Validation of a simple activity participation measure for rheumatoid arthritis clinical trials

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Objective. To examine the validity, reliability and sensitivity to change of the Activity Participation Questionnaire (APaQ), a simple measure of activity participation for patients with RA.

Methods. The questionnaire contained two items: (i) number of days in the past month of being unable to perform one's usual activities because of RA; and (ii) a score measuring how often one's usual activities could be completed. The APaQ was administered to 1043 RA patients in two clinical trials of abatacept. Construct validity was evaluated by examining changes from baseline in activity scores by clinical response measured by the European League Against Rheumatism (EULAR) and ACR criteria and minimal disease activity (MDA) state and by correlations with patient-reported outcome measures of physical function, disease activity, pain and fatigue at study end-point. Internal consistency, test–retest reliability and sensitivity to change were assessed.

Results. Both activity participation items were significantly associated with levels of EULAR and ACR response and the achievement of MDA state (P < 0.0005 for all comparisons). Moderate correlations with patient-reported outcomes were consistently found (correlations 0.5–0.6). Cronbach's α was 0.7 indicating good internal consistency, the intraclass correlation coefficient of 0.6 suggesting acceptable test–retest reliability. Sensitivity to change was demonstrated by the treatment differences and the standardized response mean (0.39 and 0.30) for the two activity items.

Conclusion. The APaQ is a simple, reliable and valid measure of patient activity, which is sensitive to change, suggesting its suitability for use in clinical trials.

KEY WORDS: Rheumatoid arthritis, Activity participation, Quality of life, Abatacept.

Introduction

Participation is the new central concept of the International Classification of Functioning, Disability and Health (ICF) [1–3] that needs to be properly measured in RA studies. The effects of RA—joint damage, pain, fatigue and disability—significantly limit patients' ability to participate in and perform their normal daily activities, including work, social and leisure activities. Participation in such activities is a pivotal aspect of personal identity and well-being that has been adopted recently in ICF framework [4]. Limitations in these activities imposed by RA are experienced by patients in terms of a failure to contribute to society, a loss of a sense of identity and purpose, and feelings of dependence and isolation [5]. The patterns of activity participation that are valued most vary by patient demographic, cultural background and personal preference [4].

Body function and structure impairments, activities limitation (i.e. difficulty of carrying out certain tasks) and restrictions in participation are three key concepts in the ICF framework [3]. The ICF core set advocates measurement of all three aspects in RA clinical trials [2, 3]. Although several instruments have been developed for RA to measure the effect of body function and structure impairment (such as the joint counts) and activity limitations (such as the HAQ and the Arthritis Impact Scales) [6, 7], few address the question whether a patient is actually able to participate in usual daily work and non-work activities. Available questionnaires on activity participation are often multi-item questionnaires focusing on some specific aspects of activity, such as social role [8, 9], instrumental activities in RA [10–12] and work productivity [13]. Questionnaires on work productivity are appropriate only for a subset of RA patients—in this case, people of working age with paid employment—and are not necessarily cross-culturally applicable. In addition, multi-item questionnaires can be long and hence burdensome when completed at repeated time points. Such questionnaires are not necessarily suitable for use in large-scale international clinical trials [14]. Therefore, there is a need for a questionnaire that is short, simple and universally applicable to all patients to measure participation restrictions.

We sought to develop a measure of the effect of RA on patients’ participation in their usual activities that could be applied in the setting of an international clinical trial. The desired instrument would have three properties. First, the task of completing the questionnaire would place a minimal burden on the respondent. Second, the questionnaire would be applicable to all patients with RA, regardless of age, gender and work status. Third, the measure would be applicable across the cultural and socio-economic differences that exist among the populations that typically participate in international clinical trials. The Activity Participation Questionnaire (APaQ) was designed to meet these criteria.

The APaQ was administered in two international clinical trials of the biologic disease-modifying therapy, abatacept: AIM (Abatacept in Inadequate Responders to Methotrexate) and ATTAIN (Abatacept Trial in Treatment of Anti-TNF Inadequate Responders) [15, 16]. The objective here is to assess the psychometric properties of the APaQ in terms of its validity, reliability and sensitivity to change.

Patients and methods

Study populations

The data were collected from two randomized, double-blind, placebo controlled trials of abatacept in patients with active RA [15, 16]. The AIM study was of 12-month duration, and a total of 652 patients were randomized 2:1 to receive abatacept or placebo on a background of MTX [15]. The ATTAIN study was a 6-month trial with a total of 391 patients randomized 2:1 to receive abatacept or placebo on a background of DMARDs [16].
The Activity Participation Questionnaire

These questions concern your usual activities. Usual activities are your work, whether or not you work for pay, and any other activities you do during the day.

1. During the past 30 days, on about how many days did your rheumatoid arthritis keep you from doing your usual activities? __ days

2. During the past 30 days, how often were you able to perform your usual activities completely, in spite of your rheumatoid arthritis? (select one answer)

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- None of the time

Fig. 1. The Activity Participation Questionnaire (APaQ).

Both studies were approved by ethical review boards, and patients completed informed consent forms.

The APaQ

The APaQ is a two-item instrument that measures the degree to which a patient has been unable to perform his or her usual activities in the past 30 days because of RA. ‘Usual daily activities’ encompasses paid and non-paid work and any other activities a patient does during the day (e.g. household chores, personal care, etc.). The wording of the APaQ is shown in Fig. 1. The first item (‘days of limited activity’) assesses how many days in the past 30 days that the patient was not able to participate in usual activities; the second item (‘activity completion’) measures how often the patient was able to perform the activities completely with response categories scored from 1 (for ‘all of the time’) to 6 (for ‘none of the time’). Lower scores on both items represent greater activity participation. The APaQ emphasizes the concept of participation in the ICF framework. The term ‘activity participation’ used in the questionnaire and throughout this manuscript refers to participating in usual daily activities.

The APaQ was developed to be clinically relevant, simple and easy to use in international clinical trials. The concept of participation was first considered by an advisory board including practising rheumatologists with expertise in outcome measures. This group of experts determined that two key aspects of participation should be assessed: missed days of activities and the degree of participation when the patient does carry out the activities. To maintain the principle of simplicity, the group recommended using one question for each of the two concepts. Given that there were available items to measure these concepts from validated questionnaires, adaptation from existing questionnaires was feasible. Available questionnaires were then reviewed and assessed on the best fit in measuring activity participation in RA. As a result, the first question of the APaQ on number of days of missed activity was adapted from the National Health Interview Survey Adult Core Questionnaire [17], and the response categories of the second question were adapted from the 36-item short-form (SF-36) [18]. Before use in international clinical trials, the APaQ underwent cognitive debriefing and cultural adaptation including RA patients in multiple countries. Wordings of the items were clarified and modified based on the feedback from the cognitive debriefing process to ensure the questions were understood by the patients cross-culturally. The questionnaire was translated into 20 languages and the accuracy of the translations was linguistically validated by forward and backward translations.

Criteria for determining clinical response

Three measures were used to assess clinical response and disease activity in the AIM and ATTAIN trials. The first was the ACR response criteria, including the ACR 20, -50 and -70 responses. An ACR 20 is defined as ≥20% improvement in both tender and swollen joint counts, and in at least three of the following measures: patient’s assessment of pain, patient’s and physician’s global assessments of disease activity, and physical function as evaluated by the HAQ and CRP level [19].

The second measure was the EULAR (European League Against Rheumatism) response criteria with three response categories: good, moderate and none [20]. The EULAR criteria are based on the disease activity score 28 (DAS28) [21], and are a function of current disease activity and the change in disease activity. The DAS28 is an index that combines joint counts, biomarker and patient global assessment, scored on a scale of 0–10 with scores of <3.2, 3.2 to <5.1 and >5.1 representing low, moderate and high disease activity, respectively [21–23]. A change of 1.2 is considered to be clinically significant [23]. The EULAR response criteria have been validated in several clinical trials [24, 25].

The third measure was the state of Minimal Disease Activity (MDA), which has been defined conceptually as ‘that state of disease activity deemed a useful target of treatment by both the patient and the physician’, given current treatment possibilities and limitations [26]. As described by the OMERACT (Outcome Measures in Rheumatoid Arthritis Clinical Trials) group, MDA is a disease state that exists between high disease activity and remission, and by definition anyone in remission will also be in a state of MDA [26]. Two definitions of MDA have been proposed, corresponding to the DAS28 index and the ACR core set [26, 27].

Patient-reported outcome measures

Patient-reported outcome measures that were closely related to disease status were considered in this analysis: the HAQ, and scales measuring patients’ global assessment of their disease activity, pain and fatigue. The HAQ questionnaire assesses patients’ ability to complete eight categories of common tasks: dressing and grooming, arising, eating, walking, hygiene, reach, grip and common activities [6]. Within each category patients report the degree of difficulty they experience in performing the activity (none, some difficulty, much difficulty, unable to do). An aggregate HAQ disability index (HAQ-DI) which takes into account the use of aids and devices is computed on a scale of 0–3, with 0 representing no disability and 3 indicating complete disability.

The measures of the patient’s global assessment of disease activity, pain and fatigue [28] were single-item 100-mm visual analogue scales (VAS), scored 0–100, with higher scores representing greater disease activity, pain, or fatigue severity.

Statistical methods

The APaQ was assessed in terms of its construct validity, reliability and sensitivity to change (i.e. responsiveness) using the combined data set from the AIM and ATTAIN trials. Construct validity was evaluated in two ways: (i) the relationship between changes in APaQ values and clinical response. Changes from baseline to study end-point in the two APaQ items were compared to ACR criteria (ACR20, ACR 50, or ACR70 response), EULAR criteria (none, moderate, or good response) and by attainment of a state of MDA (yes/no) by both DAS28-based and ACR core set-based definitions. Study end-point was defined as 12 months in the AIM trial and 6 months in the ATTAIN trial. The F-test was used to determine the statistical significance of the association between APaQ change scores and...
EULAR or ACR response, and the t-test to determine the statistical significance of the association between APaQ change scores and state of MDA. Tukey’s honest significance difference (HSD) multiparameter test (with \( P = 0.05 \)) was used to determine specific pair-wise differences in the categories of the EULAR or ACR response. (ii) Spearman’s correlations were used to assess the relationship between values on the two APaQ items and scores on the HAQ, patient global assessment, pain and fatigue measures at study end-point.

Reliability was determined in terms of test–retest reliability. For the two APaQ items, the intraclass correlation coefficient (ICC) between baseline and 1 month was calculated for the subset of patients who showed little or no change in disease activity (i.e. \(<2\%\) change in patient global assessment of disease activity) between the baseline and the first assessment at 1 month. Internal consistency was assessed by the Cronbach’s \( \alpha \). The standardized value for the coefficient was used, since there was a mixture of multipoint scales in the items (i.e. a number of days and a Likert scale). Nunnally [29] suggested that a reliability coefficient of 0.7 is acceptable. Higher values indicate greater consistency, and a value between 0.7 and 0.9 is considered to have high consistency without redundancy.

Sensitivity to change (i.e. the ability of the APaQ to detect a treatment effect) was assessed by treatment difference (the difference in the mean change from baseline between the abatacept group and the placebo group) and the standardized response mean (SRM) [30]. The SRM is the ratio of the treatment difference at study end-point to the pooled s.d. of the mean change (baseline to study end-point) scores. By convention, an SRM value 0.2 is regarded as small, and a value of 0.5 as moderate [30]. All statistical calculations were done using SAS Version 9.1 (SAS Institute, Cary, NC, USA).

Results

Patient characteristics at baseline

Patients entering the AIM and ATTAIN trials were mostly female (77–82\%), of average age (50 yrs), and with an average RA duration of 8–9 yrs in AIM and 11–12 yrs in ATTAIN (Table 1). Average baseline HAQ scores of 1.7 in AIM and 1.8 in ATTAIN, and average scores in the range of 63–73 on the scales for patient global assessment of disease activity, pain and fatigue, were all indicative of moderate-to-severe RA (Table 1). At baseline, patients were not able to participate in usual activities for 14 days in the previous month (i.e. about half of the time), whereas mean APaQ activity completion scores of 3.6–3.8 indicated that on average patients had been able to complete their usual activities between ‘a good bit of the time’ and ‘some of the time’.

![Image](318x541 to 564x726)

**FIG. 2.** Change in days of limited activity from baseline to study end-point, by clinical response according to EULAR and ACR criteria, and by state of MDA based on DAS28 ACR core set. The F-test was used to determine the statistical significance of the association between APaQ change scores and EULAR or ACR response, and the t-test for the state of MDA. (A) EULAR response, \( P < 0.0001 \) (\( P < 0.05 \) for all pair-wise comparisons); (B) ACR response, \( P = 0.001 \) (\( P < 0.05 \) for ACR 20 vs ACR70); (C) MDA based on DAS28, \( P < 0.0001 \); and (D) MDA based on ACR core set, \( P = 0.0002 \). In this analysis, ACR 20 responders represented patients with responses \( >20\% \) but \( <50\% \), ACR 50 with responses \( \geq 50\% \) but \( <70\% \) and ACR 70 \( \geq 70\% \) responses.

**Construct validity**

Reductions in days of limited activity were significantly associated with the clinical response measured by EULAR and ACR response criteria, and by both sets of criteria for a state of MDA (Fig. 2). Patients with a good EULAR response experienced a reduction of 10.9 days of limited activity between baseline and study end-point, compared with reductions of 8.2 and 3.5 days for patients with moderate and no response, respectively (\( P < 0.0001 \); Fig. 2A). Pairwise comparisons between the EULAR response categories were all statistically significant (\( P < 0.05 \)). Similarly, patients showing an ACR70 response experienced a reduction of 12.4 days of limited activity between baseline and study end-point, compared with reductions of 10.6 and 8.1 days for patients with an ACR50 and ACR20 response, respectively (\( P < 0.0001 \); Fig. 2B). The change in days of limited activities from ACR70 responders was significantly higher than from ACR20 responders. Patients attaining a state of MDA by DAS28 or by ACR core set criteria experienced reductions in days of limited activity of 11.5 days and 10.5 days, respectively, compared with reductions of only 6.6 days for patients not attaining a state of MDA by either definition (\( P < 0.0001 \), Fig. 2C; \( P = 0.0002 \), Fig. 2D). Results for the activity completion score (APaQ item 2) are presented in Fig. 3. The activity completion score improved (decreased) by 1.8, 0.9 and 0.5 for those with a good, moderate and no EULAR response, respectively (\( P < 0.0001 \); Fig. 3A). Pairwise comparisons between the EULAR response categories were all statistically significant (\( P < 0.05 \)). Results for ACR response were similar with improvements of 1.9, 1.2 and 1.1 for ACR70, ACR50 and ACR20, respectively. Among the ACR response categories, change from ACR70 responders was significantly higher than from ACR50 or ACR20 responders (\( P < 0.05 \)). Patients attaining a state of MDA by DAS28 or by ACR core set criteria had activity score improvements of 1.9 for either definition, compared with improvements of only 0.8 and 0.7 for each definition, respectively (\( P < 0.0001 \), Fig. 2C and D).

Correlations between APaQ scores and HAQ, patient global assessment of disease activity, pain and fatigue scores at study end-point are presented in Table 2. The correlation coefficients are in the range of 0.56–0.61 for days of limited activity (APaQ item 1)
Validation of an activity participation measure

The treatment differences (i.e. mean change from baseline in the
clinical response and disease activity (ACR and EULAR
response and MDA). Improvements in activity participation
(reduction in limited activity days and activity completion score)
clearly showed the trend to correspond with clinical improvement,
with the improvement in the highest response category to be
nearly twice as much as the lowest category (Figs 2 and 3).
Moderate correlations (coefficient of 0.5–0.6) were observed
between the APaQ and patient-reported outcome measures on
physical function (the HAQ), pain, fatigue and patient global
assessment of disease activity. The APaQ also showed acceptable
reliability and internal consistency, and sensitivity to change.

The strength of this study is that it uses actual data on the
APaQ from two international clinical trials of 1043 patients.
Extensive evaluations on clinical response and patient-reported
outcomes were included in the clinical trial, which enabled the
evaluation of validity, reliability and sensitivity to change of the
APaQ. Since an important goal for RA treatment is to restore
patients’ functional abilities and improve their ability to be active
members of society, the APaQ can play a vital role in deciding
when a treatment is assessed. The strengths of the APaQ are
discussed below and can be summarized as follows: providing a
broad assessment of activity that can be applicable to all patients;
emphasizing participation in activities rather than limitation;
being simple to administer; and being readily interpretable.

The APaQ was designed to provide a broad assessment of
activity that is applicable to all patients in their own activity
context. It does not focus on one specific activity or on an itemized
list of activities, but encompasses all dimensions of activity. In this
respect, the APaQ is consistent with the framework of the ICF,
where activities (execution of a task or action) and participation
(involvement in a life situation) are recognized as equally
important and are in one integrated component of activities
[1–3]. Unlike the APaQ, previously developed measures of activity
typically focus on limitations on specific itemized activities. The
HAQ [6] and the Arthritis Impact Measurement Scales 2 (AIMS2)
[7] use pre-defined lists of activities and are widely used for
assessing activity limitation in RA. The AIMS2 addresses basic
activities of daily living (ADL)—bathing, dressing, eating, getting
in or out of chairs, walking and toileting—as well as more
complex tasks associated with independent living (instrumental
ADL or IADL), such as housework and transportation [7]. The
recently developed 19-item Measure of Activity Limitation (MAL)
[12] questionnaire assesses the impact of RA symptoms on 12
areas of activities, such as personal care, mobility, household
activities, paid employment, caring for others, etc. Among these,
five activities were identified by patients as important; however,
they were shown to be not applicable to everyone. The
questionnaire thus includes a response option of ‘does not apply’.

Other instruments used to study the effects of RA on specific dimensions of activity participation have largely addressed
remunerative employment, which has been measured with
questionnaires, such as the validated Work Limitation
Questionnaire (WLQ) on limitation in specific job demands
[13, 31]. However, work questionnaires are applicable only to a
minority of RA patients. It was shown in two studies of adults
aged under 65 yrs that only 37–43% of the RA patients were
employed, compared with 65–72% of the general population [32].
In a clinical trial setting, such loss of information (and data) can
be critical and could compromise the randomization principle
when comparing treatment groups. For example, in a recent
report from a clinical trial, the analysis of the work productivity
questionnaire was restricted to patients who reported working at
baseline; which was 38% of the total sample [33]. The missing data
complicated the interpretation of treatment group comparison,
and the ability to demonstrate change in patients who were not
working at baseline. In addition, non-work activities can be
equally important to patients and must be addressed. Working
status can be influenced by patients’ age, family financial
needs and personal preference. Therefore, measuring working

Discussion
In the AIM and ATTAIN trials, both items of the APaQ
demonstrated strong construct validity in the ability to distinguish

and 0.50–0.56 for the activity completion score (APaQ item 2),
indicating moderate correlations.

Reliability and internal consistency
Test–retest reliability was determined for patients (n=35) who
had <2% change in patient global assessment of disease activity
between baseline and 1 month. ICC of 0.62 for both APaQ items
indicated acceptable test–retest reliability. The value of the
standardized Cronbach’s α coefficient was 0.702, indicating
good internal consistency between the APaQ items.

Sensitivity to change
The treatment differences (i.e. mean change from baseline in the
abatacept group minus mean change from baseline in the placebo
and 95% CIs for the two APaQ items were: −4.72 (−6.27, −3.18) for
days of limited activities (score range 0–30), −0.51 (−0.73, −0.29) for the activity completion score (score range 1–6),
with negative changes indicating improvements. Thus, both items
demonstrated statistically significantly greater improvement from
the abatacept group compared with placebo. The SRMs (95% CI)
were 0.39 (0.26, 0.52) and 0.30 (0.17, 0.43), respectively, for days
of limited activity and activity completion scores. These suggest
the APaQ items were sensitive to changes.

![Figure 3](image-url)

**FIG. 3.** Change in activity completion score from baseline to study end-point, by
clinical response according to EULAR and ACR criteria, and by state of MDA
based on DAS28 ACR core set. The F-test was used to determine the statistical
significance of the association between APaQ change scores and EULAR or ACR
response, and the t-test for the state of MDA. (A) EULAR response, P = 0.0001
(\( P < 0.05 \) for all pair-wise comparisons); (B) ACR response, P = 0.0001 (\( P < 0.05 \)
for ACR20 vs ACR70, P = 0.05 for ACR50 vs ACR70); (C) MDA based on DAS28,
\( P < 0.001 \); and (D) MDA based on ACR core set, \( P < 0.001 \). In this analysis,
ACR 20 responders represented patients with responses ≥20% but <50%, ACR
50 with responses ≥50% but <70%, and ACR 70 ≥70% responses.

| Table 2. Correlation between activity participation and HAQ, patient global
  assessment of disease activity, pain and fatigue scores at study end-point |
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<td>APaQ items</td>
<td>HAQ</td>
<td>Patient global assessment</td>
<td>Pain</td>
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<td>Days of limited activity (0–30)</td>
<td>0.614</td>
<td>0.592</td>
<td>0.565</td>
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<td>Activity completion score (1–6)</td>
<td>0.564</td>
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\( ^a \) Spearman coefficient.
productivity alone does not provide a complete assessment of the change a patient experienced related to an intervention in carrying out daily activities.

The APaQ is a direct measure of participation (e.g. how many days a patient can take part in usual activities), while other instruments (including the HAQ and SF-36) mostly address activity limitation (i.e. difficulty of carrying out certain types of activities). Several of the SF-36 domains (role physical, role emotional and social functioning) relate to the concept of activity participation, but the questions only ask the degree a patient cut down the time of involvement (e.g. most of the time, some of the time), and are thus indirect measures of participation. The MAL questionnaire used similar response categories which represent the degree of activity limitation rather than actual participation.

A main advantage of the APaQ for the clinical trial setting is that it is simple and easy to administer. Multi-item indices provide a comprehensive profile of domains of activity, but at the cost of increased burden and of asking potentially irrelevant questions [14]. Instruments as simple as single-item analogue scales can be as valid as multi-item indices. For example, a single-item analogue scale measuring emotional well-being was found to be a valid measure, comparable with a 28-item scale but more feasible to use in multicentre, multicultural clinical trials [34]. Similarly, the single-item VAS fatigue scale correlates well with clinical variables and performs at least as well as longer questionnaires in terms of sensitivity to change [26].

The APaQ was designed to be readily interpretable. Unlike many other outcome measures, the meaning of a change in APaQ score from before to after an intervention is readily apparent in the lives of patients. Item 1 of the APaQ yields a number of days on which patients are unable to carry out their normal activities, a statistic that is easily understandable and could be applied in calculating economic impact of a treatment. Item 2 captures an additional aspect of activity participation, i.e. restrictions experienced while carrying out usual activities. APaQ items 1 and 2 are akin to measures of absenteeism and presenteeism in the study of productivity loss, where absenteeism is assessed as a number of days, and presenteeism as a score [35]. The APaQ can be used adjunctive to commonly used patient-reported outcome (PRO) measures, such as the HAQ and the SF-36. Although these measures provide information on numerical changes in summary scores, they do not depict the impact of an intervention on a patient’s real life, i.e. whether the patient is more active than before. The APaQ supplements the PRO measures and provides additional insight into the effect of a treatment.

It is acknowledged that the APaQ items were adapted from existing questionnaires rather than developed de novo, and thus they did not go through the traditional process of item generation and selection. Nevertheless, necessary changes in the wordings of the APaQ were made based on cognitive debriefing to RA patients, and the simplicity of the questionnaire was maintained. The present study is an initial validation of the APaQ and further research is warranted to investigate the property and usage of the instrument in broader patient populations. The study used data from two clinical trials, which consist of primarily moderate-to-severe RA patients. Future studies should test the instrument in other RA populations including those with milder disease. Since no other direct measure of participation was available from the clinical trials, construct validity was evaluated against measures of disease activity and functional abilities rather than participation. Further research should evaluate the APaQ against other measures of participation in settings outside of clinical trials, and compare the APaQ with a broader range of activity measures, such as the WLQ and questionnaires addressing social participation. In addition, while the clinical trial setting is appropriate for determining validity and sensitivity to change, it is not well suited to measuring test–retest reliability. Measurement of test–retest reliability assumes a stable population, whereas the idea of a clinical trial is to measure a change in the population in response to treatment. We addressed this by identifying a set of patients whose RA manifestations changed minimally over the first month, but consequently test–retest reliability was measured in only a small subset of the patient population.

In conclusion, the APaQ is a simple, two-item measure of activity participation that reflects real changes in patients’ clinical status and quality of life. It demonstrated validity, reliability and sensitivity to change, which suggests that it is a suitable outcome measure for clinical trials.

Rheumatology key messages

- The APaQ is a valid, reliable and sensitive measure for RA.
- It is simple and easy to administer and suitable to use in clinical trials.

Acknowledgements

The authors would like to thank Sophie Shen of Bristol-Myers Squibb and Alan Morrison of Scribco for their help on literature search and editorial assistance.

Funding: This work was supported by an unrestricted research grant from Bristol-Myers Squibb.

Disclosure statement: T.L. is an employee of Bristol-Myers Squibb and owns company stock. G.W. has received honoraria from Bristol-Myers Squibb for work in patient-reported outcomes related to activity. P.T. has received consulting fees from Bristol-Myers Squibb. R.W. is a consultant for Bristol-Myers Squibb and Schering-Plough Belgium.

References

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