

Agreement between patient-reported outcome measures collected via a smartphone application vs a touchscreen solution in an outpatient clinic among patients with inflammatory arthritis: a randomised, within-participant trial

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Background:

Patient-reported outcome measures (PROMs) are essential to understand the patient's perception of arthritis activity. In Denmark, PROMs are registered on a touchscreen in the outpatient clinic. However, some patients find it inconvenient e.g. waiting in queue, lack of privacy, uncomfortable seating position, reduced upper limb strength and dexterity or with seeing the touchscreen due to deformity of the cervical spine. The widespread use of smartphones makes it possible for patients to register PROMs via an application (app) on their own device.

Objectives:

The primary aim is to evaluate the agreement (i.e. similarity) between the two devices assessed by the Health Assessment Questionnaire Disability Index (HAQ-DI) status among patients with inflammatory arthritis.

Methods:

The study was a randomised, crossover, agreement trial (NCT03486613) conducted at Aalborg University Hospital. Participants were recruited through an invitation on the touchscreen in the outpatient clinic. Patients with an established diagnosis (≥ 12 months) of rheumatoid arthritis (RA), psoriatic arthritis (PsA) or axial spondyloarthritis (axSpA) and experience with the PROM questionnaires (≥ 3 previous registrations) were enrolled and randomised in ratio 1:1 (stratified by diagnosis) to PROM registration through the DANBIO app and the touchscreen in random order. Figure 1A and 1B shows the two devices.

The sample size calculation was based on a prespecified equivalence margin of ± 0.11 HAQ-DI points (i.e. $\leq$ half of the minimal important difference of 0.22 points) yielding a power of 99.2% for 60 enrolled patients. There was a wash-out period of 1-2 days between the two device registrations to minimise the potential carryover effect.

A paired t-test was used to calculate the mean HAQ-DI score for the two devices and the difference in HAQ-DI score with a 95% confidence interval (CI). A Bland-Altman plot was used to assess limits of agreement (LoA).

Results:

The touchscreen invitation was seen by 948 patients of whom 212 agreed to hear more about the trial. 60 patients (20 with RA, 20 with PsA and 20 with axSpA) were randomised of whom 51.7% were male. Mean age was 53.7 years (range 22-77) and mean disease duration was 12.5 years (range 1.0-34.8).

Mean HAQ-DI was 0.608 (95%CI 0.437;0.779) for the DANBIO app and 0.614 (95%CI 0.446;0.783) for the touchscreen (Table 1). Agreement between scores obtained with the two devices is illustrated with Bland-Altman plots in figure 2A and 2B. The paired mean difference of HAQ-DI between the two devices was -0.006 (95%CI -0.0424; 0.030); thus the 95% confidence

interval for the mean difference was within the prespecified equivalence margin of ± 0.11 HAQ-DI points.

Conclusion:

The current study showed no statistical or clinically important difference in HAQ-DI measurement captured by a mobile app or outpatient touchscreen. Therefore, we feel confident that the two devices perform similarly enough to be used interchangeably in patients with inflammatory arthritis.

Table 1: HAQ-DI scores, difference and LoA for the two devices.

	App, mean (SD)	Touchscreen, mean (SD)	Difference, mean (95%CI)	LoA	Missing values
HAQ-DI (0-3)	0.608 (0.656)	0.614 (0.646)	- 0 . 0 0 6 (-0.042;0.030)	-0.277;0.264	1

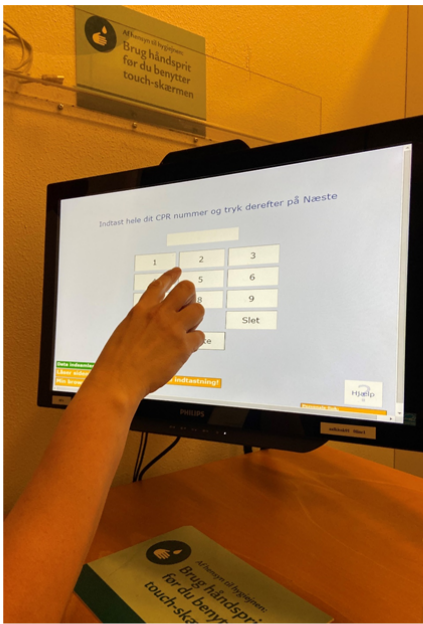


Figure 1A: The touchscreen in the outpatient clinic

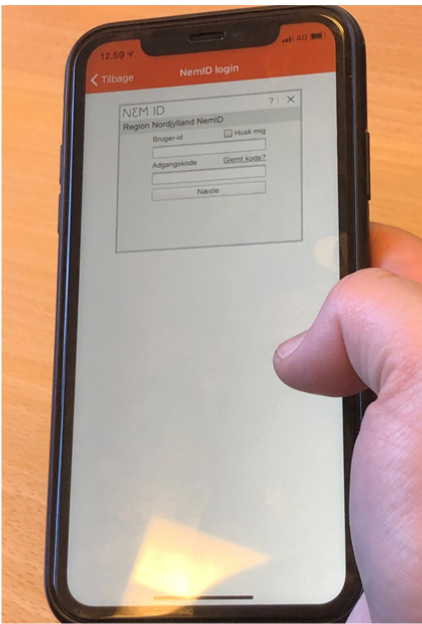


Figure 1B: The DANBIO app on a smartphone

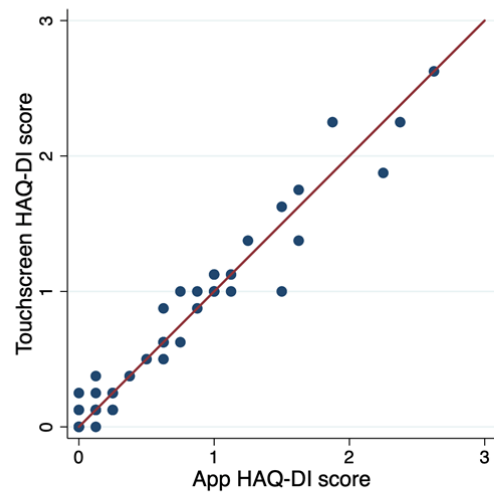


Figure 2A: HAQ-DI scores measured with the two devices with a line of equality.

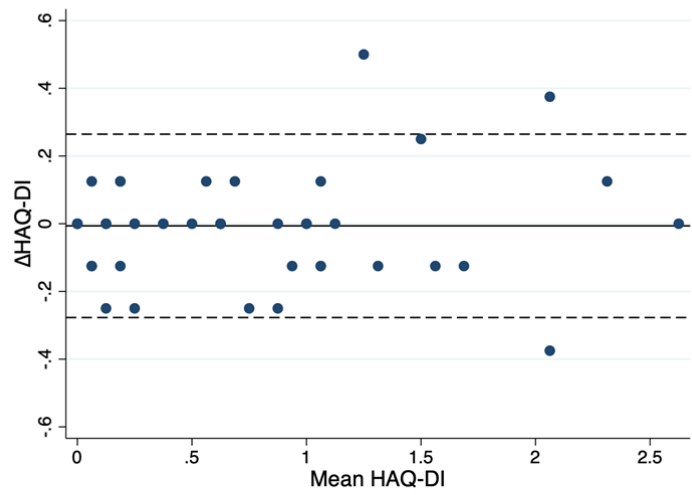


Figure 2B: HAQ-DI difference against mean. The dashed horizontal lines represents 95% limits of agreement and the solid horizontal line the mean difference.