Conclusions: Rheumatology nurse consultation is not inferior to regular rheumatologist follow-up for rheumatoid arthritis patients with low disease activity.

Disclosure of Interest: None declared

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HPR Measuring health (development and measurement properties of PROs, tests, devices)___

SAT0716-HPR PATIENTS PREFERENCE GOES TO METHOTREXATE AUTOINJECTORS OVER PREFILLED SYRINGES: RESULTS FROM A PHASE III TRIAL, SELF

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Background: The offer of injectable MTX in Europe expanded during past few years with different types of enhanced devices such as prefilled syringes and autoinjector pens.

Objectives: SELF trial intended to compare historical MTX prefilled syringes vs a new MTX autoinjector in terms of treatment adherence, functional capacity and patients' preference at 6 months in RA patients.

Methods: SELF was a phase III, randomised open-label trial, conducted in France between Sept. 2015 and March 2017. It included RA patients, treated by oral or injectable MTX for ≥3 months (monotherapy or association). Patients were randomised in two arms: MTX in prefilled syringes (PS) or MTX in autoinjectors (AI) at the dosage decided by the investigator. Primary objectives of the trial were to prove the 4% non-inferiority of AI vs PS in terms of patients' adherence and functional capacity (HAQ-DI) at 6 months. Secondary objectives included the evaluation of satisfaction and patients' preference.

Results: Between Sept. 2015 and Sept. 2016 50 rheumatologists, mostly in private practice, included 271 patients, 197 of which composed the *per protocol* population. Patients baseline characteristics were [mean (±SD)]: age: 59.2 (±12.3) yrs; BMI: 26.0 (±4.9) kg/m²; RA duration: 5.35 (±6.70) yrs; DAS28: 3.1 (±1.2); HAQ-DI: 0.6 (±0.6). All patients were treated by MTX (1/3 oral; 2/3 parenteral) at a mean dose of 15.4 (±4.1) mg/wk. There were no significant differences at baseline between PS and AI arms. At 6 months, the treatment adherence was over 95% for both arms, and HAQ-DI was improved by a mean of 0.05 in both arms. The AI 4% non-inferiority as compared to PS was shown for both primary criteria.

Patients' reported satisfaction was very significantly higher ($p \leq 0.001$) in AI arm vs PS for the following criteria: easy to use, pleasant, satisfying, willingness for further utilisation and significantly higher ($p < 0.05$) for reassuring and not constraining. Of the 132 patients who experienced both devices (during the study or before it), 127 (96%; $p < 0.001$) preferred the auto injector over the historical prefilled syringe. No unexpected safety issues were observed during this trial and injection point safety tolerance satisfaction was higher for AI vs PS.

Conclusions: SELF trial showed that although the new MTX autoinjector is comparable to historical prefilled syringe in terms of treatment adherence and functional capacity improvement, it is significantly superior in terms of patients'

satisfaction. Over 95% of patients who have tried both devices report preferring the pen.

Disclosure of Interest: A. Sarau Consultant for: Nordic Pharma, C. Hudry Consultant for: Nordic Pharma, E. Zinovieva Employee of: Nordic Pharma, H. Herman-Demars Employee of: Nordic Pharma

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SAT0717-HPR PSYCHOMETRIC TESTING OF A GERMAN VERSION OF THE EVALUATION OF DAILY ACTIVITY QUESTIONNAIRE IN RHEUMATOID ARTHRITIS

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Background: The Evaluation of Daily Activity Questionnaire (EDAQ) is a patient reported outcome (PRO) of activity limitations. The English EDAQ is reliable, valid and a comprehensive measure of the commonest problems experienced by people with rheumatoid arthritis (RA) and musculoskeletal conditions.^{1,2} It includes 138 items in 14 'domains' (Eating/Drinking; Personal Care; Dressing; Bathing; Cooking; Moving Indoors; House Cleaning; Laundry; Moving and Transfers; Moving Outdoors; Gardening/Household Maintenance; Caring; Leisure/Social Activities). All items are scored on a 0–3 scale (no difficulty to unable to do). There is no similar measure available in German. PROs must be tested in target languages and conditions, prior to use, to ensure validity and reliability.

Objectives: To linguistically validate a German EDAQ and test its reliability and validity in German-speaking people with RA.

Methods: The English EDAQ was forward-backward translated to German. Cognitive debriefing interviews were conducted and the German EDAQ developed. Participants from a Rheumatology clinic (Switzerland) and arthritis patient organisations (Switzerland, Germany, Austria) then completed postal questionnaires including: demographic questions, German EDAQ, Health Assessment Questionnaire (HAQ), SF36v2, RA Quality of Life scale (RAQOL), and a hand pain numeric rating scale (NRS). Three weeks later, the EDAQ was mailed again. Test-retest reliability of domain scores, and validity of the 14 German EDAQ domains against the other measures, were evaluated using nonparametric correlations. Internal consistency was tested using Cronbach's alpha.

Results: Six German-speaking people with RA were interviewed, recommended changes reviewed by the expert panel and the German EDAQ agreed. 163 people then completed questionnaires: 145 women and 18 men; mean age=52.84 (SD14.94) years; mean RA duration=15.73 years (SD12.12). 85 (45%) were employed; 21 had children<18 y at home. Median pain score=4 (IQR 2–6) and fatigue=5 (IQR 3–7).

107 (65%) completed a second questionnaire. Test-retest reliability of total domain scores was excellent for all domains ($r_s = 0.80–0.93$). Internal consistency was high in all domains: Cronbach's alpha=0.84–0.96. All EDAQ domains (except Caring) correlated significantly ($p < 0.001$) with: HAQ $r_s = 0.73–0.87$; SF36v2 (Physical Function) $r_s = -0.61$ to -0.84 ; SF36v2 Bodily Pain $r_s = -0.53$ to -0.65 ; SF36v2 (Vitality) $r_s = -0.27$ to -0.31 ; RAQOL $r_s = 0.55–0.68$; and hand pain $r_s = 0.43–0.52$. Correlations were lower in the 'Caring' domain due to the smaller sample size ($n=77$), although mostly still significant ($p < 0.01$; $r_s = 0.25$ to 0.42 ; except SF36v2 Vitality= -0.10 non-significant).

Conclusions: The German EDAQ is a valid and reliable measure of daily activity in people with RA. Either the whole EDAQ or individual domains can be used in clinical practice to identify clients' daily activity problems and help find solutions, or as an outcome measure in research and audit. A User Manual is available.³

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Patients' reported satisfaction (Likert Scale)	Easy to use	Pleasant	Satisfying	Motivating for further utilisation	Reassuring	Not constraining	Not stressful	Not painful
Strongly agree (AI/PS)	60%/21%	7%/0%	63%/21%	61%/35%	30%/14%	51%/36%	55%/41%	51%/38%
Agree (AI/PS)	32%/42%	20%/11%	31%/50%	23%/34%	52%/60%	18%/17%	23%/26%	21%/31%
Neither agree nor disagree (AI/PS)	4%/23%	32%/26%	2%/19%	9%/17%	9%/15%	19%/24%	14%/17%	25%/24%
Disagree (AI/PS)	1%/6%	26%/30%	2%/6%	6%/10%	4%/5%	10%/15%	4%/8%	1%/6%
Strongly disagree (AI/PS)	4%/8%	14%/33%	1%/4%	5%/4%	5%/6%	2%/8%	8%/9%	1%/1%
Significance level	p<0.001	p<0.001	p<0.001	p=0.001	p=0.02	p=0.02	p=0.05	p=0.15