Research Project

1. Project Title

The potential role of the "Rheumatoid Arthritis Impact of Disease" score in the management of RA

2. Introduction

2.1. Background

Disease remission, previously a "guiding utopia" in rheumatoid arthritis (RA),(1) has become a frequently achievable goal,(2-5) representing the best possible path to halt joint damage, prevent disability and protect quality of life.(6-13) This remarkable improvement has been made possible by new therapies and treatment strategies,(1) whose development and validation was decisively supported by the establishment of perfected outcome measures.(14, 15)

It is also known that RA impacts patient's lives in a variety of dimensions that are not captured by the most commonly used composite indices, which integrate the patient global assessment (PGA) as the sole Patient Reported Outcome (PRO).(4, 14, 15) Using dedicated instruments to measure all disease dimensions relevant from the patient's perspective could be the solution to this problem. However, their application in clinical practice is problematic because: a) would be extremely time consuming, b) most are not specifically designed for RA, and c) it is difficult to interpret the relative importance of each PRO on the global impact of the disease upon the individual patient.

In order to solve these problems, a task force convened under EULAR auspices proposed the Rheumatoid Arthritis Impact of Disease (RAID) score.(16, 17) It includes 7 numeric rating scales (NRS, one per domain), which are weighted to provide a final score: pain (21%), functional disability (16%), fatigue (15%), emotional well-being (12%), sleep (12%), coping (12%), and physical well-being (12%). It proved to be an feasible, robust and reasonably comprehensive representation of the impact of RA upon patients (16, 17, 18)[1]. At its launch the RAID score was immediately seen as a promise and a considerable step forward in the field (19, 20). However, some concerns have also been raised (17, 19, 20). A research agenda was suggested, which included: a) to assess its usefulness in clinical practice(17), b) to assess its sensitivity to change in larger studies and in intervention studies with a control group,(17, 18) c) to define RAID's cut-offs related with the patient acceptable symptom state (PASS) and with minimal clinically important improvements (MCII)(17); and d) to compare RAID with already-assessed measures (VAS Pain, PGA, HAQ, EQ-5D,…) in RA.(17)

We have felt inspired by the concept that in clinical practice, the global weighted score initially designed, could be substituted with great advantage by considering the seven domains separately. We hypothesise that this strategy can provide the health professional with a clear view of the causes underlying patient dissatisfaction and an opportunity to select appropriate tailored interventions. We, furthermore, hypothesise that, in clinical practice,

[1] Further details about the RAID score are available at the "EULAR Outcome Measures Library" website at http://oml.eular.org/oml_search_results.cfm?action=showResults

the RAID PASS and MCII may (and perhaps should) be designed to tailor the individual patients needs and priorities. RAID will, in this context, surely facilitate a healthier and more effective patient-professional communication and cooperation. With this project we aim to accomplish most of these objectives. In the process, adherent rheumatology departments will benefit both in research and quality of care.

2.2. Preliminary data

Two cross-sectional studies using the RAID score, from two Portuguese centres, were presented at the last symposium of the Portuguese Society for Rheumatology.(21-23) Results indicated that RAID has moderate correlation with the established composite indices of disease activity and also with PROs. It was strongly correlated with PGA (r=0.70) but weakly with PhGA, indicating that the use of RAID in clinical practice may allow capturing a more comprehensive representation of the impact of RA than other scores.(22) Additionally, it was found that disease remission by DAS often did not correspond to a RAID's PASS.(23)

2.3. Hypotheses to be tested

Part I

1. The RAID score is sensitive to changes associated with the amelioration of disease activity obtained through medication
2. The RAID score may reveal significant fluctuations even when the disease activity remains stable
3. The individual items of RAID (RAID7i) will show a differential response to disease activity control and to other (potentially RA-independent) factors (e.g. depression, sleep).

Part II

4. The weights attributed by Portuguese RA patients to the individual items of RAID7i do not differ significantly from the weights attributed in the original studies
5. The PASS and MCII of the RAID score for Portuguese RA patients differs from the PASS and MCII of the RAID score established with French RA patients in the above-mentioned report
6. Values of PASS for RAID and each of its seven items (RAID7i) attributed by individual patients will vary considerably around the population mean
7. Values of PASS for RAID and each of its seven items (RAID7i) attributed by individual patients will be reasonably stable over time

Part III

8. Some items of the RAID7i (sleep, emotional well-being, fatigue, coping and physical well-being) have a weaker relationship with disease activity than others (function, pain)

Part IV

9. When physicians take in consideration the RAID7i instead of solely the RAID global score, in addition to the usual care, they are more prone to introduce therapeutic measures aiming beyond the control of inflammation.

2.4. Potential interest and originality

This project may represent an important progress towards the incorporation of PROs in the current management of RA and, thus, in the much needed implementation of patient centred care: we believe that this is the case not only because RAID gives a more comprehensive view of the overall impact of disease, in comparison with PGA, but especially because the use of its individual items and, eventually, individually tailored scores is totally novel and highly promising.

3. Study objectives

3.1. Primary Objective

To assess the sensitivity of the "Rheumatoid Arthritis Impact of Disease (RAID) score" and its seven items (RAID7i) to changes in disease activity [measured by CDAI, SDAI and DAS28(4v)CRP definition] in people with RA in Portugal.

3.2. Secondary & Exploratory Objectives

The secondary and exploratory objectives of this study are in accordance with the hypothesis listed above, also divided in four parts. In order to avoid repetition we present them in a table together with the statistical analysis (bullet 4.6.)

4. Methodology

4.1. Study design

This is an observational, longitudinal (also with transversal analysis), prospective, pragmatic (current practice), multicentre study (all Portuguese partners will be invited), designed to make use of Reuma.pt. The core study is designed to last for two years: 12 months for recruitment, 6 months for follow-up, 6 months for data analysis and paper writing. Depending on success, we envisage the possibility of continuing this study, with different aims, into the future.

4.2. Population and data collection

The inclusion criteria will be: (1) diagnosis of RA (using the ACR and/or the ACR/EULAR classification criteria),(2) aged 18 years or above, (3) ability to understand and fill the questionnaires unaided, and 4) willingness to sign the informed consent form and to fulfil the questionnaires. The exclusion criteria will be: (1) predictable inability to provide data at 3 and 6 months.

For each partner it is expected that at least 30% of the patients included will have active disease (DAS4vPCR≥3.2) and are about to start an efficient change in medication (GC, CSDMARD, bDMARD).

Patients will be assessed at baseline (first registration into this study), 3 and 6 months. Patient questionnaires will be fulfilled in paper and transposed by local researchers to Reuma.pt, or directly by competent patients in the Reuma.pt website. This second option will be promoted.

Ethical approval was obtained from the Faculty of Medicine from Universidade de Coimbra ethics committee (ref. CE-037/2015). All patients will be asked to sign a written informed consent.

4.3. Variables

The following variables will be collected from the Reuma.pt database:

- Sociodemografic variables: patient id; visit date, age, gender, ethnicity, years of formal education, disease duration, comorbidity (fibromyalgia, depression, osteoporotic fractures, osteoarthritis, and low back-pain)

The following variables will be collected at each visit:

- Clinical Variables: - TJC, SJC, ESR, CRP, Pain, PGA, PhGA (baseline, 3 and 6 months)
  - HAQ, HADS (baseline and 6 months)
- Medication: DMARDS, corticosteroids, analgesics and psychoactive drugs (baseline, 3 and 6 months)
- The RAID score – needs to be incorporated in Reuma.pt (baseline, 3 and 6 months)
- Ten Item Personality Inventory (Personality) (TIPI)(24) – needs to be incorporated in Reuma.pt (baseline and 6 months)
- Subjective Happiness Scale (Happiness) (SHS)(25, 26) – needs to be incorporated in Reuma.pt (baseline and 6 months)
- Additional questions: in order to establish the PASS, MCII and relative weights for RAID and its individual items, participants will be asked to indicate the maximum acceptable level for each RAID domain and whether significant changes have occurred since last visit.

4.4. Potential confounders (and how will be measured)

The potential confounders, namely depression, anxiety, comorbidity, personality and happiness are part of the core variables.

4.5. *Outcomes*

The outcomes will be the changes in the RAID score and its relationships with other variables.

4.6. Statistical Analysis

All requested variables will be downloaded trough Reuma.pt in a single excel file (guarantying the confidentiality) in which we will precede to the database cleaning. Data will then be analysed with IBM SPSS (27).

In the next page we provide a table (Table 1) with details about the descriptive analysis and statistical models that will be performed specifically for each objective.

Table 1 – Statistical analysis and additional methodology specifications for each study objective

Objective	Statistical analysis	Additional Methodology Specifications
1) To assess the sensitivity to change of the "Rheumatoid Arthritis Impact of Disease (RAID) score" and its seven items (RAID7i) to changes in disease activity (measured by CDAI, SDAI and DAS28(4v)CRP definition) in people with RA in Portugal.	Descriptive statistics: - mean (and SD) and frequencies for each of the RAID's domains, divided by disease activity categories (baseline, 3 and 6 months). - standardised response means (SRM) of the RAID score and its items,(28) stratified by DAS response rates	Possible floor and ceiling effects will be examined for the RAID score and its items. Such effects will be considered as present if more than 15% of the respondents achieve the highest or the lowest score, respectively.(29)
2) To assess the stability of the RAID score and RAID7i in the context of stable disease activity	Same as objective 1), but selecting only patients that are in stable disease activity for 3 or for 6 months (i.e. DAS28 change within 0.6 of baseline)	
3) To assess the stability of the RAID in test-retest within 2 weeks in the context of clinical stability	Test-retest coefficient	
4) To determine the relative weights of RAID items to its global score in Portuguese RA patients	Regression analysis with global impact as dependent variable and RAID7i as independent variables	For this purpose, an eighth item will be add to the RAID, asking (baseline, 3m and 6m) about the "Global impact" of the disease: "Considering now all the above mentioned aspects together, circle the number that best describes the global impact that your rheumatoid arthritis had in your life during the last week" (anchors: Without impact and Extreme impact). Portuguese translation in Appendix I (question 8).
5) To determine the PASS of the RAID score for Portuguese RA patients	75th percentile & receiver operating characteristic (ROC) curves	We will adopt a methodology similar to that used by Bellamy et al.(30) Patients will be asked (baseline, 3m and 6m): "If you were to remain for the rest of your life as you were during the last 48 hours, would this be acceptable or unacceptable for you?", with a dichotomous response mode: acceptable or unacceptable (question 10 - Appendix I).
6) To determine the PASS of the RAID7i for Portuguese RA patients	Same as in objective 5)	Patients will be asked (baseline, 3m and 6m): "What would be the maximum value that you would consider acceptable to live for the rest of you life, for each of the following items?", providing a NRS for each of the RAID domains (question 11 - Appendix I).
7) To determine the MCII of the RAID score for Portuguese RA patients	Same as in objective 5) Both the absolute difference (= final value - baseline value) and relative difference (= final value - baseline value/baseline value) will be evaluated.	The same rheumatologist should perform the initial and the final visit of patients to patients whom had therapy change initiated to control active disease. Patients will be asked: "Compared to the previous visit (3 months back), how have you been during the last 48 hours?" (improved, no change, worse), and "If you answered 'improved' at the previous question, how important is this improvement to you?" (very important, moderately important, slightly important, not at all important) (Questions 9 and 9.1. - Appendix I). Only patients who describe a slightly or moderately important improvement will be considered. Like Bellamy et al. (30), we will exclude patients who reported their improvement as being "very important" because these patients might bias the estimate toward values that far exceeded minimal improvement.

Table 1 (Cont.) - Statistical analysis and additional methodology specifications for each study objective

Objective	Statistical analysis	Additional Methodology Specifications
8) To assess the associations between the RAID score and other PROs (PGA, HAQ, HADS, Happiness (SHS) and Personality (TIPI))	Pearson's or Spearman's correlation coefficients as appropriate.	
9) To assess which of the RAID7i are typically involved in not achieving RAID's PASS (defined by this study for RAID and for RAID7i) by patients under disease remission or Low Disease Activity (controlling for covariates, e.g. age, educational level, disease duration, function, depression, anxiety, comorbidities…)	Generalized Estimating Equations, with PASS at 6 months being the dependent variable and each of RAID's domains being tested together with the defined covariates.	
10) To determine the rate of agreement between RAID's PASS and disease remission status, considering	Qui-square test and K statistic	
11) To determine the rate of near misses in the ACR/EULAR Boolean definition (i.e. patients not fulfilling only the PGA criterion) if the PGA≤1 were replaced by the RAID's PASS (defined by the following)	Descriptive statistics	Near miss is defined as a case not full filling the ACR/EULAR Boolean definition of remission exclusively due to the PGA. Three groups will be created based on this definition: 1) remission 2) near remission **3)** non remission
12) To determine which RAID items are typically involved in near misses	Descriptive statistics	
13) To assess if individual physicians would adopt any additional measures when faced with the RAID score in addition to the disease activity score, PGA and Pain VAS	Qui-square test and K statistic	We will use real cases obtained from this study (anonymized) and present them to a group of representative rheumatologists. This may happen trough a web questionnaire or, preferentially, during a national meeting. The cases will be presented sequentially, without and with the RAID/RAID7i scores. Rheumatologists will be asked whether they would change their therapy when faced with the RAID results.
14) To assess if individual physicians would adopt any additional measures when faced with the RAID7i scores in addition to the disease activity score, PGA and Pain VAS.		

4.6.1. Sample Size and Power Calculations

We used the "Sample Size Calculator" provided by Raosoft®.[2] Assuming 5% of accepted margin error, a confidence level of 95%, a population size of 5000 (number of patients with RA registered in Reuma.pt in 2014 (31)) and a response distribution of 50% (which gives the largest sample size), the recommended sample size is 357 patients. Thus, we established 400 patients as the first target and 800 patients as the ideal target (e.g. 100 patients in 8 centres). Efforts will be made to have the biggest possible number of patients.

5. Limitations

Involving other Portuguese centres will involve both advantages and difficulties. The main advantage will be the wider experiences from patients and health professionals, improving generalizability and strengthening the validations and also the future impact upon patient care. However, a very clear and close communication will be required in order to have procedures being performed in a standardized manner. To facilitate this, Standardized Operative Procedures (SOP) will be created, discussed collectively and presented in face-to-face meetings in each centre by the coordinator of the project. In each centre, the head of department will select a liaison person.

The missing data is another potential problem, which can happen due to not fulfilling the questionnaire in one visit or due to the fact of being different physicians performing the visit for the same patient. We will develop efforts to create a specific environment in Reuma.pt and/or "alerts" (e.g. remembering if the patient is on this study, in which visit he is and who was the physician who performed the first visit). We will also promote that patients fulfil the questionnaires directly trough Reuma.pt.

6. Project Activities and Timelines

Task	Months after project approval																							
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Discussing the project with Reuma.pt																								
Presenting the project to the interested centres																								
Inclusion period																								
Data collection																								
Visiting centres																								
Data download & cleaning																								
Statistical Analysis																								
Paper writing and revision																								
Paper submission																								

[2] Available at http://www.raosoft.com/samplesize.html

7. Study Team

Ricardo Ferreira, RN, PhD student (Coimbra, Portugal). Project Manager - Ricardo has experience in data collection, database cleaning (in excel and SPSS) and statistical analysis with SPSS. He will be responsible for: managing the data collection in the centre(s); cleaning the database after download from Reuma.pt; performing the statistic analysis; writing the article(s).

Cátia Duarte, MD (Coimbra, Portugal) - Cátia has the same competencies than Ricardo. She adds a greater experience in research and the clinical perspective. She will helps in the data collection.

Mwidimi Ndosi, RN, PhD (Leeds, UK) - Mwidimi has experience in PRO's development and also in performing its cross-cultural adaptation and validation. He is an expert in Rasch analysis as like as in statistic analysis. He will act as a methodologist of this study.

Laure Gossec, MD, PhD (Paris, France) – Laure is a world leading young rheumatologist with great experience in research. She is involved in OMERACT group for PRO and she was the main author of the RAID´s development. She will also act as a methodologist of this study.

José António Pereira da Silva, MD, PhD (Coimbra, Portugal) - José is also a world known rheumatologist and researcher. He is the mentor and Principal Investigator of this project.

7.1. Expected Papers

1) Responsiveness of the RAID score in clinical practice
2) Relative weights of RAID items to global score in Portugal
3) Establishing RAID PASS and MCII for Portugal
4) Exploring the meaning and value of individual PASS, its variable composition (7i) and its "predictors"
5) Clinical and psychological correlates of the RAID score and each of its 7Is
6) Exploratory analysis of the application of RAID and RAID7i PASS to the definition of remission
7) The consideration of RAID7i prompt physicians to introduce changes in therapy of RA patients

7.2. Authorship

The paper will be submitted on behalf of the "Portuguese RAID study Group". For each set of 25 complete patients, each centre will have one researcher listed as a member of the group. For each set of 50, one of the two eligible researchers will be included in the list of primary co-authors. The final authorship distribution will be submitted to consensus between all researchers.

8. Budget and Payment scheduled

There is no grant support for this project. The direct costs regards to the questionnaires printing. Each centre will cover these costs.

No conflicts of interest exist.

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Appendix I – RAID adaptation for determination of weights, PASS and MCII

Baseline

Impacto da Doença – Artrite Reumatóide
Questionário RAID

1. Dor
Faça um círculo à volta do número que melhor descreve a dor que sentiu devido à sua artrite reumatoide durante os últimos 7 dias.

Nada	0	1	2	3	4	5	6	7	8	9	10	Extrema

2. Avaliação de deficiência funcional
Faça um círculo à volta do número que melhor descreve as dificuldades que sentiu nas suas atividades físicas diárias devido à sua artrite reumatoide durante os últimos 7 dias.

Não foi difícil	0	1	2	3	4	5	6	7	8	9	10	Extremas dificuldades

3. Fadiga
Faça um círculo à volta do número que melhor descreve a fadiga que sentiu devido à sua artrite reumatoide durante os últimos 7 dias.

Sem fadiga	0	1	2	3	4	5	6	7	8	9	10	Totalmente Exausto(a)

4. Sono
Faça um círculo à volta do número que melhor descreve os distúrbios de sono (ou seja, descansar de noite) que teve devido à sua artrite reumatoide durante os últimos 7 dias.

Não foi difícil	0	1	2	3	4	5	6	7	8	9	10	Extremas Dificuldades

5. Bem-estar físico
Tendo em conta o estado geral da sua artrite, como avaliaria o seu nível de bem-estar físico durante os últimos 7 dias? Faça um círculo à volta do número que melhor descreve o seu nível de bem-estar físico.

Muito bom	0	1	2	3	4	5	6	7	8	9	10	Muito mau

6. Bem-estar emocional
Tendo em conta o estado geral da sua artrite, como avaliaria o seu nível de bem-estar emocional durante os últimos 7 dias? Faça um círculo à volta do número que melhor descreve o seu nível de bem-estar emocional.

Muito bom	0	1	2	3	4	5	6	7	8	9	10	Muito mau

7. Convívio com a doença
Tendo em conta o estado geral da sua artrite, como conviveu (enfrentou, lidou) com a sua doença nos últimos 7 dias?

Muito bem	0	1	2	3	4	5	6	7	8	9	10	Muito mal

8. Impacto global
Considerando agora todos os aspectos acima referidos em conjunto, coloque um círculo no número que melhor descreve o impacto global que a sua artrite reumatóide teve na sua vida, nos últimos 7 dias.

Sem impacto	0	1	2	3	4	5	6	7	8	9	10	Impacto extremo

Baseline

9. Se tivesse de permanecer o resto da sua vida tal como esteve nas últimas 48 horas, seria isso aceitável ou inaceitável para si?

☐ Aceitável
☐ Inaceitável

10. Qual seria o valor máximo com que consideraria aceitável viver para o resto da sua vida, para cada um dos itens seguintes?

Ao valor "0" corresponde a ausência do problema (ou o melhor estado possível) e ao valor "10" o estado extremo do problema (ou o pior estado possível).

Dor	0	1	2	3	4	5	6	7	8	9	10
Deficiência funcional	0	1	2	3	4	5	6	7	8	9	10
Fadiga	0	1	2	3	4	5	6	7	8	9	10
Sono	0	1	2	3	4	5	6	7	8	9	10
Bem-estar físico	0	1	2	3	4	5	6	7	8	9	10
Bem-estar emocional	0	1	2	3	4	5	6	7	8	9	10
Convívio com a doença	0	1	2	3	4	5	6	7	8	9	10
Impacto Global	0	1	2	3	4	5	6	7	8	9	10

3 e 6 meses

Impacto da Doença – Artrite Reumatóide
Questionário RAID

1. Dor
Faça um círculo à volta do número que melhor descreve a dor que sentiu devido à sua artrite reumatoide durante os últimos 7 dias.

Nada	0	1	2	3	4	5	6	7	8	9	10	Extrema

2. Avaliação de deficiência funcional
Faça um círculo à volta do número que melhor descreve as dificuldades que sentiu nas suas atividades físicas diárias devido à sua artrite reumatoide durante os últimos 7 dias.

Não foi difícil	0	1	2	3	4	5	6	7	8	9	10	Extremas dificuldades

3. Fadiga
Faça um círculo à volta do número que melhor descreve a fadiga que sentiu devido à sua artrite reumatoide durante os últimos 7 dias.

Sem fadiga	0	1	2	3	4	5	6	7	8	9	10	Totalmente Exausto(a)

4. Sono
Faça um círculo à volta do número que melhor descreve os distúrbios de sono (ou seja, descansar de noite) que teve devido à sua artrite reumatoide durante os últimos 7 dias.

Não foi difícil	0	1	2	3	4	5	6	7	8	9	10	Extremas Dificuldades

5. Bem-estar físico
Tendo em conta o estado geral da sua artrite, como avaliaria o seu nível de bem-estar físico durante os últimos 7 dias? Faça um círculo à volta do número que melhor descreve o seu nível de bem-estar físico.

Muito bom	0	1	2	3	4	5	6	7	8	9	10	Muito mau

6. Bem-estar emocional
Tendo em conta o estado geral da sua artrite, como avaliaria o seu nível de bem-estar emocional durante os últimos 7 dias? Faça um círculo à volta do número que melhor descreve o seu nível de bem-estar emocional.

Muito bom	0	1	2	3	4	5	6	7	8	9	10	Muito mau

7. Convívio com a doença
Tendo em conta o estado geral da sua artrite, como conviveu (enfrentou, lidou) com a sua doença nos últimos 7 dias?

Muito bem	0	1	2	3	4	5	6	7	8	9	10	Muito mal

8. Impacto global
Considerando agora todos os aspectos acima referidos em conjunto, coloque um círculo no número que melhor descreve o impacto global que a sua artrite reumatóide teve na sua vida, nos últimos 7 dias.

Sem impacto	0	1	2	3	4	5	6	7	8	9	10	Impacto extremo

9. Em comparação com a sua última consulta (há 3 meses), como se tem sentido nas últimas 48 horas?

- ☐ Melhor
- ☐ Sem alteração
- ☐ Pior

9.1 Se respondeu "Melhor" na questão anterior, como valoriza essa melhoria

- ☐ Muito importante
- ☐ Moderadamente importante
- ☐ Pouco importante
- ☐ Nada Importante

10. Se tivesse de permanecer o resto da sua vida tal como esteve nas últimas 48 horas, seria isso aceitável ou inaceitável para si?

- ☐ Aceitável
- ☐ Inaceitável

11. Qual seria o valor máximo com que consideraria aceitável viver para o resto da sua vida, para cada um dos itens seguintes?

Ao valor "0" corresponde a ausência do problema (ou o melhor estado possível) e ao valor "10" o estado extremo do problema (ou o pior estado possível).

Dor	0	1	2	3	4	5	6	7	8	9	10
Deficiência funcional	0	1	2	3	4	5	6	7	8	9	10
Fadiga	0	1	2	3	4	5	6	7	8	9	10
Sono	0	1	2	3	4	5	6	7	8	9	10
Bem-estar físico	0	1	2	3	4	5	6	7	8	9	10
Bem-estar emocional	0	1	2	3	4	5	6	7	8	9	10
Convívio com a doença	0	1	2	3	4	5	6	7	8	9	10
Impacto Global	0	1	2	3	4	5	6	7	8	9	10