Using a novel smartphone application for capturing of patient-reported outcome measures among patients with inflammatory arthritis:

A randomised, crossover, agreement study

Line Uhrenholt (ORCID ID 0000-0002-4047-7175)[1,2,3,4], Robin Christensen (ORCID ID 0000-0002-6600-0631)[3,5], Lene Dreyer[1,2], Annette Schlemmer[1], Ellen-Margrethe Hauge (ORCID ID 0000-0003-2562-9174)[6,7], Niels S. Krogh (ORCID ID 0000-0002-8520-1674)[8], Mikkel K. Abildtoft[8], Peter C. Taylor (ORCID ID 0000-0001-7766-6167)[9], Salome Kristensen (ORCID ID 0000-0001-5812-5234)[1,2]

Affiliations

[1]: Department of Rheumatology, Aalborg University Hospital, Aalborg, Denmark

[2]: Department of Clinical Medicine, Aalborg University, Aalborg, Denmark

[3]: Musculoskeletal Statistics Unit, The Parker Institute, Frederiksberg Hospital, Copenhagen, Denmark

[4]: The DANBIO Registry, Center for Rheumatology and Spine Diseases, Centre of Head and Orthopedics, Rigshospitalet, Glostrup, Denmark.

[5]: Research Unit of Rheumatology, Department of Clinical Research, University of Southern Denmark, Odense University Hospital, Odense, Denmark.

[6]: Department of Rheumatology, Aarhus University Hospital, Aarhus, Denmark

[7]: Department of Clinical Medicine, Aarhus University, Aarhus, Denmark

[8]: Zitelab ApS, Copenhagen, Denmark

[9]: Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK.

Short running title

Smartphone app vs outpatient touchscreen

Corresponding author

MD Line Uhrenholt

Department of Rheumatology

Aalborg University Hospital

Reberbansgade 15, 9000 Aalborg, Denmark

Email: l.uhrenholt@rn.dk or line_uhrenholt@hotmail.com

ORCiD iD: 0000-0002-4047-7175

ABSTRACT

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) for which the Danish Rheumatology Database (DANBIO) app was developed. The study aims to evaluate agreement of PROMs between the DANBIO app and outpatient touchscreen among patients with IA.

Methods

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

Results

The touchscreen invitation was accepted by 138 patients. Sixty patients (20 of each diagnosis) were included. The differences in Health Assessment Questionnaire Disability Index between the two device types were -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 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 optimise outpatient visits; thereby, improving health care for the individual patient and society.

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

KEY WORDS: rheumatoid arthritis, axial spondylarthritis, ankylosing spondylitis, psoriatic arthritis, patient-reported outcome measures, quality of life, smartphone application, minimally clinically important difference, equivalence, crossover study.

INTRODUCTION

Patient-reported outcome measures (PROMs) are pivotal in the management of inflammatory arthritis (IA) as PROMs illustrates 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). Additionally, a recent study validated a web-based solution accessed from home against the outpatient touchscreen in a Danish IA population (6).

During the past years, novel technologies have made it possible and feasible to capture PROMs via a downloaded application (app) on the participant's own 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 entering caused by joint and spine deformities. Furthermore, an app has the major advantage over a web-based solution that PROMs can be answered without internet connection as the app stores responses on the device until an internet connection is available (3). Thus, an app could be a pivotal tool for optimising 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 prioritise 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]).

METHODS

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. 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 randomised, within-participants, crossover, agreement trial, patients with IA were included from the outpatient clinic at Aalborg University Hospital. Eligible patients had an established diagnosis (≥ 12 months) of RA, PsA or axSpA and experience with the PROM questionnaires (≥ 3 previous answered PROMs). Exclusion criteria were language barrier (the PROMs were only available in Danish), visual impairment and no access to a smartphone that could download and run the DANBIO app.

Procedures

The screening period started on April 24th 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/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 randomised in ratio 1:1 to:

- App device first → touchscreen solution (AD → TS): i.e. PROMs were answered through the DANBIO app first and after a "washout period" through the outpatient touchscreen.
- Touchscreen screen first → app device (TS → AD): i.e. PROMs were answered through the outpatient touchscreen first and after a "washout period" through the DANBIO app.

To minimise recall bias, there was a washout period of one to two days between the two PROM registrations.

As 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 onto 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 among patients with IA.

Secondary outcomes were to evaluate equivalence between the two device types for the following PROMs: Visual Analog 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 was evaluated.

Collected variables

The DANBIO database is a nationwide Danish registry including patients with IA treated with biologics and/or conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) (2). The following demographic data were obtained from DANBIO: sex, age, disease duration and current arthritis medication as well as the last registration of the following variables prior to enrollment: patient PROMs, CRP and VAS physician. In addition, IgM-RF, ACPA, x-ray and DAS28crp status were obtained for patients with RA and PsA whether as HLA-B27, x-ray, BASMI and ASDAS status was 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; thereafter, 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 *a priori* defined as a difference in PROMs between groups ≤ half of the Minimally Clinically Important Difference (MCID). Thus, the equivalence margin for HAQ-DI was ± 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 ± 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 -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 0.95 (between measures). In order 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 randomisation 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 randomisation sequences were made by the senior biostatistician RC, with 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 pre-specified 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 ITT principle i.e. all randomised 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 random participant (patient ID number) effects, further adjusted for the PROM-level at enrolment. Agreement/equivalence was obtained if the 95% CI of differences between the two device types lie within ± half the MCID (18). A Bland-Altman plot was performed to illustrate agreement between the two device types for the primary outcome HAQ-DI (19).

RESULTS

During the inclusion period from April 24th 2019 to September 3rd 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. 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 sex, age, disease duration, HAQ-DI score or disease activity were observed between enrolled or excluded patients nor among patients who declined to participate.

Patient demographics for enrolled subjects were well balanced between the groups, as presented in **Table 1**. 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 biologic or targeted synthetic disease modifying anti-rheumatic drug (bDMARD or tsDMARD, respectively).

As visualised in the Bland-Altman plots (**Figure 2A+2B**), reliability between 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 the prespecified equivalence margins as presented in **Table 2** except for BASDAI as the 95% CI for the difference in BASDAI of (-5.4 to 2.4) exceeded the prespecified equivalence margin of ±5.0. However, the 95% CI was well within the minimally clinically important difference of ±10.0 for BASDAI.

Subgroup analyses showed no significant difference in HAQ-DI score between sexes, diagnosis (RA versus PsA/axSpA), younger half versus older half or participant > 65 years old (i.e. less anticipated IT-experience) or younger as presented in **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, 6 (10%) slightly preferred the DANBIO app, 12 (20%) had no preference, 0 (0%) slightly preferred the outpatient touchscreen and 1 (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 ± 5.0. Nevertheless, as the 95% CI for BASDAI are well within the MCID of ± 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 has 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 are 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 are 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, *Schefte and Hetland* found no statistically significant difference in HAQ, VAS pain, VAS fatigue, VAS global, BASDAI and BASFI score between paper-based forms and the outpatient touchscreen among patients with RA or ankylosing spondylitis (4). Similarly, *Hofstedt et al.* showed no statistically significant difference in VAS pain, VAS fatigue, VAS global, BASDAI, BASFI and DAS28 score between paper-based forms and a web-based solution among patients with polyarthritis (10% with axial disease) (21). However, in both the study by *Hofstedt et al.* as well as *Schefte and Hetland* the 95% CI for the difference between paper and electronic device exceeded the limits of the MCID. In contrast, a recent 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 among 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% CI of the difference between device types are within the limits of the MCID for all PROMs. Furthermore, equivalence for all PROMs except BASDAI were 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 from home solution to the outpatient touchscreen (6). A possible explanation could be, 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 internet connection in contrast to a web-based solution. Furthermore, the DANBIO app eliminates problems with the outpatient touchscreen such as waiting in queue, lack of privacy, disturbance, uncomfortable seating position, problems with registering answers due to reduced upper limb strength and difficulties with seeing the touchscreen due 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 difference in sex, age, disease duration, HAQ-DI score or disease activity was observed between patients who accepted the touchscreen invitation and was 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 one to two days is much longer than the washout period of 5 minutes to 24 hours reported in previous trials capturing PROMs among 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 influence on the optimal time interval between the two PROM registrations it was decided that a washout period of one to two days in this trial would be long enough to minimise these potential bias'. Furthermore, the participants were advised to answer the PROM questionnaires at approximately the same time of the day to avoid impact of daily arthritis fluctuations. A third possible limitation is that the patient population largely was restricted to patients with well controlled disease activity; thus, the variability in PROMs for patients with low disease activity might 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% CI for the difference in PROMs are well within the MCID it is highly unlikely that the variability in PROMs due to difference in disease activity will 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 significant level, 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 can help physicians to prioritise patient visits e.g. patients who need an acute consult due to flare or patients in sustained remission who can be monitored with a telephone consult. Therefore, implementation of remote monitoring of patients with IA through an app could optimise outpatient visits to be more cost-effective from the healthcare system perspective and more beneficial from the patients' perspective i.e. more effective and timesaving.

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 prioritise outpatient visits; thereby, improving the management of IA both for the individual patient as well as the society.

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) nor by the Danish Medical Agency (2018011261). The trial was registered at clinicaltrials.gov (NCT03486613) on April 3rd, 2018 before start of participant enrollment. The trial was conducted in compliance with the protocol and the Helsinki Declaration. Written informed consent was obtained from all patients before enrolment.

ACKNOWLEDGEMENTS

The authors thank the two patient research partners for their contribution to the trial and to the national implementation of the DANBIO app in Denmark. Furthermore, the authors thank Carsten Juhl for providing statistical assistance regarding commands in STATA. PT thanks the National Institute of Health Research for their funding of The NIHR Biomedical Research Centre in Musculoskeletal Disease at Oxford University Hospitals NHS Trust and the University of Oxford.

FUNDING

This work was supported by Aalborg University Hospital (150.000 d.kr. in salary to LU). Zitelab ApS funded the development of the DANBIO app and has the ownership; however, the company had no influence on the study design, data collection, data analyses nor writing or submission of this article. Musculoskeletal Statistics Unit at the Parker Institute are supported by a core grant from the Oak Foundation (OCAY-18-774-OFIL).

CONFLICT OF INTEREST

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:*** none.

AUTHORS' CONTRIBUTION

LU, SK and AS conceived the trial hypothesis and LU, SK, AS, EMH and RC have 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 PT contributed with refinement and approved the final draft.

DATA AVAILABILITY STATEMENT

All data generated or analysed during this study are included in this published article (and its supplementary information files).

REFERENCES

1. Callahan LF. The History of Patient-Reported Outcomes in Rheumatology. Rheum Dis Clin N Am 2016;42:205–17.
2. Ibfelt EH, Jensen DV, Hetland ML. The Danish nationwide clinical register for patients with rheumatoid arthritis: DANBIO. Clin Epidemiol 2016;8:737–42.
3. Coons SJ, Eremenco S, Lundy JJ, O'Donohoe P, O'Gorman H, Malizia W. Capturing Patient-Reported Outcome (PRO) Data Electronically: The Past, Present, and Promise of ePRO Measurement in Clinical Trials. Patient 2015;8:301–9.
4. Schefte DB, Hetland ML. An open-source, self-explanatory touch screen in routine care. Validity of filling in the Bath measures on Ankylosing Spondylitis Disease Activity Index, Function Index, the Health Assessment Questionnaire and Visual Analogue Scales in comparison with paper versions. Rheumatology (Oxford) 2010;49:99–104.
5. Wæhrens EE, Amris K, Bartels EM, Christensen R, Danneskiold-Samsøe B, Bliddal H et al. Agreement between touch-screen and paper-based patient-reported outcomes for patients

with fibromyalgia: a randomized cross-over reproducibility study. Scand J Rheumatol 2015;44:503–10.

6. Secher AE, Glintborg B, Gudbergsen H, Krogh NS, Sørensen IJ, Jensen DV et al. Comparing patient-reported outcomes entered at home versus at hospital, and testing touch screens for initial recruitment to scientific trials in arthritis patients. Scand J Rheumatol 2019;48:178–84.
7. Dixon WG, Michaud K. Using technology to support clinical care and research in rheumatoid arthritis. Curr Opin Rheumatol 2018;30:276–81.
8. Maska L, Anderson J, Michaud K. Measures of functional status and quality of life in rheumatoid arthritis: Health Assessment Questionnaire Disability Index (HAQ), Modified Health Assessment Questionnaire (MHAQ), Multidimensional Health Assessment Questionnaire (MDHAQ), Health Assessment Questionnaire II (HAQ-II), Improved Health Assessment Questionnaire (Improved HAQ), and Rheumatoid Arthritis Quality of Life (RAQoL). Arthritis Care Res 2011;63:S4–13.
9. Palominos PE, Gaujoux-Viala C, Fautrel B, Dougados M, Gossec L. Clinical outcomes in psoriatic arthritis: A systematic literature review. Arthritis Care Res 2012;64:397–406.
10. Zochling J. Measures of symptoms and disease status in ankylosing spondylitis: Ankylosing Spondylitis Disease Activity Score (ASDAS), Ankylosing Spondylitis Quality of Life Scale (ASQoL), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), ath Ankylosing Spondylitis Functional Index (BASFI), Bath Ankylosing Spondylitis Global Score (BAS-G), Bath Ankylosing Spondylitis Metrology Index (BASMI), Dougados Functional Index (DFI), and Health Assessment Questionnaire for the Spondylarthropathies (HAQ-S). Arthritis Care Res 2011;63:S47–58.
11. Kirwan JR, Hewlett SE, Heiberg T, Hughes RA, Carr M, Hehir M et al. Incorporating the patient perspective into outcome assessment in rheumatoid arthritis - Progress at OMERACT 7. J Rheumatol 2005;32:2250–6.
12. Strand V, Boers M, Idzerda L, Kirwan JR, Kvien TK, Tugwell PS et al. It's good to feel better but it's better to feel good and even better to feel good as soon as possible for as long as possible. Response criteria and the importance of change at OMERACT 10. J Rheumatol 2011;38:1720–7.
13. Wells G, Tugwell P, Kraaq G, Baker PRA, Groh J, Redelmeier DA. Minimum important difference between patients with rheumatoid arthritis: the patient's perspective. J Rheumatol 1993;20:557–60.

14. Pavy S, Brophy S, Calin A. Establishment of the minimum clinically important difference for the bath ankylosing spondylitis indices: A prospective study. J Rheumatol 2005;32:80–5.
15. Christensen R, Bliddal H, Henriksen M. Enhancing the reporting and transparency of rheumatology research: a guide to reporting guidelines. Arthritis Res Ther 2013;15:109.
16. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzche PC, Devereaux PJ et al. CONSORT 2010 explanation and elaboration: Updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c869.
17. Dwan K, Li T, Altman DG, Elbourne D. CONSORT 2010 statement: Extension to randomised crossover trials. BMJ 2019;366:l4378.
18. Piaggio G, Elbourne DR, Pocock SJ, Evans SJW, Altman DG. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. JAMA 2012;308:2594–604.
19. Bland J, Altman D. Statistical methods for assessing agreement between two methods of clinical measurement. Lancet 1986;1:307–10.
20. Coons SJ, Gwaltney CJ, Hays RD, Lundy JJ, Sloan JA, Revicki DA et al. Recommendations on evidence needed to support measurement equivalence between electronic and paper-based patient-reported outcome (PRO) measures: ISPOR ePRO good research practices task force report. Value Heal 2009;12:419–29.
21. Hofstedt O, Di Giuseppe D, Alenius GM, Stattin N, Forsblad-D'Elia H, Ljung L. Comparison of agreement between internet-based registration of patient-reported outcomes and clinic-based paper forms within the Swedish Rheumatology Quality Register. Scand J Rheumatol 2019;48:326–30.
22. Epis OM, Casu C, Belloli L, Schito E, Filippini D, Muscarà M et al. Pixel or Paper? Validation of a Mobile Technology for Collecting Patient-Reported Outcomes in Rheumatoid Arthritis. JMIR Res Protoc 2016;5:e219.
23. Pincus T, Castrejon I, Riad M, Obreja E, Lewis C, Krogh NS. Reliability, Feasibility, and Patient Acceptance of an Electronic Version of a Multidimensional Health Assessment Questionnaire for Routine Rheumatology Care: Validation and Patient Preference Study. JMIR Form Res 2020;4:e15815.
24. Richter JG, Becker A, Koch T, Nixdorf M, Willers R, Monser R et al. Self-assessments of patients via Tablet PC in routine patient care: Comparison with standardised paper questionnaires. Ann Rheum Dis 2008;67:1739–41.

LEGENDS

- **Figure 1:** Flow diagram of patient recruitment.
- **Figure 2A+2B:** ***Figure 2A:*** HAQ-DI scores measured with the two device types with a line of equality. ***Figure 2B:*** HAQ-DI score difference (i.e. app HAQ-DI score minus touchscreen HAQ-DI score) against HAQ-DI score mean. The dashed horizontal lines represents 95% limits of agreement and the solid horizontal line the mean difference.

Table 1: Patient demographics and clinical characteristics.

Variable	**AD → TS** **n = 30**	**TS → AD** **n = 30**	**All** **n = 60**
General characteristics			
Male, n (%)	17 (56.7%)	14 (46.7%)	31 (51.7%)
Age in years, mean (SD)	52.2 (12.4)	55.2 (12.3)	53.7 (12.3)
Disease duration in years, median (IQR)	10.5 (6.5;17.0)	12.3 (5.2;15.8)	10.9 (6.3;15.9)
Last HAQ-DI score (0-3), median (IQR)	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), median (IQR)	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), median (IQR)	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), median (IQR)	34.0 (17.8;70.0)	40.5 (16.8;66.8)	35.0 (17.3;68.3)
Last PASS "Yes" score, n (%)	19 (63.3%)	18 (60.0%)	37 (61.7%)
Last anchoring question (-3-3) score, median (IQR)	0.0 (-1.0;0.0)	-0.5 (-1.0;0.0)	0.0 (-1.0;0.0)
Current on csDMARD, n (%)	15 (50%)	18 (60%)	33 (55%)
MTX, n (%)	9 (30.0%)	14 (46.7%)	23 (38.3%)
MTX treated dose in mg/week, median (IQR)	20.0 (11.3;25.0)	18.8 (15.0;25.0)	20.0 (15.0;25.0)
Current on oral steroids, n (%)	1 (3.3%)	0 (0.0%)	1 (1.7%)
Current on bDMARD or tsDMARD, n (%)	15 (50%)	9 (30%)	24 (40%)
Last VAS physician score (0-100 mm), median (IQR)	2.0 (0.0;12.0)	3.0 (0.8;8.0)	2.5 (0.0;8.0)
Last CRP (mg/L), median (IQR)	4.4 (1.4;19.0)	3.6 (1.1;9.2)	3.6 (1.3;12.8)
Disease specific measures			
Diagnosed with RA, n (%)	***10 (33.3%)***	***10 (33.3%)***	***20 (33.3%)***
IgM-RF positive, n (%)	9 (90%)	8 (80%)	17 (85%)
ACPA positive[a], n (%)	8 (80.0%)	8 (88.9%)	16 (84.2%)
Erosive, n (%)	7 (70%)	7 (70%)	14 (70%)
Last Das28crp (0.96-9.4), median (IQR)	3.2 (2.4;4.0)	3.0 (2.3;3.6)	3.1 (2.4;3.9)
Diagnosed with PsA, n (%)	***10 (33.3%)***	***10 (33.3%)***	***20 (33.3%)***
Erosive[b], n (%)	4 (44.4%)	3 (30.0%)	7 (36.8%)
Last Das28crp (0.96-9.4), median (IQR)	2.2 (1.5;3.7)	2.7 (1.9;3.6)	2.6 (1.6;3.6)
Diagnosed with axSpA, n (%)	***10 (33.3%)***	***10 (33.3%)***	***20 (33.3%)***
HLA-B27 positive, n (%)	10 (100%)	9 (90%)	19 (95%)
Diagnosed with ankylosing spondylitis, n (%)	4 (40%)	8 (80%)	12 (60%)
Last BASDAI score (0-100 mm), median (IQR)	21.5 (18.5;37.3)	41.5 (18.5;62.5)	30.0 (19.3;49.5)
Last BASFI score (0-100 mm), median (IQR)	24.5 (16.3;29.0)	31.0 (13.3;48.0)	24.5 (15.5;42.8)
Last BASMI[c] (0-100), median (IQR)	20.0 (15.0;40.0)	10.0 (10.0;45.0)	20.0 (10.0;40.0)
Last ASDAS (0.6-∞), median (IQR)	2.4 (1.4;3.1)	2.3 (1.7;2.7)	2.4 (1.5;2.8)

AD: app device, TS: touchscreen solution, n: number, SD: standard deviation, IQR: interquartile range, HAQ-DI: Health Assessment Questionnaire Disability Index, VAS: Visual Analog Scale, PASS: Patient Acceptable Symptom State, csDMARD: conventional synthetic Disease-Modifying Anti-Rheumatic Drug, MTX: Methotrexate, bDMARD: biologic Disease-Modifying Anti-Rheumatic Drug, tsDMARD: targeted synthetic Disease-Modifying Anti-Rheumatic Drug, CRP: CRP: C-reactive protein, RA: rheumatoid arthritis, IgM-RF: IgM Rheumatoid Factor, ACPA: Anti-Citrullinated Peptide Antibodies, DAS28crp: Disease Activity Score28crp, PsA: psoriatic arthritis, axSpA: axial spondyloarthritis, HLA-B27: Human leukocyte 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.

[a]: 1 missing value in group TS → AD

[b]: 1 missing value in group AD → TS for erosive on x-ray

[c]: 1 missing value in group TS → AD and 1 missing value in group AD → TS

Table 2: Comparison between groups for all PROMs and clinical outcomes

Outcome	**Group AD → TS**				**Group TS → AD**				**Difference**	
	AD		***TS***		***TS***		***AD***		***AD - TS***	
Primary outcome	***LSMeans***	***SE***	***LSMeans***	***SE***	***LSMeans***	***SE***	***LSMeans***	***SE***	***Difference between LSMeans***	***95% CI***
HAQ-DI score[a] (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%)[b]	
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[c] (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[d] (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

PROMs: Patient-reported outcome measures, AD: app device, TS: touchscreen solution, LSMeans: least square means, SE: standard error, CI: confidence interval, HAQ-DI: Health Assessment Questionnaire Disability Index, VAS: Visual Analog Scale, PASS: Patient Acceptable Symptom State, IQR: interquartile range, RA: rheumatoid arthritis, PsA: psoriatic arthritis, axSpA: axial spondyloarthritis, BASDAI: Bath Ankylosing Spondylitis Disease Activity Index, BASFI: Bath Ankylosing Spondylitis Functional Index.

[a]: 1 missing value from the DANBIO app in Group AD → TS.

[b]: Number and percentage of patients who had no change in PASS score between the two device typess i.e. difference = 0.

[c]: 11 missing values from 6 individual patients: in Group AD → TS 4 missing values from the DANBIO app and 5 missing values from the touchscreen and in Group TS → AD 1 missing value from the touchscreen and 1 missing value from the DANBIO app.

[d]: 9 missing values from 5 individual patients: in Group AD → TS 4 missing values from the DANBIO app and 3 missing values from the touchscreen and in Group TS → AD 1 missing value from the touchscreen and 1 missing value from the DANBIO app.

Table 3: Subgroup analyses on HAQ-DI score.

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

HAQ-DI: Health Assessment Questionnaire Disability Index, AD: app device, TS: touchscreen solution, n: number, SD: standard deviation, CI: confidence interval, p: p-value, RA: rheumatoid arthritis.

[a]: Subgroup "Yes" – Subgroup "No"

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

[c]: Median age = 56 years; thus, the younger half is < 56 years old.