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

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SAT0718-HPR ARE THERE SYMPTOMS DISTINGUISHING FIBROMYALGIA FROM CHRONIC PAIN THAT ARE MISSING FROM THE 2016 CRITERIA?

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Background: Fibromyalgia (FM) patients have a wide range of symptoms.

Objectives: Herein we analysed 20 common symptoms to determine those that best discriminate between FM patients and chronic pain patients without FM (Chronic Pain).

Methods: 352 patients (mean age 50+/16.3 years, 70% female) scheduled for a routine examination in two primary care practices were studied. 50 patients (14.2%) had FM (based on 1990 ACR) and 108 patients (30.7%) had Chronic Pain. All subjects completed a survey of 20 symptoms commonly found in FM patients – 10 were from the Symptom Impact Questionnaire (SIQR).

Results: Table 1 presents the 20 symptoms ranked by magnitude of Somers' D. This is a statistic that provides an estimate of predicting a diagnosis of fibromyalgia versus no fibromyalgia (OR: 1.87–8.00; $p < 0.001$). The top 10 symptoms showed strong correlations with diagnosis ($D = 0.49$ to 0.64) and large mean differences between the 2 groups (Means: 2.8–4.3). Notably, there was a 4.3 score difference in Persistent Deep Ache and only a 1.4 difference in SIQR Pain ($p < 0.001$). Using a 4-point criterion as a clinical cut-off (0–10), symptoms best discriminating patients with FM from Chronic Pain were: Persistent Deep Aching (86% vs. 36%), Environmental Sensitivity (82% vs. 38%), Poor Balance (82% vs. 35%), Tenderness to Touch (84% vs. 39%) and Pain after exercise (96% vs. 54%). The symptoms of Pain, Unrefreshing Sleep, Muscle Stiffness and Low Energy were high in both groups, thus they are not good discriminators.

Abstract SAT0718HPR – Table 1. Twenty common fibromyalgia symptoms ranked by Somers' D. The top 10 symptoms are shaded. SIQR symptoms are italicised.

Symptom	Somers'D (rank)	FM Mean (%)	Chronic Pain Mean (%)	Mean difference
Persistent Deep Aching	.641 (1)	7.40 (86)	3.14 (36)	4.26
Intolerance to Noise	.592 (2)	6.98 (86)	3.27 (34)	3.71
Environmental Sensitivity	.574 (3)	6.82 (82)	3.04 (38)	3.78
Poor Balance	.552 (4)	6.26 (82)	3.06 (35)	3.20
Pain after Exercise	.534 (5)	8.08 (96)	4.07 (54)	4.01
Muscle Weakness	.524 (6)	6.92 (88)	3.77 (42)	3.15
Tenderness to Touch	.511 (7)	6.82 (84)	3.61 (39)	3.21
Muscle Stiffness	.505 (8)	7.68 (94)	4.86 (57)	2.82
Intolerance to Bright Lights	.492 (9)	6.58 (72)	3.41 (33)	3.17
Tender Muscles	.491 (10)	7.90 (94)	4.94 (56)	2.96
Non-refreshing Sleep	.452 (11)	7.54 (84)	4.60 (52)	2.94
Poor Memory	.421 (12)	5.66 (66)	3.03 (37)	2.63
Intolerance to Cold	.414 (13)	6.62 (74)	3.82 (40)	2.80
Irritable Bowel Symptoms	.412 (14)	5.68 (66)	3.05 (31)	2.63
Swollen Joints	.409 (15)	6.16 (76)	3.78 (41)	2.39
Depression	.398 (16)	5.44 (64)	3.17 (42)	2.27
Stiffness	.396 (17)	6.92 (88)	4.54 (53)	2.38
Chronic Headaches	.390 (18)	5.62 (66)	3.45 (38)	2.17
Low Energy	.349 (19)	6.82 (84)	4.92 (61)	1.90
Pain Level	.320 (20)	6.54 (94)	5.12 (69)	1.42

Conclusions: In this sample from 2 primary care practices, Persistent Deep Aching, Tenderness to Touch, Environmental Sensitivity, Poor Balance and Pain after Exercise were the best discriminators between FM patients and patients with Chronic Pain. Notably: Depression, Headaches, Poor Memory and Irritable Bowel symptoms were weak discriminators; in fact, none of the top 10 discriminators appear in the 2016 Fibromyalgia Diagnostic Criteria.

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SAT0719-HPR PERFORMANCE-BASED PHYSICAL FUNCTION MEASURE WAS MORE SENSITIVE TO DETECT RESPONDERS THAN SELF-REPORTED MEASURE AFTER A PHYSICAL THERAPY EXERCISE INTERVENTION IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS

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Background: Physical function is regarded as an important outcome in axial spondyloarthritis (axSpA) and the self-reported questionnaire Bath Ankylosing Spondylitis Functional Index (BASFI) is recommended for the evaluation. However, it is shown that BASFI may not be sufficiently sensitive to detect changes after physical therapy. Based on BASFI a disease-specific performance-based measure has been developed; the Ankylosing Spondylitis Performance-based Improvement (ASPI).

Objectives: To compare the proportion of patients with axSpA considered as responders in the performance-based function measure ASPI and the self-reported BASFI after a physical therapy exercise intervention.

Methods: This study was part of the ESAP-study (Exercise for SpondyloArthritis) which examines the effect of 12 weeks, supervised high intensity exercise intervention. Patients with axSpA were included from 4 centres in Scandinavia. Physical function was assessed with ASPI and BASFI at baseline and after 3 months. The ASAS20 response criteria were used to categorise patients as intra-individual responders or non-responders. In BASFI, patients were classified as responders if they showed an improvement of $\geq 20\%$ and ≥ 1 unit. In ASPI, patients were classified as responders if they showed an improvement of $\geq 20\%$ on 1 or more subtest(s) and the absence of deterioration on the potential remaining test. Deterioration was defined as a worsening of $\geq 20\%$ in 1 or more subtest(s). The proportion of patients categorised as intra-individual (non-) responders was examined with Chi square test.

Results: A total of 58 patients (intervention $n=30$, control $n=28$) with complete data on ASPI and BASFI were included in the analyses, 41% were male, mean age (SD) was 45 (10.7) years, 55% had radiographic axSpA and mean disease activity (ASDAS) (SD) was 2.6 (0.7). In BASFI, a score of < 1 was present in 14% at baseline and in 22% at 3 months, indicating a ceiling effect (figure). The proportion of responders in the total group was 53% in ASPI and 36% in BASFI, $p=0.13$ (table 1). In the intervention group, 70% were responders in ASPI and 43% were responders in BASFI, $p=0.02$.

Table. Number of responders measured with performance-based function test (ASPI) and self-reported physical function (BASFI) according to study sub-group

	All patients (n=58)	Intervention (n=30)	Control (n=28)
ASPI			
Responder	31 (53%)	21 (70%)	10 (36%)
Non-responder	27 (47%)	9 (30%)	18 (64%)
BASFI			
Responder	21 (36%)	13 (43%)	8 (29%)
Non-responder	37 (64%)	17 (57%)	20 (71%)
p-value*	0.13	0.02	0.45

Values are number (percentages). *Chi square test between (non-) responder in ASPI and BASFI within groups

Abstract SAT0719HPR – Figure 1. Distribution of BASFI scores and time in seconds in ASPI assessed at baseline and at 3 months follow-up ($n=58$). Lower values indicates better physical function in both measures