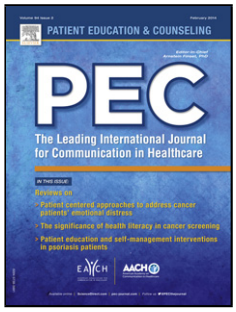

Title: Development of an item bank to measure factual disease and treatment related knowledge of rheumatoid arthritis patients in the treat to target era

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Title: Development of an item bank to measure factual disease and treatment related knowledge of rheumatoid arthritis patients in the treat to target era

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Highlights

- We describe the development of an item bank for measuring patient knowledge in RA.
- The results presented here support its construct validity and reliability.
- The item bank can be used to identify educational needs of RA patients.
- It can also be used to monitor patient outcomes.

Abstract

Objective: To develop a Disease and treatment associated Knowledge in RA item bank (DataK-RA) based on item response theory.

Methods: Initial items were developed from a systematic review. Rheumatology professionals identified relevant content trough a RAND modified Delphi scoring procedure and consensus meeting. RA patients provided additional content trough a

focus group. Patients and professionals rated readability, feasibility and comprehensiveness of resulting items. Cross-sectional data were collected to evaluate psychometric properties of the items.

Results: Data of 473 patients were used for item reduction and calibration. Twenty items were discarded based on corrected item-total point biserial correlation <0.30. Confirmatory factor analysis with weighted least squares estimation on the polychoric correlation matrix suggested good fit for a unidimensional model for the remaining 42 items (CFI .97 TLI=.97, RMSEA=0.02, WRMR=0.97), supporting the proposed scoring procedure. Scores were highly reliable and normally distributed with minimal ceiling (1.8%) and no floor effects. 75% of tested hypotheses about the association of DataK-RA scores with related constructs were supported, indicating good construct validity.

Conclusion: DataK-RA is a psychometrically sound item bank.

Practice implications: DataK-RA provides health professionals and researchers with a tool to identify and target patients' information needs or to assess effects of educational efforts.

Keywords: Item Response Theory; Item bank; Measurement instrument; (Patient) education; (Patient) knowledge; Personalized healthcare; Quality indicator; Rheumatoid Arthritis

1. Background

Patient involvement and personalisation of healthcare have become increasingly important in managing chronic diseases. Currently ‘good clinical practice’ includes that patients are well informed about their disease and its treatment, and treatment choices are based on their preferences.[1, 2] Knowledge about their disease and its treatment is an important precondition for patients to be able to be involved in their own care.[3] Many patients with a chronic disease therefore receive basic education about their disease and its treatment, either from their medical team or through patient information and educational meetings.[4]

Rheumatoid Arthritis (RA) is one of those chronic diseases where patients need to be well informed about their disease to be able to successfully manage it. Guidelines recommend patient education to be an integral and continuous element of RA management, so that patient can be involved in their RA care.[5-7]

Several instruments have been proposed and validated over time that can be used to measure RA patients’ disease and treatment related knowledge. However, the most recent of these instruments was introduced in 2004.[8-11] A shared limitation of previous instruments is that they predate significant advances in the management of RA, such as the introduction of biological monoclonal antibodies and the treat to target paradigm.[12, 13] Similarly, questions about RA treatment that are included in previous instruments were based on clinical best practices that have not always withstood the test of time. In fact, a general limitation of patient knowledge questionnaires is that their content may become outdated as new insights into the disease process or its treatment develop.

To address these issues we decided to develop a new, item response theory (IRT) based instrument that can be used to measure disease and treatment related knowledge in rheumatoid arthritis patients. A useful feature of an IRT based item

bank, compared with a traditional questionnaire is that new items can be added and outdated items removed from the item bank, without changing the underlying scale on which the scores are expressed. This allows comparability with studies to be maintained as new insights about the disease evolve. Another advantage is that IRT based disease knowledge scores are directly comparable even if different items are administered to different patients.[14] This feature can be used to tailor the level of questions to the knowledge level of patients, either using computer algorithms or manually by developing targeted short forms. The ability to present alternate forms that yield comparable scores is particularly important when assessing the effects of educational programs, since the validity of knowledge questionnaires in longitudinal studies may be undermined by the presence of learning effects. The items included in the item bank were partially build upon previously proposed patient knowledge questionnaires in RA and partially newly developed, using a rigorous qualitative process in cooperation with the prospective users (patients, rheumatologists and rheumatology nurses). The newly developed items focus in particular on previously unaddressed content areas such as treating to target and biological medication. This paper describes the development process and initial validation of the Disease and treatment associated Knowledge in RA item bank (DataK-RA).

2. Methods

2.1 Literature review

Initial item content was derived from a critical review of the content of previously proposed patient knowledge questionnaires in RA. A systematic search of the PubMed, Embase and Cinahl database was performed to identify previously proposed and validated questionnaires on knowledge about RA and its treatment. The search was aimed at questionnaires that assess patients' general factual knowledge about RA and its treatment, not just one area of the disease (e.g., knowledge about Sjögren's syndrome or knowledge about Methotrexate use). Only self-administered questionnaires with pre-defined answering options were included. Furthermore, publications before 1990 or in other languages than English or Dutch were excluded. A detailed description of the search strategy can be found in the supplemental material. A list of all existing questionnaire items on knowledge about RA and its treatment was compiled.[8-11] Items were grouped within topics and topics were grouped within categories. Items that were considered outdated by the authors or on other topics than the disease and its treatment were removed. Finally, topics on treat to target and biological treatment were added. These topics were based on items adapted from a questionnaire we previously used to evaluate the effectiveness of decision supportive information on treat to target.

2.2 Professionals phase

The relevance and comprehensiveness of the topics was evaluated among a panel of rheumatology nurses and rheumatologists. All participating rheumatologists and nurses were affiliated with the Dutch Rheumatoid Arthritis Monitoring registry (DREAM). DREAM is a partnership between various Dutch rheumatology departments for scientific research and to improve the quality and efficiency of rheumatology care (www.dreamregistry.nl).

In a RAND modified Delphi procedure, participants were asked to rate the relevance of each topic for the knowledge questionnaire via an on-line questionnaire.[15] For each topic, participants were asked to score the following: “How important do you think it is for patients to have knowledge about this subject, on a scale of one to nine?”. Furthermore, professionals were asked to propose topics that might have been omitted. Based on tertile scores, topics were either accepted, rejected or discussed for use in the questionnaire (see figure 1). During a consensus meeting, participants were asked to debate on topics that met the criterion for ‘discussion’ in the scoring round as well as on additional topics that participants suggested for use in the questionnaire.

< *Figure 1: Topic scoring (criterions set beforehand)*>

After the consensus meeting, the original list of existing questionnaire items was re-assigned to the topics that were accepted in the questionnaire. In addition, the authors formulated items for added topics based on discussion during the consensus meeting and on information on the website of the Dutch Arthritis Association. All cooperating professionals were asked to provide written feedback on the preliminary items. Feedback could either be on wording, content or coverage of a topic and was used to revise the preliminary items.

2.3 Patients phase

Subsequently, a focus group among patients was organised to identify additional content areas that might have been omitted from the item pool. A total of 10 patients

were recruited from the Rheumatology department of Bernhoven, a regional hospital in Uden, the Netherlands. During the focus group, an experienced moderator asked patients about their (experiences with) informational needs in dealing with their RA. The moderator made sure that all categories scored during the professional phase were discussed in the focus group meeting. Topics were identified by analysing the focus group transcript using AtlasTi.[16] Items on additional topics were then developed by the authors and added to the list of items. Following the focus group, participating patients were asked to rate readability, feasibility and comprehensiveness of the resulting items. Final adjustments to the items were then made. In figure one, all steps taken in the development of the questionnaire are depicted. A detailed description of the origin of each item can be found in the supplemental material.

2.4 Psychometric analysis

Cross-sectional data were collected to evaluate psychometric properties of the item pool by asking all 721 RA patients from Bernhoven Rheumatology department and all 90 RA patients from the Rheumatology Research Panel of the University of Twente to complete the pool of items. Patients received a questionnaire via mail. Patients who did not return the questionnaire after three weeks, received one reminder.

An initial analysis of item quality was performed to weed out weak items. Since items that are either weakly associated with the total score or that most patients either fail or pass discriminate poorly between patients with high and low disease knowledge, items with item-total point biserial correlation $r < 0.30$, as well as items that were failed or passed by >95% of patients were considered for omission from the definitive instrument.[17]

Subsequently, we evaluated the validity of a scoring procedure where all items are combined to obtain a single score, as well as the IRT assumption of unidimensionality by performing confirmatory factor analysis (CFA) with weighted least squares estimation on the polychoric correlation matrix, using MPLUS. Model fit was evaluated using conventional cut-off points of model fit indices that have been proposed for binary response data.[18] All fit indices provided by MPLUS were examined.

The item pool was calibrated under a unidimensional item response model. We used a 2-parameter logistic model (2-PLM), which is an IRT model that describes the relationship between dichotomous (patient knowledge) questions and the overall (patient knowledge) trait level:

$$P_{1ni} = \frac{\exp \alpha(\theta_n - \beta_i)}{1+\exp \alpha(\theta_n - \beta_i)} \quad ,$$

Where P_{1ni} = patient *n*'s probability of a correctly answering item *i*, θ_n is a patient's overall level of factual disease and treatment related rheumatoid arthritis knowledge, *α* reflects the discriminatory power of an item, such that item scores with a higher α are weighed more heavily in the trait estimate and β_i is a parameter reflecting the difficulty of an item *i*, defined as the position on the latent scale where $P_{1ni} = P_{0ni}$. Once item parameters were obtained, Lagrange Multiplier (LM) statistics were used to identify items that were subject to differential item functioning (DIF). Differential item functioning occurs if the probability that a patient correctly answers an item depends on factors besides overall disease knowledge. The presence of DIF suggests that item scores are spuriously inflated for a certain subgroup and therefore compromises the validity of the test score.[20] We evaluated DIF related to gender, disease duration, educational level and study center. For disease duration, DIF was

evaluated for patients with disease duration below and above the median of 8 years, while for educational level patients were categorized as low, intermediate and high in accordance with the International Standard Classification of Education. Items were flagged for DIF in case the LM test was statistically significant ($p<0.05$) and effect size >0.10. Fit of the overall model was again evaluated using Lagrange Multiplier statistics (LM) and accompanying effect size statistics.[21]

Measurement precision across different levels of factual disease and treatment related rheumatoid arthritis knowledge was evaluated using scale level information functions. Information functions provide detailed information about score reliability across different levels of the measured trait.

Convergent validity was assessed by examining Pearson's correlations between disease knowledge scores and related constructs. Since previous studies found that higher educated patients achieve higher scores on previously validated knowledge questionnaires, we hypothesized, before data was collected, that a moderate, positive correlation ($0.30 \leq r < 0.60$) should exist between education level and knowledge scores.[10, 11, 22] Similarly, we expected a moderate, negative correlation between age and knowledge because younger people are thought to have greater education needs.[11, 22] It is suggested in previous studies that patients with a longer disease duration achieve higher knowledge scores because of their experience with the disease.[10, 22, 23] Therefore, a weak, positive correlation between disease duration and knowledge scores was hypothesized (effect size $0.10 < r < 0.30$). Furthermore, based on previous research, we expected for females to achieve higher knowledge scores.[22] This hypothesis was tested using the known groups validity technique by performing a t-test for independent samples.

3. Results

3.1 Literature search

The search yielded four patient knowledge questionnaires, published in 1991, 1995, 1997 and 2004.[8-11] Checking of the references of the articles did not result in additional questionnaires. A topic list was extracted from all existing questionnaires. Topics were removed from the list when they were outdated or concerned other topics then RA and its treatment. Finally, the authors added topics on treat to target

and biological treatment (see figure 2). This resulted in a list of 95 possible questionnaire topics.

<Figure 2: Development of the questionnaire (process map)>

3.2 Professionals phase

A total of six of 12 invited rheumatologists and six of 15 invited rheumatology nurses agreed to participate in the modified Delphi on-line scoring procedure. Of the 95 topics considered, 28 were rejected, 61 were accepted, and 6 were nominated for discussion in a consensus meeting (see figure 1). In addition, the participants proposed 18 topics to be added to the questionnaire. After the scoring procedure, all participants were invited to a consensus meeting. A total of four rheumatologists and six rheumatology nurses participated in the meeting. During the two-hour meeting they were asked to debate on topics that met the criterion for 'discussion' in the scoring round as well as on additional topics that participants suggested for use in the instrument. Based on consensus, 12 topics were added and six were rejected. This resulted in a total of 73 topics.

After the consensus meeting, questionnaire items were re-assigned to the topics (see figure 3 and supplemental material). All participants from the scoring procedure were asked to provide written feedback on the resulting 51 items. A total of five rheumatologists and six rheumatology nurses provided feedback on wording, content and coverage of the preliminary items, which was used to revise the preliminary items. At this stage, the participants did not suggest additional items or topics.

<Figure 3: Questionnaire structure (example)>

3.3 Patients phase

Subsequently, a focus group meeting among nine patients was organized. Based on patient input, 11 items on six additional topics were added to the item pool. After the meeting, eight of nine focus group participants provided feedback on readability, feasibility and comprehensiveness of the resulting pool of 62 items. Based on the feedback, final adjustments were made to the item pool. At this stage, the participants did not suggest additional items or topics.

3.4 Psychometric analysis

In total, 419 (response rate of 58%) patients recruited from Bernhoven and 54 (response rate of 60%) patients recruited from the University of Twente returned the questionnaire (see table 1). The sample was typical for RA, with the majority of the patients female (64.5%) and the mean age around 65 years. Average disease duration was around 13 years and disease impact and pain were quite variable according to the patient reported outcomes. The mean percentage of missing values for the knowledge items was 3.2% (SD=2.0%).

<Table 1: Demographics of the respondents to the 62-item questionnaire (N=473)>

A total of 23 items were identified with low item corrected total correlation (n = 23) or that were answered correctly by ≥ 95% of patients (n = 3). Of these items, only item 26 (Why do we use corticosteroids (such as prednisone) to treat RA?), item 31 (How long does it take before corticosteroids (such as prednisone) begin to work?) and item 59 (Why are people with RA advised to maintain a healthy lifestyle (for example, not smoking, using alcohol moderately, and watching their weight)?) were kept in the

item pool. Items 26 and 31 were kept in the item pool because they are part of a set of items addressing rheumatic medication. Item 59 was kept because it was considered an important issue in modern RA treatment that would not be covered by the item bank when the item would have been discarded.

CFA was performed on the remaining 42 items. The results strongly supported the hypothesized unidimensional measurement model; All goodness-of-fit statistics indicated excellent fit, with comparative fit index = 0.97, Tucker Lewis index = 0.97, Root Mean Square Error Of Approximation = 0.02, p (RMSEA < 0.05) = >0.99 and Weighted Root Mean Square Residual = 0.97. Standardized factor loadings were generally high (Median=0.53, IQR= 0.48 -0.63).

The results of the IRT analyses are summarized in the supplementary material. In initial DIF analyses we found no items that met the criteria for DIF for any of the evaluated external variables. In the evaluation of overall model fit, we found 5 items with statistically significant LM tests. However, for none of these the ES cut-off point of 0.10 was exceeded (Max ES = 0.05).

Figure 4 presents the information functions plotted over the distribution of factual disease and treatment related RA knowledge scores, expressed on a scale with mean = 0 and SD ≈ 1. The mean percentage of questions answered right for the total sample was 70%, with none of the patients answering all questions incorrect and 8 (1.7%) patients answering all questions correct. IRT based RA knowledge scores were normally distributed, with almost all patients scores within 2.5 SDs of the mean. It can be seen in the figure that measurement precision of the 42 item bank was optimal (ρ=0.92) for estimating knowledge scores 1 SD below the mean in this

population and was still highly reliable (ρ ≥0.90) for scores 2 SDs below the mean and scores around the mean. Sufficient precision for group level applications (ρ >0.70) was observed 3 SDs below and 1 SD above the mean and then dropped sharply for patients with knowledge levels outside this range. However, in the present sample few patients scored in this range.

<Figure 1: Reliability>

As expected, women outperformed men on the knowledge test ($p < 0.01$). Moreover there was a moderate positive correlation between educational level and knowledge scores (see table 2). Age and knowledge scores were also moderately correlated. However, opposite to our expectations, a weak negative correlation was found between disease duration and knowledge scores.

<Table 2: Convergent validity>

4. Discussion and conclusion

4.1 Discussion

This study introduces the DataK-RA item bank to measure patient knowledge about RA and its treatment, that provides health professionals with a tool to target individual patients' information needs and to monitor progress. It was developed using an extensive qualitative research process combining content from previously proposed knowledge questionnaires with input of professionals and patients, to comprehensively measure knowledge on relevant aspects of RA and its treatment. We hope this will make it a useful instrument in daily clinical practice as it can be used to identify and target patients' knowledge gaps on individual level as well as on group level. Moreover, it can be used to evaluate whether educational efforts have the desired effect and result in an increase of patient knowledge.

For research or quality of care applications, an overall disease and treatment knowledge score may be obtained by summing individual items. However, we also provide IRT parameters in the supplemental material that can be used to obtain IRT scores. While scores will generally be highly correlated between these approaches, IRT based scoring has the advantage that scores can be expressed on the same scale no matter which specific items were administered, whereas the summed score statistic only provides interpretable information about factual disease and treatment related knowledge in those cases where the same items were administered to all

patients and at each measurement occasion. The IRT based scoring procedure therefore provides users of the item bank with the flexibility to preselect any number of items from the item bank to meet their specific needs, while retaining comparability with other applications of the item bank. This is a useful feature that will allow users to control item exposure and to reduce bias due to learning effects from their studies. No matter if a classical or IRT based scoring procedure is used, the results presented here indicate that an overall score based on all 42 items will be highly reliable for patient populations with all but the very highest levels of knowledge. Work is currently ongoing to develop and evaluate targeted short-forms and a computerized adaptive testing algorithm that will allow more feasible, yet optimally reliable assessment of disease and treatment knowledge in practical settings.

The low measurement precision for high levels of knowledge (i.e. ≥2 standard deviations above the mean of the patient sample of this study) is a limitation of the current version of the item bank. However, if knowledge levels in this sample are representative for the overall population of RA patients, then these levels are unlikely to frequently occur in most practical settings. Also, only 1.8% of patients had a perfect score, which is considerably below the commonly employed cut-off point for ceiling effects of 15%.[24] Moreover, reliable assessment is arguably most important in populations with a low knowledge level. Nevertheless, the item bank may benefit from more difficult items in order to more reliably assess knowledge levels of individuals with high disease and treatment knowledge (e.g. patients with medical training). This might prove particularly useful for assessing post-intervention scores of studies evaluating the effects of interventions aimed at increasing disease and treatment knowledge. An advantage of the IRT based approach is that such items

can be added in the future without compromising the comparability with earlier studies.

The finding that knowledge scores were moderately related to educational level is consistent with results of previous studies that have found that highly educated patients were more interested in their disease and had higher disease knowledge scores.[9, 25] Similarly, consistent with our findings, various previous studies have observed that age is negatively associated with patient knowledge and that women have more disease related knowledge compared with men.[25, 26] However, contrary to our expectations wet observed a weak, negative correlation between disease duration and knowledge scores. The relatively strong positive association between age and knowledge scores may have confounded the results of this analysis. In addition, information on disease duration was assessed retrospectively and relied on patients' self-report, which could have contributed to its weak association with disease knowledge. Nevertheless, 75% of the hypotheses we tested in this study were supported, which is commonly considered to indicate sufficient construct validity.[24] Consequently the results of this study support the construct validity of the item bank.

4.2. Conclusion

This paper describes the development process of DataK-RA and provides an initial evaluation of its measurement properties. The results presented support its construct validity and reliability.

4.3. Practice implications

This study introduces DataK-RA, a new, promising instrument to comprehensively measure knowledge on relevant aspects of RA and its treatment. It can be used in daily clinical practice to personalize and monitor patient education, or to evaluate educational interventions. Since DataK-RA was developed using modern psychometric approaches it has the potential to be adapted to specific research needs and it can be adapted over time as disease knowledge evolves, without losing comparability with earlier studies. We have provided a detailed overview of the followed methodology (figure 2 and online supplements) to assist those interested in reproducing our research methods for other chronic illnesses.

Declarations:

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Authors' contributions: All authors have materially participated in the research and/or article preparation: All authors made substantial contributions to conception and design of the study. MdJ acquired the data. MOV, PvR and MdJ were involved in the analysis and interpretation of data. All authors have been involved in drafting the manuscript and revising it critically for important intellectual content. All authors have given final approval of the submitted article.

Competing interests: The authors declare that they have no competing interests.

Ethics approval and consent to participate: The Committee on Research Involving Human Subjects Arnhem-Nijmegen exempted our study from formal ethical approval because it did not involve research covered by the Medical Research Involving Human Subjects Act (file 2015-1728). In addition, the Ethics Committee of the Faculty of Behavioural Sciences of the University of Twente approved of our study (file 15432).

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Figures

Decision	Topic score
Acceptance	Median score of 8 or 9 AND ≥70% of the scores in the top tertile
Discussion	Median score of 8 or 9 AND <70% of the scores in the top tertile OR median score = 7 AND ≥70% of the scores in the top tertile
Rejection	Median score <7

Figure 1: Topic scoring (criterions set beforehand)

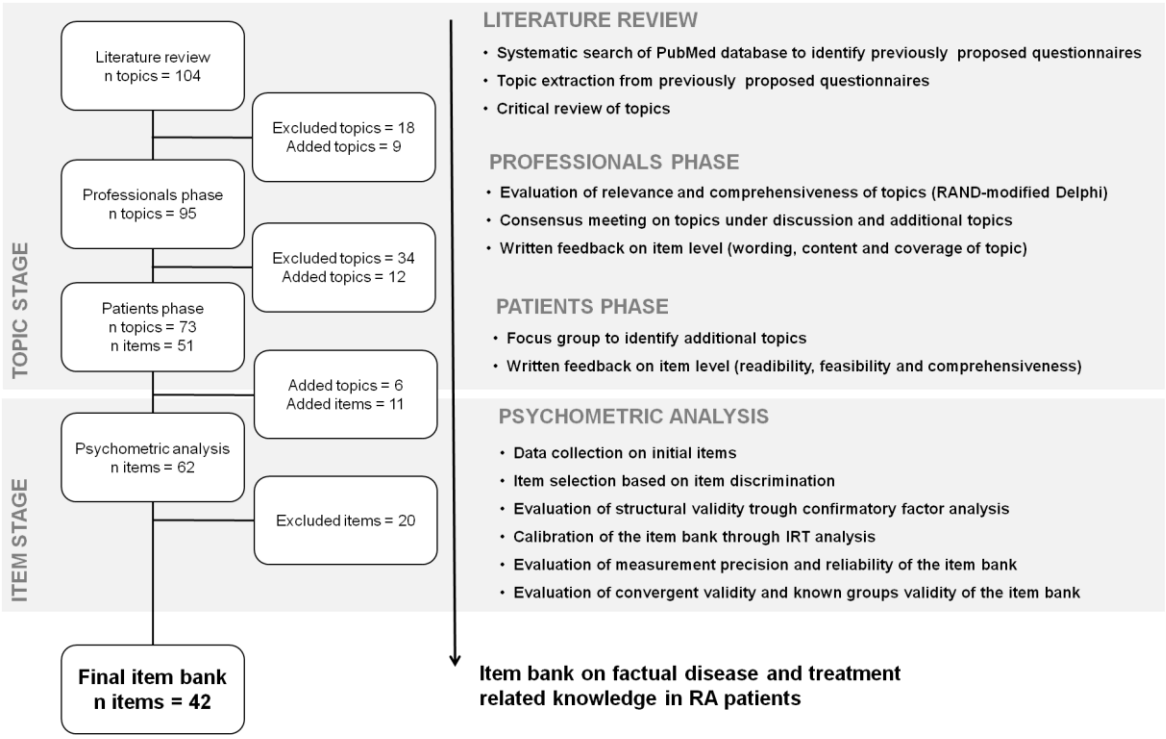

Figure 2: Development of the questionnaire (process map)

Category	Topic	Item
Disease process	Joint deformation Invalidity Impact on work Functional impairment	**What best describes the consequences of RA?** □ All people with RA get deformed joints □ Most people with RA end up in a wheelchair □ Most people with RA have to quit their jobs □ Sometimes people with RA are no longer able to completely bend or stretch joints
	Chronic disease/long term	**Can a patient with RA experience little burden of the disease due to good treatment?** □ No, once RA has become active, it cannot become inactive again □ No, because patients with RA always have damaged joints □ Yes, all patients with RA no longer have disease symptoms after a few years □ Yes, a significant number of the patients can gain control of the disease
	Disease course - irregularity Disease course - different between patients	**What do we know about the course of RA?** □ The disease course of RA is hereditary □ The disease course of RA is difficult to predict □ The disease course of RA is often seen as very similar for different patients □ The disease course of RA is mainly determined by the patient's age
	Tissue damaging	**What are the possible long-term consequences of RA?** □ All patients with RA no longer have disease symptoms after a few years □ We do not know because RA practically always occurs in elderly people □ RA can only damage bones □ RA can also damage other tissues, such as the lungs
	Sexuality, fertility and pregnancy	**What is the effect of pregnancy on RA?** □ The symptoms of RA often worsen during pregnancy □ The symptoms of RA often lessen during pregnancy □ Pregnancy very rarely affects the symptoms of RA □ Pregnancy does not affect the symptoms of RA
		What is the effect of RA on fertility and pregnancy? □ Medication for RA can have a negative effect on fertility and pregnancy □ Medication for RA can have a positive effect on fertility and pregnancy □ Medication for RA does not affect fertility and pregnancy
		What is the effect of RA on the sex lives of patients? □ Pain, fatigue and medication can have a negative effect on sex life □ Pain, fatigue and medication very rarely have a negative effect on sex life □ RA has no effect on sex life

Figure 3: Questionnaire structure (example)

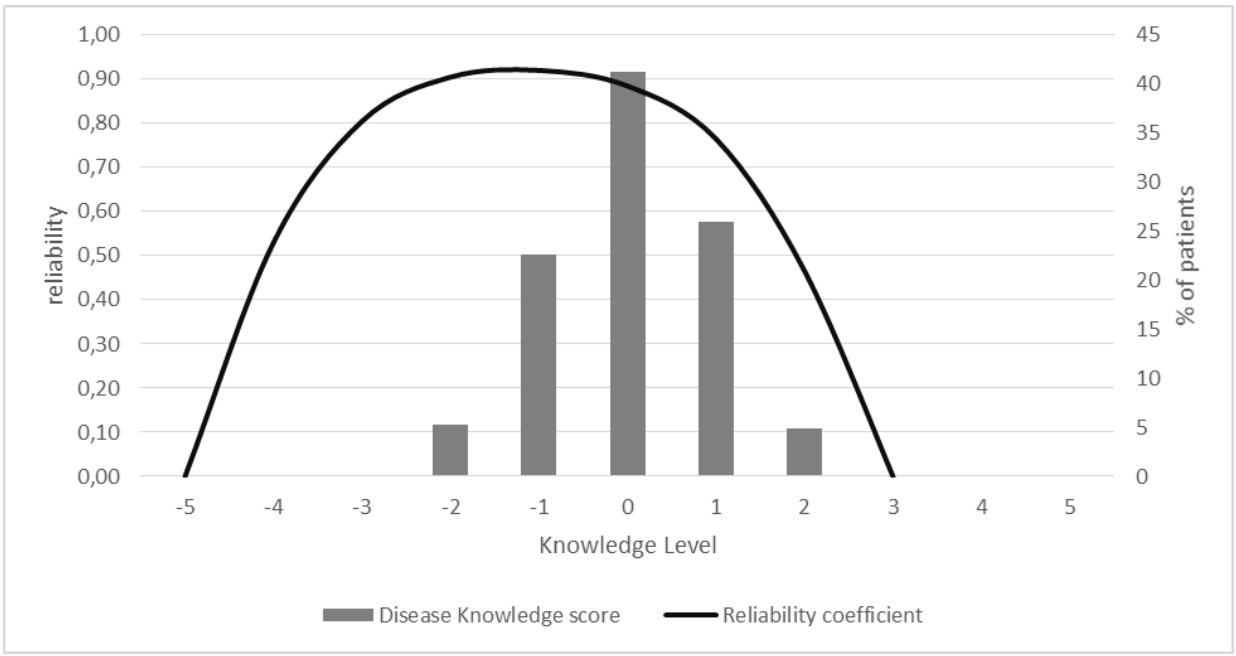

Figure 2: Reliability

Tables

Table 1: Demographics of the respondents to the 62-item questionnaire (N=473)

Gender, n (% female)	305 (64,50%)
Age (years)	64.99 ± 13.00 (23 – 101)
Disease duration (months)	12.96 ± 11.99 (1 -77)
Education level, n (%)	
Low	199 (42.8%)
Intermediate	197 (42.5%)
High	68 (14.4%)
Patient Global assessment of disease impact*	43.77 ± 26.56 (0-100)
Pain*	44.89 ± 28.96 (0-100)

Values are mean ± S.D. (range), unless indicated otherwise; *Assessed using visual analogue scales ranging from 0-100 with higher values indicating poorer health.

Table 2: Convergent validity

	Educational level	Age	Disease duration
Disease and treatment knowledge score	0.52**	-0.54**	-0.13**

*statistically significant at the 0.05 level;
** statistically significant at the 0.01 level;