

## Supplement\_D\_PICO\_3

### What is the impact of shared decision-making (SDM) and of effective communication on adherence?

No evidence was found specifically on the impact on shared decision making (SDM) and on effective communication on adherence. However, evidence was found on the impact on patient education as defined by the EULAR guideline on patient education[1].

Patient education (PE) was defined by the EULAR Taskforce for the *EULAR recommendations for patient education for people with inflammatory arthritis* as a "planned interactive learning process designed to support and enable people to manage their life with inflammatory arthritis and optimise their health and well-being." [1] They further argue that communication and shared decision making is essential for effective patient education [1]. PE includes a wide range of interventions/activities: provision of knowledge/information, written material, e-health, self-management programmes, cognitive behavioural interventions, mindfulness, stress management, individual consultations, sharing experiences among patients, motivational discussions, exercise counselling, lifestyle change interventions and self-help courses. [1, 2]

Therefore, we summarized the impact of PE on adherence.

#### Summary

In total, 5 systematic reviews, including 51 studies explored the association between PE, adherence and RMDs (see table 1 for details). Eleven studies had a positive impact on adherence (7 studies [3-9] on medication adherence; 4 on non-pharmacological/exercise adherence [10-13]), 9 studies did show positive, but not statistically significant effect (5 studies [13-17] on medication adherence, 4 on non-pharmacological/exercise adherence [18-21]). The rest of the primary studies included in the five systematic reviews (n=31) were excluded due to: communication was only a small part of the intervention [22, 23], the authors focused on other interventions (e.g. cognitive-behavioural) without a clear communicative part [24], text messages were only used as reminders [25], leaflets were used without other communicative elements [26], intervention focused only on rheumatologists [27], the intervention focused on health literacy only [28], the study design was not appropriate [29-31], adherence was not explicitly measured as the outcome of the study [32-47], or the study did not focus on RMDs (ulcerative colitis [48-52], inflammatory bowel diseases [53]). A list of excluded studies can be seen in appendix III.

#### Medication adherence

Of the 12 included studies regarding medication adherence, patients were diagnosed with rheumatoid arthritis (RA) [4-7, 13-16], osteoporosis [17], psoriasis [3, 14], systemic lupus erythematosus (SLE) [8], juvenile rheumatoid arthritis (JRA) [9]. As described in the definition of Zangi, Ndosi [1] and Chewing, Bylund [2] the interventions/activities used to provide PE varied greatly, such as daily text messages to provide reminders and education [3], information and written materials [4, 6], visualization of charts showing the disease progression [5], discussion/review of PROMs [6], behavioral strategies and discussion [9], counseling and advisory [17], (motivational) interviewing [15, 16].

Seven of these studies had a positive impact on medication adherence using an educational approach [3-8], five did not reach significance on medication adherence [13-17]: (1) In the review of Depont, Berenbaum [54] and Galo, Mehat [55] it is argued, that Brus, Van De Laar [13] lacked power [54, 55], and further, the people included in the study had an active, recent-onset RA, and people with high disease activity tend to be more adherent than those with low disease activity [13, 55]. (2) Homer, Nightingale [14] did not investigate whether PE per se is effective, but compared individual and group setting to deliver PE. This did not result in a significant difference, but the results were in favour of group settings (p=0.06). Moreover, the study had serious limitations (lack of power) [54]. (3) In the study of Zwikker, van den Ende [15] pharmacist-delivered motivational interviewing-guided group sessions were evaluated. The aim was to improve patients' balance between necessity and concern beliefs about medication to have a positive influence on medication taking. The intervention did not reach statistical significance, and it was suggested that the reason was that the included patients had a long disease duration (>14 years), and thereby a long experience with their medication. This is also discussed in another RCT where it is argued, that modifying adherence/adherent behaviour in patients with a disease duration that long may be harder than forming new behaviour in recently diagnosed patients [28, 55]. (4) In the study from McEvoy Devellis, Blalock [16] the control group did not get a placebo (the group was not intervention-naïve), which may be attributed to

unintended positive effects and may have contributed to lack of differences in outcomes[16, 55]. (5) Solomon, Iversen [17] argue in their study, that the sample size was calculated based on a 10% increase in medication regimen adherence. The increase of adherence was of 8%, thus the trial did not reach significance ( $p=0.07$ ). They further argue, that they were able to achieve modest improvements in medication adherence using a relatively simple intervention[17].

## **Exercise adherence**

Of the 8 included studies regarding exercise adherence, patients were diagnosed with osteoarthritis[10, 12, 18, 20, 21], low back pain[11] [19], and RA[13]. Similar to the strategies used to enhance medication adherence, the interventions/activities used to provide PE varied for exercise adherence too: consultation[10, 13, 19, 20], motivational approaches[11], physical activity advice[12], [18] and verbal (recorded tapes) and visualised (videos) cues to prompt correct performance of exercises[21] were used.

Four of these studies had a positive impact on exercise adherence[10-13], the others did not reach significance[18-21]: The study of O'Brien, Bassett [18] had lack of power (intervention group 17 participants, control group 10) and further, they argue that no effect is found due to because the fact that long-term exercise programmes contribute to a poor level of adherence and further, the questionnaires used may not be significant because of a ceiling effect in the scores. The questionnaires were reported to have limited sensitivity (e.g. Sport Injury Rehabilitation Adherence Scale (SIRA)). The activities were rated moderate to high, ranging from 3.4 to 4.6 out of a possible 5. The studies from Basler, Bertalanffy [19], Bennell, Kyriakides [20] and Schoo, Morris [21] included non-placebo control groups: 10 sessions with physiotherapist over 5 weeks plus tailored home exercise programme[19], up to 14 individual exercise sessions with a physiotherapist plus advice to continue with unsupervised home exercise programme[20], and 3 individual sessions with a physiotherapist consisting of face-to-face verbal instruction on the performance of home exercises and a brochure of the exercises[21]. This interventions performed in the control groups may have attributed to unintended positive effects and may have contributed to lack of differences in outcomes.

Table 1. Individual studies exploring effective communication and SDM components of interventions proven effective.

Study, Design, med/non-pharma	Review	Dig., IG, CG	Intervention	Outcome measures	Results
Studies on medication adherence					
Balato, Megna [3]; Pilot RCT; medication	Depon t, Beren baum [54]	Psoriasis IG n=20 CG n=20	IG: Daily text messages (TM), providing reminders and educational tools CG: not clear	Adherence: participants were asked how often they forgot to use psoriasis products/medications in term of days per week in the last week.	Adherence to therapy improved significant (3.86 to 6.46 days per week P<.001) whereas it remained stable in the control group.
Hill, Bird [4]; RCT; medication	Depon t, Beren baum [54]	RA IG n=51 CG n=49	IG: patient education programme: information about the types of drugs used for RA, the disease process, physical exercise, joint protection, pain control, and coping strategies. Written information, including a DPA drug information leaflet developed especially for the study, was provided as back up. CG: same DPA drug information leaflet	primary measure of adherence was by pharmacological marker (dosage of DPA) (The ratio of phenobarbitone level in the blood to prescribed dose (LDR) was calculated for each patient at each study visit: (phenobarbitone concentration (mg/l))/(daily phenobarbitone dose (mg/kg body weight)).	pharmacological marker showed the EG to be significantly more adherent on more occasions than the CG (p<0.05). Patterns of adherence over time showed that at 12 weeks 86% (38/44) of those in the EG compared with 64% (29/45) of the CG remained adherent (p=0.01). These trends continued and by the end of the study, 85% (29/34) of the EG compared with 55% (23/42) of the CG were taking their DPA as prescribed.
EI Miedany, EI Gaafary [5]; Pilot RCT; medication	Depon t, Beren baum [54]	Early RA IG n=55 CG n=56	IG: visual feedback facility (visualization of computer charts showing the disease progression) CG: Usual care	Primary outcome: change in the patients' adherence to their medications	Adherence: IG 47/54 (87%) patients were adherent to their drug therapy, whereas 23/54 (43%) in CG to their drug therapy (P < 0.01).
EI Miedany, EI Gaafary [6]; RCT; medication	Depon t, Beren baum [54]	RA IG n=74 CG n=73	IG: Joint-fitness programme combined with discussion/review of PROMs and patient education; The programme includes 4 main components: a) educational – joint-learn, b) behavioural – joint-change, c) information – joint act and d) joint-cise (joint-exercise). CG: usual care	At 3, 12 and 18 months: The primary outcome was the change in the patients' adherence to their medications	improvement of the patients' adherence to therapy: 66/74 (89.1%) patients in group I were adherent to their drug therapy in comparison to 47/73 (64.4%) in group II (p<0.01).

Study, Design, med/non-pharma	Review	Dig., IG, CG	Intervention	Outcome measures	Results
Clifford, Barber [7]; RCT; medication	Galo, Mehat [55]	RA IG n=261 CG n=239	IG: telephone-based, patient-tailored pharmacy advisory service delivered by community pharmacists to elderly patients which included RA. The pharmacist gave information, advice or reassurance in response to the patients' expressed needs. CG: usual care	Primary Outcome: Incidence of non-adherence	non-adherence significantly lower in the intervention group (9% vs. 16%, P = 0.032)
Ganachari and Almas [8]; RCT; medication	Galo, Mehat [55]	SLE IG n=21 CG n=20	IG: education regarding SLE and its management by a clinical pharmacist: including lifestyle modifications, via the distribution of patient information CG: usual care	Medication Adherence Questionnaire	mean medication adherence score increase in the IC from 3.0 to 5.8 at post-counselling and was also significantly better when compared with the CG (4.6).
Rapoff, Belmont [9]; RCT; medication	Galo, Mehat [55]	Juvenile Rheumatoid Arthritis IG n=19 CG n=15	IG: educational and behavioral strategies for enhancing adherence: 10-min audiovisual program and received a booklet which described adherence-enhancement strategies: cueing (e.g., pairing medication taking with an established behavior such as brushing teeth), monitoring (e.g., using a calendar to track medication taking), positive reinforcement (e.g., praising and rewarding with tokens that are exchanged for special privileges), and discipline (e.g., using time-out for defiant refusals to take medications). The nurse reviewed and rehearsed strategies, gave answers to questions. CG: received a general educational on JRA	Adherence: Medication Event Monitoring System (MEMS) (=electronic medication bottle cap records the date and time of each bottle opening)	significant differences in adherence as measured by Medication Event Monitoring Systems between the intervention and control groups (77.7±21.5 vs 56.9±33.0, p=0.02).
Homer, Nightingale [14] RCT; medication	Depon, Berenbaum [54]	RA or psoriatic arthritis IG n=32 CG n=30	IG: individual information about disease-modifying anti-rheumatic drugs CG: information about disease-modifying anti-rheumatic drugs in groups	The primary outcome was adherence with medication use, ascertained by pill counts, self-report diaries and prescription dispensation.	More patients counselled in groups were adherent (27/30; 90%) compared with patients counselled individually (22/32; 69%; p = 0.06) by pill counts, on self-report diaries, similar proportions were adherent (group counselling 97% (29/30) versus individual 94% (30/32); p = 1.0).
Brus, Van De Laar [13] RCT; medication	Depon, Berenbaum [54]	RA IG n=25 CG n=30	IC: education programme focused on compliance with sulphasalazine therapy, physical exercises, endurance activities (walking, swimming, bicycling), advice on energy conservation, and joint protection	number of tablets prescribed and the number of tablets obtained	In the first quarter compliance with sulphasalazine in the educated patients was 91 (12)% (mean (SD)). In the controls compliance was 87 (22)%. In the second quarter, compliance was 82 (22)% and 82 (28)% respectively. During the third and

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					fourth quarter compliance rates were 89 (16)% and 84 (21)% respectively. There were no statistically significant differences between the groups in any of these periods. After one year, 60% (n=15) of the patients in the experimental group and 76% (n=23) in the control group were still using sulphasalazine.
Zwikker, van den Ende [15]; RCT; mediation	Galo, Mehat [55]	RA IG n=63 IG n=60	IG: The intervention consisted of two motivational interviewing (MI) guided [27] group sessions regarding beliefs and concern beliefs about medication and to resolve practical barriers to medication taking. CG: received brochures at home about the DMARDs	Compliance Questionnaire Rheumatology, Medication Adherence Report Scale, pharmacy refill data	No differences in medication non-adherence were detected between the intervention and control arm CQR, OR 1.3 (95%CI 0.5, 3.3); MARS OR 1.7 (95%CI 0.8, 3.8), Refill: IC 96.6%; CG 102.0% mean difference 2.2% (95% CI -11.1%, 15.6%)
McEvoy Devellis, Blalock [16]	Galo, Mehat [55]	RA IG: n=51 CG n=50	IG: psychological interviews and problem-solving intervention CG: psychological interviews	Adherence: questionnaire: the time they had missed doing the behaviour during the past month, and the number of times they had missed doing the behaviour in the past week.	Authors cited no significant difference between groups, though did not report data.
Solomon, Iversen [17]	Ganguli, Clewell [56]	Orstoporoses IG n=1046 CG n=1041	IG: telephone-based counselling with a motivational interviewing framework CG: mailed educational materials	Medication adherence: medication possession ratio, calculated as the ratio of days with filled prescriptions to total days of follow-up.	The groups were balanced at baseline, with a mean age of 78 years; 93.8% were female. In an intention-to-treat analysis, median adherence was 49% (interquartile range, 7%-88%) in the intervention arm and 41% (2%-86%) in the control arm (P = .07, Kruskal-Wallis test).
<b>Studies on exercise adherence</b>					
Ravaud, Flipo [10]; RCT;	Ezzat, MacPh	OA/knee, IG n=154 CG n=182	IG: Standardised consultation during three goal-oriented visits: education on osteoarthritis and treatment	time spent on physical exercises (Baecke index)	physical activity score (mean 0.20 (0.65) vs 0.04 (0.78); P=0.013)

Study, Design, med/non-pharma	Reviewer	Dig., IG, CG	Intervention	Outcome measures	Results
Non-pharma	erson [57]		management, information on physical exercises, information on weight loss. CG: usual care		
Vong, Cheing [11]; RCT; Non-pharma	Nicols on, Bennel l [58]	Low Back Pain IG n=38 CG n=38	IG: motivational enhancement treatment (MET) including supporting appropriate behaviour change and increasing self-efficacy PLUS PT CG: conventional physical therapy (PT)	exercise compliance (exercise log book).	exercise compliance better than in the CG group (P=.002) The IG performed home exercises 2 times more frequently than the CG in session 10 (MET-plus-PT, 13.9±8.2 vs PT, 6.2±3.6sessions/wk) and 1-month follow-up (MET-plus-PT, 12.9±7.2 vs PT, 5.8±4.1sessions/wk).
Halbert, Crotty [12]; RCT; Non-pharma	Ezzat, MacPherson [57]	OA IG n=37 CG n=32	IG: individualized physical activity advice CG: received a pamphlet on good nutrition	Adherence was measured with intention to exercise: self-reported questionnaire	(P=0.013) reported a greater intention to exercise. Numbers are not reported, can be only estimated from the graphs.
Brus, Van De Laar [13] RCT; medication	Depon t, Berenbaum [54]	RA IG n=25 CG n=30	IC: education programme focused on compliance with sulphasalazine therapy, physical exercises, endurance activities (walking, swimming, bicycling), advice on energy conservation, and joint protection, training was given in proper execution of physical exercises. Patients were encouraged to plan their treatment regimens. Their intentions were discussed and help was given in recasting unrealistic ones. Patients made contracts with themselves regarding their intentions. Feedback on the eventual implementation of therapeutic advice was included in each meeting.	Adherence measured by questionnaire: patients were asked how many times a week and how many minutes average each time they performed these activities. Time spent on endurance activities were added.	Only at three months, the increment of time spent on physical exercises was significantly greater in the experimental group (mean IC 30 (SD 42); CG 4 (SD 56), p<0.05). During the observational period, the time spent on endurance exercise did not differ significantly between groups.
O'Brien, Bassett [18]; Feasibility RCT; Non-pharma	Ezzat, MacPherson [57]	Lower limb OA IG n=17 CG n=10	IG: Action and Coping Planning Strategies: developed a realistic functional goal, discussion of benefits, support with the completion of their planning forms, discussion barriers and strategies to overcome these barriers CG: usual care	Adherence: Attendance and Programme Completion, Sport Injury Rehabilitation Adherence Scale (SIRA), participant self-report scale (1 = not at all to 5 = as advised)	No differences regarding adherence: Classes attended (IG 17 (SD11) and CG 16 (SD 10) out of 31, p= 0.81; SIRAS IG 4.5 (SD 0.4), CG 4.6 (SD 0.9), p=0.52; Home-based stretching IG 3.7 (SD 1.3), CG 3.9 (SD 0.2), p=0.21; walking IG 3.6 (SD 1.3), CG 3.5 (SD 1.0), p=0.93). There were no significant differences between the two groups' adherence rates

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Basler, Bertalanffy [19]; RCT; Non-pharma	Nicols on, Bennell I [58]	LBP IG n=86 CG n=84	IG: Control intervention (excluding sham ultrasound) +10 min of counselling at each session, delivered by the physiotherapist, focusing on readiness to change and increasing self-efficacy. CG: 10× 20 min sessions with physiotherapist over 5 weeks + home exercise programme: stretching and tailored exercise (strength, endurance, coordination) +10 min of sham ultrasound prior to the session.	Self-reported in logbook—time/day spent training (minutes).	6 weeks IG 29.2±14.6; CG 24.7±16.3; p= not reported, Effect size (d) = 0.29  6 months IG 29.6±24.2; CG 25.3±19.7; p= not reported, Effect size (d) = 0.19
Bennell, Kyriakides [20] RCT; Non-pharma	Nicols on, Bennell I [58]	Hip/knee OA IG n=40 CG n=38	IG: Control intervention +2× 30 mi individual 'booster' sessions with a physiotherapist over 16 weeks (at weeks 8 and 16 from the end of the original RCT 12-week period). Reviewed and progressed home exercise programme content and dose, discussed barriers to exercise adherence and strategies to overcome these. CG: 10–14× 30 min individual exercise sessions with a physiotherapist over 12 weeks. Advice to continue an unsupervised home exercise programme of strengthening or neuromuscular retraining exercises 4× week for 24 weeks (from the end of the original 12-week period).	(1) Self-reported in logbook—number of exercises completed per day. Values reported as % of prescribed exercises performed over 2×1 week periods (where 100% indicates all prescribed exercises performed as directed). (2) Self-reported overall adherence to the prescribed exercise programme. Values reported as average of ratings given for the previous 8-week period at weeks 8, 16 and 24. (11-point NRS: 0= not at all, 10= completely as instructed).	24 weeks (1) IG 56±34; CG 51±37; p>0.05, Effect size (d) 0.14 (2) IG 6.1±3.2; CG 5.5±3.5 p>0.05. Effect size (d) 0.18
Schoo, Morris [21]; RCT; Non-pharma	Nicols on, Bennell I [58]	Hip/knee OA IG n=30 (Audio) IG n=30 (Video) CG n=30	IG: Audio group: Control intervention + audio tape of verbal cues to prompt correct performance of exercises. IG: Video group: Control intervention + video tape of verbal and visual cues to prompt correct performance of exercises. CG: 3× individual sessions with a physiotherapist over 8 weeks (baseline, 4 weeks and 8 weeks) consisting of face-to-face verbal instruction on the performance of 9 home exercises and a brochure of the exercises.	Self-reported in a logbook. Participants asked if all, some or none of prescribed exercises were performed each day. Values reported as median % that reported completing all exercises.	4 weeks IG Audio: 89.0%; IG Video: 92.0%; CG 93.0% p=0.690 8 weeks IG Audio: 87.0%; IG Video: 81.5%; CG 89.5% p=0.538

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