An Anthroposophical Treatment Design for Inflammatory Rheumatic Conditions

By: Ludger Simon, et al

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Results of a Two-year Pilot Study

Ludger Simon, Thomas Schietzel, Christian Gartner, (Specialist in internal medicine and rheumatology, Bonn-Bomheim. Other authors all at Herdecke Community Hospital, Germany.) Hans-Christoph Kummel, Michael Schulte

Summary
18 unselected patients with chronic inflammatory rheumatic conditions, including 10 with confirmed rheumatoid arthritis, were treated according to anthroposophical medical principles in an open, prospective, uncontrolled pilot study with a mean follow-up period of 12 months. Main target variables were local and systemic inflammation (joint index, serum CRP), subjective status and functional capacity (MOPO questionnaire).

Treatment consisted mainly of a combination of anthroposophical medicines of plant, mineral and animal origin, selected to meet individual needs, as well as special external applications, eurythmy therapy and in most cases physiotherapy, dietary measures and art therapy. A review of the treatment strategy during an average one-year period of observation showed all patients had experienced subjective and objective improvement in local and systemic inflammatory activity, functional capacity, their symptoms and general condition. This included psychosocial dimensions such as anxiety, depression and social activity.

Introduction
The anthroposophical approach in medicine is not considered to be "alternative medicine" but an extension of knowledge of pathology and cure gained through conventional science, bringing in the science of the spirit and the comparative method that Goethe brought to the study of nature.(1-3) The general treatment target is to gain symptomatic relief and set healing processes in motion as far as possible in order to stimulate autoregulative processes in body, soul and spirit (biography), avoiding surgical intervention and suppressive medication wherever possible.

In the 70 years since anthroposophical medicine was founded, many patients with rheumatic conditions have been treated in its hospitals and medical practices. Results have been reported in a number of medical publications.(4-12) So far, there have been no clinical trials to evaluate the anthroposophical approach to treatment in this area, partly because diagnosis and scientific progress records present major methodological problems in rheumatology.(13-16)

The task we set ourselves was to make a critical assessment of short- and medium-term efficacy of our approach in a preliminary two-year pilot study. This was an uncontrolled clinical observation study with a relatively small number of patients which served as a pilot study for a proposed larger research project into the treatment of early rheumatoid arthritis. (17) This is to be a 4-year, multi-center, non-randomized, clinical trial to compare efficacy of

conventional and anthroposophical treatment of early rheumatoid arthritis.

Patients and methods

The clinical phase of the study was from August 1992 to February 1994. During a 7-month recruitment period, 19 patients were included in the study who came to Herdecke Community Hospital asking for treatment of rheumatoid arthritis. To exclude seasonal variation in symptoms, final assessments were made during the cold season from mid-January to mid-February 1994. This gave a mean period of observation of 12.2 months (range 8-16.6 months).

The 19 patients aged 15-70 who came to ask for treatment during the recruitment period were all included, with no further selection. One young man admitted with suspected rheumatoid arthritis had to be excluded when differential diagnosis established chronic fatigue syndrome (confirmed by applying Holms 1991 criteria).

Ten of the remaining 18 patients (15 women, 3 men) presented with rheumatoid arthritis (RA, confirmed by applying 1987 ACR criteria,(18,19) taking account of the European League (Eular) checks in making the clinical diagnosis of RA). Five patients presented with chronic spondyloarthropathy (based on the latest ESSG criteria(20)) and 3 with other inflammatory rheumatic conditions (2 with polyarthralgia as part of connective tissue disease, 1 with adult-onset Still's disease). The descriptive data of the patients are given in Table 1.

Group	Prednisolone equivalent daily dose on adm.										II = seronegative spondyloarthropathies					III = others		
Patient reg. no.	3	7	8	10	11	12	14	15	16	17	1	2	4	13	19	5	18	9
Sex	f	f	f	f	f	f	f	f	m	f	f	f	m	f	f	m	f	f
Diagnosis[1]	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	uSpa	uSpa	Spa	Ps	Ps	Co	Co	Still
Age on admission (y)	35.2	15.6	46.5	48.6	20.0	47.2	65.4	45.5	50.8	67.8	48.2	27.6	26.3	36.1	53.8	35.3	44.3	41.5
Age at onset[2]	34.3	15.4	42.2	47.2	16.9	46.5	62.3	43.2	44.5	67.0	48.0	15.0	17.0	34.3	27.0	34.9	39.0	34.5
Duration[3] (m)	129	2	53	17	49	20	22	27	72	10	3	150	106	23	322	5	61	84
Duration of treatment as part of trial (m)	14.3	11.3	9	16.6	11.3	11.9	15.0	10.0	16.3	14.4	10	14.5	10	10	8	8	15.3	13
High disease activity (ESR > 80)				X			X			X	X							X
# of ACR criteria met on adm.	6	4	6	6	5	6	7	5	7	6								
# of Pinals remission criteria met on adm.	2	1	0	0	2	0	0	1	2	0								
# of Pinals remission criteria met at end	3	2	3	2	1	1	0	2	3	1								
Steinbrocker functional class on adm.	2	2	2	3	2	2	2	2	2	2								
Steinbrocker functional class at end	2	1	2	2	2	2	2	1	2	2								
Steinbrocker radiolog. stage on adm.	3	1	2	2	3	2	2	2	2	2								

1 RA = rheumatoid arthritis;
Spa = seronegative spondyloarthropathy (ankylosing spondylitis, psoriatic arthritis, 2 x undiff. spondyloarthropathy)
Co = rheumatic syndrome connected with collagen disease

2 Refers to primary rheumatic condition (e.g. collagen disease, in case of psoriasis the arthropathy)
3 On admission, from first articular swellings or pain in disease-characteristic joint areas.

Table 1. Descriptive details of patients.

The age range on admission to the study was 15.4-65.4 years, 42 years on average. Duration of the disease (from first occurrence of joint swelling or pain in areas characteristic of the disease) was 2 months-26.8 years, 5.4 years on average. Mean duration of treatment was 12 months, mean age at onset 36.6 years. Five of the 18 patients showed high pathological activity (ESR > 80 mm/1 h, Westergren).

Three patients were on long-acting antirheumatic medication on admission ("basic medication;" one each on sulfasalazine, methotrexate and chloro-quine). Three others had had one or more unsuccessful attempts at basic medication (auranofin, sulfasalazine, MTX, chloroquine), but this was more than 6 months previously. Most patients (12 of 18) had not been on basic medication.

Symptomatic medication for the majority of patients at the beginning of the study was limited to nonsteroidal anti-inflammatory drugs (NSAIDs, 8 of 18 patients), the mean daily dose being 47% of the maximum daily dose recommended by the manufacturers, in most cases (n = 7) taken regularly. 2 patients were on long-term oral corticoid therapy (5-10 mg, mean daily dose 7.5 mg of prednisolone equivalent; case nos 16,18). Another 2 (case nos 4,10) had discontinued their prescribed steroids in the preceding 4 weeks for fear of side effects. One patient had been taking an oral corticosteroid, an NSAID and an opioid (see Table 2).

Reg. no.	Prednisolone equiv. daily dose on adm.	Prednisolone equiv. daily dose on adm.	Analgesics on adm. (mean daily dose)[1]	Analgesics at end (mean daily dose)	Discont. basic medication in med. history	Basic medication on adm.	Basic medication at end
3	–	–	acemetacin 30 mg (17%)	–	–	sulfasalazine	– 2 x 1 g/die
7	–	–	–	–	–	–	–
8	–	–	–	–	sulfasalazine	–	–
10	–[2]	10 mg	150 mg diclofenac (100%)	–	auranofin	MTX p.o. 15 mg/wk	–
11	–	–	–	–	–	–	–
12	–	–	–	–	–	–	–
14	–	–	–	–	–	–	–
15	–	–	–	–	–	–	–
16	5 mg	–	1 tabl. Tiralex®3 (33%) (+tilidine/naloxone 30 dr.)		chloroquine diphosphate auranofin	–	–
17	–	7.5 mg	–		methotrexate	–	–
1	–	–	150 mg indomethacin (75%)	–	–	–	–
2	–	–	–	–	–	–	–
4	–	–	50 mg diclofenac (33%)	–	–	–	–
13	–	–	–	–	–	–	–
19	–	–	1.4 g paracetamol, 1 g ASA, 620 mg propyphenazone[5]	525 mg paracetamol, 543 mg propyphenazone	–	–	–
5	–	–	–	–	–	–	–
18	10 mg	15 mg	71 mg ASA (2%)	71 mg ASA (2%)	–	chloroquine 1250 mg/wk	chloroquine 1250 mg/wk
9	–	2.5 mg	3 g ASA (67%)	acemetacin 150 mg (83%)	–	–	–

1 Percentage figures in parentheses give the relationship of the daily dose taken to the max. daily dose recommended by the manufacturers.
2 This patient had gradually discontinued the methylprednisolone prescribed for her, finishing 2 weeks prior to admittance, despite clinical deterioration.
3 Peripheral antiphlogistic/analgesic no longer on the market.
4 Acetylsalicic acid.
5 Combined with caffeine in two headache preparations; patient was excluded from evaluation of analgesic use as in her case this was entirely for severe migraine, with headache medicine abuse.
6 1 tablet of ASA 500 mg if req., taken c. once a week, i.e. approx. 71 mg/die on avg.

Table 2. Prior medication taken by patients.

All patients presented with chronic synovitis in more than 3 joint areas on admission. They were divided into 3 subgroups for evaluation. The core group for the study consisted of the 10 patients with RA in Group I. One of them was at Steinbrocker stage 1, 7 at stage 2, 2 at stage 3. Functionally, one patient was Steinbrocker class 3, the others class 2.

Group II included 5 patients with seronegative arthritis associated with spondylitis (1 with ankylosing spondylitis, 2 with psoriatic arthritis, 2 with undifferentiated seronegative spondyloarthropathy).

Group HI consisted of patients with polyarthritis of other origin (two in connection with collagen disease, 1 as part of adult-onset Still's disease).

The efficacy of the anthroposophical approach to treatment was to be described as comprehensively as possible, including subjective self-assessment of subjective status and functional capacity. As this was a pilot study with a small number of patients, no X-ray studies to assess evolution of joint destruction were done. Primary target criteria were the following parameters for evaluating RA evolution which are generally used in scientific rheumatology.

1 *Systemic inflammatory activity* assessed on the basis of the ESR (plus serum CRP, albumin/globulin ratio in serum electrophoresis, thrombo-cyte count and Hgb).
2 *Local inflammatory activity* on the basis of total tenderness indices, swelling and local hyperthermia using the joint assessment of the Dusseldorf Rheumatic Register(21-23) the main target variable used for joint tenderness was the articular tenderness index (ATI) which is related to the Ritchie index.(24)
All examinations on admission to and conclusion of the study were:
3 *Functional capacity* was primarily based on the MOPO questionnaire (German version of AIMS), the primary target variable being the total MOPO score (mean for all 9 subdimensions of the instrument).(25,26) In addition, outcome was indicated by changes in grip strength (Vigori meter manuf. by Martin, Tuttlingen, measured in mbar), the grip strength deficit, button test and the modified 25-m walk (incl. getting up from a chair). (27-29)

1. The above is supplemented by the patient's *subjective status* using the scores for depressive state and pain subdimensions in the MOPO questionnaire, plus a visual analog scale to show how the patient feels about his state of health on conclusion of the study (Fig. 1).

Patients' global self-assessment of efficacy and tolerance of anthroposophical treatment is both overall (Fig. 1) and with reference to improvement in individual disease characteristic symptoms under treatment. The latter was based on a questionnaire with 7 two-part visual analog scales assessing long-term improvement or deterioration in joint pain, morning stiffness, everyday mobility, general energy levels ("inner drive") and body warmth (Fig. 2).

To assess treatment outcome in Group I (RA patients), the number of Finals criteria met for clinical remission was determined on admission and at the end of the study.(30)
To confirm results, changes/improvements in the three main target variables tenderness index (ATI), ESR and MOPO (total score) were tested for statistical significance. The first step was to use the Wilcoxon signed rank text (1945,1947) separately for each of the three parameters to test the two paired samples before and after treatment for more than random differences. After this the three individual tests were collectively tested for significance using Holm's method.

Fig. 1. Questionnaire for patients concerning efficacy and tolerance of the treatment

1 *How do you rate the effect of the anthroposophical medicines yon are now taking on your rheumatic pain and symptoms?*
Please mark the position in the scale with a cross.

no effect.....**optimum effect**

2 *How do you rate the tolerance of all the medicines you are now taking for your rheumatic condition?*

Please mark the extent to which you feel affected by undesirable side effects by marking the position in the scale with a cross.

no side effects.....**very severe side effects**

3 *How well satisfied are you with your present state of health, considering all your symptoms?*

I find my present state of health generally

highlysatisfactory.....,.....;.....**extremely worrying**

Evaluation is individual (0 -100 points per scale).

Fig. 2. Questionnaire for patients concerning longer-term changes in rheumatic symptoms

Please answer a few more questions to tell us how far your rheumatic symptoms have improved since starting anthroposophical treatment at our hospital.

1 *Has the joint pain improved with anthroposophical treatment?* (Please mark the appropriate level by putting a cross in the scale)
no improvement at all..... **optimal, steady improvement**
... *or have they got worse overall in the course of treatment?*
no change at all..... **maximum deterioration**
2 *Has the morning stiffness improved with anthroposophical treatment?*
no improvement at all..... **optimal, steady improvement**
... or has it got worse overall in the course of treatment?
no change at all..... **maximum deterioration**
3 *Has your everyday mobility improved with anthroposophical treatment?*
(Are you now able to do everyday tasks and activities - at work, around the house - better or more quickly?
no improvement at all..... **optimal, steady improvement**
... *or has mobility got worse overall in the course of treatment?*

no change at all..... **maximum deterioration**
4 *Have you gained more energy or inner impetus with anthroposophical treatment?*
no improvement at all..... **optimal, steady improvement**
... or has the lack of inner impetus got worse overall in the course of treatment?
no change at all..... **maximum deterioration**
5 *Has your body gained more inner warmth with anthroposophical treatment? (Are you less chilly, are your hands and feet less cold?)*
no improvement at all..... **optimal, steady improvement**
... or has the lack of inner warmth got worse overall in the course of treatment?
no change at all..... **maximum deterioration**

Thank you very much!

Evaluation. Visual analog scales are measured in mm from the left, each ranging from 0 -100 points.

Treatment
For most patients, treatment consisted in a 3-7 week inpatient period followed by continuous outpatient follow-up. Examinations during the outpatient phase depended on pathological activity and symptoms and on how far away patients lived and were at 1- to 6-week intervals. In view of the relatively short 12-month mean period of observation, assessment included the change in condition between admission and end of study.

The anthroposophical approach to rheumatoid arthritis and other inflammatory rheumatic conditions and the basic therapeutic concept have been published elsewhere.(11,12) The latter may be characterized as follows: On the basis of the anthroposophical view of the human being and an extended medical history and examination, the elements listed below are selectively combined to meet the situation given by the individual's symptomatology and constitution:

- Anthroposophical medicines of mineral, vegetable and animal origin, esp. preparations of insect venoms (from honey bee. *Apis mellifica*, red ant, *Formica rufa*, and hornet, *Vespa crabro*),(31) mistletoe treatment using Viscum album in relatively high homeopathic potencies,(8-10) and other potentized medicines of vegetable origin, e.g. *Atropa belladonna*, *Bryonia dioica*, *Rhus toxicodendron*.(32) The anthroposophical medicines are given by the oral or parenteral route *(s.c.*, *i.e.* and partly also *i.v.*) or by external application; posology is individual, as a rule ranging from daily to twice a week.
- Dietary measures based on a sugar-free, vegetarian diet. If the constitution indicates it, a week's fast on fruit juice, followed by low-allergen addition diet (based on Kjeldsen-Krach et al.)(33)
- External applications may help greatly to reduce local swelling and pain and stimulate active inner warming of the organism and of specific internal organ functions (e.g. locally applied ginger or cabbage packs, oil dispersion baths, medicated rubs and metal-ointment dressings).
- Remedial exercises and a range of non-medical exercise methods used in anthroposophical medicine, including eurythmy movement therapy, music therapy, painting therapy, modeling therapy and speech formation.
- Detailed biographical history. If patients wish it, this may be taken further in talks with their physician to give biography-related counseling.
- Conventional drugs are initially continued if patients are already on long-term medication or if indicated by the severity of the condition (e.g. high-level inflammatory activity that does not respond to short-term treatment, threat of organic complications, or systemic vasculitis). The additional use of systemic corticosteroids may be necessary in such cases to

suppress inflammatory activity temporarily until the parallel stimulation of autoregulative self-healing powers with the anthroposophical treatment aspects takes effect in the course of the first weeks or months, making it possible to discontinue the steroids or at least reduce them to below the Cushing threshold dose.

In the study, conventional symptomatic treatment with NSAIDs and corticosteroids was used to supplement other treatment if pathological activity was at a high level. Corticosteroids were only prescribed as long-term oral treatment with gradual step-wise reduction, mtraarticular steroids were not used, nor were chemical or radio synoviorthesis, synovectomy and other surgical methods.

The indication for conventional long-term medication (basic medication) was even more strictly controlled. Basic methotrexate treatment for highly active rheumatoid factor positive RA was discontinued in one case where it was ineffective (case no. 10). m another case (no. 3), sulfasalazine treatment initiated 2 years earlier and so far effective was discontinued on admission to the study because the patient had just become pregnant; two previous pregnancies had both been followed by severe exacerbation of the disease; with our treatment, the RA remained in remission during the postnatal period. In case no. 18, basic medication with chloroquine (SLE) was continued. In the case of an older RA patient, where a desire to be pensioned off was a complicating factor, existing symptomatic medication with corticosteroid, NSAID and an opioid analgesic was temporarily replaced by sulfasalazine with good clinical results, and it was possible to discontinue this after 12 months with no recurrence.

Apart from this a major goal of anthroposophical treatment was not only to improve articular function and the pathological symptoms but to achieve effective replacement of long-term antirheumatic drugs with individually-selected and combined anthroposophical measures. This proved successful in all other cases, and it was possible to avoid conventional basic medication in 89% (16 of 18 patients).

Results

The mean figures for target criteria changed as follows with the anthroposophical treatment outlined above, the period of observation being one year on average (figures for RA patients = Group I, in parentheses, see Figures 3 and 4):

Systemic inflammatory activity. The ESR was reduced by 69% of the initial level, from 44.8 to 13.8 mm/I h (in Group I by 70%, 45.3 to 37.7 mm), CRP from 4.3 to 1.3 mg/dl (5.3 to 1.9), thrombocyte count from 380,000 to 310,000 y\ (416,000 to 335,000). The albumin/ globulin ratio of serum electrophoresis rose from 1.35 to 1.7 (1.3 to 1.6), total hemoglobin from 12.2 g/1 on admission to 13.0 g/1 at the end (11.7 to 12.7m Group I).

Local inflammatory activity. The cumulative index for joint tenderness was reduced by 61%, from 35.2 to 13.6 (48 to 16.6 in Group I), the swelling index from 33.2 to 10.3 (41.4 to 12.9). The cumulative index for the number and severity of hyperthermic joints decreased from 5.2 to 0.3 (4.6 to 0.2) points.

Functional capacity. Scales in the MOPO questionnaire were all 0-10. During the treatment period, general mobility increased from 7.2 to 9.0 points (6.9 to 9.1 in Group I), general physical activity from 5.3 to 7.5 points (4.7 to 7.5), ability to do household tasks from 7.9 to 9.6 (7.3 to 9.5) points, fine motor function of the writing hand from 7.5 to 9.0 (6.1 to 8.5) points, and independence with reference to everyday activities from 7.2 to 9.1 (6.2 to 9.3) points.

Global determination of Steinbrocker functional classes on admission and at the end of the trial in Group I gave improvement by one class in 3 of 10 RA patients and no deterioration in any of them. The *button* test for objective assessment of function was done with both and separate hands to assess fine motor function; mean improvement was from 26.6 to 17.6 seconds (Group I 28.3 to 17.0 seconds) for both hands, 40.8 to 28.6 seconds (44.4 to 29.3) for the right and 34.8 to 22.9 seconds (39.0 to 23.9) for the left hand. *Fist deficit* (max. distal phalanx gap of individual fingers when fist was made, measured in cm) improved on average from 0.6 to 0.2 cm for the right (1.0 to 0.3 cm) and 0.5 to 0.1 cm (0.8 to 0.1 cm) for the left hand. *Grip strength* (measured in mbar using a

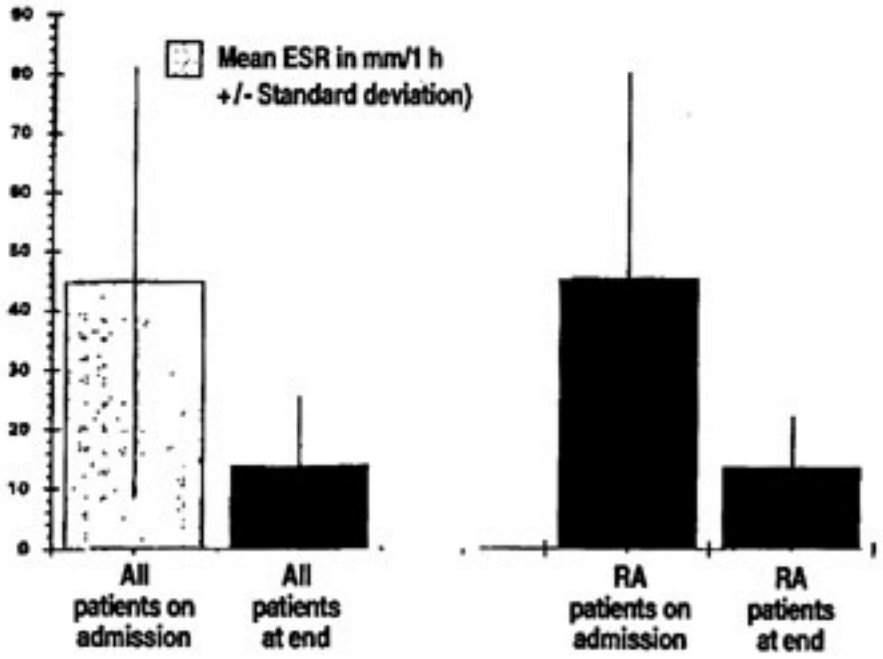

Fig. 3a. Mean changes in the 3 primary target criteria under treatment

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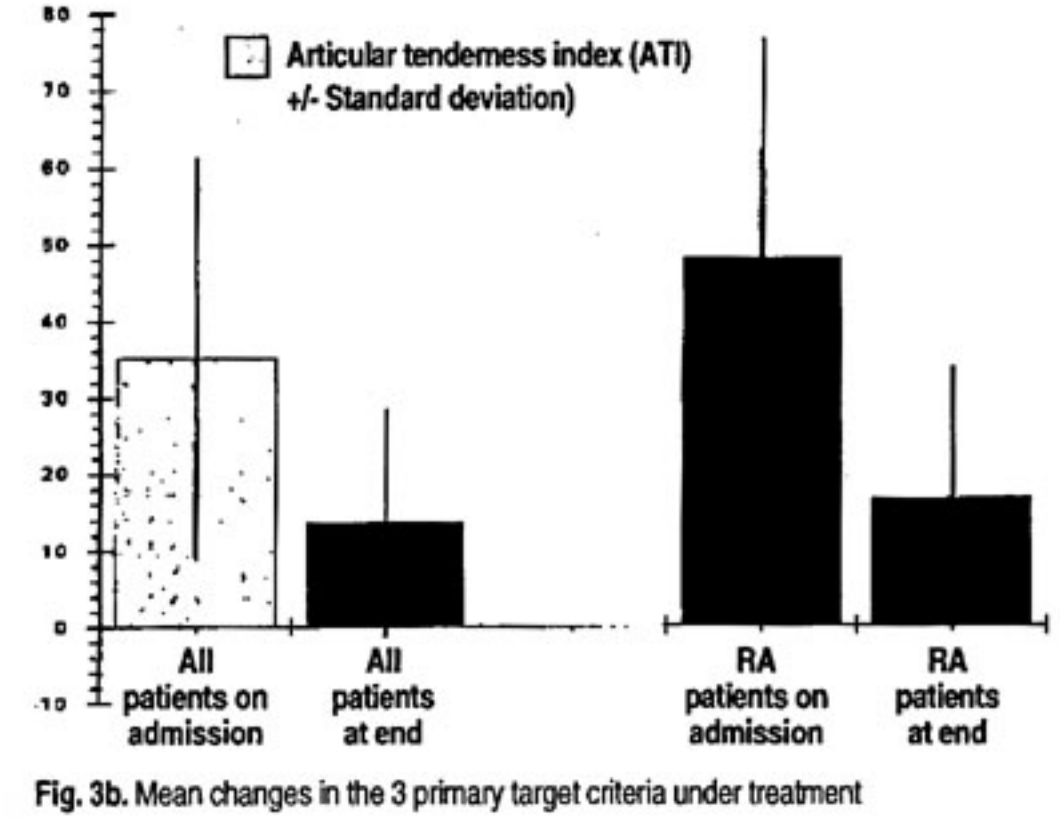

Fig. 3b. Mean changes in the 3 primary target criteria under treatment

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vigorimeter, max. of 3 attempts) rose from 571 to 805 mbar on average (469 to 710) for the right and 516 to 722 mbar (401 to 579) for the left hand. *Subjective status.* The psychosocial parts of the MOPO questionnaire showed an increase in social activity from 5.0 to 5.8 points (4.2 to 6.7 in Group I). Anxiety was reduced from 5.6 to 3.7 points (5.5. to 3.7), depressive mood from 3.8 to 3.4 points (4.3 to 2.6), pain level from 5.8 to 2.8 points (6.5 to 3.6) (The three subscales for anxiety, depression and pain reflect the degree; high ratings close to 10, therefore, mean maximum levels of the symptom, low ratings relative freedom from the symptom, i.e. a good subjective condition for the patient.) The total MOPO score (Jaeckel et al), with psychosocial scales included as figures subtracted from 10, improved by 31%, from 5.97 to 7.82 points for the whole collective. In Group I the result was even more marked at 41% (5.39 to 7.60 points).

At the final examination the efficacy of the anthroposophical medicines prescribed was given a more than average positive rating on the analog scales (Fig. 1), with a mean of 73% in the scale ranging from 0 = "no" to 100 = "optimum efficacy" (70% in Group I). As one would expect, tolerance of the anthroposophical medicines was given an even more positive score at 98.4 percentage points (98.1 in Group I). Global *satisfaction with state of health* was 77 percentage points on average for the whole population (76% in Group I). On the paired analog scales for improvement or worsening of individual disease-characteristic symptoms (whole treatment period, see Fig. 2), patients registered improved mobility (80% on average in both total population and Group I), greater warmth in extremities (73 and

67% respectively), improvement in general energy and inner drive (72 and 78%), less pain (67 and 60%), and morning stiffness (65 and 60%).

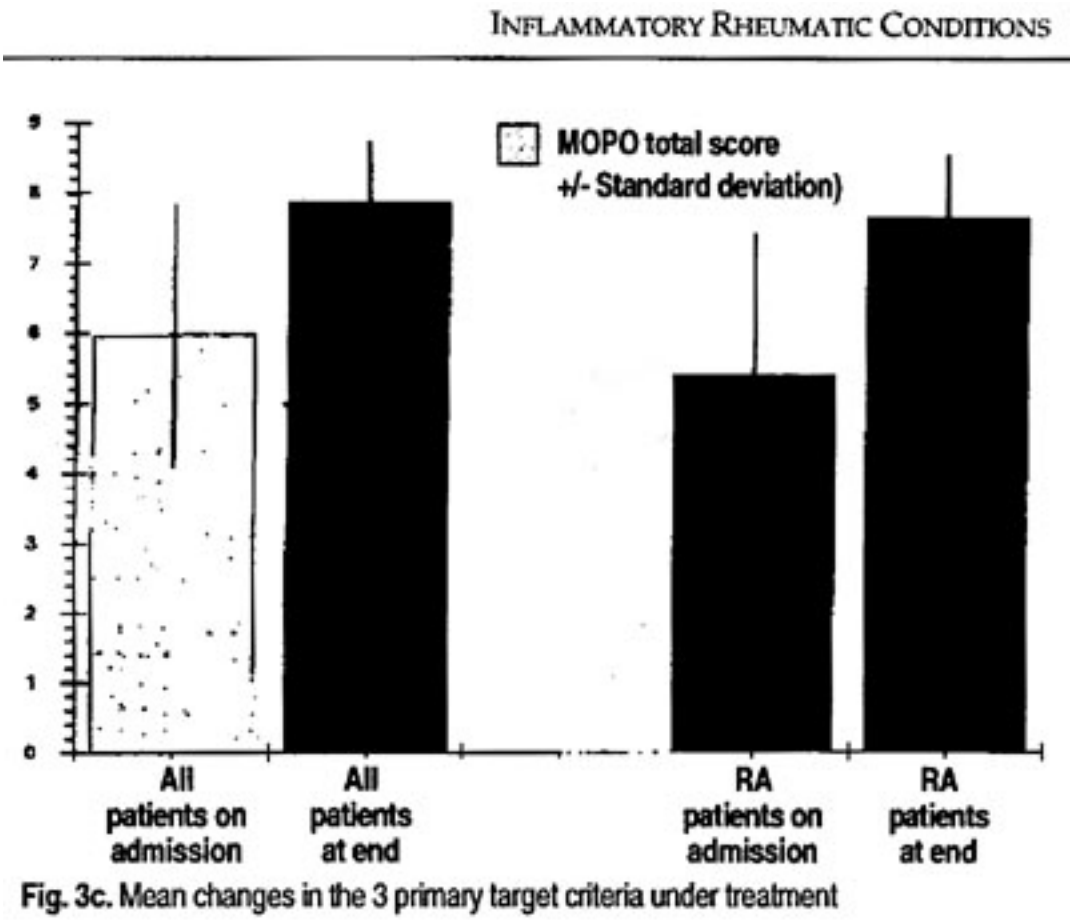

Fig. 3c. Mean changes in the 3 primary target criteria under treatment

Pinals et al. RA remission criteria. In the better defined subgroup of 10 patients with confirmed RA, the number of criteria met rose by 17%, from a mean of 0.8 on admission to 1.8 at the end of the trial. With one exception, a patient with highly active RA in old age, all patients responded with partial remission, with the number of criteria met rising by 1-3 in each individual case, or 1 criterion on average.

Additional use of conventional antirheumatoid medication. 1 patient with analgesic abuse for migraine was excluded from assessment of analgesic consumption, despite the fact that her consumption was reduced by half. The reason was that her use of analgesics was entirely for this second condition (case 19). Only 2 of the other 7 patients were still taking NSAIDs by the end of the trial, with a mean NSAIDs consumption of 47% of the maximum daily dose (manufacturer's recommendation) on admission to the trial reduced to a mean of 12%, a mean reduction by 3/4 of the original dosage.

On admission, 2 of the 18 patients were on corticosteroids (mean daily dose 7.5 mg of prednisolone equivalent); in 4 of 5 cases with high-level disease activity (ESR > 80 mm/h) steroids also had to be given for the first time. These patients had initially refused the

corticoids suggested elsewhere. As a result, 4 patients were still on a mean maintenance dose of 8.75 mg of prednisolone equivalent at the end of the trial.

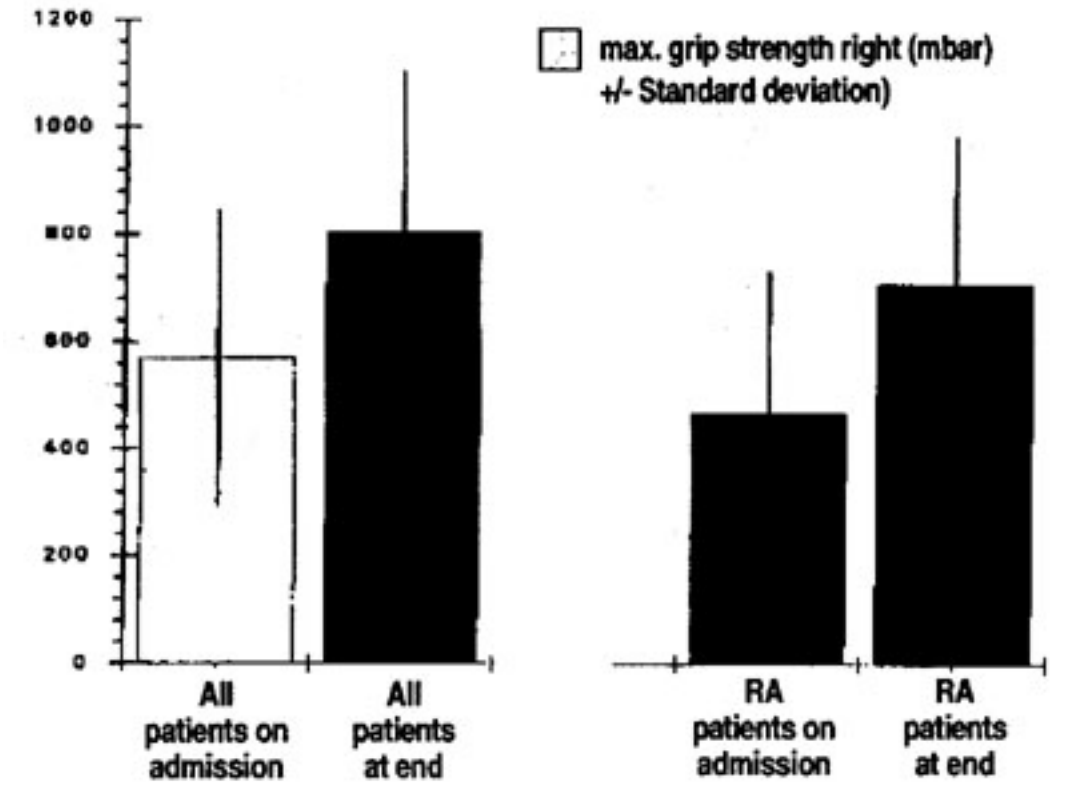

Fig. 4a. Mean changes in some secondary target criteria under treatment

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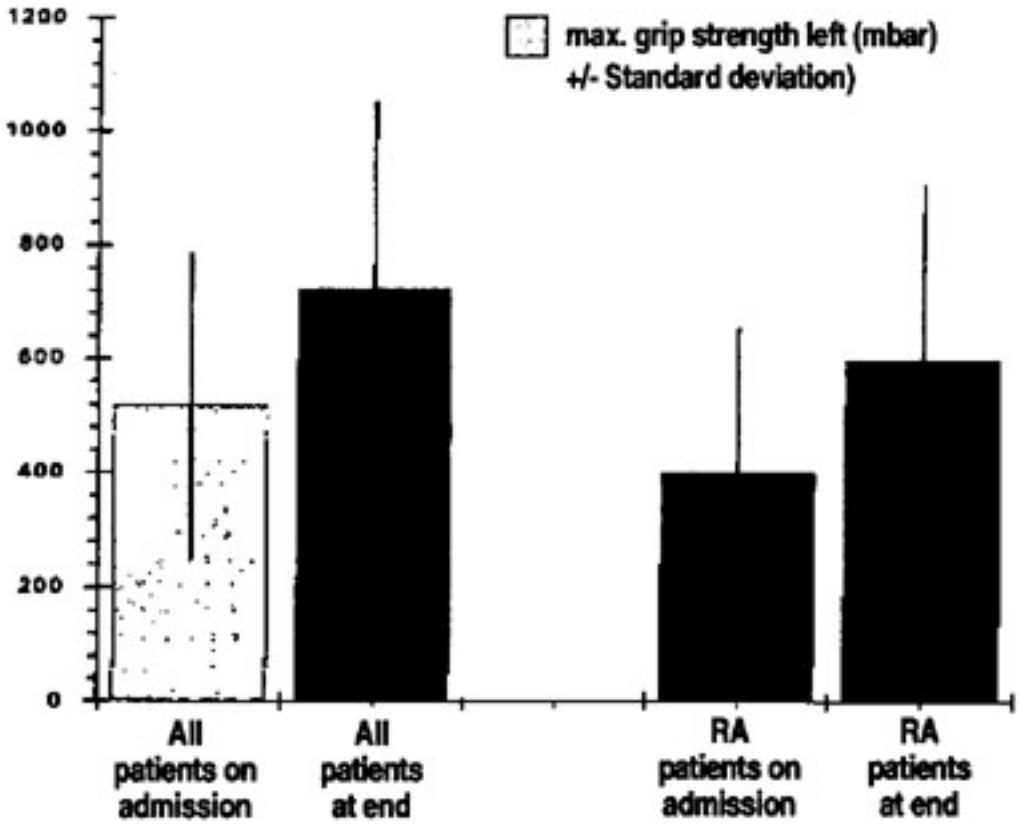

Fig. 4b. Mean changes in some secondary target criteria under treatment

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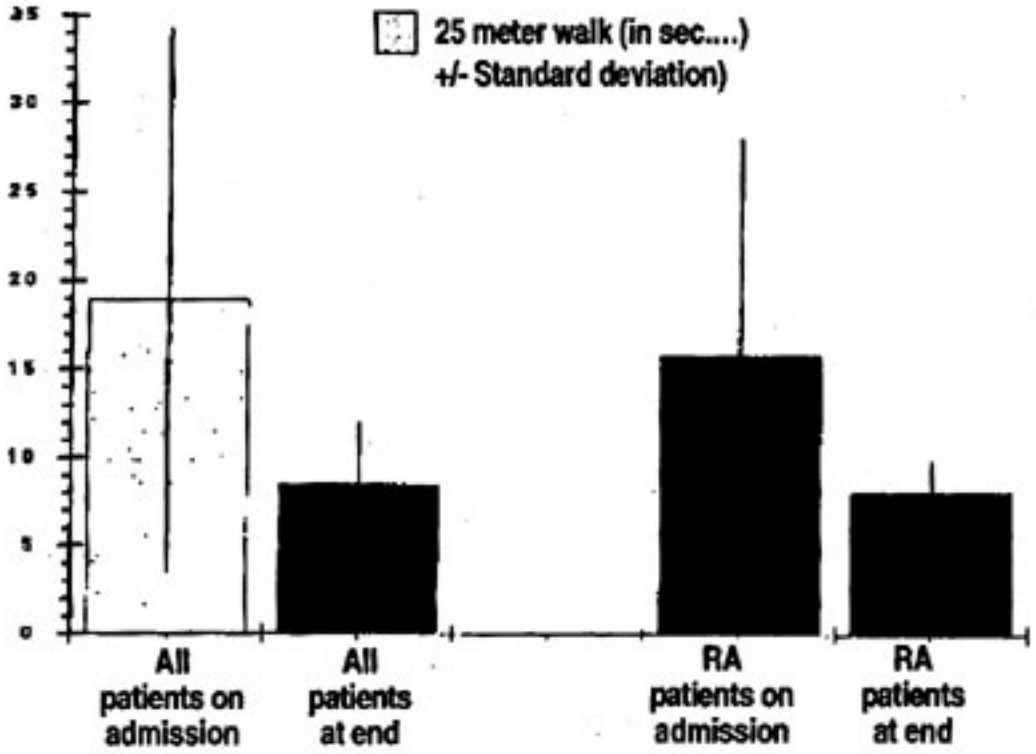

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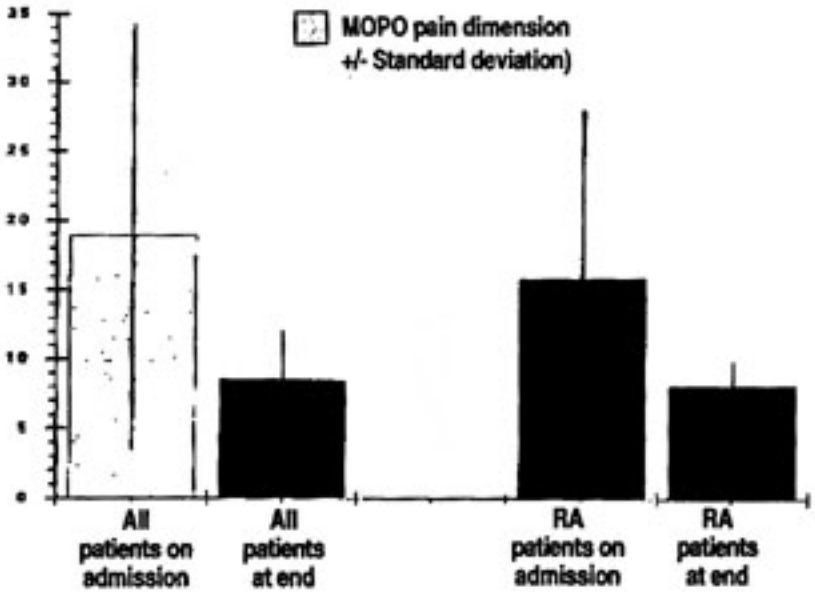

Fig. 4d. Mean changes in some secondary target criteria under treatment
(Note: The "pain" subdimension in the MOPO questionnaire includes 4 questions on pain and morning stiffness; here 0 = no, 10 points = maximum degree!)

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Tables 3 a-c. Data for statistical analysis.

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No.	Pat.	ATI before	ATI after	Difference
1	3	16	14	2
2	7	44	48	-4
3	8	44	19	25
4	10	82	4	78
5	11	82	47	35
6	12	37	13	24
7	14	6	4	2
8	15	59	3	56
9	16	25	6	19
10	17	85	8	77
11	1	31	3	28
12	2	18	7	11
13	4	24	7	17
14	13	4	0	4
15	19	17	25	-8
16	5	9	3	6
17	18	32	31	1
18	9	18	2	16

Table 3a. Articular tenderness index (ATI) before and after treatment

No.	Pat.	ESR before	ESR after	Difference
1	3	27	8	19
2	7	22	4	18
3	8	34	13	21
4	10	85	17	68
5	11	11	5	6
6	12	45	15	30
7	14	82	34	48
8	15	9	10	-1
9	16	28	11	17
10	17	110	20	90
11	1	110	51	59
12	2	52	4	48
13	4	15	5	10
14	13	12	9	3
15	19	12	6	6
16	5	13	7	6
17	18	40	10	30
18	9	100	19	81

Table 3b. ESR before and after treatment

No.	Pat.	MOPO before	MOPO after	Difference
1	3	7.75556	8.24444	-0.48889
2	7	4.95556	7.36667	-2.41111
3	8	4.94444	8.06667	-3.12222
4	10	5.91111	7.67778	-1.76667
5	11	8.64444	7.18889	1.45556
6	12	6.35556	8.64444	-2.28889
7	14	3.42222	5.58889	-2.16667
8	15	6.24444	8.43333	-2.18889
9	16	3.66667	7.27778	-3.61111
10	17	1.96667	7.52222	-5.55556
11	1	4.45556	7.50000	-3.04444
12	2	7.57778	8.21111	-0.63333
13	4	7.22222	7.76667	-0.54444
14	13	6.96667	8.37778	-1.41111
15	19	4.62222	6.36667	-1.74444
16	5	6.67778	9.13333	-2.45556
17	18	7.60000	8.65556	-1.05556
18	9	8.42222	8.74444	-0.32222

Table 3c. Total MOPO score before and after treatment

As regards long-term antirheumatic drugs (basic medication), sulfasalazine was used temporarily in one case (see above), another patient continued on chloroquine for SLE. All other 16 patients showed notable improvement in the longer term without long-acting antirheumatic drugs.

Statistical confirmation. The aim was to test the clinical changes in the three main target variables ATI, ESR and MOPO score for statistical significance. Individual tests were based on differences between parameters before and after treatment.

The Wilcoxon test establishes if the median of differences differs significantly from zero. The formula used was:
H0k: Mk = 0 versus H1k: Mk is not equal to 0 (bilateral tests)
with k = ATI, ESR and MOPO. MATI is the median for differences in ATI in the treated group, etc. In this particular case differences that are not zero represent differences in parameters before and after treatment, i.e. effects due to treatment in this sense.

Fig. 5 gives the data used for confirmatory analysis. Fig. 6 the results of the three individual tests. Sgn Rank is the value for the test statistic S and Prob > ISI the related p value.

Holm's method for multiple test problems can be used to combine the 3 individual results in a significance test with *alpha* level overall. The maximum probability of error we chose was *alpha* = 0.01

Fig. 7 gives the results of the 3 individual tests in ascending order of p values, i.e. ascending order of ISI. For multiple comparison, one tests successively for j = 1,..., 3, if

p}> (*alpha* (n+l)-j).

If this is the case the first time for j = i, the medians Ml, ..., Mj-1 are considered to differ from <*alpha*> level. All remaining medians Mj,..., Mn do not differ significantly from zero.

If no such i can be found, as in the present case, all medians may be regarded to differ from zero. Improvement in the 3 chosen parameters ATI, ESR and MOPO for the patient is, therefore, statistically significant overall. This statement is false with maximally 1% probability.

Discussion
An uncontrolled study of patients with active RA and other inflammatory rheumatic conditions served to determine the efficacy of anthroposophical treatment (in some cases concurrent with conventional antirheumatic drugs) over a period of 12 months on average. Individual case records showed a definite reduction in local and systemic inflammatory activity, improvement in disease-characteristic symptoms, and an improvement in functional capacity, including psychosocial dimensions such as anxiety, depression and social activity.

Differences		Articular tenderness index (ATI)	
n	18		
Sgn Rank	74	Prob >|S|	0.0005

Differences		ESR	
n	18		
Sgn Rank	84.5	Prob >|S|	0.0001

Differences		Articular tenderness index (ATI)	
n	18		
Sgn Rank	-78.5	Prob >|S|	0.0001

Tables 4 a-c. Results of individual tests

Parameter	S	p	j	*alpha*/4 – j
ESR	84.5	0.0001	1	0.0033
MOPO	-78.5	0.0001	2	0.005
ATI	74	0.0005	3	0.01

Table 5. Multiple comparison after Holm *alpha* = 0.01

Table 5. Multiple comparison after Holm alpha = 0.01

The total patient population showed statistically significant improvement in local and systemic inflammatory activity, functional capacity and subjective status (determined with the three main target variables: joint tenderness, ESR and total score for MOPO questionnaire).

Use of NSAIDs was reduced to about 1 /4 of the mean daily dose for the 7 patients who were taking them on admission; the remaining 11 patients (= 61%) had adequate pain control with anthroposophical treatment only (in one case of malignant RA with systemic vasculitis prednisolone was given concurrently). Long-acting conventional antirheumatic drugs were not used in 16 of the 18 patients (89%).

Use of corticosteroids was limited to the acute phase in highly active forms of the disease; here it supports the efficacy of anthroposophical treatment until this proves adequate on its own and sometimes is the only way of making active movement therapies such as eurythmy therapy possible during acute episodes.

It has to be taken into account in evaluating the results that the study was limited to patients who had asked of their own accord if treatment could be made available at our hospital. This is also evident from the fact that a relatively large number of patients had not been on long-term antirheumatic drugs, had refused it altogether or discontinued it after a short time. Nevertheless, most patients knew very little about Anthroposophy and anthroposophical medicine. Most were simply looking for an alternative to conventional treatment.

The clinical experience described in this paper will be considered in more depth shortly in a multicenter comparative clinical trial with admission limited to predefined parameters (patients with confirmed RA in the first 3 years of the disease). The trial, supported under the program for "unconventional medical approaches" of the Federal Department of Education and Research (formerly Federal Department of Research and Technology) will run for 4 years and include radiological determination of progressive joint destruction.

Ludger Simon, MD
Nagelstr. 2
D-70182 Stuttgart
Germany

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