

REVISED REVISION

The Gap between Short- and Long-term Effects of Patient Education in RA Patients: a Systematic Review

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ABSTRACT

Objective: Educational or psycho-educational interventions for patients with rheumatoid arthritis (RA) focusing on long-term effects, especially on health status, were systematically reviewed.

Methods: Two independent reviewers appraised the methodological quality of the included randomized controlled trials, published between 1980 and July 2002.

Results: The methodological quality between studies ranged from 3-9 (out of 11) validity scores. The seven educational programs mainly improved knowledge and compliance in the short- and long-term, but there was no improvement in health status.

All four psycho-educational programs generally improved coping behavior in the short-term, two of them showing a positive long-term effect on physical or psychological health variables.

Conclusions: Methodologically better designed studies had more difficulties to demonstrate positive outcome results. Short-term effects in program targets are generally observed, whereas long-term changes in health status are not convincingly demonstrated. There is a need to find better strategies to enhance the transfer of short-term effects into gains in health status.

INTRODUCTION

Patient education as *any combination of learning experiences designed to facilitate voluntary adoption of behavior conducive to health* (1), has an especially important role in completing clinical care: to enable patients to play an active role in the management of their disease and to improve their coping with the disease, including reduced demands for the health care system (2,3).

There is broad agreement on the importance of formal and additionally performed patient education interventions for patients with chronic diseases. Several patient education programs for patients with rheumatic diseases have been developed and evaluated over the last two decades (3-9). Moreover, the standards of patient education were revised in 1994 by the National Arthritis Advisory Board for Arthritis Patient Education (9,10).

Information giving is an important target of patient education interventions. The underlying assumption is that more knowledge leads to changes in attitudes and behavior and that health behavior is a result of knowledge, beliefs and attitudes. The changes attained in (health) behavior for patients with chronic diseases ought to be substantial enough to change their health status. These assumptions are the theoretical framework on which patient education interventions are built, but they have not been proven to be true (6). Self-efficacy (11) is considered as another important determinant of self-management behavior and there are studies showing associations between self-efficacy and health status (12); changes in self-efficacy might not cause changes in health status, but a better health status might influence the performance of self-efficacy.

Several reviews on patient education programs for patients with rheumatoid diseases have been conducted, to determine useful strategies and efficacy (12, 13-18). They evaluated the impact of patient educational interventions on knowledge, skills, and health status such as pain, disability or psychosocial well-being. As there are purely educational programs (aiming at increasing knowledge and improving performance) or psycho-educational programs (combining teaching intervention activities with behavioral intervention activities to improve coping and change behavior) (15), there is a great variety about the targets of the programs and about the variables measured. Only one review was restricted to randomized controlled trials (RCTs; 18).

Some reviews (13-15,17) examined patient education programs for patients with various rheumatic diseases. The results of the reviews distinguishing between the different types of arthritis (15,17) suggest that there may be a difference in efficacy by diagnosis, obtaining more effects for patients with osteoarthritis (OA) than for patients with rheumatoid arthritis (RA), though data are not thoroughly consistent. Age distribution is also divergent in OA and RA patients; RA patients are substantially younger, which may influence the effectiveness of the interventions (15).

All reviews agree on the achieved improvements diminishing of over time, however, only one (18) systematically examined the long-term effects, in this case cognitive behavioral treatment of RA pain. They found a need for interventions to enhance the long-term maintenance of treatment gains. This issue is of special interest for patients with chronic disease such as RA.

This review was performed to systematically collect randomized controlled trials examining educational and psycho-educational interventions for RA patients, with focus on their long-term effectiveness. Special attention was paid to the assessment of the methodological quality of the studies included. This seemed particularly important to us, as understanding the results of a study means understanding its design, conduct, analysis and interpretation (19). The authors should give full transparency of their study designs, as differences in the quality of methods across studies may indicate that the results of some trials are more biased than others and the conclusions of an effectiveness study may well depend on the study's methodological quality.

METHODS

Only RCTs involving patients with RA were included in this review. Studies also including patients with other rheumatic diseases, e.g. osteoarthritis, or more than one disease concurrently, were excluded. Studies were selected among the scientific publications between 1980 and July 2002, available on MEDLINE, PSYCHLIT, CINAHL and Cochrane database. Additionally we checked the citation lists to complete our selection.

Inclusion criteria were as follows:

- RCT studies assessing the effectiveness of a patient education intervention in RA patients.
- Patient education interventions aiming to improve knowledge, health behavior, skills or to influence the psychological or physical health status.
- Pre- and post-interventional measures and one long-term assessment, i.e. at least 6 months after treatment.
- Use of inferential statistics

Articles were firstly qualitatively appraised using the validity criteria (Table 1) from the Amsterdam-Maastricht Consensus List for Quality Assessment (20) and the criteria set in the Cochrane Reviewers' handbook (21) for the data extraction criteria (Table 2).

Two independent reviewers assessed the selected studies. Disagreement between the two reviewers concerning the validity criteria and data extraction criteria were resolved at a consensus meeting. To decide about the strength of evidence for patient education the outlines of van Tulder (20) were followed: Level A - strong research based evidence: generally consistent findings in multiple high quality RCTs. Level B - moderate research based evidence: generally consistent findings in one high quality RCT or general findings in multiple low quality RCTs. Level C - limited research based evidence: one RCT (either high or low quality) or inconsistent or contradictory evidence in multiple RCTs. Level D - no research based evidence: no RCTs.

A high quality study was defined by a validity score of ≥ 5 (22) and a positive result was defined as a statistically significant result for at least one outcome measure.

RESULTS

A total of 63 studies evaluating patient educational interventions were identified. All seven reviews (12-18) and another set of 45 studies were excluded, because they did not fulfill the key admission criteria: 13 because the diagnosis was not strictly limited to RA, 15 because they were not RCTs, 11 because the follow up was shorter than 6 months, and 4 studies did not meet several inclusion criteria. One study written in Spanish was dropped, as well as the Dutch version of a study also published in English. Eleven studies (23-34) fulfilled all of the given selection criteria and were therefore included in this review.

There was a great variety of interventions, program duration, outcome measures, and follow up periods.

Quality rating of the studies

The results of the validity criteria rating (Table 1) of the reviewed studies are presented in Table 3. According to these criteria, a total of seven studies met most of these requirements and were considered as high quality studies (23-29), whereas the four other studies were considered as poorly designed.

Positive validity criteria. A maximum of 9 of the 11 validity criteria was reached by two of the high quality studies. (23, 24).

Negative validity criteria. In 7 of the 11 studies (26,28-34), the rate of withdrawal or dropout was not given or remained unclear. Five of the seven educational programs (27,29-32,34) provided no intervention for their controls or put the controls on a waiting list, which was judged as an insufficient blinding procedure. The three qualitatively highest rated studies (23-25) had no negative validity scores.

Unclear validity criteria. Some criteria were not possible to judge positively or negatively by the reviewers from the data given in the study. Most problems were due to the method of randomization and the treatment allocation. In eight studies (26-34) co-interventions were not avoided or, e.g. necessary medical treatment did not seem to be standardized. Only four studies (23,24,26,28) judged the degree of adherence to the intervention.

Data extraction criteria (Table 2). Studies with higher positive validity scores clearly had higher scores on the data extraction criteria list (seven studies with at least 5 validity scores [23-29]: mean value of positive data extraction criteria= 5.6 vs. four studies (30-34) with less than 5 validity scores: mean value of positive data extraction criteria = 2.8).

Description of the studies

Type of study. Seven programs provided classical education to teach knowledge and specifically needed skills (Table 4), whereas four studies offered cognitive behavioral therapy with focus on coping strategies and psychological support (Table 5). Only one study, testing the effects of mailed educational leaflets (31/32), was not organized as group therapy.

Duration of intervention. The program duration ranged between 4 and 15 weeks (median value = 7 interventions). Eight programs were organized as weekly 1.5- to 2-hour sessions; two of them with reinforcement meetings after program conclusion (25, 26). Three programs were organized differently: a one-week hospital stay with a 12-months support program (28), nine afternoon sessions within two weeks (34) and a low-level intervention of an educational leaflet mailing (31/32).

Controls. Six of the seven educational programs provided no additional interventions for their control groups from the ongoing clinical care (25-27,30-32,34), an alternative therapy (physiotherapy) being offered in one study (29). In contrast to this, all the four psycho-educational studies had two control groups: one group receiving the standard therapy, one with no intervention (23,24,28,33).

Follow up. A minimum follow-up period of 6 months for evaluating a possible long-term effect was given as selection criteria. There were follow-ups of up to 15 months, with two studies presenting two follow-up measurements (23,24).

Patient education interventions

All studies assessed several dimensions targeted by patient education. Knowledge improvement was essential in educational programs, whereas it was usually not a goal in psycho-educational programs. All educational programs assessed compliance/performance, while the psycho-educational studies focused on (pain-) coping behavior. Physical and psychological health

status variables were measured in all studies. The seven educational programs improved mainly both knowledge and compliance in the short- and long-term, but no improvement in the health status could be found. All four psycho-educational programs did generally improve coping behavior in the short-term, two of them showing a positive effect on physical or psychological health variables in the long-term.

All studies measured and reported the changes over time for each group, but only few studies made comparisons between groups (27,28,32). The detailed results of the evaluation are presented in Tables 6 and 7. To decide about the strength of evidence for the various interventions, the outlines of van Tulder (20) were followed.

Knowledge. There were seven studies aiming to obtain an increase of knowledge (23,26,27,29-32,34). They all obtained this effect, which also mostly persisted for the long-term. In one study (27) the control group also increased their knowledge. There is strong evidence that patient education increases knowledge in the short- and long-term, as there were consistent findings in all high quality studies aiming to improve knowledge (23,26,27,29).

Coping. Coping improves the ability of managing the disease. Special emphasis for patients with RA is on coping with pain. Six studies (23,24,28,30,33,34) examined coping abilities before and after educational interventions. There is strong evidence for an increase in coping after patient education, as in all three high quality studies (23,24,28) there was at least one pain coping behavior that improved significantly after intervention. However, there is only limited evidence for long-term increase of coping behavior, as the results in the long-term were contradictory in high quality studies (23, 24, 28) and low quality studies (30,33,34).

Compliance: Compliance is an important goal in all educational programs. It is the fulfilling of the medical or therapeutic suggestions helpful for patients with RA, such as medication intake, physical exercise, energy conservation and joint protection. Six studies with educational interventions (25-27,29,30,34) targeted compliance in various dimensions. There was strong evidence for an increase of long-term compliance in general, as only one (high quality) study (27) did not find any significant change in compliance. However, evidence for specific compliance in the long-term as joint protection and medication was moderate, as the results of high quality studies

(25,26) were inconsistent, whereas low quality studies had positive long-term results. Compliance measured with a general compliance questionnaire remained unchanged (27).

Self-efficacy. The concept of self-efficacy is thought to be of major importance for patients with RA (12,35), enabling them to follow the requirements and to successfully manage their disease. But only three programs, two educational and one psycho-educational, (24,26,29) targeted self-efficacy. All these studies were of high methodological quality, but had inconsistent results. The evidence for the effect of patient education on self-efficacy is therefore moderate.

Psychological health status. The most important variables measured were depression, anxiety, helplessness, self-confidence, social support and relationship to friends. Only one study did not measure psychological health status (29). All but one (24) high quality study were not able to show any change in the psychological health status, neither in the short- nor in the long-term. One study (23) revealed a disease-related increase in depression but also a decrease in social support at the 6-month follow-up. There is limited evidence of patient education influencing the psychological health status.

Physical health status. Among the health status variables are physical functioning, pain, disability and hand function. Pain is the major problem for patients with RA, but there seems to be little impact on pain relief by patient education. All studies (23-34) measured physical health status. One study (23) showed a progressive deterioration for pain for all participating patients at the follow-up measurement. Only one high quality study (24) showed a positive change in pain in the short- and long-term. No long-term changes were shown in disability and physical function in any study. Therefore, there is limited evidence for patient education influencing the physical health status.

DISCUSSION

The goal of this review was to perform a systematic review with methodological appraisal and to evaluate the effectiveness of patient education interventions for patients with RA, emphasizing on the long-term effects. Nearly all studies included multiple health status measurements, but often, no primary outcomes were defined. Goals and interventions varied greatly and programs were organized differently, which made it difficult to decide about the most successful education interventions.

Short-term effects of patient-educational targets for RA patients are generally observed, e.g. knowledge in the educational programs or coping behavior in the psycho-educational programs, whereas there is only limited evidence for long-term changes in health status.

This is consistent with other studies (12,18), where effects of patient education for patients with rheumatic diseases were apparent immediately after the end of program, possibly lasting for some weeks, but vanishing over time. Moreover, as patient educational interventions usually are provided in addition to standard medical care, only supplementary effects might be expected (12).

Methodologically better designed studies had more difficulties to demonstrate positive outcome results. Methodological problems such as unclear intervention procedures, possible co-interventions, few specified eligibility criteria, no given dropout rate and no intention-to-treat analysis may result in potential bias, by over- or underestimating the demonstrated effects. Indeed, on the one hand this may mislead the authors in the interpretation of their results; on the other hand, methodological issues that are not described or not conducted may prevent the readers from obtaining full transparency and understanding of the study presented.

In the following section we would like to discuss possible reasons for the unsatisfying long-term results and issues for directly enhancing compliance and long-term adherence to maintain the short-term program targets.

The role of the disease: disease-specific reasons like the characteristic of RA, the disease duration and the progressive character of the disease. There is evidence that *studies using only RA patients* show a smaller effect than studies with other rheumatic diseases or mixed study populations (17). *The disease duration* may be another factor influencing the effectiveness of patient education; assuming that particularly patients with a recent onset of the disease may

benefit the most from patient education: for example from Cognitive Behavioral Therapy (CBT) as an effective intervention to change pain coping behavior (23). However, others (31/32) demonstrated in their study that the patients' level of knowledge and the increase of knowledge did not differ, regardless of the disease duration. The progressive character of RA may weaken changes and diminish them over time. The methodologically best-rated study (23) found very moderate changes and no long-term effects, instead a progressive deterioration due to the disease for all study groups could be demonstrated.

The role of the interventions: there is an implicit assumption that changes in behavior lead to changes in health, but in practice there is no consistent confirmation of this relationship or even causality (6,35). Another important reason for the difficulty of obtaining long-term effects may be the fact that we still do not understand which patient educational interventions are really effective and which mechanisms make them work or not. Moreover, the interventions are based on different theoretical frameworks and assumptions and it is not really clear, which patients will do best with which interventions and when.

While some state that knowledge is the cornerstone on which all education is built (30), others consider interventions that directly focus on changing behavior, e.g. self-efficacy, as more effective (36). There is a clear trend away from aiming at knowledge as a basic outcome (14) and the variety of target variables – and therefore outcomes - has impressively increased in the last years. Actually there is emphasis on compliance, pain coping behavior and psychological variables (25).

The role of compliance and long-term adherence: generally there are few attempts to target compliance directly and there are only limited strategies about how to enhance long-term adherence to the program. Compliance was not an issue in most of the reviewed studies. Only 4 studies (23,24,26,28) measured the adherence rate to the program or the additional exercise time at home. Neither the few dropouts due to non-adherence to study sessions (23) nor additional exercising at home (24) influenced the study results. One study (25) found high levels of compliance in patients with a recent onset of RA, combined with low disease activity, which, however, is opposed to the findings of another study (37).

However, long-term compliance and adherence to programs may be important issues for any therapeutic intervention and may play a key role for the effectiveness of an intervention. Health

care professionals are becoming aware of this situation and strategies to support compliance, at least on short term, are being adopted increasingly: interventions are tailored individually, based on the goal agreement between the patients and health care professionals; the most important concepts for supporting behavioral changes, such as enhancing self-efficacy, supporting the intention to change and making plans about how to target the goals set are adopted (38); reinforcement meetings are being offered. However, in literature self-reported adherence in the long-term to medication, home exercise and splint use is not satisfying (25, 39).

The greater the degree of behavioral change (e.g. in exercise, relaxation, sleep, diet, medication, joint protection, strategies for managing anxiety and depression, communication skills, etc.), required from a patient in one interventional setting, the less the adherence is likely to result (26).

Scores of self-efficacy (40,41) and – as an opposed but similar concept - perceived helplessness (42) seem to be important predictors for adherence. People with more self-efficacy are more likely to cooperate, also in the long-term (12). However, an RCT by the same authors (29) revealed that group education was beneficial only for the behavior for which the patients already had high self-efficacy scores prior to interventions and that high self-efficacy scores at baseline made it difficult to improve further. Adherence to health recommendations was not correlated with functional disability, pain or other aspects of health status; however, adherence problems were negatively correlated with low self-efficacy expectations of the patients about coping with the disease. Another study (28) stated that control over pain and the ability to decrease pain are typical areas of self-efficacy, where an immediate benefit may improve self-efficacy and therefore support adherence. As people with high scores in the Arthritis Helplessness Index [AHI] (43) are less likely to adopt problem-solving behavior (26), increased adherence on the other hand is associated with an increase of perceived control of arthritis, i.e. lower helplessness (26,28) and with ability of pain coping and less pain intensity. indeed, less helplessness may well enable people to learn better; people in the low anxiety group scored significantly better in knowledge at baseline and knowledge increase during the study, compared to the high anxiety group (25).

Successful long-term adaptation is associated with active coping, where the psychological health status which implies the patient's readiness to play an active role (23).

Conclusion

Methodological problems may result in potential bias, by over- or underestimating the demonstrated effects.

In effectiveness studies attention should not only be paid to the evaluation of the given intervention, but equally to the methodological issues and its reporting.

The critical appraisal of RCTs about the effectiveness of patient education for RA patients revealed that especially the long-term effects are not obvious. There may be a need to re-evaluate the theoretical framework of behavioral change and strategies to enhance the patient's long-term adherence to (psycho-) educational programs need to be tested in longitudinal studies, as only adherent patients may transfer their short-term gains in knowledge and behavioral skills into gains in health status and bring about an effective intervention.

REFERENCES

1. Green-L-W. Determining the impact and effectiveness of health education as it relates to federal policy. *Health Educ Mongr.* 1978; 6 (suppl)28, 66
2. Young-L-D, Bradley-L-A, Turner-R-A. Decreases in health care resource utilization in patients with rheumatoid arthritis following a cognitive behavioral intervention. *Biofeedback-Self-Regul.* 1995 Sep; 20(3): 259-68
3. Lorig-K, Mazonson-PD, Holman-HR. Evidence suggesting that health education for self-management in patients with chronic arthritis has sustained health benefits while reducing health care costs. *Arthritis Rheum* 1993; 36:439-46
4. Lorig-K. Arthritis self-management: a patient education program. *Rehabil-Nurs.* 1982; 7(4): 16-20
5. Lorig-K. Arthritis self-management. A five-year history of a patient education program. *Nurs-Clin-North-Am.* 1984; 19(4): 637-45
6. Lorig-K; Laurin-J. Some notions about assumptions underlying health education. *Health-Educ-Q.* 1985; 12(3): 231-43
7. Lorig-K, Lubeck-D, Kraines RG, Seleznick M, Holman HR. Outcomes of self-help education for patients with arthritis. *Arthritis Rheum.* 1985; 28:680-5
8. Lorig-Kate; Gonzalez-Virginia. The integration of theory with practice: A 12-year case study. *Health-Education-Quarterly.* 1992; Vol 19(3): 355-368
9. Lorig-K, Visser-A. Arthritis patient education standards: a model for the future. *Patient Educ Couns* 1994;24:3-7.
10. Burckhardt-CS, Lorig-K, Moncur-C, Melvin-J, Beardmore-T, Boyd-M, Boutaugh-M. Arthritis and musculoskeletal patient education standards. *Arthritis Foundation. Arthritis Care Res* 1994;7:1-4.
11. Bandura-A. Social foundations of thought and action. A social cognitive theory. 1986. Englewood Cliffs, NJ, Prentice Hall.
12. Taal-E, Rasker-JJ, Wiegman-O. Patient education and self-management in the rheumatic diseases: a self-efficacy approach. *Arthritis Care Res* 1996;9:229-38.

13. Lorig-K, Konkol-L. Gonzalez-V: Arthritis patient education: a review of the Literature. *Patient Educ Couns* 1987;10:207-52.
14. Hirano-PC, Laurent-DD, Lorig-K. Arthritis Patient Education studies, 1987-1991: a review of the literature. *Patient Educ Couns* 1994;24:9-54.
15. Hawley-DJ: Psycho-educational interventions in the treatment of arthritis. *Baillière's Clin Rheumatol.* 1995;9:803-23.
16. Taal-E, Rasker-JJ, Wiegman-O. Group education for rheumatoid arthritis patients. *Semin Arthritis and Rheum* 1997;26:805-16.
17. Superio-Cabuslay-E, Ward-M-M, Lorig-K. Patient education interventions in osteoarthritis and rheumatoid arthritis: a meta-analytic comparison with no steroidal anti-inflammatory drug treatment. *Arthritis Care and Research* 1996, 9(4), 292-301.
18. Keefe-JF, Van Horn-Y. Cognitive-Behavioral Treatment of Rheumatoid Arthritis Pain. *Arthritis-Care-Research.* 1993; 4(6), 213-22
19. Moher-D, Jadad-A-R, Tugwell-P. Assessing the quality of randomized controlled trials. *Int. J. Technology Assessment in Health Care.* 1996;12:195-208.
20. Van-Tulder-MW, Assendelft-WJ, Koes-BW, Bouter-LM. Method guidelines for systematic reviews in the Cochrane Collaboration Back Review Group for Spinal Disorders. *Spine* 1997;22:2323-30.
21. Clarke-M, Oxman-AD (eds.). *Cochrane Reviewers' Handbook 4.0*; The Cochrane Collaboration, Oxford; 1999.
22. Van der Windth-D-A-W-A, van der Heiden-G-J-M-G, van den Berg-s-G-M, ter Riet-G, de Winter-A-F, Bouter-L-M. Ultrasound therapy for musculoskeletal disorders: a systematic review. *Pain.* 1999; 81:257-271
23. Kraaimaat-F-W; Brons-M-R; Geenen-R; Bijlsma-J-W The effect of cognitive behavior therapy in patients with rheumatoid arthritis. *Behav-Res-Ther.* 1995 Jun; 33(5): 487-95
24. Parker-J-C; Smarr-K-L; Buckelew-S-P; Stucky-Ropp-R-C; Hewett-J-E; Johnson,-J-C; Wright,-G-E; Irvin,-W-S; Walker,-S-E. Effects of stress management on clinical outcomes in rheumatoid arthritis. *Arthritis-Rheum.* 1995 Dec; 38(12): 1807-18

25. Brus-HL; van-de-Laar-MA; Taal-E; Rasker-JJ; Wiegman-O. Effects of patient education on compliance with basic treatment regimens and health in recent onset active rheumatoid arthritis. *Ann-Rheum-Dis.* 1998, 57(3); 146-51
26. Hammond-A.; Lincoln-N.; Sutcliffe-L. A crossover trial evaluating an educational-behavioural joint protection programme for people with rheumatoid arthritis. *Patient-Education-and-Counseling.* 1999 May; Vol 37(1): 19-32
27. Helliwell-PS; O'Hara-M; Holdsworth-J; Hesselden-A; King-T; Evans-P. A 12-month randomized controlled trial of patient education on radiographic changes and quality of life in early rheumatoid arthritis. *Rheumatology-Oxford.* 1999 Apr; 38(4): 303-8
28. Parker-J-C; Frank-R-G; Beck-N-C; Smarr-K-L; Buescher-K-L; Phillips-L-R; Smith-E-I; Anderson-S-K; Walker-S-E. Pain management in rheumatoid arthritis patients. A cognitive-behavioral approach. *Arthritis-Rheum.* 1988 May; 31(5): 593-601
29. Taal-E, Rasker-JJ, Seydel-ER, Wiegman-O. Group education for patients with rheumatoid arthritis. *Patient Educ Couns* 1993;20:63-76.
30. Lindroth-Y.; Brattstroem-M.; Bellman-I.; Ekestaf-G.; Olofsson-Y.; Stroembeck-B.; Stenshed-B.; Wikstroem-I.; Nilsson-J.-A.; Wolheim-F.-A. A problem-based education program for patients with rheumatoid arthritis: Evaluation after three and twelve months. *Arthritis-Care-and-Research.* 1997 Oct; Vol 10(5): 325-332
31. Barlow-JH, Pennington-DC, Bishop-PE. Patient education leaflets for people with rheumatoid arthritis: A controlled study. *psychology, Health and Medicine.* 1997; 2 (3); 221-235
32. Barlow-JH; Wright-CC. Knowledge in patients with rheumatoid arthritis: a longer term follow-up of a randomized controlled study of patient education leaflets. *Br-J-Rheumatol.* 1998, 37 (4); 373-6
33. Bradley-L-A; Young-L-D; Anderson-K-O; Turner-R-A; Agudelo-C-A; McDaniel-L-K; Pisko-E-J; Semble-E-L; Morgan-T-M Effects of psychological therapy on pain behavior of rheumatoid arthritis patients. Treatment outcome and six-month follow-up. *Arthritis-Rheum.* 1987 Oct; 30(10): 1105-14

34. Scholten-C; Brodowicz-T; Graninger-W; Gardavsky-I; Pils-K; Pesau-B; Eggl-Tyl-E; Wanivenhaus-A; Zielinski-CC Persistent functional and social benefit 5 years after a multidisciplinary arthritis training program. *Arch-Phys-Med-Rehabil.* 1999 Oct; 80(10): 1282-7
35. Daltroy-L-H, Liang-M-M. Arthritis education: opportunities and state of the art. *Health Educ Q* 1993; 20:3-16
36. Lorig-K, Seleznick M, Lubeck-D, Ung E, Chastain RL, Holman HR. The beneficial outcomes of the arthritis self-management course are not adequately explained by behavior change. *Arthritis Rheum* 1989; 32:91-5
37. Owen-SG, Friesen-WT, Roberts-MS, Flux-W. Determinants of compliance in rheumatoid arthritic patients assessed in their home environment. *Br J Rheumatol.* 1985; 24:313-20
38. Ehlebracht-König-I, Bönisch A. (Principals of rheumatologic patient education: theoretical principals and didactical issues) *Grundlagen der rheumatologischen Patientenschulung. Theoretische Grundlagen und Didaktik. Z. Rheumatol* 2002; 61: 39-47.
39. Bradley-L-A. Adherence with treatment regimens among adult rheumatoid arthritis patients: current status and future directions. *Arthritis-Care-Res.* 1989 Sep; 2(3): S33-9.
40. Scherer,-Y-K; Bruce,-S. Knowledge, attitudes, and self-efficacy and compliance with medical regimen, number of emergency department visits, and hospitalizations in adults with asthma.
41. Sullum,-J; Clark,-M-M; King,-T-K. Predictors of exercise relapse in a college population. *J-Am-Coll-Health.* 2000 Jan; 48(4): 175-80.
42. Stein,-M-J; Wallston,-K-A; Nicassio,-P-M; Castner,-N-M. Correlates of a clinical classification schema for the arthritis helplessness subscale. *Arthritis-Rheum.* 1988 Jul; 31(7): 876-81
43. Nicassio,-P-M; Wallston,-K-A; Callahan,-L-F; Herbert,-M; Pincus,-T. The measurement of helplessness in rheumatoid arthritis. The development of the arthritis helplessness index. *J-Rheumatol.* 1985 Jun; 12(3): 462-7

Table 1: Validity Criteria

Validity Criteria

V1 Was a method of randomization performed (Random [unpredictable] generation of sequence. Stating only “randomization” is scored “unclear”)?

V2 Was the treatment allocation concealed (Sealed envelopes, randomization by telephone, etc.; Allocation cannot be influenced by those responsible for determining eligibility)?

V3 Were the intervention groups similar at baseline regarding prognostic variables (age, gender, duration of disease, severity of symptoms) and baseline scores of outcome measures; or was an adequate statistical adjustment procedure performed?

V4 Was the care provider blinded for the allocation intervention (use of placebo or independent providers for the interventions)? (Patients are not selectively influenced by care providers)

V5 Were interventions provided to the allocated group only (contamination: e.g. unintended provision of the intervention to members of the control group)?

V6 Were co-interventions avoided or standardized (Differential co-interventions lead to bias)?

V7 Was adherence to the intervention acceptable in all groups?

V8 Was the patient blinded to the allocated intervention (use of placebo/naïve patients)?

V9 Was the withdrawal/dropout rate described and acceptable (for intervention and follow-up period). Number of dropouts and reasons for withdrawal are specified. The reviewer determines if withdrawal does lead to substantial bias: “no”, usually <5%?

V10 Was the outcome assessor blinded to the intervention (placebo, independent assessor of effects)?

V11 Was the timing of outcome assessment comparable in all groups?

Table 2: Data Extraction Criteria

Data Extraction Criteria

- D1** Were the eligibility criteria specified (diagnosis, duration of symptoms, contra-indications, informed consent: “yes” if at least two of these criteria are specified)?
-
- D2** Were the therapeutic and control interventions explicitly described (contents, session duration and frequency, number of sessions, length of treatment period)?
-
- D3** Were data concerning relevant outcome measures presented (knowledge, behavior, skills, health status; measures related to intervention goals)?
-
- D4** Were short-term results (immediately after intervention) and a long-term follow-up (at least 6 months after randomization) reported?
-
- D5** Were adverse reactions (unintended negative effects which could be addressed to the intervention) described?
-
- D6** Was the study size for each group described immediately after randomization and at main outcome assessment?
-
- D7** Did the analysis include an intention-to-treat analysis (all randomized patients are reported/analyzed for the most important moments of effect measurements (-missing values), irrespective of non-compliance or co-interventions)?
-
- D8** Were the point estimates and measures of dispersion presented for the main outcome measures (means and standard deviations, medians and ranges, proportion (n) and %)?
-

Table 3: Quality Assessment of Studies on Patient Education with RA-Patients
(in Order of Quality Ranking)

Study (Ref)	Type of Intervention	Validity Score Positive Score (Total 11)	Validity Criteria Negative Score	Validity Criteria Unclear Score	Data Extraction (Total 8 Criteria)
Kraaimaat (23)	Psycho- educational	V3, V4, V5, V6, V7, V8, V9, V10, V11	-	V1, V2	D1, D2, D3, D4, D6, D8
Parker 1995 (24)	Psycho- educational	V3, V4, V5, V6, V7, V8, V9, V10, V11	-	V1, V2	D1, D2, D3, D4, D6,
Brus (25)	Educational	V3, V4, V6, V8, V9, V10, V11	-	V1, V2, V5, V7	D1, D2, D3, D4, D6, D8
Hammond (26)	Educational	V3, V4, V5, V8, V10, V11	V9	V1, V2, V6, V7	D1, D2, D3, D4, D6, D7, D8
Helliwell (27)	Educational	V1, V2, V3, V9, V10, V11	V8	V4, V5, V6, V7	D1, D2, D3, D4, D7, D8
Parker 1988 (28)	Psycho- educational	V1, V3, V4, V5, V8, V11	V9	V2, V6, V7, V10	D1, D2, D3, D4,
Taal (29)	Educational	V3, V5, V7, V8, V11	V9	V1, V2, V4, V6, V10	D1, D2, D3, D4, D6
Lindroth (30)	Educational	V4, V5, V10, V11	V8, V9	V1, V2, V3, V6, V7	D2, D3, D4,
Barlow (31/32)	Educational	V3, V4, V10, V11	V5, V8, V9	V1, V2, V6, V7	D3, D4, D8
Bradley (33)	Psycho- educational	V5, V8, V10	V9	V1, V2, V3, V4, V6, V7, V11	D1, D3, D4, D6, D8
Scholten (34)	Educational	V4, V10, V11	V6, V8, V9	V1, V2, V3, V5, V7	D2, D4, D8

Table 4: Description of Educational Programs

Study (Ref.)	Intervention	Authors' Aim of Study	Duration of Intervention	Control Group	Disease Duration	Study Size**	Long-term Follow Up
Brus et al. 1998 (25)	Educational group therapy	Evaluate effects of an educational program on compliance with sulphasalazine therapy / prescription with physical exercise and endurance exercise / prescriptions for ergonomic and on health	4 weeks (4 weekly 2-hour sessions) reinforcement meetings after 4 and 8 months	No intervention*	< 3 years	n = 65 EG 32 (3/4/0) CG 33 (2/1/0)	6 and 12 months
Hammond et al. 1999 (26)	Educational group therapy	Evaluate an educational-behavioral Joint Protection program for improving adherence with JP Identify factors influencing adherence	4 weeks (4 weekly 2-hour sessions) optional home visit within 2 weeks after program	Waiting list (crossover trial)	9.8 years (SD 8.0)	n = 35 EG1 17(0/4/0) CG1 18(0/4/0)	4 and 6 months
Helliwell et al. 1999 (27)	Educational group therapy	Record effects of an education program on radiological damage and quality of life in early RA	4 weeks (4 weekly 2-hour sessions)	No intervention*	3.5 years Range:0-5	n = 77 EG 43 (0/2/0) CG 34 (0/0/0)	12 months
Taal et al. 1993 (29)	Educational group therapy + physiotherapy	Evaluate effects of participation in group education program on health status, behavior, self-efficacy, outcome expectation, knowledge	5 weeks (5 weekly 2-hour sessions)	Physio-therapy (PT)	3.9 years Range 1-20	n = 75 EG 38(7/0/4) PT 37(7/0/0)	14 months

Lindroth et al. 1997 (30)	Educational group therapy	Evaluate effect of program on increase of individual's behavior in practicing exercise and work simplification and if this leads to a better outcome (pain and disability)	8 weeks (8 weekly 2.5 hour sessions)	No intervention*	11 years (sd 8)	n = 100 (4/?/0) EG 49 (1/4/0) CG 47 (3/?/0)	12 months
Barlow et al. 1998 (31/32)	Mailing of educational RA-related leaflets to individuals with RA	Evaluate if increased knowledge is maintained at 6 months follow-up and relationships between knowledge and anxiety and knowledge and disease duration	3 weeks (2 nd assessment)	Waiting list (related mailing)	16.0 years (sd 11.7)	n=142 (34/0/0) EG 53 (0/11/0) CG 55 (0/13/0)	6 months
Scholten et al. 1999 (34)	Educational group therapy	Assess the sustainable benefits of a professional, multidisciplinary training program for patients with RA	9 days (9 half days within 2 weeks)	No intervention*	8.9 years (sd 1.2)	n = 68 EG 38 (0/0/0) CG 30 (0/0/0) n=64 after 60 months	12 months 60 months

EG=Educated Group ; CG= Control group with no intervention *No intervention means ongoing (rheumatological) care, but no adjunct therapy

** n= number of randomized patients, including (x/y/z): (x) drop-outs / (y) lost to follow-up / (z) exclusions for non adherence to intervention (if given)

Table 5: Description of Psycho-Educational Programs

Study	Interventions	Authors' Aim of Study	Duration of Intervention	Control Groups*	Disease Duration	Study Size**	Long term follow up
Kraaimaat et al. 1995 (23)	Cognitive behavioral group therapy (CBT)	Evaluate effect of CBT in comparison to standard OT and no treatment	10 weeks	Standard occupational group therapy (OT) or no intervention* (CG)	15.6 years (Sd 12.7)	n = 77 CBT 27 (0/0/3) OT 31 (0/0/3) CG 19 (0/0/0)	6 months
Parker et al. 1995 (24)	Stress management group therapy (SM) + Ongoing rheumatological care	Examine the effectiveness of a stress-management program for improving clinical outcomes in patients with RA	10 weeks (10 weekly 1.5-hour sessions)+ 15-months maintenance program (at least 5 visits)	Attention control group (AC) = placebo (+ ongoing care) or no intervention (CG)	12.2 years (Sd 9.8)	n = 141 SM 47 (1/0/2) AC 49 (0/0/4) CG 45 (1/0/0)	15 months
Parker et al. 1988 (28)	Cognitive behavioral pain management group therapy (CBT)	Examine the effectiveness of a cognitive behavioral pain management program for reducing pain	1 week hospital stay 12 months support group program	General educational program group (GP) or no intervention (CG)	11.4 years	n = 83 CBT 29 (0/0/0) GP 26 (0/0/0) CG 28 (0/0/0)	12 months
Bradley et al. 1987 (33)	Cognitive behavioral group therapy (CBT)	Evaluation of CBT in comparison to STG and no intervention on pain reduction and coping strategies	CBT: 15 sessions 5 individual thermal biofeedback training and 10 group sessions	STG: structured social group therapy or no intervention (CG)	11.5 years (sd 11.41)	n = 68 (2/0/0) CBT 17 (6/1/0) STG 18 (4/1/0) CG 18 (1/0/0)	6 months

CG=Control group with no intervention. * No intervention means ongoing rheumatologic (standard) care, but no adjunct therapy

** n= number of randomized patients, including (x/y/z): (x) drop-outs / (y) lost of follow-up / (z) exclusions for non adherence to intervention (if given)

Table 6: Evaluation of Educational Programs (Results)

Study (quality ranking)	Knowledge	Coping	Compliance / Performance	Self-efficacy	Psychological Health Status	Physical Health Status
Brus (3) T1=4 weeks T2= 12 months			Medication: all ns Rest EG ++ CG 0 0 Joint protection EG + 0 CG 0 0		Psychological Functioning all ns	Physical Functioning all ns RA-Activity all ns
Hammond (4) T1=4 weeks T2= 6 months	Joint protection EG1 + • CG1 0 •		Joint protection EG1 • + CG1 • +	ns	Helplessness all ns	Pain, Strength, Hand Function; Physical Functioning all ns
Helliwell (5) T1=4 weeks T2=12 months	RA EG ++ CG ++ EG:CG ++		Compliance: ns		QOL: all ns	Radiographic scores all ns
Taal (7) T1=5 weeks T2=14 months	RA EG ++ CG 0 0		Performance physical activity EG ++ CG 0 0	Self-efficacy EG ++ CG 0 0		Physical functioning /Pain EG + 0 CG 0 0

Lindroth (8)	RA		Pain relief capacity		Joint protection		Depression, Social		Pain
T1=8 weeks	EG	•+	EG	•+	EG	•+	Relations, Fears		EG +0
T2=12 months	CG	•0	CG	•+	CG	•0	All ns		CG 00
							self-confidence		
							EG ++		
							CG 00		
Barlow (9)	RA						Depression		Pain
T1=3 weeks	EG	++					EG ++		EG ++
T2=6 months	CG	00					CG 00		CG 0+
							EG:CG ++		
Scholten (11)	RA		Coping with		Compliance Joint protection ,		Depression:		Disability
T1=9 days	EG	++	disease		physical activity, rest,		EG ++		EG ++
T2=12 months	CG	00	EG ++		medication		CG 00		CG 00
			CG 00		EG ++				
			Distraction		CG 00				
			EG ++						
			CG 00						

EG=Educated Group; CG=Control Group

Usually only in-group differences are given; differences between groups are given if available.

First sign: evaluation after intervention (T1) / Second sign: long-term follow up (T2)

+ = significant positive change / 0 = no change / • = not measured

Table 7: Evaluation of Psycho-Educational Programs (Results)

Study (quality ranking)	Knowledge	Pain Coping Behavior	Compliance	Self- Efficacy	Psychological Health Status	Physical Health Status
Kraaimaat (1)		Distraction			Depression	Pain
T1 = 10 Weeks	CBT + 0	CBT + 0			CBT 0 -	CBT 0 -
T2 = 6 Months	OT + 0	OT: 0 0			OT 0 -	OT 0 -
	CG 0 0	CG 0 0			CG 0 -	CG 0 -
					Social support	
					CBT 0 -	
					OT 0 -	
					CG 0 -	
Parker (2)		Coping Strategies			Helplessness	Pain
T1 = 10 Weeks		SM ++		SM ++	SM ++	SM ++
+ 15 Months		AC 0 0		AC 0 0	AC 0 0	AC 0 0
T2= 15 Months		CG 0 0		CG 0 0	CG 0 0	CG 0 0
Parker (6)		CSQ subscales:			All ns	All ns
T1 = 1 Week		Diverting Attention				
Inpatient		CBT:AC / CG • +				
+ 12 Months		Control Over Pain				
T2 = 12 Months		CBT:AC / CG • +				

**Decreasing/Ignoring
Pain**
CBT: CG • +
Catastrophizing
CBT:CG / AC:CG • +

Bradley (10)	Pain Behavior	Anxiety	Pain Intensity
T1=15 Weeks	CBT + 0	CBT ++	CBT ++
T2=6 Months	SGT + 0	SGT + 0	SGT + 0

CBT=Cognitive Behavioral Therapy Group; OT=Occupational Therapy Group, SM=Stress Management Group, AC=Attention Control Group, SGT=Structured Social Group Therapy, CG=Control Group.

Usually only in-group differences are given; differences between groups are given if available.

First sign: evaluation after intervention (T1) / Second sign: long-term follow up (T2)

+ = significant change / - = significant negative change / 0 = no change / • = not measured