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# Using a novel smartphone application for capturing of patient-reported outcome measures among patients with inflammatory arthritis: A randomized, crossover, agreement study

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**Objectives:** In Denmark, patients with inflammatory arthritis (IA) have completed patient-reported outcome measures (PROMs) via touchscreens in the outpatient clinic since 2006. However, current technology makes it possible for patients to use their own smartphone via an application (app) developed for the Danish Rheumatology Database (DANBIO). This study aims to evaluate the agreement of PROMs between the DANBIO app and outpatient touchscreen in patients with IA.

**Method:** Patients with IA (rheumatoid arthritis, psoriatic arthritis, and axial spondyloarthritis) were enrolled in a randomized, crossover, agreement study. Participants answered PROMs through the two device types in a randomized order. Differences in PROM scores with 95% confidence intervals (CIs) were evaluated for similarity according to prespecified equivalence margins.

**Results:** The touchscreen invitation was accepted by 138 patients. Sixty patients (20 with each diagnosis) were included. The difference in Health Assessment Questionnaire Disability Index between the two device types was  $-0.007$  (95% CI  $-0.043$  to  $0.030$ ); thus, equivalence was demonstrated. In addition, all other PROMs obtained with the two device types were equivalent, except for the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), which was within the limits of minimally clinically important difference (MCID). In total, 78.3% preferred the DANBIO app.

**Conclusion:** In patients with IA, equivalence was demonstrated between two device types for all PROMs except BASDAI; however, BASDAI was within the limits of the MCID. Implementation of the DANBIO app is expected to optimize outpatient visits, thereby improving healthcare for the individual patient and society.

Patient-reported outcome measures (PROMs) are pivotal in the management of inflammatory arthritis (IA), as PROMs illustrate the patient's own assessment of arthritis activity, e.g. pain, fatigue, and morning stiffness of the joints (1). Historically, PROMs were collected in paper form; however, in Denmark, PROMs have been collected

electronically through an outpatient touchscreen since 2006 (2). Electronic collection of PROMs has major advantages: more accurate and complete data, avoidance of secondary data entry errors, less administrative burden, and potential cost savings (3). It has previously been shown in a Danish rheumatology patient population that capturing PROMs through an electronic outpatient touchscreen versus paper-based forms yields comparable results (4, 5). In addition, a 2019 study validated a web-based solution accessed from home against the outpatient touchscreen in a Danish IA population (6).

During the past few years, novel technologies have made it possible and feasible to capture PROMs via a downloaded application (app) on the participant's own

**Trial registration:** clinicaltrials.gov, <https://clinicaltrials.gov/ct2/show/NCT03486613?cond=Psoriatic+Arthritis&entry=DK&city=Aalborg&draw=2&rank=4>, NCT03486613.

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device, whenever and wherever it suits the individual (3). The Danish Rheumatology Database (DANBIO) app was created for this purpose. Answering PROMs with an app could eliminate problems with the outpatient touchscreen, such as having to wait in a queue, lack of privacy, disturbance, and uncomfortable position during data entry caused by joint and spine deformities. Furthermore, an app has the major advantage over a web-based solution that PROMs can be answered without an internet connection, since the app stores responses on the device until an internet connection is available (3). Thus, an app could be a pivotal tool for optimizing the management of patients with IA, as patients easily can report PROMs on their own device without having to attend the outpatient clinic. Based on the PROM answers, the physician can then prioritize outpatient visits (7).

The Health Assessment Questionnaire Disability Index (HAQ-DI) is among the most frequently used and essential PROMs in the assessment of patients with IA (8–10). In accordance with the Outcome Measures in Rheumatology (OMERACT), self-reported patient health status measures should always be adequately validated (11). Thus, the primary aim of this trial is to demonstrate equivalence in HAQ-DI score when using the two device types among patients with IA [i.e. rheumatoid arthritis (RA), psoriatic arthritis (PsA), and axial spondyloarthritis (axSpA)].

## Method

### Patient and public involvement

Two patient research partners are members of the steering committee for national implementation of the DANBIO app and acknowledged the purpose of this trial and commented on early drafts of the trial hypothesis and study design. The results of this study were discussed at an informal meeting at Aalborg University Hospital prior to submission of this article.

### Study design and participants

In a randomized, within-participants, crossover, agreement trial, patients with IA were included from the outpatient clinic at Aalborg University Hospital. Eligible patients had an established diagnosis ( $\geq 12$  months) of RA, PsA, or axSpA, and experience with the PROM questionnaires (at least three previous answered PROMs). Exclusion criteria were a language barrier (the PROMs were only available in Danish), visual impairment, and having no access to a smartphone that could download and run the DANBIO app.

### Procedures

The screening period started on 24 April 2019 with an invitation on the touchscreen in the outpatient clinic.

Patients who accepted the invitation were contacted by telephone and screened. At the telephone screening visit, the investigator asked the potential participant if he or she had a smartphone that could download and run apps. If so, the participant was instructed on how to access and download the DANBIO app in App Store or Google Play. Furthermore, the investigator ensured that the participant was familiar with accessing apps with their Danish personal identification number. After written informed consent was obtained, participants were randomized in a 1:1 ratio to either:

- App device first  $\rightarrow$  touchscreen solution (AD  $\rightarrow$  TS): PROMs were answered through the DANBIO app first and then, after a ‘washout’ period, through the outpatient touchscreen.
- Touchscreen screen first  $\rightarrow$  app device (TS  $\rightarrow$  AD): PROMs were answered through the outpatient touchscreen first and then, after a washout period, through the DANBIO app.

To minimize recall bias, there was a washout period of 1–2 days between the two PROM registrations.

Following usual practice, PROMs were reported through the outpatient touchscreen with the patient’s personal civil registration number (Supplementary Figure S1). Before answering PROMs through the DANBIO app, the participants had to download the app on their smartphone and log on to the app with their personal identification number (Supplementary Figure S2). The PROMs and the item order were exactly the same as on the outpatient touchscreen.

### Objectives and outcomes

The primary objective was to evaluate whether electronic reporting of HAQ-DI through a smartphone app is equivalent to the touchscreen in the outpatient clinic in patients with IA.

Secondary outcomes were to evaluate equivalence between the two device types for the following PROMs: visual analogue scale (VAS) pain, VAS fatigue, VAS global health, Patient Acceptable Symptom State (PASS), anchoring question (i.e. “Since your last visit is your arthritis: much worse, worse, a little worse, unchanged, a little better, better, or much better?”), and, for patients with axSpA: Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Bath Ankylosing Spondylitis Functional Index (BASFI). In addition, patient preferences between the two device types were evaluated.

### Collected variables

The DANBIO database is a nationwide Danish registry including patients with IA treated with biological and/or conventional synthetic disease-modifying anti-rheumatic

drugs (bDMARDs and/or csDMARDs) (2). The following demographic data were obtained from DANBIO: gender, age, disease duration, and current arthritis medication; as well as the last registration of the following variables prior to enrolment: patient PROMs, C-reactive protein (CRP), and VAS physician. In addition, immunoglobulin M rheumatoid factor (IgM-RF), anti-citrullinated peptide antibody (ACPA), X-ray, and Disease Activity Score based on 28-joint count–C-reactive protein (DAS28-CRP) status were obtained for patients with RA and PsA, whereas human leucocyte antigen subtype B27 (HLA-B27), X-ray, Bath Ankylosing Spondylitis Metrology Index (BASMI), and Ankylosing Spondylitis Disease Activity Score (ASDAS) status were collected for patients with axSpA.

Data regarding the primary and secondary outcomes, i.e. the participant PROM registrations on the two device types, were entered into the device by the patient, after which they were uploaded electronically from the device to a dedicated electronic case report form (e-CRF) within the DANBIO server.

### Power and sample size calculation

Equivalence margins were defined a priori as a difference in PROMs between groups less than or equal to half of the minimally clinically important difference (MCID). Thus, the equivalence margin for HAQ-DI was  $\pm 0.11$  points, i.e. half of the MCID of 0.22 points (12). The equivalence margin for VAS pain, VAS fatigue, VAS global, BASDAI, and BASFI was set to  $\pm 5$ , i.e. half of the MCID of 10 (4, 6, 12–14).

As described in the Protocol (Supplementary Data S1) and the Statistical Analysis Plan (SAP) (Supplementary Data S2), we applied two one-sided tests' analysis for additive equivalence of paired means with bounds of  $-0.11$  and  $0.11$  for the mean difference in HAQ-DI score, with a common standard deviation of 0.62 HAQ-DI points (6) and correlation of 0.95 (between measures). To explore equivalence margins within each disease group separately, a sample size of 60 (20 patients with each diagnosis) was feasible, corresponding to a power of 99.2%.

### Allocation concealment and implementation

A computer-generated randomization sequence was produced in SAS PROC PLAN before any patients were enrolled, allocating the participants to one of the two different sequences using permuted blocks stratified by diagnosis (i.e. RA, PsA, or axSpA). The randomization sequences were made by the senior biostatistician (RC), who had no clinical involvement in the study, and entered into the e-CRF in DANBIO by the independent data manager (NSK).

### Statistical analyses

All analyses were performed in accordance with the prespecified SAP (Supplementary Data S2) and in accordance with the EQUATOR network recommendation (15) and the CONSORT statements (16, 17). Analyses for the primary and secondary endpoints were performed according to the intention-to-treat principle, i.e. including all randomized individuals having at least the first outcome measures collected, independent of subsequent protocol violations.

Mixed linear models were applied that included both fixed [first or second registration; device (App or Touchscreen); rheumatic condition (RA or PsA or axSpA)] effects and random participant (patient ID number) effects, further adjusted for the PROM level at enrolment. Agreement/equivalence was obtained if the 95% confidence interval (CI) of differences between the two device types lie within  $\pm$  half the MCID (18). A Bland–Altman plot was constructed to illustrate agreement between the two device types for the primary outcome, HAQ-DI (19).

### Results

During the inclusion period from 24 April 2019 to 3 September 2019, 138 patients with IA accepted the outpatient touchscreen invitation (28.4%) and 348 patients declined the invitation. Figure 1 illustrates patient recruitment for those who accepted the touchscreen invitation, including reason for exclusion. The main reasons for non-enrolment were: unable to visit the outpatient clinic in the study period, 24 (30.8%), interested in participating but did not send the signed informed consent form back to the investigator, 20 (25.6%), and not answering the telephone, 12 (15.4%). In total, 60 patients out of 111 contacted for a telephone screening were enrolled (54%). However, as presented in Supplementary Table S1, no important differences in gender, age, disease duration, HAQ-DI score, or disease activity were observed between enrolled and excluded patients, or among patients who declined to participate.

Patient demographics for enrolled subjects were well balanced between the groups, as presented in Table 1. The mean age was 53.7 years, 51.7% were males, median disease duration was 10.9 years, 55% were treated with a csDMARD, and 40% were treated with a bDMARD or targeted synthetic disease-modifying anti-rheumatic drug (tsDMARD).

As visualized in the Bland–Altman plots (Figure 2A, B), reliability between the HAQ-DI scores obtained by the two device types was very high (Figure 2A) and agreement was demonstrated (Figure 2B). According to the analyses in Table 2, HAQ-DI scores were equivalent for the two device types, with a difference of  $-0.007$  (95% CI  $-0.043$  to  $0.030$ ). The score differences in PROMs between the two device types were all within

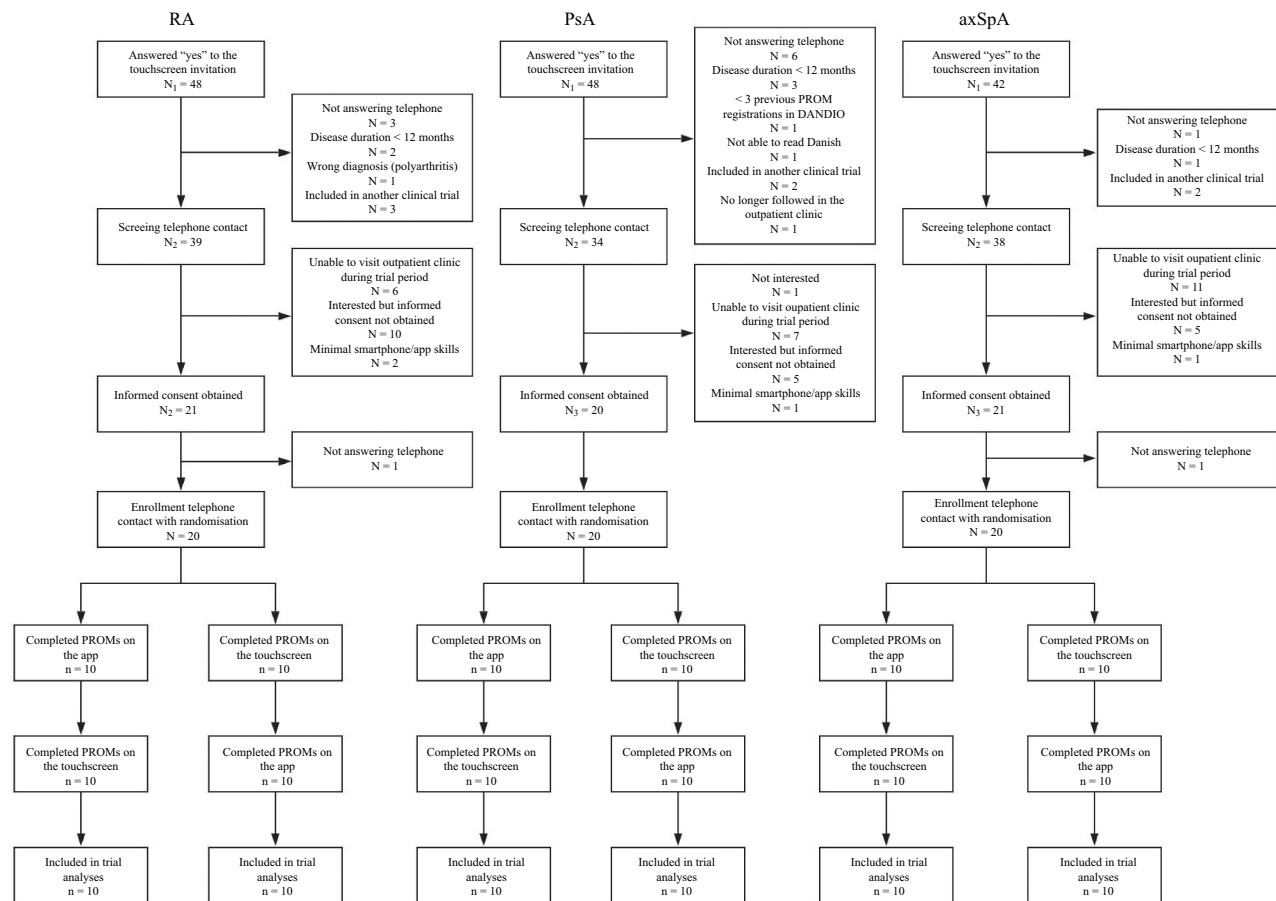


Figure 1. Flow diagram of patient recruitment. RA, rheumatoid arthritis; PsA, psoriatic arthritis; axSpA, axial spondyloarthritis; PROM, patient-reported outcome measure; DANBIO, Danish Rheumatology Database.

the prespecified equivalence margins (Table 2), except for BASDAI, as the 95% CI for the difference in BASDAI ( $-5.4$  to  $2.4$ ) exceeded the prespecified equivalence margin of  $\pm 5.0$ . However, the 95% CI was well within the MCID of  $\pm 10.0$  for BASDAI.

Subgroup analyses showed no significant difference in HAQ-DI score between genders, diagnosis (RA vs PsA/axSpA), younger half versus older half, or participants > 65 years old (i.e. less anticipated information technology experience) versus younger (Table 3).

Finally, participant preference for answering PROMs through the outpatient touchscreen versus the DANBIO app were explored: 41 (68.3%) highly preferred the DANBIO app, six (10%) slightly preferred the DANBIO app, 12 (20%) had no preference, none (0%) slightly preferred the outpatient touchscreen, and one (1.7%) highly preferred the outpatient touchscreen. Thus, in total, 47 (78.3%) preferred PROM data entry through the DANBIO app.

## Discussion

This study is, to our knowledge, the first to demonstrate equivalence in HAQ-DI, VAS pain, VAS fatigue, VAS

global, PASS, anchoring question, and BASFI score obtained with a smartphone app and an outpatient touchscreen among patients with various IA diseases. However, equivalence was not demonstrated for BASDAI, as the lower limit of the 95% CI of  $-5.4$  was just below the prespecified equivalence margin of  $\pm 5.0$ . Nevertheless, as the 95% CI for BASDAI was well within the MCID of  $\pm 10.0$ , we feel confident that answering BASDAI on the two device types will be similar enough to be used interchangeably. Thus, for patients with IA who have access to a smartphone that can run the DANBIO app, it is a feasible alternative for reporting PROMs.

The major difference between the DANBIO app and the outpatient touchscreen is screen size, which results in different font size. A significant reduction in font size in PROMs between a paper-based form and an electronic device is considered a moderate modification by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) (20), thus requiring equivalence testing. This study demonstrated a smaller difference between devices than the MCID; hence, the two device types can be used interchangeably.

Previously, Schefté and Hetland found no statistically significant differences in HAQ, VAS pain, VAS fatigue,

Table 1. Patient demographics and clinical characteristics.

Variable	AD → TS (n = 30)	TS → AD (n = 30)	All (n = 60)
General characteristics			
Male	17 (56.7)	14 (46.7)	31 (51.7)
Age (years)	52.2 ± 12.4	55.2 ± 12.3	53.7 ± 12.3
Disease duration (years)	10.5 (6.5;17.0)	12.3 (5.2;15.8)	10.9 (6.3;15.9)
Last HAQ-DI score (0–3)	0.4 (0.1;0.8)	0.8 (0.1;1.4)	0.6 (0.1;1.2)
Last VAS pain score (0–100 mm)	34.5 (15.5;54.3)	41.5 (17.0;65.0)	38.0 (17.3;61.8)
Last VAS fatigue score (0–100 mm)	41.0 (20.0;64.0)	63.5 (27.8;73.0)	53.5 (24.8;72.0)
Last VAS global health score (0–100 mm)	34.0 (17.8;70.0)	40.5 (16.8;66.8)	35.0 (17.3;68.3)
Last PASS 'Yes' score	19 (63.3)	18 (60.0)	37 (61.7)
Last anchoring question (–3 to +3) score	0.0 (–1.0;0.0)	–0.5 (–1.0;0.0)	0.0 (–1.0;0.0)
Currently on csDMARD	15 (50)	18 (60)	33 (55)
MTX	9 (30.0)	14 (46.7)	23 (38.3)
MTX treated dose (mg/week)	20.0 (11.3;25.0)	18.8 (15.0;25.0)	20.0 (15.0;25.0)
Currently on oral steroids	1 (3.3)	0 (0.0)	1 (1.7)
Currently on bDMARD or tsDMARD	15 (50)	9 (30)	24 (40)
Last VAS physician score (0–100 mm)	2.0 (0.0;12.0)	3.0 (0.8;8.0)	2.5 (0.0;8.0)
Last CRP (mg/L)	4.4 (1.4;19.0)	3.6 (1.1;9.2)	3.6 (1.3;12.8)
Disease-specific measures			
Diagnosed with RA	10 (33.3)	10 (33.3)	20 (33.3)
IgM-RF positive	9 (90)	8 (80)	17 (85)
ACPA positive*	8 (80.0)	8 (88.9)	16 (84.2)
Erosive	7 (70)	7 (70)	14 (70)
Last DAS28-CRP (0.96–9.4)	3.2 (2.4;4.0)	3.0 (2.3;3.6)	3.1 (2.4;3.9)
Diagnosed with PsA	10 (33.3)	10 (33.3)	20 (33.3)
Erosive†	4 (44.4)	3 (30.0)	7 (36.8)
Last DAS28-CRP (0.96–9.4)	2.2 (1.5;3.7)	2.7 (1.9;3.6)	2.6 (1.6;3.6)
Diagnosed with axSpA	10 (33.3)	10 (33.3)	20 (33.3)
HLA-B27 positive	10 (100)	9 (90)	19 (95)
Diagnosed with ankylosing spondylitis	4 (40)	8 (80)	12 (60)
Last BASDAI score (0–100 mm)	21.5 (18.5;37.3)	41.5 (18.5;62.5)	30.0 (19.3;49.5)
Last BASFI score (0–100 mm)	24.5 (16.3;29.0)	31.0 (13.3;48.0)	24.5 (15.5;42.8)
Last BASMI‡ (0–100)	20.0 (15.0;40.0)	10.0 (10.0;45.0)	20.0 (10.0;40.0)
Last ASDAS (0.6–∞)	2.4 (1.4;3.1)	2.3 (1.7;2.7)	2.4 (1.5;2.8)

Data are shown as n (%), mean ± sd, or median (interquartile range).

AD, app device; TS, touchscreen solution; HAQ-DI, Health Assessment Questionnaire Disability Index; VAS, visual analogue scale; PASS, Patient Acceptable Symptom State; csDMARD, conventional synthetic disease-modifying anti-rheumatic drug; MTX, methotrexate; bDMARD, biological disease-modifying anti-rheumatic drug; tsDMARD, targeted synthetic disease-modifying anti-rheumatic drug; CRP, C-reactive protein; RA, rheumatoid arthritis; IgM-RF, immunoglobulin M rheumatoid factor; ACPA, anti-citrullinated peptide antibody; DAS28-CRP, Disease Activity Score based on 28-joint count–C-reactive protein; PsA, psoriatic arthritis; axSpA, axial spondyloarthritis; HLA-B27, human leucocyte antigen subtype B27; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index; BASMI, Bath Ankylosing Spondylitis Metrology Index; ASDAS, Ankylosing Spondylitis Disease Activity Score.

\*One missing value in group TS → AD.

†One missing value in group AD → TS for erosions on X-ray.

‡One missing value in group TS → AD and one missing value in group AD → TS.

VAS global, BASDAI, or BASFI scores between paper-based forms and the outpatient touchscreen in patients with RA or ankylosing spondylitis (4). Similarly, Hofstedt et al showed no statistically significant differences in VAS pain, VAS fatigue, VAS global, BASDAI, BASFI, or DAS28 between paper-based forms and a web-based solution in patients with polyarthritis (10% with axial disease) (21). However, in both the studies by Hofstedt et al and Schefté and Hetland, the 95% CI for the difference between paper and electronic device exceeded the limits of the MCID. In contrast, a study by Secher et al showed no clinically relevant differences in HAQ, VAS pain, VAS fatigue, VAS

global, BASDAI, and BASFI score between a web-based from-home solution and the outpatient touchscreen in patients with RA or axSpA, as the 95% CI for the difference between device types was within the limits of the MCID (6). Thus, the findings in this trial are in agreement with the findings from Secher et al, as the 95% CIs of the difference between device types are within the limits of the MCID for all PROMs. Furthermore, equivalence for all PROMs except BASDAI was demonstrated in this trial.

Patient preference for the DANBIO app was very high (78.3%), and considerably higher than reported by Secher et al, where 50% preferred the web-based

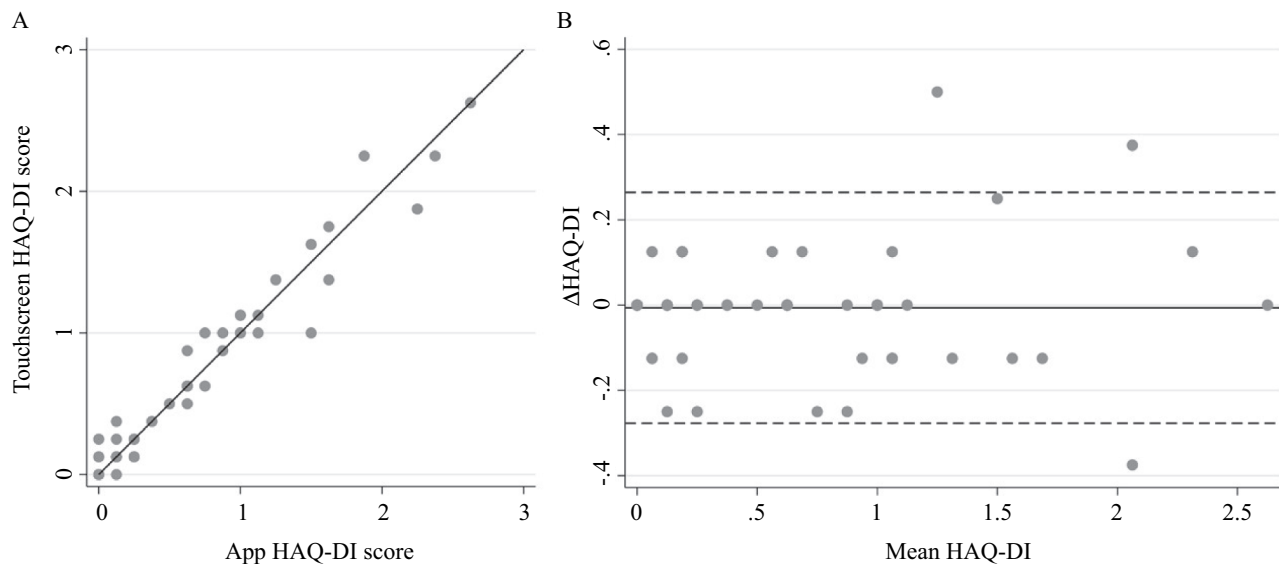


Figure 2. (A) Health Assessment Questionnaire Disability Index (HAQ-DI) scores measured with the two device types, with a line of equality. (B) HAQ-DI score difference (i.e. app HAQ-DI score minus touchscreen HAQ-DI score) against HAQ-DI score mean. The dashed horizontal lines represent 95% limits of agreement and the solid horizontal line represents the mean difference.

from-home solution to the outpatient touchscreen (6). A possible explanation for this is that an app allows the patient to answer their PROMs when and where it suits them best, as an app can capture and store data without an internet connection, in contrast to a web-based solution. Furthermore, the DANBIO app eliminates problems with the outpatient touchscreen such as waiting in a queue, lack of privacy, disturbance, uncomfortable seating position, problems with registering answers owing to reduced upper limb strength, and difficulties with seeing the touchscreen owing to deformity of the cervical spine.

There are limitations to consider in this trial, as only 138 out of 486 patients accepted the touchscreen invitation, which could lead to sampling bias, thereby undermining the external validity of the trial. However, the only significant difference between enrolled participants and patients who declined the touchscreen invitation was that patients with RA who declined the touchscreen invitation had less disease activity. Thus, we feel confident that the observed difference is not substantial and therefore does not affect the external validity of the trial. In addition, no differences in gender, age, disease duration, HAQ-DI score, or disease activity were observed between patients who accepted the touchscreen invitation and were enrolled and those who were excluded. Another possible limitation is that the washout period was too short, thereby increasing the risk of carryover bias, i.e. the effect of questionnaire recall. However, the washout period in this trial of 1–2 days is much longer than the washout period of 5 min to 24 h reported in previous trials capturing PROMs in patients with rheumatic diseases (4–6, 22–24). As the risk of carryover bias and the risk of bias from fluctuation in disease activity have opposite influences on the optimal

time interval between the two PROM registrations, it was decided that a washout period of 1–2 days in this trial would be long enough to minimize these potential biases. Furthermore, the participants were advised to answer the PROM questionnaires at approximately the same time of day to avoid the impact of daily arthritis fluctuations. A third possible limitation is that the patient population was largely restricted to patients with well-controlled disease activity; therefore, the variability in PROMs for patients with low disease activity may be less than for patients with high or moderate disease activity, as indicated by the Bland–Altman plot in Figure 2B. However, as the 95% CIs for the difference in PROMs are well within the MCID, it is highly unlikely that the variability in PROMs due to differences in disease activity would affect the results in a significant way. Fourthly, another possible limitation is that the subgroup analyses presumably not are adequately powered; therefore, a p-value of < 0.10 was considered to be potentially important. Using this level of significance, no important differences were observed in the subgroup analyses.

The DANBIO app is a pivotal new tool in the management of patients with IA as it allows fast and reliable capture of PROMs whenever needed. Thus, it is expected that remote PROM collection through the app will help physicians to prioritize patient visits, e.g. patients who need an acute consultation owing to flare, or patients in sustained remission who can be monitored with a telephone consultation. Therefore, the implementation of remote monitoring of patients with IA through an app could optimize outpatient visits, making them more cost-effective from the healthcare system perspective and more beneficial from the patients' perspective, i.e. more effective and time-saving.



Table 2. Comparison between groups for all patient-reported outcome measures and clinical outcomes.

Outcome	Group AD → TS			Group TS → AD			Difference			
	AD		TS	TS		AD	Difference between LSMeans	95% CI		
	LSMeans	se	LSMeans	se	LSMeans	se				
Primary outcome										
HAQ-DI score* (0–3)	0.644	0.054	0.593	0.054	0.653	0.053	0.589	0.054	-0.007	-0.043 to 0.030
Secondary outcomes										
VAS pain (0–100 mm)	34.0	3.0	30.8	3.0	32.6	3.0	32.2	3.0	1.4	-0.8 to 3.5
VAS fatigue (0–100 mm)	42.9	3.3	43.3	3.3	39.5	3.3	42.2	3.3	1.1	-1.5 to 3.8
VAS global health (0–100 mm)	35.6	2.9	34.0	2.9	34.5	2.9	33.8	2.9	0.5	-2.1 to 3.0
PASS 'Yes', n (%)	21/30 (70)		23/30 (77)		21/30 (70)		22/30 (73)		57/60 (95)†	
Anchoring question (-3 to +3), median (IQR)	0	(0;0)	0	(-1;0)	0	(0;0)	0	(-1;0)	0	(0;0)
axSpA outcomes										
BASDAI‡ (0–100 mm)	31.3	6.2	38.1	4.9	33.4	6.3	37.2	4.9	-1.5	-5.4 to 2.4
BASFI§ (0–100 mm)	27.8	3.7	28.7	3.2	27.1	3.7	27.6	3.2	-0.2	-2.6 to 2.2

AD, app device; TS, touchscreen solution; LSMeans, least square means; CI, confidence interval; HAQ-DI, Health Assessment Questionnaire Disability Index; VAS, visual analogue scale; PASS, Patient Acceptable Symptom State; IQR, interquartile range; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index.

\*One missing value from the DANBIO app in group AD → TS.

†Number and percentage of patients who had no change in PASS score between the two device types, i.e. difference = 0.

‡Evening values from six individual patients: in group AD → TS four missing values from the DANBIO app and five missing values from the touchscreen, and in group TS → AD one missing value from the touchscreen and one missing value from the DANBIO app.

§Nine missing values from five individual patients: in group AD → TS four missing values from the DANBIO app and three missing values from the touchscreen, and in group TS → AD one missing value from the touchscreen and one missing value from the DANBIO app.

Table 3. Subgroup analyses on Health Assessment Questionnaire Disability Index (HAQ-DI) score.

Subgroup	Subgroup 'Yes'			Subgroup 'No'			Difference between subgroups*		
	n	Mean	sd	n	Mean	sd	Mean	95% CI	p†
Yes = Male gender	31	-0.012	0.118	28	0.000	0.160	-0.012	-0.085 to 0.061	0.74
No = Female gender									
Yes = RA diagnosis	20	-0.031	0.167	39	0.006	0.121	-0.038	-0.114 to 0.038	0.33
No = PsA or axSpA diagnosis									
Yes = Younger half‡	28	0.009	0.144	31	-0.020	0.133	0.029	-0.043 to 0.101	0.42
No = Older half									
Yes = Age > 65 years	9	-0.069	0.155	50	0.005	0.134	-0.074	-0.174 to 0.025	0.14
No = Age ≤ 65 years									

AD, app device; TS, touchscreen solution; CI, confidence interval; RA, rheumatoid arthritis; PsA, psoriatic arthritis; axSpA, axial spondyloarthritis.

\*Subgroup 'Yes' – subgroup 'No'.

†A p-value of < 0.10 from the test for interaction was considered to be potentially important as subgroup analyses presumably were not adequately powered.

‡Median age = 56 years; thus, the younger half is < 56 years old.

## Conclusion

Remote PROM collection through the DANBIO app on a smartphone is a valid and feasible approach for capturing PROMs among patients with IA. Equivalence between an app and an outpatient touchscreen was demonstrated for all PROMs except BASDAI; however, BASDAI was within the limits of the MCID. Patient preference for the DANBIO app was very high. Implementation of the DANBIO app is expected to help physicians to prioritize outpatient visits, thereby improving the management of IA both for the individual patient and for society.

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## Authors' contributions

LU, SK, and AS conceived the trial hypothesis, and LU, SK, AS, EMH, and RC designed the trial. LU is the sponsor-investigator. NSK and MKA developed the DANBIO app and provided technical support. LU, SK, AS, EMH, RC, and LD were responsible for the conduct of the trial, data analyses, and publication. LU wrote this article, and SK, AS, LD, EMH, RC, NSK, MKA, and PCT contributed with refinement and approved the final draft.

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influence on the study design, data collection, or data analyses, or on the writing or submission of this article. The Musculoskeletal Statistics Unit at the Parker Institute is supported by a core grant from the Oak Foundation [OCAY-18-774-OFIL].

## Data availability statement

All data generated or analysed during this study are included in this published article (and its supplementary information files) <https://clinicaltrials.gov/ct2/show/NCT03486613?cond=Psoriatic+Arthritis&cntry=DK&city=Aalborg&draw=2&rank=4>.

## Disclosure statement

**LU:** Speakers bureau (AbbVie, Eli Lilly, Novartis), **RC:** Honorarium paid to Parker Institute (Biogen, Celgene, Eli Lilly, LEO, Mundipharma, Novartis, Pfizer, Orkla Health) **LD:** Grants (BMS), Speakers bureau (Galderma), **PT:** Grants (Celgene, Eli Lilly, Galapagos, Gilead), Consultant (AbbVie, Biogen, Eli Lilly, Fresenius, Galapagos, Gilead, GlaxoSmithKline, Janssen, Nordic Pharma, Bristol-Myers Squibb, Pfizer, Roche, Sanofi), Speakers bureau (Biogen). **AS, EMH, NSK, MKA and SK:** no potential conflict of interest.

## Ethics and consent

The study was approved by the Danish Data Protection Agency (2018-86) but did not require approval by the Ethics Committee (2018-000367) or by the Danish Medical Agency (2018011261). The trial was registered at [clinicaltrials.gov](https://clinicaltrials.gov) (NCT03486613) on 3 April 2018, before the start of participant enrolment. The trial was conducted in compliance with the protocol and the Declaration of Helsinki. Written informed consent was obtained from all patients before enrolment.

## Supplementary material

Supplemental data for this article can be accessed [here](#)

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