (e.g. *Friends and family support me in my illness*). Factors related to views and expectations of a splint's positive and negative effects were grouped under *perceived splint value (e.g. Wearing a splint will help reduce my pain)*.

A 0 to 10 scaling was used (i.e. *Please read each statement and, respond with an answer from 0 to 10 with 0 indicating "STRONGLY DISAGREE" to 10 indicating "STRONGLY AGREE").* For example, for the item *"Wearing a splint will help me rest my hand"* an individual is required to provide a response corresponding to a number from 0 to 10. An 11-point scale has been validated for use in studies of chronic medical illness[39,40,41].

DISCUSSION

This paper describes the content development of a new measure of readiness to adhere to wrist splint use – the RA-SAM. The preliminary 38 item version has been developed based on an extensive review of published literature on adherence along with consultation with expert

clinicians and clients with RA. Interestingly, the themes that emerged from the literature on adherence were for the most part brought up spontaneously in both focus groups suggesting that it is likely we achieved saturation in themes. Indeed, when Veehof et al.[28] (2008) in the Netherlands recently conducted a study of knowledge and opinions about functional wrist splints in 18 individuals with RA[28] the themes that emerged were similar with one exception: in our study the role of family and friends was identified as important to splint adherence. Their role has long been recognized as important for adherence in other conditions, such as diabetes[42].

As we go forward with further development of the RA-SAM, we are pre-testing the preliminary version of measure on individuals with RA or who are familiar with RA, in order to refine and finalise the new measure, and to establish its content validity. We will conduct factor analysis to identify whether the items group together within the proposed themes. In addition, we are testing the comparability of responses on the English and French language versions.

LIMITATIONS

While the literature review and focus groups elicited many similar themes, the focus group of individuals with RA included 5 individuals who were retired; therefore, some themes might have been missed by not including younger individuals. Another limit is that there were only female participants with RA. There may be gender factors associated with willingness to adhere to splint wearing, that were not discussed. As well, the value placed on adherence issues related to economic considerations may differ in countries where universal health care is not available to cover costs associated with splinting, medications, health visits etc.

CONCLUSION

Adherence to splint use is an important component of self-management in individuals with RA. To accurately identify splint adherence readiness in those with RA, prior to providing them with a hand splint, we have created a preliminary version of a new standardized measure – the RA-SAM. Measure development involved a multiple step process including a literature review, two focus groups, and feedback about the initial version from expert clinicians. This preliminary version of the RA-SAM consists of 38-items that we have grouped thematically and hypothetically into 4 domains (*health-care context, motivation/locus of control, social context, and perceived splint value).* The RA-SAM has been shown to be usable and acceptable to patients. Both English and French versions are available from the authors upon request. It is now undergoing further psychometric testing including factor analyses to determine if the items are indeed grouping in the four theorized domains.

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Table 4.1: Overview of the study design

PHASE	***METHODS***
Phase 1 **Theme Identification & Item Generation (selection of the item pool)**	*Literature review* o Defining the constructs o Identified several domains important to adherence to splint wear o Developing question for the focus groups
	Focus groups o Obtaining input from experts in RA and individuals with RA o Confirming literature finding o Identifying missing domains
	Review of the information collected o Developing an item pool by domain by study investigators
Phase 2 **Development and Refinement of the Measure**	*Establishing logical construct validity of items per domain* o Creation of the preliminary version of the measure by study investigators o Obtaining input from experts in RA and individuals with RA
	Creation of the French version

5. INTEGRATION OF MANUSCRIPT 1 AND 2

The first manuscript of this thesis explores the content development of the new measure. In the second manuscript, the refinement and content validation were addressed. Both address the creation of a new measure – the *Rheumatoid Arthritis Splint Adherence Measure – RA-SAM*. This measure is intended for use by clinicians (primarily occupational therapists) before hand splints are provided to individuals with RA. By identifying the barriers to adherence, clinicians will be better able to address issues and resistance to use that are specific to the individual. While the literature does contain several studies that have identified barriers and facilitators to adherence to treatment, including splints, no assessment specific to splint adherence was uncovered.

In Phase 1, presented in the first manuscript, the preliminary version of the *Rheumatoid Arthritis Splint Adherence Measure* (RA-SAM) was created through a multiple step process including content development using a combination of an extensive literature review, two focus groups, and feedback about the initial version from expert clinicians. The initial version consisted of 45 items and was then circulated among the group of expert clinicians and in the group of patients with RA. Based on comments of participants, it was reduced to a 38-item version that grouped into what we hypothesized were 4 domains (*health-care context, motivation/locus of control, social context, and perceived splint value).* In Phase 2, addressed in the second manuscript, we refined and finalised the new measure, and established its content validity, using the results of pre-testing of the preliminary version, on individuals with RA or who are familiar with RA. Also we described the process of factor analysis that was conducted to identify whether the items group together within the hypothesized themes. In addition, the comparability of the English and French language versions was assessed by reviewing the meaning of the measure items in English and in French items, and by comparing mean scores and

standard deviations of the items between the versions, scaled on a 0 to 10 scale. The final item reduction based on the accumulation of information (comments of participants, comparison of the English and French items, factor analysis, and a review of comments posted in social media discussions about arthritis) was addressed.

MANUSCRIPT 2:

REFINEMENT AND CONTENT VALIDATION OF THE RHEUMATOID ARTHRITIS SPLINT ADHERENCE MEASURE (RA-SAM)

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ABSTRACT

Background: In a first study we created the 38-item *Rheumatoid Arthritis Splint Adherence Measure (RA-SAM)* - that evaluates readiness of individuals with rheumatoid arthritis (RA) to use a prescribed working splint. We hypothesized that the items grouped around four domains including *health-care context*, *motivation/locus of control*, *social context*, and *perceived splint value*.

Objectives: The specific objectives addressed in the current study were: refinement of the preliminary *RA-SAM,* validation of the English and French versions; and, content validation of the final measure.

Methods and Data Analyses: The 38-item version of the RA-SAM was pilot tested on 82 individuals. It was administered in English or French depending on the language preference of the participants. Participants were asked to read the 38 items twice; the first time while reflecting on the clarity of each item so that they could identify redundancies, omissions, unclear questions, and a second time by responding to each question using a 0 to 10 scale where 0 indicated "*strongly disagree*" – and 10 indicated "*strongly agree*". For example, on the item "*I feel ready to wear a splint*" participants had to first indicate whether this was a clear question or if they had any suggestions for change. They were then presented with the question again and asked to provide a response corresponding to a number from 0 to 10 as it related to them personally. The first set of responses were analyzed to identify items that were unclear, and to identify redundancies and missing items. Then, the responses on the 0 to 10 scale were examined to see whether there was a difference in terms of scoring between

the versions. Next, the comments of participants were reviewed again with the goal of better capturing the cultural aspects of the wording in English and French. Furthermore, exploratory factor analysis was performed to identify whether the measure items falling in each of the four hypothesized domains, defined in Phase-1, were indeed measuring that domain. Final item reduction was performed by two study investigators based on the accumulation of "evidence against items" from all available sources: comments of participants, comparison of the English and French items, factor analysis, and review of comments posted in social media discussions about arthritis.

Results: A total of 82 participants completed the study: 43 responded to the English language version and 39 to the French language version. Through a multistep process 10 items were eliminated and two were added; several were rephrased. The results of the exploratory factor analysis indicated 35 items with a factor loading equal to or greater than .25, corresponding to 4 factors, explaining 44.8% of the total variance. In light of these results, we concluded that our theoretical groupings (*health-care context*, *motivation/locus of control*, *social context*, and *perceived splint value)* were too broad, and that there are more than four underlying factors. Nevertheless, the exploratory factor analysis provided evidence of content validity of the RA-SAM. The domain of *Preparedness for splint use* incorporates 12 items, *Nuisance* – 7 items, *Commitment* - 7 items, and *Social support* – 4 items. The final 30-item version of the RA-SAM is now ready for further psychometric testing under 4 new domains.

Conclusion: This study resulted in the development of a measure to identify the level of readiness of an individual with RA to adhere to splint use. In future studies it will be important to test the predictive validity and test-retest reliability of the RA-SAM. As well, to

assist clinicians working with this clientele of new splint users, we are developing a RA Splint Readiness Knowledge Translation Kit consisting of "helpful guidelines" for clinicians to enhance wrist splint adherence.

Key words: Rheumatoid arthritis, wrist, functional hand splint, readiness to adhere, adherence, occupational therapy, occupational therapists.

INTRODUCTION

Rheumatoid arthritis (RA) is a chronic, autoimmune disease characterized by pain, swelling, destruction, and functional disability in the joints[1]. It affects approximately 1% of the world's population and is more prevalent in women [2, 3].

It is estimated that approximately 75% of individuals with RA have inflammatory involvement of the wrist[4,5,6] that must be addressed early to avoid rapid deterioration of the joint. A working hand splint is commonly prescribed to address pain and to prevent joint destruction[5,6]. Splints are effective in reducing joint pain and inflammation of the surrounding tissue and in minimizing the workload of the affected joint, with the added benefit of allowing the affected joint to rest[5,7,8,9]. Unfortunately, wrist splints continue to be prescribed to patients who are not ready to adhere to their use which is wasteful of money as well as clinician time and patient energies[10,11]. While a number of tools[12,32] have been created to assess readiness to adhere to medical treatment, none evaluate adherence readiness specific to splint use. Therefore the global aim was to develop a predictive measure that assesses readiness to adhere to a working wrist splint in individuals with RA.

In the first manuscript of this thesis[13] we addressed the process of item generation and creation of the *Rheumatoid Arthritis Splint Adherence Measure – RA-SAM*. The final 38-item version grouped into what we hypothesized to be 4 domains (*health-care context, motivation/locus of control, social context, and perceived splint value).* The specific objectives of the work described in the current paper include: refinement of the preliminary Rheumatoid *Arthritis Splint Adherence Measure (RA-SAM)*; (2) comparison of the English and French versions and adjustment of the two versions as needed; and, (3) content validation of the final measure.

METHODS

Protocol for Pre-testing of the Measure

Ethical considerations: The study was approved by the Institutional Review Board of the University at which the study was conducted. The recruitment strategy using the web-page of Facebook was approved the Arthritis Society of Quebec and the Institutional Review Board of the University.

Sample Size Justification: Sample size calculations were based on the subject to item ratio that is required for factor analysis. According to Cattell (1978) a subjects-to-item ratio of 3:1 to 6:1[14] is considered satisfactory. For the final version of the measure we expected to identify to 25-30 items; thus, a minimum 3:1 subject-to-item ratio resulted in a minimum requirement of 80 individuals in order to conduct exploratory factor analysis.

Recruitment of Participants: For the pre-testing phase we sought to recruit 80 individuals with sufficient English and/or French language comprehension to complete the measure and provide written comments in one of the languages. Potential participants were recruited using two major channels including social media – specifically the *Facebook* page of the Quebec's Arthritis Society and the Quebec's Juvenile Arthritis Group – and through clinicians working in the rheumatology departments of two University-affiliated teaching sites – one outpatient rehabilitation site, the other an acute care site. The measure itself was hosted on a secure Internet site that complied with all of the usual standards of participant confidentiality set by the Institutional Review Board (the questionnaire was completed anonymously and the information collected was kept confidential). In the clinical sites clinicians approached individuals diagnosed with RA to ask about their willingness to hear more about the study. If the person indicated

willingness, a research assistant explained the study and if the individual agreed to participate s/he was provided with an envelope containing the measure, a consent form, and an envelope with a postal stamp and return address. The individual could either mail the completed measure or return it in the sealed envelope to the treating therapist. Individuals who had already been discharged from outpatient services, but who met the inclusion criteria, were also contacted by a research assistant. Those who agreed were phoned by a trained research assistant who explained the purpose of study and asked about the person's availability and willingness to complete the measure by phone or by email.

Measure administration: Individuals were invited to complete the questionnaire in the language of their choice (English or French). Participants were asked to read the 38 items twice (Table 6.9); the first time while reflecting on the clarity of each item so that we could identify redundancies, omissions, unclear questions, and the second time by responding to each question using a 0 to 10 scale. To elucidate, the first time participants were instructed to: "*Please indicate whether each statement below is CLEAR by indicating "YES" or "NO". If your answer is NO, please indicate why you found the statement unclear in the text box below*". The second time the participant read each item the instructions were: "*Please read each statement again but this time, respond with an answer from 0 to 10 with 0 indicating "STRONGLY DISAGREE" to 10 indicating "STRONGLY AGREE"*. For example, for on the item *"People important to me support me in my illness"* participants had to provide a response corresponding to a number from 0 to 10.

Data analysis -Objective 1 - Refinement of the Measure

The first objective was to refine the 38 item version of the *RA-SAM*. All comments made by participants regarding the items were reviewed and analyzed by the research team. The potential for item reduction was examined using endorsement patterns on the response options and missing responses. To elucidate, items with missing values of greater than 10% were reviewed to identify whether there was a lack of clarity or ambiguous wording and if deemed so, rephrasing was attempted. At this stage we did not eliminate items.

Data analysis -Objective 2 - Validation of the English and French versions

The second objective was to validate the English and French versions of the measure, first by comparing them to make the necessary adjustments in item wording, if needed. For this three bilingual Quebec expert clinicians reviewed the meaning of the measure items in English and in French for comparability. Next the responses of the 82 participants on the 0 to 10 scaling (39 French and 43 English) were examined to see whether there was a difference in terms of scoring. Specifically, the mean scores and standard deviations were compared on each item in English and in French (Figure 6.1). The items showing noticeable differences in average scores (more than 2 points) were considered to be potentially in need of rephrasing. Next, the comments of participants were reviewed again, but this time specifically to focus on questions that were considered unclear in one or both languages (English or French) with the goal of better capturing poorly phrased items and those that might have poor cultural translation. Divergence from a purely literal translation of the original English version was permitted when this was deemed to improve the semantic, conceptual, and grammatical similarities between the English and French

versions. Finally, the altered English and French versions were compared by the two authors (MV and NKB) to insure that the changes in one were reflected accurately in the other.

Data analysis -Objective 3 - Content validation

The final objective was to establish content validity using two strategies – (1) factor analysis, and (2) a review of the comments posted in a social media discussion about arthritis called *"Arthritis Is Unacceptable because_____?"*[15]. This discussion was used as an additional assessment of content validity. It should be emphasised that the use of this social media discussion was not initially planned. It occurred that one of the research investigators came across the Arthritis Foundation discussion forum which was hosted for a short period right at the point when the RA-SAM's validity was being analyzed. As the subject of the discussion was relevant to the study, it was thought to be interesting to use the comments as an additional post-hoc opportunity for further content validation.

Strategy 1- Factor analysis: To carry out factorial *(intra-test)* validation, factor analysis was used. Factor analysis is a statistical method that assists in identifying related variables that cluster to identify a domain[16]. The goal here was to further substantiate whether the items hypothesized to group into four factors related to adherence (*health-care context, motivation/locus of control, Social context, perceived splint value)* were indeed grouping together to represent each domain.

Prior to conducting the factor analysis, the Kaiser-Meyer-Olkin Measure of Sampling Adequacy Test (KMO), and Bartlett's Test of Sphericity, were performed. KMO gives an index (between 0 and 1) of the proportion of variance among the items that might be indicative of underlying or latent common factors. To proceed with the factor analysis, the KMO value should be greater

than 0.5[17]. Bartlett's test of sphericity was used to test the null hypothesis that the items in the correlation matrix are uncorrelated[17].

As previously mentioned, the average scores of the English and French items of the RA-SAM were compared. Items with significantly different averages (more than 2 points) were reviewed for possible elimination prior to including them in factor analysis. Thus, in conducting the factor analyses two assumptions were made: (1) the items of the English and French versions were equivalent in their meaning; and (2) any item of the RA-SAM may be associated with any factor[18]. A *pairwise* approach was used, where the correlation matrix was calculated with all available values. "*Not applicable*" responses on items were excluded from the factor analysis. The criteria used in identifying the underlying factor structure were: (1) retain items with a factor loading of .25 or above, and, (2) retain four factors that explain most of the variance.

Varimax rotation was performed to obtain a clear pattern of factor loadings for items. It was also used to evaluate how well the item groupings related to each of the four hypothesized domains established a priori *(Health-Care Context, Motivation/Locus of Control, Social Context, and Perceived Splint Value)*. From this analysis, the item groupings of the measure were compared side-by-side with those identified *a priori* by the research team (table 6.7).

Furthermore, we wanted to make sure that each item of the RA-SAM made a meaningful (face validity) and useful (non-redundant) contribution to an identifiable factor. We identified items that challenged the measure's integrity and tagged them for possible removal. Our criteria included the following: (1) redundant items, as suggested by items factor correlation of >0.7; (2) items with factor loading of $\leq$0.5 relative to other items were reviewed for wording[19,20]. Those items, along with the others that were tagged for potential removal, were reviewed by the

research team at the stage of final reduction to permit final decision-making regarding the items to be retained.

Strategy 2- Comparing items to the themes that emerged from a Social Network discussion: The social media discussion about arthritis called *"Arthritis Is Unacceptable because_____?"* was posted on October 26, 2011, on a Facebook page of the Arthritis Foundation[15]. Members were invited to share their thoughts. Forty-nine comments were posted during the period from October 26th through November 3rd 2011. We reviewed these comments and grouped them into themes using qualitative thematic evaluation[21]. We then compared these themes to those that had emerged during the focus group and literature review to identify any additional themes that may have been missed through the literature review and the focus groups[13]. In this way we were able to use an unexpected but rich source of information to go one extra step in the content validity process.

Final item reduction

The goal was to eliminate unnecessary items on the 38 item version of the RA-SAM before going forward with further validity and reliability testing. Final item reduction was performed by two study investigators based on the accumulation of the "evidence against items" from all previously described sources: (1) comments of participants (endorsement patterns on the response options and missing responses), (2) review of the meaning of the measure items in English and in French; (3) comparison of average scores of English and French items; (4) factor analysis; and (5) review of the comments posted in the social media discussions. Based on this accumulated information, we identified items with questionable measure integrity and tagged them for possible rephrasing or removal.

RESULTS

Socio-demographic information: A total of 82 English and French speaking participants completed the questionnaire for the pre-testing of the measure: 43 responded to the English language version; and, 39 to the French language version; 50 of the participants were female. The average age of participants was 43.7 years (from 22 to 89 years old). Among participants 29 reported using splints in the past (table 6.1). Thirty-three participants with RA were recruited through clinicians working in the field of rheumatology of two University affiliated teaching sites, and 49 were recruited through the Quebec's Arthritis Society (Société de l'arthrite) and Juvenile Rheumatoid Arthritis site.

Refinement of the Measure

The review of comments of participants suggested that four questions (items 6, 14, 17 and 24, see Table 6.9) were found by the majority of participants to be "*vague*", "*too general*", "*redundant*" or "*unclear*". In addition, several statements were rephrased or the wording changed based on a review of the comments. For instance "*people important to me*" was replaced by "*family and friends*" in order to be more specific; the word "*instruction*" was replaced by "*recommendations*", to eliminate the "obliging" connotation of the initial expression; the statement *"I think it is awkward wearing a splint in public*" was thought to not be precise enough; therefore it was changed to *"Wearing a splint in public will make me feel uncomfortable"*. The expression *"irritating to wear"* was reported to be ambiguous and was changed to "*frustrating to wear"* etc. (Items 22 vs. 26 in Table 6.9, 6.10, respectively)

There was no item with missing values of greater than 10%, therefore no item was eliminated based on this criterion. The measure was reviewed for a second time by the research team after

revision: 3 items were considered redundant (items 1, 8, 21) (Table 6.9, 6.10). Overall, based on these various forms of item reduction, 7 items (item 1, 6, 8, 14, 17, 21, and 24) were tagged for possible elimination.

Comparison of the English and French versions of the Measure

The rating averages of the items (scaled from 0 to 10) in English and in French were very similar (Figure 6.1) with the exception of two (items 17, 20). For items 17 and 20, the differences between the average values could be explained by the fact that the French version was formulated negatively (Table 6.9): (ex. *"I will wear a splint only if I feel that it is helping me*" vs. "*Je ne porterai une orthèse que si je vois du progrès*"). After comparing the English and the French versions of the measure, in terms of wording and cultural similarity, five other questions were tagged for rephrasing (items 1, 6, 8, 21, and 37, see Table 6.9)

Content validation

Strategy 1- Factor Analysis: As mentioned above the analysis of scores revealed that two items were formulated in the negative in French (figure 6.1) but positive in English and as such the scores were reversed in the French version to permit their inclusion in the factor analyses.

Prior to beginning the factor analysis we analyzed the results of Kaiser-Meyer-Olkin Measure of Sampling Adequacy test (KMO) and Bartlett's test of sphericity; the results were satisfactory (table 6.3). The value of KMO was greater than 0.5[17], being suitable to proceed with factor analysis (Tables 6.2-6.6). The observed significance level in the Bartlett's test was .0000, meaning that the strength of the relationship among the 38 items was strong. The Principal Axis Factoring with Varimax with Kaiser Normalization and the criterion of eigenvalue greater than

1.00, produced a 11-factor solution (Figure 6.2). This factor solution explained 76.9% of the total variance (Table 6.6, Table 6.9). The results indicated 35 items with a factor loading equal to or greater than .25, corresponding to 4 factors, explaining 49.7% of total variance (Table 6.5 and 6.6). These factors accounted for 23.6% (*preparedness for splint use)* 11.1% (*nuisance),* 8.1% (c*ommitment*), and 6.9% *(social support)* of the total variance respectively (Table 6.5). Following side by side comparison of the 4 emerging factors with the 4 hypothesized domains *(Health-Care Context, Motivation/Locus of Control, Social Context, and Perceived Splint Value)* (Table 6.7), one could see that Factor 1 consisted of items that were initially under the domains of *Perceived Splint Value* and *Motivation/Locus of Control*. Factor 2 included items that were initially under three domains: *Perceived Splint Value*, *Motivation/Locus of Control,* and *Social Context.* With the exception of one item, all items that were grouped under Factor 3 corresponded to the initial domain of *Motivation/Locus of control*. Finally, all items under Factor 4 matched with the original grouping of *Social Context*. In light of these results, we concluded that our original theoretical groupings were in some instances too broad. For instance two domains *Motivation/ Locus of Control* and *Perceived Splint Value* were very general. The domain of *Social Context* could be separated in two factors – *Nuisance* and *Social Support*. Given this information, we can suppose that there are more than four underlying factors, however due to the relatively small data set, further factor analysis would not be conclusive based on the current sample size. Using the new grouping, we were able to establish four factor labels: 1-*Preparedness for splint use, 2-Nuisance, 3-Commintment,* and 4- *Social Support* (Table 6.6).

Next, four items with factor correlations of >0.7 were tagged for elimination due to redundancies (Items 10, 24, 30, 37). For example, item 30 was eliminated because of its similarity with Item 13 (*30-Wearing a splint will help me complete activities with less pain* vs. *13-I believe that a*

splint will help me function better) (Table 6.9). The wording of any item with a factor loading ≤0.5 was reviewed given that items with values of factor loading of ≤0.5 relative to other items might not fit well with the factor solution[19,20]. Three items were tagged for potential elimination (items 6, 14, 17) based on this criteria.

Strategy 2- Comparing items to the themes from the Social Network discussion:

The responses on the social network site to the question *"Arthritis is unacceptable because _____?"(*Table 6.8) –were compared to the items of the RA-SAM with the intention of verifying whether the items capture the important themes. . One of the recurrent themes was pain: "*arthritis hurts physically and emotionally*", "*arthritis is incredibly painful*", "*it hurts like hell*". Some individuals mentioned that arthritis makes them feel "*old*" or "*grumpy*". Many expressed the feeling of not being understood by others: "*other people do not even try to understand*", "*the fights with my husband have increased. He says I do not understand his side…*", "*nobody believes how bad it hurts*". In addition, the theme of major life changes was frequently mentioned: "*arthritis steals life*", *"my life will never be the same"*, *"arthritis is a thief that steals the quality of our lives", "because of arthritis, the beautiful ballerina does not dance anymore"*. Furthermore, through numerous comments people expressed their frustration with the early onset of the disease and its impact on function and productivity: "*I am only 34 years old, single mom, and about to lose my house because I cannot work due to arthritis*", "*arthritis stole the best years of my life…*", "*I have RA diagnosed at 29; it has robbed me of many dreams*", "*I can no longer do 70% of activities I used to do. I just turned 34*". In addition, in many comments a feeling of guilt towards family was evident: *"… the work gets the best of me and my family and home get that what little is left over"*, "*Arthritis steals the fun part of me from my sweet girls! They deserve a mommy that can run and play*". Despite the expressed difficulties, pain and loss of function, a

theme of fighting the disease and taking control over the situation was perceived: "*I will not let it win*", "*I refuse to let the disease take over my life; I am still the same person. I am not the disease!*", "*With my arthritis, I still was able to have my most precious one come true, a beautiful little boy. Ha RA, take that!*", "*you do not have a choice of getting it, but you have a choice in how you react to it*".

Based on the accumulation of evidence against items completed through the multistep process described above, 10 items were eliminated and several were rephrased. Two new items (item 11 and 30) were added under the *Commitment* domain (Table 6.10). The final version of the RA-SAM readied for further testing consists of 30 items allocated under 4 domains. The domain of *Preparedness for splint use* incorporates 12 items, *Nuisance* – 7 items *Commitment* - 7, and *Social support* – 4 (Table 6.10).

DISCUSSION

The provision of a wrist splint is an important component of RA management[22]. Functional hand splints (custom-made or prefabricated) have been shown to be effective in reducing wrist joint pain and inflammation, and in minimizing the workload of the affected joint, with the added benefit of allowing the affected joint to rest[5,7,8,9,23]. Despite the evidence of the usefulness and beneficial effects of splints, clinicians frequently cite poor adherence[7,24,25,26] with studies showing adherence ranging from 25% to 60-70%[7,27, 33].

The preliminary 38-item version of the *Rheumatoid Arthritis Splint Adherence Measure (RA-SAM*) has been developed based on an extensive review of published literature on adherence

along with consultation with expert clinicians and clients with RA (addressed in the first manuscript). This paper describes the process of refinement and content validation.

It should be noted that an additional strategy that was not initially planned was used as part of the content validation process when we came across a social media discussion - "*Arthritis is unacceptable because ____?*" posted by the Arthritis Foundation. Interestingly, despite the fact that this discussion was not about wearing splints in particular, most of the themes were covered in the focus groups conducted during the theme identification stage[13], and were reflected directly or indirectly in the RA-SAM items. Reviewing these comments helped us to better understand the difficulties that individuals with RA face in their daily life. Thus, based on the accumulation of information from all available sources including comments of participants, comparison of the English and French items, factor analysis, and review of the posted comments, the *RA-SAM* was reworked and refined.

The latest version consists of 30 items allocated under four domains – *Preparedness for splint use, Nuisance, Commitment,* and *Social support.* The measure is scored on a 0 to 10 scale, where 0 indicates "*strongly disagree*" – and 10 indicates "*strongly agree*". An 11-point scale has been validated for use in studies of chronic medical illness[28,29,30]**.**

Overall the RA-SAM demonstrates adequate content validity, representing all facets of adherence readiness. However, further psychometric testing is warranted. Specifically, as we go forward we will need to test its predictive validity in identifying adherence issues, in individuals with RA who are prescribed a splint.

LIMITATIONS

The study has limitations. First, using a dual recruitment strategy increased our recruitment opportunities and increased our ability to have individuals with varying degrees of severity of RA but, limited our ability to verify through medical dossiers whether participants indeed had RA. Therefore, the recruited participants might have included some individuals with as yet unconfirmed RA. Our assumption was that the participants who did not have RA would answer "*not applicable*" to the questions specific to RA on the RA-SAM. These items were eliminated for the factor analysis.

Second, a larger sample would be more suitable for further factor analysis since the results would provide more precise estimates of population loadings and would be more stable, or less variable, across repeated sampling.

CONCLUSION

This study has resulted in the development of a 30-item readiness measure - the *Rheumatoid Arthritis Splint Adherence Measure (RA-SAM)* that has undergone rigorous item creation and refinement and as such is ready for further psychometric testing.

FUTURE DIRECTIONS

The various phases have provided knowledge about splint use adherence readiness leading to creation of a new measure - the *Rheumatoid Arthritis Splint Adherence Measure (RA-SAM)*. In future studies it will be important to test the predictive validity of this measure to better understand its ability to identify individuals who are at high versus low likelihood of adhering to

splint use. As splints are often provided to an individual who is newly diagnosed with RA and has never used a splint before, we anticipate that this individual will be at the stage of *pre-contemplation, contemplation,* or *preparation*. Thus, the use of RA-SAM will help in identification of the individual's "stage of change", enabling implementation of an adherence intervention that is congruent with the individual's readiness level and adapted to their specific needs. We are currently building the structure of this intervention specifically, a RA Splint Readiness Knowledge Translation (KT) Kit consisting of "helpful guidelines" for clinicians to enhance wrist splint adherence. To elucidate, the KT kit is envisioned to include a web-based information page and user-friendly bookmarks with the RA-SAM on one side and a recto side with suggestions for increasing adherence presented in a bulleted "hints for maximizing adherence". A web-based information page is intended to increase understanding by individuals with RA and their family and friends about their condition, and reasons for wearing splints. The knowledge accumulated from the literature review and focus groups about the factors related to use and abandonment of functional hand splint, will help us to build this knowledge translation strategy. The KT strategy will be structured using the stages of behavior change indentified by the Transtheoretical model (TTM). This model describes the change of the health behaviour through six stages: *pre-contemplation, contemplation, preparation, action, maintenance,* and *termination*. The identification of an individual's "stage" can facilitate in adapting the intervention to the individual's needs in the most appropriate way. ([31].

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TABLES

Table 6.1: Characteristics of individuals who participated in pilot testing

Characteristics	**N = 82 n (%)**
English Speakers	43 (52.5)
Gender (female)	50 (63)
Average age	43.7 (SD=15.1)
18-29	13 (16)
30-39	23 (28)
40-49	20 (24)
50-59	14 (17)
60+	12 (15)
Splint use in past (yes)	29 (35)

SD –Standard deviation

Table 6.2: Factor Analysis: Descriptive Statistics

	Mean	Std. Deviation	Analysis N	Missing N
q1	4.27	3.249	79	3
q2	8.55	2.055	78	4
q3	7.99	2.574	79	3
q4	8.40	2.132	80	2
q5	8.01	2.097	79	3
q6	5.13	3.148	80	2
q7	8.90	1.357	81	1
q8	9.05	1.176	79	3
q9	8.68	1.653	79	3
q10	8.40	2.146	78	4
q11	7.27	2.586	79	3
q12	7.90	2.302	79	3
q13	7.88	2.095	80	2
q14	2.92	2.975	78	4
q15	7.68	2.425	78	4
q16	7.90	2.409	77	5
q17	6.27	3.560	77	5
q18	4.73	3.519	78	4
q19	8.65	2.213	79	3
q20	2.73	3.442	80	2
q21	8.57	2.035	76	6
q22	7.11	2.735	76	6
q23	7.39	2.498	77	5
q24	7.22	2.716	76	6
q25	7.79	2.630	78	4
q26	8.29	2.128	76	6
q27	7.89	2.287	79	3
q28	7.74	2.029	78	4
q29	6.24	3.163	79	3
q30	7.88	2.045	77	5
q31	5.22	3.507	79	3
q32	4.31	3.200	78	4
q33	4.17	3.147	77	5
q34	4.82	3.381	79	3
q35	4.77	3.049	78	4
q36	7.40	2.365	78	4
q37	8.04	2.242	78	4
q38	6.45	2.868	76	6

Mean - The means of participants' responses for 38 items used in the factor analysis.
Std. Deviation - Standard deviations of the 38 items used in the factor analysis.
Analysis N – The number of cases used in the factor analysis. "Not applicable" responses were not includes in the analysis
Missing N - The number of "Not applicable" responses that was not included in factor analysis.

Table 6.3: Factor Analysis: KMO and Bartlett's Test

Kaiser-Meyer-Olkin Measure of Sampling Adequacy.		.609
Bartlett's Test of Sphericity	*Approx. Chi-Square*	1972.885
	df	703
	Sig.	.000

Table 6.4: Factor Analysis: Communalities

	Initial	Extraction
q1	.755	.435
q2	.827	.730
q3	.831	.777
q4	.760	.560
q5	.817	.725
q6	.573	.142
q7	.864	.348
q8	.900	.517
q9	.820	.318
q10	.871	.620
q11	.842	.501
q12	.845	.584
q13	.846	.581
q14	.643	.079
q15	.843	.555
q16	.753	.385
q17	.706	.121
q18	.845	.507
q19	.727	.130
q20	.502	.038
q21	.842	.473
q22	.918	.727
q23	.961	.894
q24	.926	.675
q25	.705	.370
q26	.623	.106
q27	.816	.347
q28	.883	.509
q29	.682	.225
q30	.880	.664
q31	.854	.612
q32	.859	.349
q33	.881	.409
q34	.778	.485
q35	.777	.441
q36	.877	.324
q37	.880	.514
q38	.648	.263

Extraction Method: Principal Axis Factoring.
Initial communalities: are estimates of the variance in each item accounted for by all factors.
Extraction communalities: are estimates of the variance in each item accounted for by the factors in the factor solution.

Table 6.5: Factor Analysis: Total Variance Explained

	Initial Eigenvalues			Extraction Sums of Squared Loadings		
Factor	Total	% of Variance	Cumulative %	Total	% of Variance	Cumulative %
1	8.979	23.629	23.629	8.520	22.420	22.420
2	4.207	11.072	34.702	3.690	9.709	32.129
3	3.077	8.099	42.800	2.688	7.075	39.204
4	2.612	6.873	49.673	2.144	5.642	44.846
5	2.100	5.527	55.200			
6	1.721	4.529	59.729			
7	1.595	4.198	63.927			
8	1.517	3.993	67.920			
9	1.228	3.231	71.151			
10	1.157	3.045	74.196			
11	1.018	2.680	76.876			
12	.947	2.491	79.367			
13	.867	2.283	81.649			
14	.793	2.088	83.737			
15	.694	1.826	85.563			
16	.642	1.690	87.253			
17	.577	1.519	88.772			
18	.511	1.346	90.118			
19	.458	1.206	91.324			
20	.408	1.072	92.396			
21	.386	1.017	93.413			
22	.330	.867	94.281			
23	.310	.817	95.097			
24	.271	.712	95.809			
25	.244	.643	96.452			
26	.230	.604	97.056			
27	.195	.514	97.571			
28	.170	.447	98.017			
29	.152	.401	98.418			
30	.122	.321	98.739			
31	.103	.271	99.010			
32	.090	.236	99.246			
33	.083	.219	99.465			
34	.066	.174	99.638			
35	.054	.142	99.781			
36	.035	.093	99.873			
37	.027	.070	99.943			
38	.021	.057	100.000			

Extraction Method: Principal Axis Factoring.
Factor- The initial number of factors is the same as the number of items used in the factor analysis.
Initial Eigenvalues - are the variances of the factors; **Total** – eigenvalues; **% of Variance** - total variance accounted for by each factor.
Cumulative % - cumulative percentage of variance accounted for by the current and all preceding factors
Extraction Sums of Squared Loadings - The number of rows in this panel of the table correspond to the number of factors retained. Four factors were retained. The values in this panel of the table are calculated in the same way as the values in the left panel, except that here the values are based on the common variance.

Table 6.6: Factor Analysis: Rotated Component Matrix

Item	Factor			
	Preparedness for splint use	Nuisance	Commitment	Social support
q30	.789			
q10	.773			
q13	.739			
q37	.709			
q28	.701			
q12	.697		.278	
q15	.688	-.279		
q8	.668			
q16	.612			
q9	.552			
q21	.537	-.291	.289	
q27	.529	-.256		
q7	.520			
q36	.516			
q38	.462			
q19				
q26				
q31	.252	.732		
q34		.682		
q18		.675		
q1		.635		
q35		.625		
q33		.534	.285	
q32		.516	.260	
q29	.319	.346		
q17		.300		
q24			.779	
q23	.495		.777	
q22	.376		.706	
q11	.408		.538	
q25		.311	.517	
q6			.329	
q14			.263	
q3				.869
q2				.828
q5				.806
q4				.708
q20				

Extraction Method: Principal Axis Factoring.
Rotation Method: Varimax with Kaiser Normalization.
Rotated Factor Matrix - This table contains the rotated factor loadings, which are the correlations between the items and the factor. To make the output easier to read the option blank (-.25)
Factor- Four factors were extracted
***4 factors extracted. Rotation converged in 6 iterations.

Table 6.7: Comparison of hypothesized factors and those identified using factor analysis

Item #	Item	Factors	Initial factor grouping
7	In general, I follow the instructions of my doctors	Factor 1	Health care context
8	In general, I follow the instructions of my therapists	Factor 1	Health care context
9	I feel that wearing a splint will help my arthritis	Factor 1	Perceived splint value
10	I am willing to start wearing a splint as soon as possible	Factor 1	Motivation / locus of control
12	I am confident that wearing a splint will help with my pain	Factor 1	Perceived splint value
13	I believe that a splint will help me function better	Factor 1	Perceived splint value
15	I feel ready to wear a splint	Factor 1	Motivation / locus of control
16	I will take the necessary time to learn how to do my daily activities with a splint	Factor 1	Motivation / locus of control
21	If necessary, I will wear a splint at work	Factor 1	Motivation / locus of control
27	Wearing a splint will help me rest my hands	Factor 1	Perceived splint value
28	Wearing a splint will reduce swelling in my hands	Factor 1	Perceived splint value
30	Wearing a splint will help me complete activities with less pain	Factor 1	Perceived splint value
36	I will wear a splint even if I have to take it off frequently to do my daily activities	Factor 1	Motivation / locus of control
37	I will try to do as many activities as possible with a splint on because it protects my hands	Factor 1	Motivation / locus of control
38	Wearing a hand splint will make it easier for me to perform many of my activities	Factor 1	Perceived splint value
1	Many things prevent me from wearing a splint	Factor 2	Motivation / locus of control
6	I believe that I will lose use of my hands if I do not wear a splint	Factor 2	Perceived splint value
17	I will wear a splint only if I feel that it is helping me	Factor 2	Motivation / locus of control
18	I think it is awkward wearing a splint in public	Factor 2	Social context
29	The look of a splint is very important to me	Factor 2	Social context
31	Wearing a splint will attract undesirable attention of others	Factor 2	Social context
32	Wearing a splint will make my hands stiff	Factor 2	Perceived splint value
33	Wearing a splint will make my hands weaker	Factor 2	Perceived splint value
34	Wearing a splint will make me look sick or disabled	Factor 2	Social context
35	No matter what I do, the symptoms of my arthritis will get worse with time	Factor 2	Motivation / locus of control
11	I will wear a splint as much as possible even if it interferes with some of my daily activities	Factor 3	Motivation / locus of control
14	No matter what I do, my arthritis will be cured with time	Factor 3	Motivation / locus of control
22	I will wear a splint for my daily activities even if I find it irritating to wear	Factor 3	Motivation / locus of control
23	I will wear a splint for my daily activities even if it slows me down	Factor 3	Motivation / locus of control
24	I will persist in wearing a splint even if it takes more effort to complete my daily activities	Factor 3	Motivation / locus of control
25	I feel that some activities will be more difficult to complete with a splint on	Factor 3	Perceived splint value
26	My arthritis is a serious problem in my life	Factor 3	Motivation / locus of control
2	People important to me support me in my illness	Factor 4	Social context
3	People important to me offer help with my household duties	Factor 4	Social context
4	I can speak freely with people important to me about my arthritis	Factor 4	Social context
5	People important to me understand how difficult it is for me to perform my daily activities	Factor 4	Social context

Table 6.8: "*Arthritis is unacceptable because ___?* " - Social media discussion posted by the Arthritis Network on October 26 2011 *(*The names of the participants were hidden for the privacy reasons)

Arthritis is unacceptable because _____?
Participant-1: *it has stolen my life. Most people don't understand the daily challenges that I have. And knowing that it will only continue to get worse makes me very sad.* October 26 at 3:34pm • 4
Participant-2: *it hurts AND makes me grumpy and I don't like that.* October 26 at 3:38pm • 2
Participant-3: *Although I am grateful I can still work, it is unacceptable that work gets the best of me and my family and home get what little is left over.* October 26 at 3:48pm • 3
Participant-4: *other people don't even try to understand.* **October 26 at 4:07pm • 2**
Participant-5: *It stole the best years of my life... I was 32 years old with a new 6 month old baby.* October 26 at 4:19pm • 1
Participant-6: *It steals life. My artificial shoulder doesn't even allow me to raise my arm to praise my Lord!* October 26 at 4:24pm • 2
Participant-7: *It stops me being able to do normal things with my children :(* October 26 at 4:31pm • 2
Participant-8: *Because it limits what I can do, but I will not let it win!! I take one day at a time and keep a positive outlook on life.* October 26 at 4:50pm • 1
Participant-9: *It makes me feel old before my time.* October 26 at 5:06pm • 2
Participant-10: *It steals the fun parts of me from my sweet girls! They deserve a mommy that can run and play and throw them in he air!* October 26 at 5:12pm • 1
Participant-11: *it steals your life!* October 26 at 5:35pm • 2
Participant-12: *life is fun. no more RA with Hydrotherapy Benefits.* October 26 at 5:36pm
Participant-14: *You don't have a choice in getting it but you have a choice in how you react to it.* October 26 at 5:38pm • 3

Participant-15: *It makes my best friend hurt,but she has not let it kick her a$$. Renee is my hero!!!!!* October 26 at 5:43pm • 2
Participant-16: *it is very expensive physically, finacially and emotionally!* October 26 at 5:47pm • 5
Participant-17: *Incredibly painful.* October 26 at 5:47pm • 3
Participant-18: *no child should have to suffer from it everyday!* October 26 at 5:54pm • 3
Participant-19*: life will never be the same.* October 26 at 5:57pm • 2
Participant-20: *because it tries to take over what I can and cannot do, but I refused to let it!* October 26 at 6:03pm • 1
Participant-21:...*it has hurt so many of my family members! From 10 years old to 70 years old! It can take the life out of the living :(* October 26 at 6:07pm • 1
Participant-22: *Painful & meds side affects are scary,makes life hard.* October 26 at 6:19pm • 3
Participant-23: *I cannot do the things I used to do. It's embarrassing when I'm around other ppl because I'm constantly in pain which makes me look grumpy. I hate this and ppl don't understand how much pain your in all the time.* October 26 at 6:23pm • 4
Participant-24: *The fights with my husband have increased. He says I don't understand his side and I act like I'm the only one with the disease.* October 26 at 6:46pm • 1
Participant-25: *because a beautiful ballerina doesn't dance anymore.* October 26 at 6:52pm • 1
Participant-26*: it has forever altered my life at age 33.* October 26 at 7:19pm • 1
Participant-27: *Its difficult to explain.* October 26 at 7:22pm • 1
Participant-28: *Of the pain.* October 26 at 7:46pm • 1

Participant-29: *People do don't have it have absolutely no clue how much it hurts physically and emotionally.* October 26 at 8:18pm
Participant-30: *it is a thief that steals the quality of our lives.* October 26 at 8:23pm
Participant-31: *... Of it I have to give my baby a shot every week and he doesn't know why! (JIA mom, son dx @ 18mo old)* October 26 at 8:41pm
Participant-32: *Because no one should have to go through the nightmare of a roller coaster ride that never ends, physical and emotional. And people who don't have it, don't understand how draining it can be in both ways. I have RA, diagnosed at 29, now 35. It has robbed me of many dreams, but I still was able to have my most precious one come true, a beautiful little boy, now 3 1/2:) Ha RA, take that!* October 26 at 8:53pm
Participant-33: *I have seen and lived with my wife who suffers from this disease, pain crises it has suffered, has had surgeries on his hip, ankle, neck, fractured femur and tibia and fibula, in addition to suffering and pain a little of osteporosis, but this i want a cure for mi wife for the other people.* October 26 at 9:09pm
Participant-34: *have to do something for children to stop living with pain, our adults, and those who suffer from this disease.* October 26 at 9:12pm
Participant-35: ******I am only 34 years old, single mom and about to lose my house because I can't work due to arthritis and other medical issues, get the run around from doctors, feel like nobody believes how bad I hurt and waiting many many months on disability hearing!* October 26 at 10:51pm • 1
Participant-36: *it bloody hutrs!* October 27 at 1:56am
Participant-37: *the Government says so!!* October 27 at 2:36am
Participant-38: *it has stolen my husband's profession from him, attacked his entire body and left him with chronic pain, and prevented him and our son from playing catch and riding bicycles together. It is evil.* October 27 at 4:11am • 1
Participant-39: *It affects your life in so many ways, both good and mostly bad.* October 27 at 5:30am
Participant-40: ***it hurts*** October 27 at 10:11am

Participant-41: *Arthritis is unacceptable because I am too busy being an active single woman to deal with it's childish antics. It will sit in the corner crying before I indulge & let it whine & tug at my shirt.* October 27 at 3:33pm
Participant-42: *Because as the weather changes, so does the amount of pain I deal with....three weeks of pain in my hand, knees not feeling so good, good days and bad....but I keep on, keeping on :)* October 27 at 5:37pm
Participant-43: *A 2 year old that can't even say it ,shouldn't have to suffer from it* October 27 at 9:02pm • 1
Participant-44: *it ruthlessly robbed me of my mobility and life as I knew it at age 36...and I agree with everyone else...no one understands the disease and the impact of the pain. It just sucks!* October 27 at 11:46pm
Participant-45: *the amount of painkillers we should consume to alleviate the pain :(* October 28 at 7:02am
Participant-46: *I can't run or take long walks with my stepdaughter* October 28 at 6:27pm
Participant-47: *it hurts like hell* October 29 at 6:31am
Participant-48: *My doctor has found multiple RA diagnosed patients that come up positive for Lyme disease. I plead worth all of you to find a Lyme literate doctor and get tested. I found out I had chronic Lyme almost two years ago, my life has changed foo...See More* October 30 at 10:06pm
Participant-49: *I can no longer do 70% of activities i use to do. I just turned 34* November 3 at 1:35pm

Table 6.9: Preliminary 38-item version of the *Rheumatoid Arthritis Splint Adherence Measure (RA-SAM)* (used for pre-testing)

Item #	*English Version*	*French Version*
1	*Many things prevent me from wearing a splint*	*Plusieurs facteurs m'empêchent de porter une orthèse*
2	*People important to me support me in my illness*	*Mes proches me soutiennent dans ma maladie*
3	*People important to me offer help with my household duties*	*Mes proches m'aident avec mes tâches ménagères*
4	*I can speak freely with people important to me about my arthritis*	*Je peux parler ouvertement de mon arthrite avec mes proches*
5	*People important to me understand how difficult it is for me to perform my daily activities*	*Mes proches comprennent à quel point il est difficile pour moi de compléter mes activités quotidiennes*
6	*I believe that I will lose use of my hands if I do not wear a splint*	*Je crois que je perdrai l'usage de mes mains si je ne porte pas une orthèse*
7	*In general, I follow the instructions of my doctors*	*En règle générale, je suis les instructions de mes médecins*
8	*In general, I follow the instructions of my therapists*	*En règle générale, je suis les instructions de mes thérapeutes*
9	*I feel that wearing a splint will help my arthritis*	*Je pense que le port d'orthèse va m'aider*
10	*I am willing to start wearing a splint as soon as possible*	*J'ai bien l'intention de porter une orthèse le plus tôt possible*
11	*I will wear a splint as much as possible even if it interferes with some of my daily activities*	*Je porterai une orthèse le plus souvent possible même si cela entrave certaines de mes activités quotidiennes*
12	*I am confident that wearing a splint will help with my pain*	*Je suis confiant que le port d'orthèse diminuera ma douleur*
13	*I believe that a splint will help me function better*	*Je crois qu'une orthèse me permettra de mieux fonctionner*
14	*No matter what I do, my arthritis will be cured with time*	*Peu importe ce que je fais, mon arthrite sera guérie avec le temps*
15	*I feel ready to wear a splint*	*Je me sens prêt à porter une orthèse*
16	*I will take the necessary time to learn how to do my daily activities with a splint*	*Je prendrai le temps nécessaire pour apprendre à faire mes activités avec une orthèse*
17	*I will wear a splint only if I feel that it is helping me*	*Je ne porterai une orthèse que si je vois du progrès*
18	*I think it is awkward wearing a splint in public*	*Je me sens gêné de porter une orthèse en public*
19	*I feel that I can talk to my health care provider if the splint causes discomfort*	*Je peux parler à mon professionnel de santé si l'orthèse n'est pas confortable*
20	*I will wear a splint only when I have pain*	*Je ne porterai une orthèse que si j'ai de la douleur*

21	*If necessary, I will wear a splint at work*	*S'il le faut, je porterai une orthèse au travail*
22	*I will wear a splint for my daily activities even if I find it irritating to wear*	*Je porterai une orthèse durant mes activités quotidiennes, même si je trouve cela irritant*
23	*I will wear a splint for my daily activities even if it slows me down*	*Je porterai une orthèse pendant mes activités quotidiennes, même si cela me ralentit*
24	*I will persist in wearing a splint even if it takes more effort to complete my daily activities*	*Je persisterai à porter une orthèse même si je dois forcer un peu plus pour compléter mes activités*
25	*I feel that some activities will be more difficult to complete with a splint on*	*Je pense que certaines activités seront plus difficiles à compléter avec une orthèse*
26	*My arthritis is a serious problem in my life*	*L'arthrite me pose un sérieux problème*
27	*Wearing a splint will help me rest my hands*	*Le port d'orthèse me permettra de reposer mes mains*
28	*Wearing a splint will reduce swelling in my hands*	*Le port d'orthèse réduira l'enflure dans mes mains*
29	*The look of a splint is very important to me*	*Pour moi, l'allure d'une orthèse est très importante*
30	*Wearing a splint will help me complete activities with less pain*	*Le port d'orthèse me permettra de compléter mes activités avec moins de douleur*
31	*Wearing a splint will attract undesirable attention of others*	*Je ne veux pas attirer d'attention avec le port d'orthèse*
32	*Wearing a splint will make my hands stiff*	*Le port d'orthèse rendra mes mains raides*
33	*Wearing a splint will make my hands weaker*	*Le port d'orthèse rendra mes mains plus faibles*
34	*Wearing a splint will make me look sick or disabled*	*Une orthèse me donnera l'air malade ou handicapé*
35	*No matter what I do, the symptoms of my arthritis will get worse with time*	*Que je me fasse soigner ou pas les symptômes de mon arthrite vont empirer avec le temps*
36	*I will wear a splint even if I have to take it off frequently to do my daily activities*	*Je porterai une orthèse même si je dois l'enlever fréquemment pour faire mes activités quotidiennes*
37	*I will try to do as many activities as possible with a splint on because it protects my hands*	*J'essaierai de porter le plus souvent possible une orthèse car elle protège mes mains*
38	*Wearing a hand splint will make it easier for me to perform many of my activities*	*Le port d'orthèse rendra plus faciles la plupart de mes activités*

Table 6.10: Final 30-item version of the Rheumatoid Arthritis Splint Adherence Measure (RA-SAM*)*

Item #	***English Version***	***French Version***
1	*Friends and family support me in my illness*	*Mes proches me soutiennent dans ma maladie*
2	*Friends and family are there for me if I need help with household tasks*	*En cas de besoin, mes proches sont là pour m'aider dans les tâches ménagères*
3	*I can speak freely about my arthritis with friends and family*	*Je peux parler ouvertement de mon arthrite avec mes proches*
4	*Friends and family understand how difficult it is for me to do my daily activities*	*Mes proches comprennent combien il est difficile de faire mes activités quotidiennes*
5	*Wearing a splint in public will make me feel uncomfortable*	*Le port d'orthèse en public me mettra mal à l'aise*
6	*Wearing a splint will attract undesirable attention*	*Le port d'orthèse m'attirera une attention indésirable*
7	*The appearance of a splint is very important to me*	*L'apparence d'une orthèse m'est très importante*
8	*Wearing a splint will make me look sick*	*Le port d'orthèse me donnera l'air malade*
9	*In general, I follow recommendations of my health care providers*	*En général, je suis les recommandations de mes professionnels de la santé*
10	*With or without treatment, the symptoms of my arthritis will get worse with time*	*Que je me fasse soigner ou pas mes symptômes d'arthrite vont empirer avec le temps*
11	*I believe that education about arthritis will influence my splint wear*	*Je crois que l'éducation sur l'arthrite m'influencera quant au port d'orthèse*
12	*It is important that I can talk openly to my health care provider about my arthritis*	*Il est important que je puisse discuter ouvertement de mon arthrite avec mon professionnel de la santé*
13	*Wearing a splint will help me*	*Le port d'orthèse va m'aider*
14	*Wearing a splint will help reduce my pain*	*Le port d'orthèse soulagera ma douleur*
15	*Wearing a hand splint will make it easier for me to perform many of my activities*	*Le port d'orthèse me facilitera plusieurs activités*
16	*If I am in pain, wearing a splint will help me function better*	*En cas de douleur le port d'orthèse m'aidera à mieux fonctionner*
17	*I will wear a splint only if I have pain*	*Je porterai une orthèse seulement si j'ai mal*
18	*Wearing a splint will help me to rest my hand*	*Le port d'orthèse me reposera la main*
19	*Wearing a splint will reduce swelling in my hand*	*Le port d'orthèse réduira l'enflure de ma main*

20	*Wearing a splint will make my hand stiff*	*Le port d'orthèse me rendra la main raide*
21	*Wearing a splint will make my hand weak*	*Le port d'orthèse m'affaiblira la main*
22	*My arthritis is a serious problem that I need to address*	*L'arthrite me pose un sérieux problème auquel je dois faire face*
23	*I feel ready to wear a splint*	*Je me sens prêt à porter une orthèse*
24	*I will do what it takes to learn how to do my daily activities while wearing a splint*	*Je ferai tout mon possible pour apprendre à faire mes activités avec une orthèse*
25	*I will try to do as few activities as possible with a splint on*	*J'essaierai de faire le moins d'activités possible avec une orthèse*
26	*I will wear a splint for daily activities even if it frustrating*	*Je porterai une orthèse pendant les activités quotidiennes, même si c'est frustrant*
27	*I will wear a splint for daily activities even if it slows me down*	*Je porterai une orthèse pendant les activités quotidiennes, même si cela me ralentit*
28	*Some activities will be more difficult to do with a splint on*	*Certaines activités seront plus difficiles à faire avec une orthèse*
29	*I will wear a splint even if I have to put it on and take it off frequently during the day*	*Je porterai une orthèse même si je dois l'enlever et la remettre fréquemment durant la journée*
30	*If my health care provider is competant I will be more motivated to wear my splint*	*Je serai plus motivé à porter mon orthèse si mon professionnel de la santé est compétant*

Figure 6.1: Comparison of English and French versions of the Measure

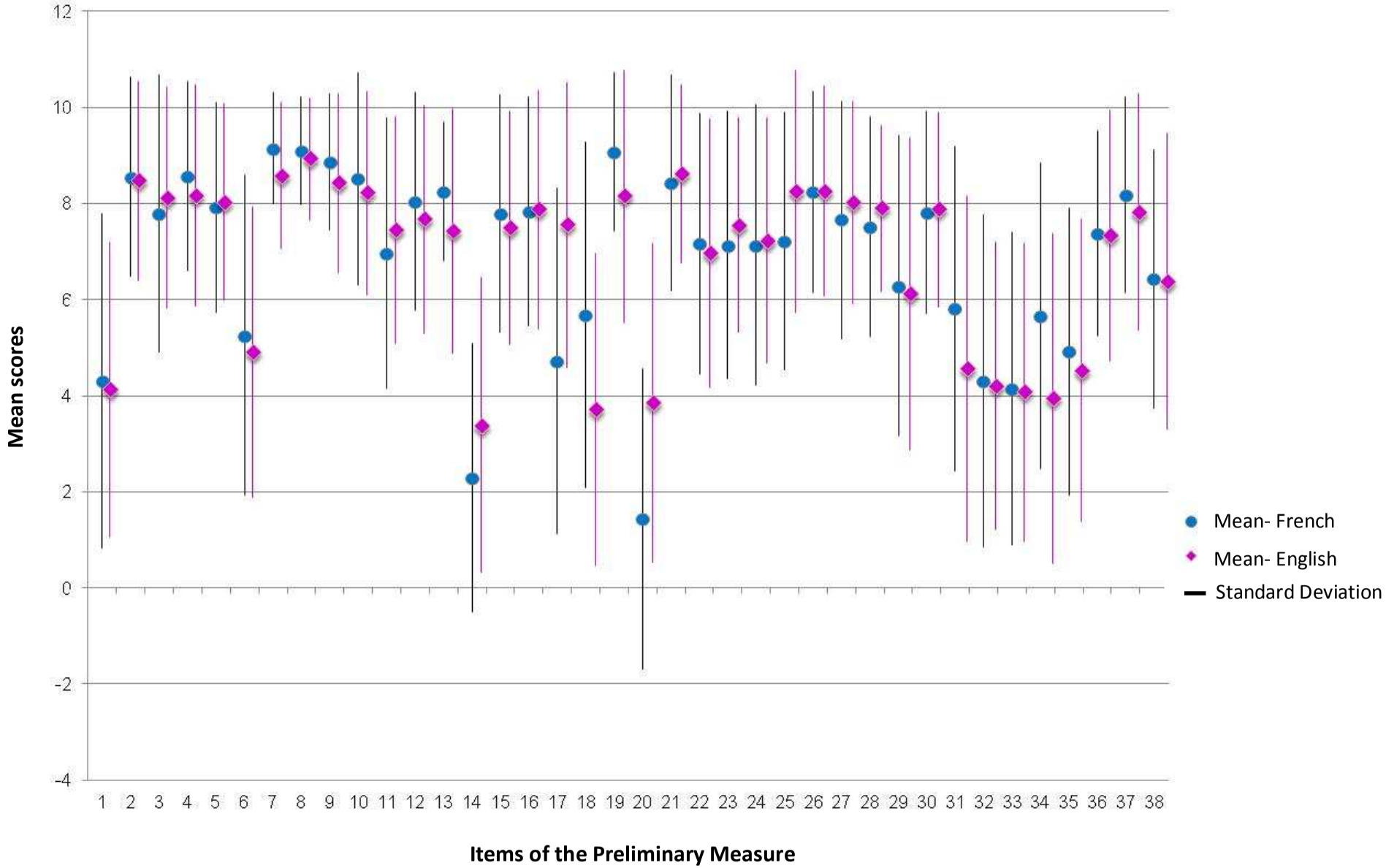
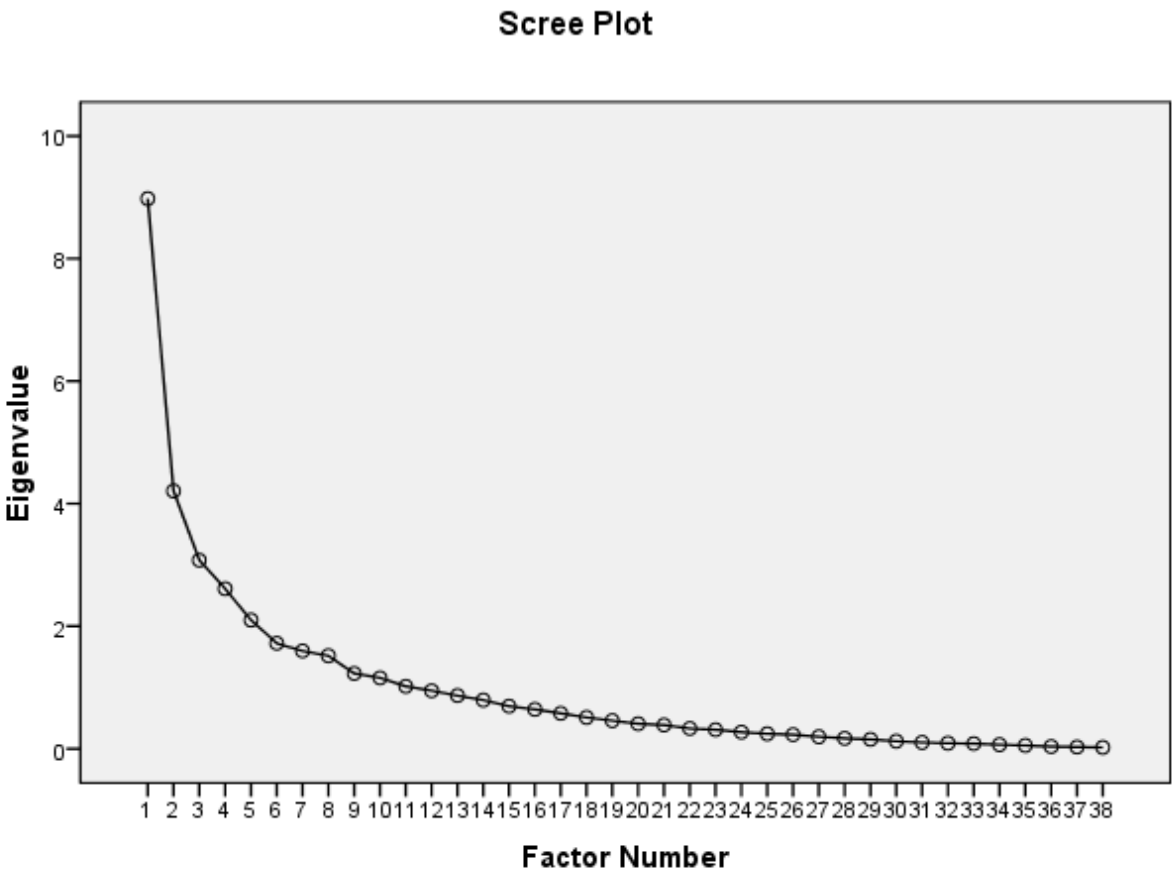


Figure 6.2: Factor extraction by Kaiser criterion and the inflection point in the scree plot for RA-SAM pre-testing



The scree plot graphs the eigenvalue against the item number (1-38). From the 11th item on, the line gradually flattens, meaning the each successive factor is accounting for smaller and smaller amounts of the total variance.

7. THESIS SUMMARY

The results of the studies presented in the two manuscripts offer valuable information for occupational therapists, rehabilitation professionals and researchers working with individuals with RA, especially those who provide or fabricate functional hand splints.

The global objective of the study was to develop a predictive measure, the Rheumatoid Arthritis Splint Adherence Measure (RA-SAM) that evaluates readiness of individuals with RA to use a newly prescribed working splint.

The first manuscript demonstrated the process of theme identification, item generation specific to splint use readiness and the development of the preliminary version of the RA-SAM. The reader was taken through the process of item generation based on an extensive literature review and two focus groups, one with health care professionals and another with individuals with RA. We discussed how the initial version was created by the research team and then reviewed by experts in rheumatology for content, clarity, and pertinence of items. As well we described how the RA-SAM was translated into French.

In Phase-1 (content development), based on the multi-modal stepwise process key themes were identified and tentatively grouped around four domains: *health-care context, motivation/locus of control, social context, and perceived splint value.* The initial version consisted of 45 items and was then circulated among the group of expert clinicians and in the group of patients with RA. Based on comments of participants, it was reduced to a 38-item version that grouped into what we hypothesized were 4 domains (*health-care context, motivation/locus of control, social context, and perceived splint value).* Once the English preliminary version was finalized, the

items were forward-translated into French, spoken in Canada, and then back-translated into English using standardized methodology. Three bilingual clinicians independently evaluated the items for clarity in English and French and examined the items for comparability in meaning and possible cultural differences. Both English and French versions of the measure were deemed appropriate for use in a pilot phase.

The second manuscript addressed the refinement and content validation of the preliminary 38-item measure. The preliminary version of the RA-SAM was pilot tested on 82 individuals (33 participants with RA were recruited through clinicians and 49 - through the Quebec's Arthritis Society (Société de l'arthrite) and Juvenile Rheumatoid Arthritis site.);. Forty-three responded to the English language version and 39 to the French language version. Participants were asked to read the 38 items twice; the first time while reflecting on the clarity of each item so that we could identify redundancies, omissions, unclear questions, and the second time by responding to each question using a 0 to 10 scale. Their responses were reviewed and analyzed by the research team. The comparability of the English and French language version was assessed in terms of similarity in meaning of the items and cultural similarity.

Through a multi-step process 10 items were eliminated and two were added; several were rephrased. The content validity was tested through exploratory factor analysis to identify whether the measure items falling in each of the four proposed domains were indeed measuring that domain. The results of the exploratory factor analysis indicated 35 items with a factor loading equal to or greater than .25, corresponding to 4 factors, explaining 44.8% of total variance. In light of these results, we concluded that our theoretical grouping (*health-care context*, *motivation/locus of control*, *social context*, and *perceived splint value)* was too broad, and there

are more than four underlying factors. Nevertheless, the exploratory factor analysis provided evidence of content validity of the RA-SAM. Based on the accumulated information, final item reduction was performed. Items with questionable measure integrity were identified and tagged for possible rephrasing or removal. The final version of the RA-SAM readied for further testing consists of 30 items grouping under 4 new domains. The domain of *Preparedness for splint use* incorporated 12 items, *Nuisance* – 7 items *Commitment* - 7 items, and *Social support* – 4.

Further psychometric testing of the RA-SAM (including content, construct validity, criterion related validity, predictive validity, and test-retest reliability) was initially planned as part of this thesis. However, the first two phases as completed for the purposes of this dissertation were deemed sufficiently challenging by the graduate committee and protocol review committee.

As such, we are continuing to recruit participants who are receiving a working hand splint for the first time (funding received by the Edith Strauss Knowledge Translation grant (awarded Voznyak et al 2011)). Recruitment is taking place in the two McGill University affiliated teaching sites that have rheumatology departments or rehabilitation departments where splints are provided.

Recruitment has been challenging. Over a six-month period we have successfully identified only 14 individuals referred to occupational therapy, of which 5 had recently been prescribed a working wrist splint. In an attempt to speed up recruitment and better understand the barriers, mid-way through the six month period we used a semi-structured interview to interview three occupational therapists (OT) working with this clientele in three McGill University affiliated teaching centers (two were working in rehabilitation setting, and one in acute setting). According to all, there are very few rheumatologists who currently refer individuals with RA for splinting. It

was their impression that current treatment relies predominantly on medication (analgesics or non-steroidal anti-inflammatory drugs (NSAIDS), disease-modifying anti-rheumatic drug (DMARDS), and biologic agents). All found it difficult to estimate the number of referrals they receive specific for individuals with RA per month. One OT working in the acute settings mentioned "*one month I can have three new patients, while sometimes I may not have referrals for several month*". In addition, it was their impression that those with RA referred to rehabilitation services are not recently diagnosed and most already use a hand splint making them ineligible for our study.

This unexpected dearth of potential participants intrigued us sufficiently and as such we conducted a review of what is currently known about referral patterns in Canada specific to those with arthritis. We postulated that the delayed referrals to occupational therapy might be due to several reasons. For instance, Delaurier (2011) described the trajectories of referral to rheumatology and to rehabilitation services for individuals with arthritis in Quebec[58]. According to typical practices, once a primary care provider suspects symptoms of rheumatoid arthritis, s/he would refer the person to a rheumatologist[58]. The rheumatologist would then provide a diagnosis and start treatment (pharmacological referral to the rehabilitation services including occupational and physical therapy, to the community resources, and/or to the orthopaedic surgery). However, within this referral trajectory multiple delays may take place due to: 1- the waiting time from symptom onset to initial consultation with a primary care provider (27% of the total lag time[59]); 2- the waiting time from primary care provider consultation until referral to rheumatologist and/or rehabilitation services (51% of the total lag time[59]), and 3- the waiting time from referral by primary care provider until rheumatology and rehabilitation consultation. In addition, almost

60% of people with new onset RA are not being seen by a rheumatologist within three months [58]. The study also found that only 26% of the individuals with arthritis (osteoarthritis and rheumatoid arthritis) were given an appointment with a rehabilitation professional (i.e. occupational therapist or physical therapist) within 12 months of referral.

In addition, Lacaille et al. (2005), who used the data of the entire RA cohort in British Columbia, Canada in 1996–2000, determined that only 34% and 48% saw a rheumatologist over 2 and 5 years, respectively[60]. Regarding rehabilitation referrals, Li et al. (2003) found that in Ontario about 26% of individuals with RA are referred for physical therapy and/or occupational therapy after a rheumatologist visit[61]. Altogether – the delay in the referrals, low rates of consultation with rheumatologist and, the low rates of referral to rehabilitation specialists may lead to the situations when individuals with RA either do not receive rehabilitation services at all or often are referred late during the course of the disease. While we did not expect that this was the health service delivery that is now in place in Quebec - or at least in the Montreal area, it appears that the majority of individuals recently diagnosed with RA remain without adequate treatment that includes prescription of splints to reduce pain and provide wrist joint stability.

In conclusion, the results of this study have important clinical relevance. The 30-item readiness measure - *Rheumatoid Arthritis Splint Adherence Measure* (RA-SAM) - was developed and finalised for further psychometric testing. This study has also opened the door to exciting avenues for future research projects aiming to address the predictive validity and test-retest reliability. Furthermore, the results of this study are the foundation for the development of a RA Splint Readiness Knowledge Translation Kit consisting of "helpful guidelines" for clinicians to enhance wrist splint adherence. This study may also have, inadvertently, shed light on a critical

gap in health service delivery – a gap that results in those with newly diagnosed RA not receiving prevention. Given that RA is often characterized by a rapid progression[29,32], and that early destruction of joints results in a serious change in life and work, it is critical to initiate early intervention focusing on reducing pain and inflammation, and on preventing excessive stress on joints in order to slow down the disease progression and control symptoms. Along with other intervention wrist splint should be used since they have been shown to be effective in reducing joint pain and oedema of the surrounding tissue and in minimizing the workload of the affected joint[11,12,13,14].

8. CONCLUSIONS

Although a number of tools have been created to assess readiness to adhere to treatment, there currently exists no "gold standard" to evaluate adherence behaviour for splint usage in individuals with RA. During the course of this study we developed a measure – the *Rheumatoid Arthritis Splint Adherence Measure (RA-SAM)*, that addresses an individual's readiness to adhere to prescribed splint use. By identifying the specific barriers and facilitators linked to use of hand splints, it should be possible for occupational therapists treating individuals with RA to determine key components necessary for improving splint use.

Through a multistep process involving extensive literature review, two focus groups, and content validation of the measure via a pilot testing on 82 individuals, we refined multiple versions leading to a final 30-item English and French version of the RA-SAM. Before it can be used as a predictive measure, further testing will be required to assess the measure's psychometric properties including, predictive validity, criterion related validity, and test-retest reliability. We are currently in the process of recruiting participants for this phase.

The results of this study will now also be used as a foundation for the development of Splint Readiness Knowledge Translation Kit consisting of "helpful hints" to enhance adherence for both clinicians and splint users. More specifically, a web-based information page and user-friendly bookmarks with the RA-SAM on one side and a recto side with suggestions for increasing adherence presented in a bulleted "hints for maximizing adherence". The KT strategy will be structured using the stages of behavior change indentified by the TTM (*pre-contemplation, contemplation, preparation, action, maintenance*, and *termination)*[31].

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10. APPENDIX

Appendix A: Group Discussion Questions

Focus Group Discussion Questions (Health care professionals)

QUESTION 1: *Based on your observations and experience, is there a problem with abandonment (lack of use) of hand splints in people with RA*

QUESTION 2: *In your opinion, what factors explain why some individuals do not use their splints?*

QUESTION 3: *What specific reasons do individuals give you for not wearing their splints?*

QUESTION 4: *In your opinion, what are the factors that explain adherence to splint use? Among your patients, can you tell upfront who will wear their splints and who will not?*

QUESTION 5: *In you experience, do patients have specific expectations when hand splints are provided?*

QUESTION 6: *When you provide an individual with a splint, what do you discuss with him /her regarding the splint wear? If you do not discuss, why not?*

QUESTION 7: *In a literature, several factors related to the adherence were identified. Let's go through some of them, one by one and, please, tell me, based on your experience, how they affect adherence to prescribed splints?*

Factors:

- *Disease severity*
- *Socio-demographic background*
- *Individual's psychological perspectives (level of acceptance of own condition, perception of illness, etc)*
- *Social support*
- *Economic background*
- *Perspectives from a user's point of view (expectations/ anticipation of the beneficial effects)*
- *Job requirements*
- *Factors related to the device (adjustment, aesthetics, etc.)*

QUESTION 8*: In your opinion, what could be done from a system perspective to increase splint wear?*

QUESTION 9: *In your opinion, what could be done from a client/therapist perspective to increase splint wear?*

QUESTION 10: *As a wrap up tonight, is there anything you would like to share that we have not covered?*

Focus Group Discussion Questions (Individuals with RA)

QUESTION 1: *Why do you think hand splints are prescribed?*

QUESTION 2: *What were your expectations when you first received a hand splint?*

QUESTION 3: *What difficulties, if any, did you have the first time – days, weeks – you used a hand splint?*

QUESTION 4: *Speaking about yourself, what do you think are the reasons for wearing hand splint?*

QUESTION 5: *Speaking about yourself, what are the reasons, if any, for not wearing (barriers to wear) hand splints?*

QUESTION 6: *What improvements do you notice when wearing a splint?*

QUESTION 7: *Are there any side effects that you notice when wearing as splint? If so, what are they?*

QUESTION 8*: What details did you discuss with your occupational therapist when you received your hand splint?*

QUESTION 9: *Among the following things, what did influence your adherence to the splint you were prescribed? How did that impact your use or non use of the splint?*

Factors:

- *Disease severity*
- *Level of acceptance of own condition/ perception of illness*
- *Social and family support*
- *Economic situation*
- *Expectations or the beneficial effects*
- *Job requirements*
- *Adjustments of the splint*
- *Look*

QUESTION 10: *In your opinion, what could be done by therapists to improve the splint use?*

QUESTION 11: *As we wrap up tonight, is there anything you would like to share that we have not covered?*

Appendix B: Consent forms

McGill University

Consent to Participate in a Focus Group (Health Care Professionals)

Title of Study: Creation and testing of a measure addressing readiness to adhere to functional hand splint use in people with rheumatoid arthritis.

Dr. Nicol Korner-Bitensky, School of Physical and Occupational Therapy, Faculty of Medicine, McGill University, Tel:(514)398-5457; Marina Voznyak, MSc OT Candidate, Tel:(514)892-1837

What should you in general know about research studies?
You are being asked to take part in a focus group. Your participation is voluntary. Research studies are designed to obtain new knowledge. For a study's findings to be useful, researchers need the participation of people who have information about the subject being investigated.

What is the purpose of this study?
The goal is to identify factors that contribute to the use and abandon of functional wrist splints prescribed to people with rheumatoid arthritis. The information will be used in creating the – Rheumatoid Arthritis Splint Adherence Measure (referred to as the Questionnaire). The purpose of the Questionnaire will be to evaluate a patient's readiness to use a splint. You will be asked questions like: "In your opinion, what are the most bothersome symptoms that influence adherence to hand splint wear?"

How many people will take part in this study?
You will be one of approximately 12 health professionals. The focus group will be held in English and will be conducted in Hosmer House Room 101 at McGill University, Montreal. We are also holding a focus group with individuals with rheumatoid arthritis.

How long will my participation in this focus group last?
You are being asked to attend one focus group lasting 2 to 2.5 hours. A supper will be served. The focus group will take place in the late afternoon on a day that is convenient for you. There is no preparation required prior to the focus group. It is your opinion that we are interested in.

What will be my role in the focus group?
You will discuss factors that in your opinion influence the use or abandon of functional wrist splints. The questions will be directed towards the group and not towards any one participant in particular. You may choose not to answer at any point during the discussion. The group leaders will record comments on a flipchart so that everyone can follow along. They will then read these comments back to make sure that they have correctly recorded comments. With your consent, the group discussions will be recorded so that we can refer back if something is not clear.

What are the possible benefits from being in this focus group?
You may not benefit personally from participating in this study. However, your participation in this focus group will help in the creation of a new Questionnaire for clinical use.

What are the possible risks or discomforts from participating in this focus group?
We do not anticipate any risks or discomforts to you from participating in the focus group. Although we will emphasize the importance of confidentiality and reinforce the need to keep any comments or opinions expressed during the group session inside the focus group, it is possible that participants may repeat some comments and opinions outside of the group.

Will I be able to withdraw from the focus group?
You may withdraw from the focus group for any reason, at any time.

How much does it cost me to participate in this study?
There will be absolutely no costs charged for your participation.

Will I receive any compensation for being in this study?
There will be no monetary compensation. However, a supper will be served.

How will my privacy be protected?
Every effort will be made to protect your identity. No names will be used in any publication of the findings. Also, during the focus group, participants will be referred to by first name only.

What if I have questions about this study?
Should you have any question or concerns, please contact Marina Voznyak by tel. (514) 892-1837 or Dr. Nicol Korner-Bitensky, (514) 398-5457.

What if I have questions about my rights as a research participant?
This study has been reviewed and has received clearance by an ethics committee that works on protecting your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously or not, Ms. Ilde Lepore of the Faculty of Medicine's Institutional Review Board at (514) 398-8302 or by email to ilde.lepore@mcgill.ca.

Participant's Agreement

I,_____, agree to participate in the focus group described above. I give permission to Dr. Nicol Korner-Bitensky and Marina Voznyak to use the information that I provide during the group discussion for the purpose and under the conditions described above. All questions I had have been answered to my satisfaction. I have read and understand the procedures and willingly give my consent to participate.

_____ _____
Participant's Signature Date

_____ _____
Witness Date

I _____ hereby certify that I have explained to _____ the nature of the focus group and that they have the option of withdrawing at any time.

_____ _____
Signature Date

McGill University

Consent to Participate in a Focus Group (Individuals with Rheumatoid Arthritis)

Title of Study: Creation and testing of a Measure addressing readiness to adhere to functional hand splint use in people with rheumatoid arthritis.

Dr. Nicol Korner-Bitensky, School of Physical and Occupational Therapy, Faculty of Medicine, McGill University, Tel:(514)398-5457; Marina Voznyak, MSc OT Candidate, Tel:(514)892-1837

What should you in general know about research studies?
You are being asked to take part in a focus group. Your participation is voluntary. Research studies are designed to obtain new knowledge. For a study's findings to be useful, researchers need the participation of people who have information about the subject being investigated.

What is the purpose of this study?
The goal of this study is to learn some of the causes and reasons that, according to you, contribute to use or non-use of wrist splints. The information will be used in creating the – Rheumatoid Arthritis Splint Adherence Measure (referred to as the Questionnaire). The purpose of the Questionnaire will be to evaluate a patient's readiness to use a splint. You will be asked questions like: Are there any activities in your daily life for which you perceive that a splint might be useful? Another question might be "what are the reasons that you think best explain why people stop wearing a wrist splint"?

How many people will take part in this study?
You will be one of approximately 8 to 10 people with rheumatoid arthritis. The focus group will be held in English and will be conducted in Hosmer House Room 101 at McGill University, Montreal. We are also holding a focus group with health professionals to ask them the same questions we will ask you.

How long will my part in this focus group last?
You are being asked to attend one focus group lasting 2 to 2.5 hours. A supper will be served. The focus group will take place in the late afternoon on a day that is convenient for you. There is no preparation required prior to the focus group. It is your opinion that we are interested in.

What will be my role in the focus group?
You will be asked to discuss your concerns and expectations about splints, to share your perceptions about the splint prescription process, and your satisfaction with splints if you have used them in the past. The questions will be directed towards the group and not towards any one participant in particular. You may choose not to answer at any point during the discussion. The group leaders will record comments on a flipchart so that everyone can follow along. They will then read these comments back to make sure that they have correctly recorded comments. With your consent, the group discussions will be recorded so that we can refer back if something is not clear.

What are the possible benefits from being in this focus group?
You may not benefit personally from participating in this study. However, your participation in this focus group will help in the creation of a new Questionnaire for clinical use.

What are the possible risks or discomforts from participating in this focus group?
We do not anticipate any risks or discomforts to you from participating in the focus group. Although we will emphasize the importance of confidentiality and reinforce the need to keep any comments or opinions expressed during the group session inside the focus group, it is possible that participants may repeat some comments and opinions outside of the group.

Will I be able to withdraw from the focus group?
You may withdraw from the focus group for any reason, at any time.

How much does it cost me to participate in this study?
There will be absolutely no costs charged for your participation.

Will I receive any compensation for being in this study?
There will be no monetary compensation. However, a supper will be served.

How will my privacy be protected?
Every effort will be made to protect your identity. No names will be used in any publication of the findings. Also, during the focus group, participants will be referred to by first name only.

What if I have questions about this study?
Should you have any question or concerns, please contact Marina Voznyak by tel. (514) 892-1837 or Dr. Nicol Korner-Bitensky, (514) 398-5457.

What if I have questions about my rights as a research participant?
This study has been reviewed and has received clearance by an ethics committee that works on protecting your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously or not, Ms. Ilde Lepore of the Faculty of Medicine's Institutional Review Board at (514) 398-8302 or by email to ilde.lepore@mcgill.ca.

Participant's Agreement

I,_____, agree to participate in the focus group described above. I give permission to Dr. Nicol Korner-Bitensky and Marina Voznyak to use the information that I provide during the group discussion for the purpose and under the conditions described above. All questions I had have been answered to my satisfaction. I have read and understand the procedures and willingly give my consent to participate.

_____ _____
Participant's Signature Date

_____ _____
Witness Date

I _____ hereby certify that I have explained to _____ the nature of the focus group and that they have the option of withdrawing at any time.

_____ _____
Signature Date

McGill University │CLRC│ Jewish Rehabilitation Hospital │ Jewish General Hospital

Consent to Participate in Measure Pre-Testing (preliminary validation)

Title of Study: Creation and testing of a measure addressing readiness to adhere to functional hand splint use in people with rheumatoid arthritis.

Dr. Nicol Korner-Bitensky, School of Physical and Occupational Therapy, Faculty of Medicine, McGill University, Tel: (514) 398-5457; Marina Voznyak, MSc OT Candidate, Tel: (514) 892-1837

Introduction

You are being asked to take part in a study because we would like to have your input into a study. Your participation is voluntary. For a study's findings to be useful, researchers need the participation of people like you who have information about the subject being investigated. Details about this study are discussed below.

What is the purpose of this study?

We are interested in evaluating a new measure called the Rheumatoid Arthritis Splint Adherence Measure (RA-SAM) (referred to as the Questionnaire). Specifically, we are interested in your opinion regarding the questions we have created. This questionnaire is designed to help clinicians to determine whether rheumatoid arthritis patients will use a prescribed wrist splint, as well as identify situations where clinicians may need to address concerns or hesitations with the use of a splint. Please note that you do not need to have a wrist splint to participate in this study.

How many people will take part in this study?

We anticipate the participation of approximately 80 individuals with rheumatoid arthritis.

How much time will I commit to this study?

It will take you approximately 20 minutes to complete the Questionnaire and answer questions about what you like and what you do not like about it – for example which questions are not clear and you think need to be clarified. The Questionnaire can be completed either in person, at a place and time that is convenient for you, by e-mail, or sent by post, at your convenience. If you prefer to receive and complete the questionnaire by e-mail or by post, we will ask you to send your feedback by email to Marina Voznyak at marina.voznyak@mail.mcill.ca or by post to Nicol Korner-Bitensky, to School of Physical and Occupational Therapy, 3630 Promenade Sir William Osler Montreal, Quebec, Canada H3G 1Y5

What will be my role?

We will ask you to complete the Questionnaire as honestly as possible. If you don't understand a question or a statement, you will be asked to leave the answer blank and to explain why you left it blank. You will also be asked to provide written comments on questions and statements that you find unclear, redundant, or ambiguous. Based on your opinion and those of other participants, some questions and statements will be eliminated or rephrased.

What are the possible benefits from participating in this study?

You may not directly benefit from participating in this study. Your role in this study will assist the researchers in developing a new questionnaire for future clinical use.

What are the possible risks or discomforts involved from being in this study?

We do not anticipate any risk or discomfort to you from participating in this study.

Will I be able to withdraw from the study?

Participation in this study is voluntary. You can refuse to participate or withdraw your consent to participate at any time.

Are there costs to participating in this study?
There are no costs to you for participating in the study.

Will I receive any compensation for being in this study?
You will receive no compensation for participating in the study.

How will my privacy be protected?
All data will be kept completely confidential. There will be no identifying information used (i.e. names) that will link you to your answers. Your name will not be identified in any report or publication or presentation of this study's findings. The information obtained during this study will be kept confidential in a locked desk/cabinet at the office of the principal study investigator. Information kept on a computer will be protected by a password. Once the study has been completed, and the final report has been written, the data will be destroyed. The Institutional Review Board of McGill University may also access the study data to ensure the ethical conduct of this study.

What if I have questions about this study?
Should you have any question or concerns, please contact Marina Voznyak by tel. (514) 892-1837 or Dr. Nicol Korner-Bitensky, (514) 398-5457.

What if I have questions about my rights as a research participant?
This study has been reviewed and has received clearance by an ethics committee that works on protecting your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously or not, Ms. Ilde Lepore of the Faculty of Medicine's Institutional Review Board at (514) 398-8302 or by email to ilde.lepore@mcgill.ca and Anik Nolet, Research Ethics Co-ordinator for the CRIR'S Institutions at (514) 527-4527 extension 2649 or by e-mail anolet.crir@ssss.gouv.qc.ca.
Responsibility clause
While agreeing to participate in this study, I do not give up any of my legal rights nor release the researchers, sponsors or institutions involved of their legal and professional obligations

Participant's Agreement
I,_____, agree to participate in the study described above. I give permission to Dr. Nicol Korner-Bitensky and Marina Voznyak to use the information that I provide in the questionnaire for the purpose and under the conditions described above. I do not waive my legal rights by signing this consent form. I will receive a copy of this consent form for my records. All questions that I had have been answered to my satisfaction. I have read and understand the procedures and willingly give my consent to participate.

_____ _____
Participant's Signature Date

_____ _____
Witness Date

I _____ hereby certify that I have explained to _____ the nature of the study and the benefits and known risks of taking part in the study, and that they have the option of withdrawing from the study at any time.

_____ _____
Signature Date

Université McGill │CRCL│ Hôpital Juif de Réadaptation │ Hôpital Juif Général

Formulaire de consentement: pré-test de questionnaire (validation préliminaire)

Titre d'étude: Création et test d'une mesure portant sur la volonté d'adhérer à l'utilisation d'orthèses de main fonctionnelles chez les personnes atteintes de polyarthrite rhumatoïde

Nicol Korner-Bitensky, école de physiothérapie et ergothérapie, faculté de médicine, Université McGill, Tel: (514) 398-5457; Marina Voznyak, MSc OT Candidate, Tel: (514) 892-1837

Introduction:

Pour mener à bien une étude scientifique et obtenir des résultats valides et utiles, les chercheurs ont recours à des gens, comme vous, qui détiennent de l'information sur le sujet de recherche. Aujourd'hui, nous nous adressons à vous comme détenteurs d'information clé pour solliciter votre participation à notre projet de recherche. Les détails de notre projet sont décrits ci-après.

But de l'étude

L'étude vise la mise en place et l'évaluation d'un nouveau questionnaire dénommé *Rheumatoid Arthritis Splint Adherence Measure* (RA-SAM) (Questionnaire). Plus précisément, nous aimerions avoir votre avis sur la qualité des questions et des énoncés que nous avons créés. Ce Questionnaire est conçu pour aider les cliniciens à déterminer d'avance si les patients atteints de polyarthrite rhumatoïde utiliseront ou non l'orthèse de main qui leur est prescrite. L'identification d'un risque de non-adhérence permettra aux cliniciens d'aborder les hésitations et/ou les inquiétudes des patients concernant l'utilisation d'orthèses. Veuillez noter que vous n'avez pas besoin d'avoir une orthèse de main pour participer à cette étude.

Combien de personnes vont participer dans cette étude?

Nous comptons sur la participation d'environ 80 personnes atteintes de polyarthrite rhumatoïde.

Combien de temps consacrerai-je à cette étude?

Il vous faudra environ 20 minutes pour remplir le questionnaire et répondre aux questions sur votre appréciation des questions du Questionnaire. Par exemple il vous sera demandé d'identifier les questions qui ne sont pas claires ou d'indiquer les choses qui doivent être clarifiées. Le Questionnaire peut être complété à votre guise, soit en personne, en temps et lieu de votre choix, soit par e-mail, ou vous être envoyé par la poste. Si vous préférez recevoir et remplir le Questionnaire par courrier électronique ou par courrier régulier, nous vous demanderons d'envoyer vos commentaires par courriel à Marina Voznyak à marina.voznyak@mail.mcill.ca ou par la poste à Nicol Korner-Bitensky, à École de physiothérapie et d'ergothérapie – 3630, promenade Sir-William-Osler Montréal, Québec, Canada H3G1Y5

Quel sera mon rôle?

Nous vous demanderons de remplir le Questionnaire le plus fidèlement possible à votre propre opinion. Il n'y a pas de bonne ou de mauvaise réponse, il y a seulement votre réponse. Si vous ne comprenez pas une question ou un énoncé et que vous ne pouvez pas y répondre, nous vous demandons de nous donner une explication plutôt que de laisser la question sans réponse. Il vous sera également demandé de fournir des commentaires écrits sur les questions et les énoncés qui vous semblent confus, redondants, ou ambigus. Vos réponses et votre opinion ainsi que celles des autres participants nous aideront à sélectionner ou à reformuler les questions qui répondent le plus exactement possible aux besoins de notre évaluation.

Quels sont les avantages possibles de ma participation dans cette étude?
Vous ne bénéficierez qu'indirectement de votre participation dans cette étude par la satisfaction que vous tirerez de votre contribution à l'avancement de la science. Votre participation aidera les chercheurs à élaborer un nouveau questionnaire pour utilisation dans le milieu clinique, ce qui pourrait avoir un impact positif sur les patients atteints de polyarthrite rhumatoïde.

Quels sont les risques ou inconvénients possibles de ma participation dans cette étude?
Il n'y a pas de risques ou d'inconvénients pour vous associés à votre participation dans cette étude.

Pourrais-je me retirer de cette étude?
La participation dans cette étude est volontaire. Vous pouvez refuser de participer ou retirer votre consentement à participer à tout moment.

Y a t-il des frais associés à ma participation dans cette étude?
Il n'y a pas de frais associés à votre participation dans cette étude.

Est-ce-que je recevrai une rémunération pour ma participation dans cette étude?
Étant donné le peu de moyens financiers que nous avons, nous ne prévoyons aucune compensation pour votre participation à l'étude.

Comment ma vie privée serat-elle protégée?
Toutes les données seront strictement confidentielles. Aucune information liant votre identité à vos réponses ne sera utilisée. Votre nom ne sera identifié dans aucun rapport, publication, ou présentation des résultats de cette étude. Les informations obtenues au cours de cette étude seront gardées de façon sécuritaire et confidentielle par le chercheur principal. Une fois l'étude terminée et le rapport final rédigé, les données seront détruites. Le Comité de Protection des Personnes de l'Université McGill pourrait également accéder aux données d'étude pour assurer une conduite éthique de cette étude.

Que faire si j'ai des questions à propos de cette étude?
Si vous avez des questions, veuillez contacter MarinaVoznyak par tél. (514) 892-1837 ou Nicol Korner-Bitensky à (514) 398-5457.

Que faire si j'ai des questions sur mes droits en tant que participant à la recherche?
Cette étude a été examinée et a reçu l'autorisation du comité d'éthique dont le but est de veiller à la protection de vos droits et de votre bien-être lors des études, auxquelles vous décidez de participer. Si vous avez des questions ou des inquiétudes concernant vos droits en tant que participant à la recherche, vous pouvez contacter, de façon anonyme ou non, Mme Ilde Lepore de Comité de Protection des Personnes de la faculté de médecine au (514) 398-8302 ou par courriel à ilde.lepore @mcgill.ca et Anik Nolet, Coordonnatrice à l'éthique de la recherche des établissements du CRIR, au (514) 527-4527, extension 2649, ou par e-mail anolet.crir@ssss.gouv.qc.ca.

Clause de responsabilité
Tout en acceptant de participer à cette étude, je ne renonce à aucun de mes droits légaux, et je ne soustrais pas non plus les chercheurs, les commanditaires ou les institutions concernées à leurs obligations légales et professionnelles

Consentement du participant

Je,_____, accepte de participer dans l'étude décrite ci-dessus. Je donne mon autorisation à Nicol Korner-Bitensky et Marina Voznyak d'utiliser les informations que je fournis dans le questionnaire dans le but et sous les conditions décrites ci-dessus. Je ne renonce pas à mes droits en signant ce formulaire de consentement. Je recevrai une copie de ce formulaire de consentement pour mes archives. J'ai reçu des réponses satisfaisantes à mes questions. J'ai lu et je comprends les procédures et je donne volontiers mon consentement à participer.

_____ _____
Signature de participant Date

_____ _____
Personne qui a obtenu le consentement Date

Je, _____ certifie avoir expliqué à _____ _____ la nature de l'étude ainsi que les modalités de participation à l'étude. J'ai également notifié au participant son plein droit et la possibilité qu'il a de se retirer de l'étude à tout moment.

_____ _____
Signature Date