

# The Patient based Disease Activity Score (PDASII) validation study

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Autoimmune disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON35066

### Source

ToetsingOnline

### Brief title

The PDASII study

## Condition

- Autoimmune disorders
- Muscle disorders

### Synonym

chronic joint inflammation, Rheumatoid Arthritis

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Het Reumafonds

## Intervention

**Keyword:** Disease Activity, Patient reported outcomes, PDASII, Rheumatoid Arthritis

## Outcome measures

### Primary outcome

The primary focus of this study is the effect of training on the concurrent criterion validity of the PDASII. Primary outcome of the study will be the mean difference between the PDASII and DAS28 at 6, 9 and 12 months after baseline.

### Secondary outcome

Secondary outcomes will be other clinimetric aspects of the PDASII:

#### Validity

- face/content; percentage found to be comprehensive and percentage missing elements
- construct; convergent correlation analysis with other measures of disease activity and related components of health assessment questionnaires, discriminant correlation analysis with non-related components of health assessment questionnaires measures of disease activity and health state measures
- criterion; with joint damage progression over the course of one year

#### Reliability

- intraobserver intra-class correlation coefficient

## Sensitivity to change

- standardised response mean
- effect size
- minimal important difference (ROC + 75th percentile)

## Feasibility

- average time to complete
- average cost to complete
- percentage positive interpretability
- percentage full-completion

## Acceptance

- percentage physicians and patients willing to use patient reported measure for monitoring

# Study description

## Background summary

In recent years there has been a trend in medical practice towards patient-centred care. Within rheumatology attention is being paid to finding outcome measures with which patients can track their disease process; hereby exploring effective and efficient ways to evaluate therapy.

## Study objective

The aim of this study is to assess the effect of training on the measurement properties of a recently developed disease activity score based on patient reported outcomes and to investigate if such a measure could be implemented in current clinical practice.

## Study design

This study has a randomised parallel group design. Patients seen in daily clinical practice are studied with three-monthly follow-up assessments for the duration of one year. After being invited to take part in the study, patients will be randomised to receive elaborate training or standard written instructions on how to perform joint counts. The group of patients receiving elaborate training will receive verbal and written instructions, and a video how to assess and report joint counts. During the first two visits (out of five) discrepancies between the PRO\*s and standard clinical assessments will be discussed in order to minimize these. The group of patients randomised not to receive training will be given standard written instructions on how to perform joints counts.

## Intervention

During the course of one year, various patient reported measures, such as the Patient-based Disease Activity Score (P-DASII), the modified Rheumatoid Arthritis Disease Activity Index (RADAI-5), the Routine Assessment of Patient Index Data (RAPID 2-5), the Patient derived Disease Activity Score 28 joint count (Pt-DAS28) the Health Assessment Questionnaire Disability Index (HAQ-DI), the Short Form 36 questions (SF36) and the Euroqol 5D (EQ-5D) will be collected at baseline and three-monthly follow-up visits. A trained research nurse will assess patients during these visits providing a Disease Activity Score 28 joint count (DAS28) and a Clinical Disease Activity Index (CDAI), which are currently used in clinical practice. Furthermore radiographs of the hands and feet will be taken at baseline and twelve months follow-up to assess joint damage progression.

## Study burden and risks

Due to the nature of this study, there is no extra risk involved with participation in de study. Patient burden will be approximately 45 minutes for each visit.

## Contacts

### Public

UMC St Radboud

Geert Grooteplein 8  
6500HB Nijmegen  
NL

### Scientific

UMC St Radboud

Geert Grooteplein 8  
6500HB Nijmegen  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

1. Diagnosis RA according to the ACR criteria
2. Patients starting on either their first DMARD or biological therapy

### Exclusion criteria

Patients who are unable to complete the questionnaires/PDASII

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

**Primary purpose:** Other

## Recruitment

NL  
Recruitment status: Recruiting  
Start date (anticipated): 05-10-2011  
Enrollment: 200  
Type: Actual

## Ethics review

Approved WMO  
Date: 07-10-2010  
Application type: First submission  
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)  
Approved WMO  
Date: 12-07-2012  
Application type: Amendment  
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
CCMO	NL31935.091.10