HOW DOES
ANTHROPOSOPHIC MEDICINE
PERFORM
IN CLINICAL PRACTICE?

ABSTRACTS

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IVAA (International Federation of Anthroposophic Medical Associations)
General Reviews


BACKGROUND AND OBJECTIVE: The aim of this Health Technology Assessment Report was to analyse the current situation, efficacy, effectiveness, safety, utilization, and costs of anthroposophic medicine (AM) with special emphasis on everyday practice.

DESIGN: Systematic review. MATERIAL AND METHODS: Search of 20 databases, reference lists and expert consultations. Criteria based analysis was performed to assess methodological quality and external validity of the studies. RESULTS: AM is a complementary medical system that extends conventional medicine and provides specific pharmacological and non-pharmacological treatments. It covers all areas of medicine. 178 clinical trials on efficacy and effectiveness were identified: 17 RCTs, 21 prospective and 43 retrospective NRCTs, 50 prospective and 47 retrospective cohort studies/case-series without control groups. They investigated a wide range of AM-treatments in a variety of diseases, 90 x mistletoe in cancer. 170 trials had a positive result for AM. Methodological quality differed substantially; some studies showed major limitations, others were reasonably well conducted. Trials of better quality still showed a positive result. External validity was usually high. Side effects or other risks are rare. AM-patients are well educated, often female, aged 30-50 years, or children. The few economic investigations found less or equal costs in AM because of reduced hospital admissions and less prescriptions of medications.

CONCLUSION: Trials of varying design and quality in a variety of diseases predominantly describe good clinical outcome for AM, little side effects, high satisfaction of patients and presumably slightly less costs. More research and more methodological expertise and infrastructure are desirable.


Anthroposophic medicine includes special medications and special artistic and physical therapies. More than 200 clinical studies of varying design and quality have been conducted on anthroposophic treatment. Half of these studies concern anthroposophic mistletoe therapy for cancer. Clinical effects of mistletoe products include improvement of quality of life, reduction of side effects from chemotherapy and radiation, and possibly increased survival. Apart from cancer therapy, the largest studies of anthroposophic treatment have been 2 naturalistic system evaluations: In German outpatients with mental, musculoskeletal, respiratory, and other chronic conditions, anthroposophic treatment was followed by sustained improvements of symptoms and quality of life. In primary care patients from 4 European countries and the United States treated for acute respiratory and ear infections by anthroposophic or conventional physicians, anthroposophic treatment was associated with reduced use of antibiotics and antipyretics, quicker recovery, and fewer adverse reactions; these differences remained after adjustment for relevant baseline differences.

ANTHROPOSOPHIC MEDICINE OUTCOMES STUDY (AMOS)

OVERVIEWS


CONTEXT: Anthroposophic medicine (AM) is used worldwide for chronic diseases. OBJECTIVE: To study clinical outcomes and costs in patients treated with AM therapies for chronic conditions. DESIGN: Prospective cohort study. SETTING: 141 medical practices in Germany providing AM treatment. PARTICIPANTS AND INTERVENTIONS: 898 outpatients aged 1-75 years referred to AM therapies (art, eurythmy or rhythmic massage, n = 665) or starting AM medical treatment (counselling, medicines, n = 233). MAIN OUTCOME MEASURES: Disease severity assessed independently by physician (Disease Score) and patient (Symptom Score), and health-related quality of life (SF-36, KINDL, KITA) after 3, 6, 12, 18, and 24 months; health costs in pre-study year and first study year. RESULTS: Most common indications were mental disorders (32.0%), and musculoskeletal disorders (18.9%). Disease duration at baseline was median 3.0 years (interquartile range = i.q.r. 1.0-8.5, mean 6.5 +/- 8.4 years). Median number of AM therapy sessions was 12 (i.q.r. 10-20), median therapy duration was 120 days (i.q.r. 81-195). From baseline

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to 6-month follow-up, Disease Score (0-10) improved from 6.40 +/- 1.76 to 3.43 +/- 2.23 (p < 0.001), Symptom Score (0-10) improved from 5.89 +/- 1.75 to 3.35 +/- 2.09 (p < 0.001). In adults, SF-36 Physical Component Summary improved from mean 43.34 +/- 10.58 at baseline to 47.44 +/- 10.32 after 6 months (p < 0.001), SF-36 Mental Component Summary improved from 38.83 +/- 12.45 to 44.93 +/- 10.92 (p < 0.001). Similar HRQoL improvements were observed in children (KINDL, KITA). All improvements remained stable until 24-month follow-up. Adverse effects from AM therapies occurred in 2.7% (19/712) of patients. Three (0.5%) patients stopped therapy due to adverse effects. Health costs were 3,637 Euro per patient in the pre-study year and 3,484 Euro in the first study year, a decrease of 152 Euro (4.2%) per patient.

CONCLUSION: Anthroposophic therapies were associated with long-term reduction of chronic disease symptoms, improvement of health-related quality of life, and health cost reduction.


BACKGROUND: Many children with chronic disease use complementary therapies. Anthroposophic treatment for paediatric chronic disease is provided by physicians and differs from conventional treatment in the use of special therapies (art therapy, eurythmy movement exercises, rhythmical massage therapy) and special medications. We studied clinical outcomes in children with chronic diseases under anthroposophic treatment in routine outpatient settings.

METHODS: In conjunction with a health benefit program, consecutive outpatients starting anthroposophic treatment for any chronic disease participated in a prospective cohort study. Main outcome was disease severity (Disease and Symptom Scores, physicians' and caregivers' assessment on numerical rating scales 0-10). Disease Score was documented after 0, 6, and 12 months, Symptom Score after 0, 3, 6, 12, 18, and 24 months.

RESULTS: A total of 435 patients were included. Mean age was 8.2 years (standard deviation 3.3, range 1.0-16.9 years). Most common indications were mental disorders (46.2% of patients; primarily hyperkinetic, emotional, and developmental disorders), respiratory disorders (14.0%), and neurological disorders (5.7%). Median disease duration at baseline was 3.0 years (interquartile range 1.0-5.0 years). The anthroposophic treatment modalities used were medications (69.2% of patients), eurythmy therapy (54.7%), art therapy (11.3%), and rhythmical massage therapy (6.7%). Median number of eurythmy/art/massage therapy sessions was 12 (interquartile range 10-20), median therapy duration was 118 days (interquartile range 78-189 days). From baseline to six-month follow-up, Disease Score improved by average 3.00 points (95% confidence interval 2.76-3.24 points, p < 0.001) and Symptom Score improved by 2.41 points (95% confidence interval 2.16-2.66 points, p < 0.001). These improvements were maintained until the last follow-up. Symptom Score improved similarly in patients not using adjunctive non-anthroposophic therapies within the first six study months.

CONCLUSION: Children under anthroposophic treatment had long-term improvement of chronic disease symptoms. Although the pre-post design of the present study does not allow for conclusions about comparative effectiveness, study findings suggest that anthroposophic therapies may play a beneficial role in the long-term care of children with chronic illness.

COST ANALYSIS


BACKGROUND: Anthroposophic therapies (counseling, special medication, art, eurythmy movement, and rhythmical massage) aim to stimulate long-term self-healing processes, which theoretically could lead to a reduction of healthcare use. In a prospective two-year cohort study, anthroposophic therapies were followed by a reduction of chronic disease symptoms and improvement of quality of life. The purpose of this analysis was to describe health costs in users of anthroposophic therapies.

METHODS: 717 consecutive outpatients from 134 medical practices in Germany, starting anthroposophic therapies for chronic diseases, participated in a prospective cohort study. We analysed direct health costs (anthroposophic therapies, physician and dentist consultations, psychotherapy, medication, physiotherapy, ergotherapy, hospital treatment, rehabilitation) and indirect costs (sick leave compensation) in the pre-study year and the first two study years. Costs were calculated from resource utilisation, documented by patient self-reporting. Data were collected from January 1999 to April 2003.

RESULTS: Total health costs in the first study year (bootstrap mean 3,297 Euro; 95% confidence interval 95%-CI 3,157 Euro to 3,923 Euro) did not differ significantly from the pre-study year (3,186 Euro; 95%-CI 3,037 Euro to 3,711 Euro), whereas in the second year, costs (2,771 Euro; 95%-CI 2,647 Euro to 3,256 Euro) were significantly reduced by 416 Euro (95%-CI 264 Euro to 960 Euro) compared to the pre-study year. In each period hospitalisation and
sick-leave together amounted to more than half of the total health costs. Anthroposophic therapies and medication amounted to 3%, 15%, and 8% of total health costs in the pre-study year, first year, and second study year, respectively. The cost reduction in the second year was largely accounted for by a decrease in inpatient hospitalisation, leading to a hospital cost reduction of 519 Euro (95% CI 377 Euro to 904 Euro) compared to the pre-study year.

CONCLUSION: In patients starting anthroposophic therapies for chronic disease, total health costs did not increase in the first year, and were reduced in the second year. This reduction was largely explained by a decrease in inpatient hospitalisation. Within the limits of a pre-post design, study findings suggest that anthroposophic therapies are not associated with a relevant increase in total health costs.

DIAGNOSIS GROUPS


BACKGROUND: Depressive disorders are common, cause considerable disability, and do not always respond to standard therapy (psychotherapy, antidepressants). Anthroposophic treatment for depression differs from ordinary treatment in the use of artistic and physical therapies and special medication. We studied clinical outcomes of anthroposophic therapy for depression. METHODS: 97 outpatients from 42 medical practices in Germany participated in a prospective cohort study. Patients were aged 20-69 years and were referred to anthroposophic therapies (art, eurythmy movement exercises, or rhythmical massage) or started physician-provided anthroposophic therapy (counselling, medication) for depression: depressed mood, at least two of six further depressive symptoms, minimum duration six months, Center for Epidemiological Studies Depression Scale, German version (CES-D, range 0-60 points) of at least 24 points. Outcomes were CES-D (primary outcome) and SF-36 after 3, 6, 12, 18, 24, and 48 months. Data were collected from July 1998 to March 2005. RESULTS: Median number of art/eurythmy/­massage sessions was 14 (interquartile range 12-22), median therapy duration was 137 (91-212) days. All outcomes improved significantly between baseline and all subsequent follow-ups. Improvements from baseline to 12 months were: CES-D from mean (standard deviation) 34.77 (8.21) to 19.55 (13.12) (p < 0.001), SF-36 Mental Component Summary from 26.11 (7.98) to 39.15 (12.08) (p < 0.001), and SF-36 Physical Component Summary from 43.78 (9.46) to 48.79 (9.00) (p < 0.001). All these improvements were maintained until last follow-up. At 12-month follow-up and later, 52%-56% of evaluable patients (35%-42% of all patients) were improved by at least 50% of baseline CES-D scores. CES-D improved similarly in patients not using antidepressants or psychotherapy during the first six study months (55% of patients).

CONCLUSION: In outpatients with chronic depression, anthroposophic therapies were followed by long-term clinical improvement. Although the pre-post design of the present study does not allow for conclusions about comparative effectiveness, study findings suggest that the anthroposophic approach, with its recourse to non-verbal and artistic exercising therapies can be useful for patients motivated for such therapies.


OBJECTIVE: To compare anthroposophic treatment (eurythmy, rhythmical massage or art therapy; counselling, anthroposophic medication) and conventional treatment for low back pain (LBP) under routine conditions. METHODS: 62 consecutive outpatients from 38 medical practices in Germany, consulting an anthroposophic (A-) or conventional (C-) physician with LBP of >or= 6 weeks duration participated in a prospective non-randomised comparative study. Main outcomes were Hanover Functional Ability Questionnaire (HFAQ), LBP Rating Scale Pain Score (LBPRS), Symptom Score, and SF-36 after 6 and 12 months. RESULTS: At baseline, LBPR duration was >6 months in 85% (29/34) of A-patients and 54% (15/28) of C-patients (p = 0.004). Unadjusted analysis showed significant improvements in both groups of HFAQ, LBPRS, Symptom Score, SF-36 Physical Component Summary, and three SF-36 scales (Physical Function, Pain, Vitality), and improvements in A-patients of three further SF-36 scales (Role Physical, General Health, Mental Health). After adjustment for age, gender, LBPR duration, and education, improvements were still significant in both groups for Symptom Score (p = 0.030), SF-36 Physical Component Summary (p = 0.004), and three SF-36 scales (Physical Function, p = 0.025; Role Physical, p = 0.014; Pain, p = 0.003), and in A-patients for SF-36-Vitality (p = 0.032). Compared to C-patients, A-patients had significantly more pronounced improvements of three SF-36 scales (Mental Health: p = 0.045; General Health: p = 0.006; Vitality: p = 0.005); other improvements did not differ significantly between the two groups.

CONCLUSION: Compared to conventional therapy, anthroposophic therapy for chronic LBP...
was associated with at least comparable improvements.


BACKGROUND: Anthroposophic treatment for chronic low back pain (LBP) includes special artistic and physical therapies and special medications. In a previously published prospective cohort study, anthroposophic treatment for chronic LBP was associated with improvements of pain, back function, and quality of life at 12-month follow-up. These improvements were at least comparable to improvements in a control group receiving conventional care. We conducted a two-year follow-up analysis of the anthroposophic therapy group with a larger sample size.

METHODS: Seventy-five consecutive adult outpatients in Germany, starting anthroposophic treatment for discogenic or non-specific LBP of ≥ 6 weeks’ duration participated in a prospective cohort study. Main outcomes were Hanover Functional Ability Questionnaire (HFAQ; 0–100), LBP Rating Scale Pain Score (LBPRS; 0–100), Symptom Score (0–10), and SF-36 after 24 months.

RESULTS: Eighty-five percent of patients were women. Mean age was 49.0 years. From baseline to 24-month follow-up all outcomes improved significantly; average improvements were: HFAQ 11.1 points (95% confidence interval [CI]: 5.5–16.6; p < 0.001), LBPRS 8.7 (95% CI: 4.4–13.0; p < 0.001), Symptom Score 2.0 (95% CI: 1.3–2.8; p < 0.001), SF-36 Physical Component Summary 6.0 (95% CI: 2.9–9.1; p < 0.001), and SF-36 Mental Component Summary 4.0 (95% CI: 1.1–6.8; p = 0.007).

CONCLUSION: Patients with chronic LBP receiving anthroposophic treatment had sustained improvements of symptoms, back function, and quality of life, suggesting that larger multicenter rigorous studies may be worthwhile.


BACKGROUND AND METHODS: Anthroposophic treatment for anxiety disorders includes special artistic and physical therapies and special medications. We conducted a prospective cohort study of 64 consecutive adult outpatients starting anthroposophic treatment for anxiety disorders under routine conditions. Main outcomes were Anxiety Severity (physician and patient ratings 0–10), Self-rating Anxiety Scale (0–100), Center for Epidemiological Studies Depression Scale, German version (CES-D, 0–60), and SF-36 Mental Component Summary.

RESULTS: Mean age was 42.3 years. Most frequent diagnoses were generalized anxiety disorder (44% of patients, n = 28/64) and panic disorder (39%). Median disease duration was 4.5 years. The anthroposophic treatment modalities used were medications (56% of patients), eurythmy therapy (41%), art therapy (30%), and rhythmical massage therapy (3%). Median number of eurythmy/ art/ massage sessions was 12, median therapy duration was 120 days. From baseline to six-month follow-up, all outcomes improved significantly; average improvements were: Physician-rated Anxiety Severity 3.60 points (95% confidence interval 2.97–4.22, p < 0.001), patient-rated Anxiety Severity 3.50 (2.88–4.12, p < 0.001), Self-rating Anxiety Scale 11.88 (7.70–16.05, p < 0.001), CES-D 8.79 (5.61–11.98, p < 0.001), and SF-36 Mental Component 9.53 (5.98–13.08, p < 0.001). All improvements were maintained until last follow-up after 24 months.

CONCLUSION: Patients with anxiety disorders under anthroposophic treatment had long-term improvements of symptoms and quality of life.

ANTHROPOSOPHIC THERAPY MODALITIES


BACKGROUND: The short consultation length in primary care is a source of concern, and the wish for more consultation time is a common reason for patients to seek complementary medicine. Physicians practicing anthroposophic medicine have prolonged consultations with their patients, taking an extended history, addressing constitutional, psychosocial, and biographic aspect of patients’ illness, and selecting optimal therapy. In Germany, health benefit programs have included the reimbursement of this additional physician time. The purpose of this study was to describe clinical outcomes in patients with chronic diseases treated by anthroposophic physicians after an initial prolonged consultation.

METHODS: In conjunction with a health benefit program in Germany, 233 outpatients aged 1-74 years, treated by 72 anthroposophic physicians after a consultation of at least 30 min participated in a prospective cohort study. Main outcomes were disease severity (Disease and Symptom Scores, physicians’ and patients’ assessment on numerical rating scales 0-10) and quality of life (adults: SF-36, children aged 8-16: KINDL, children 1-7: KITA). Disease Score was documented after 0, 6 and 12 months, other outcomes after 0, 3, 6,
12, 18, 24, and (Symptom Score and SF-36) 48 months. **RESULTS:** Most common indications were mental disorders (17.6% of patients; primarily depression and fatigue), respiratory diseases (15.5%), and musculoskeletal diseases (11.6%). Median disease duration at baseline was 3.0 years (interquartile range 0.5-9.8 years). The consultation leading to study enrolment lasted 30-60 min in 51.5% (120/233) of patients and >60 min in 48.5%. During the following year, patients had a median of 3.0 (interquartile range 1.0-7.0) prolonged consultations with their anthroposophic physicians, 86.1% (167/194) of patients used anthroposophic medication. All outcomes except KITA Daily Life subscale and KINDL showed significant improvement between baseline and all subsequent follow-ups. Improvements from baseline to 12 months were: Disease Score from mean (standard deviation) 5.95 (1.74) to 2.31 (2.29) (p < 0.001), Symptom Score from 5.74 (1.81) to 3.04 (2.16) (p < 0.001), SF-36 Physical Component Summary from 44.01 (10.92) to 47.99 (10.43) (p < 0.001), SF-36 Mental Component Summary from 42.34 (11.98) to 46.84 (10.47) (p < 0.001), and KITA Psychosoma subscale from 62.23 (19.76) to 76.44 (13.62) (p < 0.001). All these improvements were maintained until the last follow-up. Improvements were similar in patients not using diagnosis-related adjunctive therapies within the first six study months.

**CONCLUSION:** Patients treated by anthroposophic physicians after an initial prolonged consultation had long-term reduction of chronic disease symptoms and improvement of quality of life. Although the pre-post design of the present study does not allow for conclusions about comparative effectiveness, study findings suggest that physician-provided anthroposophic therapy may play a beneficial role in the long-term care of patients with chronic diseases.


**BACKGROUND:** Many patients with chronic diseases use complementary therapies, often provided by their physicians. In Germany, several physician-provided complementary therapies have been reimbursed by health insurance companies as part of health benefit programs. In most of these therapies, the patient has a predominantly passive role. In eurythmy therapy, however, patients actively exercise specific movements with the hands, the feet or the whole body. The purpose of this study was to describe clinical outcomes in patients practising eurythmy therapy exercises for chronic diseases. **METHODS:** In conjunction with a health benefit program, 419 outpatients from 94 medical practices in Germany, referred to 118 eurythmy therapists, participated in a prospective cohort study. Main outcomes were disease severity (Disease and Symptom Scores, physicians’ and patients’ assessment on numerical rating scales 0-10) and quality of life (adults: SF-36, children aged 8-16: KINDL, children 1-7: KITA). Disease Score was documented after 0, 6 and 12 months, other outcomes after 0, 3, 6, 12, 18, 24, and (SF-36 and Symptom Score) 48 months. **RESULTS:** Most common indications were mental disorders (31.7% of patients; primarily depression, fatigue, and childhood emotional disorder) and musculoskeletal diseases (23.4%). Median disease duration at baseline was 3.0 years (interquartile range 1.0-8.5). Median number of eurythmy therapy sessions was 12 (interquartile range 10-19), median therapy duration was 119 days (84-188). All outcomes improved significantly between baseline and all subsequent follow-ups (exceptions: KITA Psychosoma in first three months and KINDL). Improvements from baseline to 12 months were: Disease Score from mean (standard deviation) 6.65 (1.81) to 3.19 (2.27) (p < 0.001), Symptom Score from 5.95 (1.75) to 3.49 (2.12) (p < 0.001), SF-36 Physical Component Summary from 43.13 (10.25) to 47.10 (9.78) (p < 0.001), SF-36 Mental Component Summary from 38.31 (11.67) to 45.01 (11.76) (p < 0.001), KITA Psychosoma from 69.53 (15.45) to 77.21 (13.60) (p = 0.001), and KITA Daily Life from 59.23 (21.78) to 68.14 (18.52) (p = 0.001). All these improvements were maintained until the last follow-up. Improvements were similar in patients not using diagnosis-related adjunctive therapies within the first six study months. Adverse reactions to eurythmy therapy occurred in 3.1% (13/419) of patients. No patient stopped eurythmy therapy due to adverse reactions.

**CONCLUSION:** Patients practising eurythmy therapy exercises had long-term improvement of chronic disease symptoms and quality of life. Although the pre-post design of the present study does not allow for conclusions about comparative effectiveness, study findings suggest that eurythmy therapy can be useful for patients motivated for this therapy.


**OBJECTIVE:** Rhythymical massage therapy is used in 24 countries but has not yet been studied in outpatient settings. The objective was to study clinical outcomes in patients receiving rhythymical massage therapy for chronic diseases. **DESIGN:** Prospective 4-year cohort study. **SETTING:** Thirty-six (36) medical
practices in Germany. **PARTICIPANTS:** Eighty-five (85) outpatients referred to rhythmical massage therapy. **OUTCOME MEASURES:** Disease and Symptom Scores (physicians' and patients' assessment, respectively, 0-10) and SF-36. Disease Score was measured after 6 and 12 months, and other outcomes after 3, 6, 12, 18, 24, and 48 months. **RESULTS:** Most common indications were musculoskeletal diseases (45% of patients; primarily back and neck pain) and mental disorders (18%, primarily depression and fatigue). Median disease duration at baseline was 2.0 years (interquartile range 0.5-6.0). Median number of rhythmical massage therapy sessions was 12 (interquartile range 9-12), and median therapy duration was 84 (49-119) days. All outcomes improved significantly between baseline and all subsequent follow-ups. From baseline to 12 months, Disease Score improved from (mean +/- standard deviation) 6.30 +/- 2.01 to 2.77 +/- 1.97 (p < 0.001), Symptom Score improved from 5.76 +/- 1.81 to 3.13 +/- 2.20 (p < 0.001), SF-36 Physical Component score improved from 39.55 +/- 9.91 to 45.17 +/- 9.88 (p < 0.001), and SF-36 Mental Component score improved from 39.27 +/- 13.61 to 43.78 +/- 12.32 (p = 0.028). All these improvements were maintained until the last follow-up. Adverse reactions to rhythmical massage therapy occurred in 4 (5%) patients; 2 patients stopped therapy because of adverse reactions.

**CONCLUSIONS:** Patients receiving rhythmical massage therapy had long-term reduction of chronic disease symptoms and improvement of quality of life.


**BACKGROUND:** Anthroposophic art therapy (painting, clay modeling, music, and speech exercises) is used in 28 countries but has not yet been studied in primary care. **OBJECTIVE:** To study clinical outcomes in patients treated with anthroposophic art therapy for chronic diseases. **DESIGN:** Prospective cohort study. **SETTING:** Fifty-four medical practices in Germany. **PARTICIPANTS AND INTERVENTIONS:** One hundred sixty-one consecutive outpatients (primary care: n = 150), aged 5-71 years, were treated by 52 different art therapists. **MAIN OUTCOME MEASURES:** Disease and symptom scores (physician and patient assessment, respectively, 0-10) and quality of life (adults: SF-36 Health Survey, children: KINDL Questionnaire for Measuring Health-Related Quality of Life in Children and Adolescents). Outcomes were measured after 3, 6, 12, 18, and 24 months; SF-36 and symptom scores were also measured after 48 months. **RESULTS:** Most common indications were mental disorders (60.9% of patients, primarily depression, fatigue, and anxiety) and neurological diseases (6.8%). The median number of therapy sessions was 15; median therapy duration was 161 days. All outcomes except KINDL improved significantly between baseline and all subsequent follow-ups. Improvements from baseline to 12 months were: disease score from (mean +/- standard deviation) 6.69 +/- 1.72 to 2.46 +/- 1.90 (p < 0.001), symptom score from 5.99 +/- 1.69 to 3.40 +/- 2.08 (p < 0.001), SF-36 physical component summary measure from 44.12 +/- 10.03 to 48.68 +/- 9.47 (p < 0.001), and SF-36 mental component summary measure from 35.07 +/- 12.23 to 42.13 +/- 11.51 (p < 0.001). All these improvements were maintained until last follow-up.

**CONCLUSION:** Patients receiving anthroposophic art therapy had long-term reduction of chronic disease symptoms and improvement of quality of life.

**ANTHROPOSOPHIC MEDICATIONS**


**BACKGROUND AND OBJECTIVE:** Anthroposophic medications (AMED) are prescribed by physicians in 56 countries worldwide and are used for the treatment of a variety of conditions. However, safety data on long-term use of AMED from large prospective studies are sparse. The objective of this analysis was to determine the frequency of patient-reported and physician-assessed adverse drug reactions (ADRs) to AMED in outpatients using AMED for chronic diseases over a 2-year period. **METHODS:** We conducted a prospective observational cohort study involving 131 medical practices in Germany. In total, 662 consecutive outpatients aged 1-75 years were enrolled in the study. The patients were using AMED for mental (primarily depression and fatigue), musculoskeletal, respiratory, neurological and other chronic diseases. Main outcome measures were use of AMED and ADRs to AMED. **RESULTS:** Throughout the 2-year follow-up, patients used 949 different AMED for a total of 11 487 patient-months. The origin of AMED was mineral (8.1%, 77 of 949 AMED), botanic (41.8%), zoological (7.8%), chemically defined (10.5%) and mixed (31.7%). Most frequently used AMED ingredients were Viscum album (11.5%, 76 of 662 patients), Bryophyllum (9.4%), Arnica (7.9%) and Silicea (7.7%). Non-AMED products were used by 94.2% of patients for a total of 11 202 patient-months; 45.2% of this use was accounted for by medication for the CNS, the cardiovascular system and the alimentary tract and metabolism. A total of
1861 adverse events (AEs) were documented. The most frequent AEs were non-specific symptoms, signs and findings (International Classification of Diseases [10th Edition] R00-R99: 27.6%, 513 of 1861 AEs), musculoskeletal (M00-M99: 16.9%), respiratory (J00-J99: 8.2%) and digestive diseases (K00-K93: 6.6%). No serious AEs attributable to any medication occurred. Out of the 1861 reported AEs, 284 (15.3%) AEs were suspected by the physician or the patient to be an adverse reaction to non-medication therapy (n = 42 AEs), non-AMED (n = 187) or AMED (n = 55 AEs in 29 patients). Twenty of these 29 patients had confirmed ADRs to 21 AMED. These ADRs were local reactions to topical application (n = 6 patients), systemic hypersensitivity (n = 1) and aggravation of pre-existing symptoms (n = 13). In ten patients, AMED was stopped due to ADRs; two patients had ADRs of severe intensity. Median number of days with ADRs was 7 (range 1-39 days). All ADRs subsided, none were serious. The frequency of confirmed ADRs to AMED was 2.2% (21 of 949) of all different AMED used, 3.0% (20 of 662) of AMED users and one ADR per 382 patient-months of AMED use.

**CONCLUSION:** In this 2-year prospective study, AMED therapy was generally well tolerated.


**BACKGROUND:** Anthroposophic medications (AMED) are prescribed in 56 countries. **OBJECTIVE:** To study clinical outcomes in patients prescribed AMED for chronic disease. **DESIGN:** Prospective cohort study. **SETTING:** 110 medical practices in Germany. **PARTICIPANTS:** 665 consecutive outpatients aged 1–71 years, prescribed AMED for mental, respiratory, musculoskeletal, neurological, genitourinary, and other chronic diseases. **MAIN OUTCOMES:** Disease and Symptom Scores (physicians’ and patients’ assessment, 0–10) and SF-36. **RESULTS:** During the first six months, an average of 1.5 AMED per patient was used, in total 652 different AMED. Origin of AMED was mineral (8.0%) of 652 AMED, botanical (39.0%), animal (7.2%), chemically defined (13.0%), and mixed (33.0%). From baseline to six-month follow-up, all outcomes improved significantly: Disease Score improved by mean 3.15 points (95% confidence interval 2.97–3.34, p < 0.001), Symptom Score by 2.43 points (2.23–2.63, p < 0.001), SF-36 Physical Component Summary by 3.04 points (2.16–3.91, p < 0.001), and SF-36 Mental Component Summary by 5.75 points (4.59–6.92, p < 0.001). All improvements were maintained at 12-month follow-up. Improvements were similar in adult men and women, in children, and in patients not using adjunctive therapies.

**CONCLUSION:** Outpatients using AMED for chronic disease had long-term reduction of disease severity and improvement of quality of life.

**METHODOLOGY**


**RATIONALE, AIMS AND OBJECTIVES:** For therapy evaluation studies, control groups are sometimes not feasible. In single-arm studies, various bias factors apart from the test therapy can affect clinical outcomes. The objective of this analysis was to improve the methods to minimize bias in single-arm studies.

**METHOD:** We present a procedure for combined suppression of several bias factors, using two methods: sample restriction to patients unaffected by bias, and score adjustment. The procedure was used for a secondary analysis of disease score (doctors’ global rating, 0-10) in a cohort of patients receiving anthroposophic therapies for chronic diseases. Four bias factors were suppressed stepwise: attrition bias (by replacing missing values with the baseline value carried forward), bias from natural recovery (by sample restriction to patients with disease duration of ≥/≤12 months), regression to the mean due to symptom-driven self-selection (by replacing baseline scores with scores three months before enrolment) and bias from adjunctive therapies (by sample restriction to patients not using adjunctive therapies). **RESULTS:** In the cohort analysed, these four bias factors could together explain a maximum of 37% of the 0- to 6-month improvement of disease score.

**CONCLUSION:** Combined bias suppression, using sample restriction and score adjustment, is a transparent procedure to minimize bias in single-arm therapy studies. Further applicability of the procedure should be tested in future studies.

Hamre HJ, Glockmann A, Tröger W, Kienle GS, Kiene H: Assessing the order of magnitude of outcomes in single-arm cohorts through systematic comparison with corresponding cohorts: an example from the AMOS study. BMC Medical Research Methodology 2008, 8:11.

**BACKGROUND:** When a therapy has been evaluated in the first clinical study, the outcome is often compared descriptively to outcomes in corresponding cohorts receiving other treatments. Such comparisons are often limited to selected studies, and often mix different outcomes and follow-up periods. Here we give an example of a systematic comparison to all cohorts with identical outcomes and follow-up peri-
Anthroposophic Medicine in Clinical Practice – Abstracts

Anthroposophic vs. Conventional Therapy of Acute Respiratory and Ear Infections (IIPCOS Study)

Main Analysis


Context: Acute respiratory and ear symptoms are frequently treated with antibiotics. Anthroposophic treatment of these symptoms relies primarily on anthroposophic medications. Objective: To compare anthroposophic treatment to conventional treatment of acute respiratory and ear symptoms regarding clinical outcome, medication use and safety, and patient satisfaction. Design: Prospective, non-randomised comparison of outcomes in patients self-selected to anthroposophic or conventional therapy under real-world conditions. Setting: 29 primary care practices in Austria, Germany, Netherlands, UK, and USA. Participants and Therapy: 1016 consecutive outpatients aged ≥ 1 month, consulting an anthroposophic (n = 715 A-patients) or conventional physician (n = 301 C-patients) with a chief complaint of acute (≤ 7 days) sore throat, ear pain, sinus pain, runny nose or cough. Patients were treated according to the physician’s discretion. Primary Outcome: Patients’ self-report of treatment outcome (complete recovery / major improvement / slight to moderate improvement / no change / deterioration) at Day 14. Results: Most common chief complaints were cough (39.9% of A-patients vs. 33.9% of C-patients, p = 0.0772), sore throat (26.3% vs. 23.3%, p = 0.3436), and ear pain (20.0% vs. 18.9%, p = 0.7302). Baseline chief complaint severity was severe or very severe in 60.5% of A-patients and 53.3% of C-patients (p = 0.0444), mean severity (0 - 4) of complaint-related symptoms was 1.3 ± 0.7 vs. 1.2 ± 0.6 (p = 0.5197). During the 28-day follow-up antibiotics were prescribed to 5.5% of A-patients and 33.6% of C-patients (p < 0.0001), anthroposophic medicines were prescribed to all A-patients and no C-patient. Outcomes: Improvement within 24 hours occurred in 30.9% (221/715) of A-patients and 16.6% (50/301) of C-patients (p < 0.0001), improvement within 3 days in 73.1% and 57.1% (p < 0.0001). At Day 7 complete recovery or major improvement was reported by 77.1% of A-patients and 66.1% of C-patients (p = 0.0004), at Day 14 by 89.7% and 84.4% (p = 0.0198). Complete recovery rates at Day 7 were 30.5% and 23.3% (p < 0.0001); at Day 14 they were 64.2% and 49.5% (p < 0.0001). 69.9% of A-patients and 60.5% of C-patients were very satisfied with their physician (p = 0.0043); 95.7% and 83.4% would choose the same therapy again for their chief complaint (p < 0.0001). After adjustment for country, gender, age, chief complaint, duration of complaint, previous episode of complaint within last year, and baseline symptom severity, odds ratios favoured the A-group for all these outcomes. Adverse drug reactions were reported in 2.7% of A-patients and 6.0% of C-patients (p = 0.0157).
CONCLUSION: Compared to conventional treatment, anthroposophic treatment of primary care patients with acute respiratory and ear symptoms had more favourable outcomes, lower antibiotic prescription rates, less adverse drug reactions, and higher patient satisfaction.

SAFETY ANALYSIS

OBJECTIVE: Anthroposophic medications (AMED) are widely used, but safety data on AMED from large prospective studies are sparse. The objective of this analysis was to determine the frequency of adverse drug reactions (ADR) to AMED in outpatients using AMED for acute respiratory and ear infections.

METHODS: A prospective four-week observational cohort study was conducted in 21 primary care practices in Europe and the U.S.A. The cohort comprised 715 consecutive outpatients aged ≥1 month, treated by anthroposophic physicians for acute otitis and respiratory infections. Physicians’ prescription data and patient reports of adverse events were analyzed. Main outcome measures were use of AMED and ADR to AMED. RESULTS: Two patients had confirmed ADR to AMED: 1) swelling and redness at the injection site after subcutaneous injections of Prunus spinosa 5%, 2) sleeplessness after intake of Pneumodoron® 2 liquid. These ADR lasted one and two days respectively; both subsided after dose reduction; none were unexpected; none were serious. Frequency of confirmed ADR to AMED was 0.61% (2/327) of all different AMED used, 0.28% (2/715) of patients, and 0.004% (3/73,443) of applications.

CONCLUSION: In this prospective study, anthroposophic medications used by primary care patients with acute respiratory or ear infections were well tolerated.

ANTHROPOSOPHIC MISTLETOE EXTRACTS

BACKGROUND: Anthroposophic Mistletoe therapy is a widely used complementary cancer treatment.

OBJECTIVE: To evaluate prospective clinical trials on the effectiveness of anthroposophic mistletoe therapy for cancer.

DESIGN: Systematic review.

MATERIAL and METHODS: Search of 9 electronic databases, reference lists and extensive expert consultations. Criteria-based assessment of methodological study quality. RESULTS: 16 randomized (RCT) and 9 non-randomized (N-RCT) controlled trials were identified that investigated mistletoe treatment of malignant diseases. Statistically significant benefit for survival was reported in 8 of 17 trials (in 5 of 10 RCTs), for disease-free survival and tumour recurrence in none of 2 RCTs, for remission of tumour and malignant effusion in 1 RCT and 1 N-RCT of 4 controlled trials, for quality of life (QoL) in 3 of 5 RCTs, and for QoL and reduction of side effects of cytoreductive therapies (chemotherapy, radiation or surgery) in 5 of 7 trials (3 of 5 RCTs). Methodological quality of the controlled trials differed substantially; some had major limitations while others were reasonably well conducted. 12 single-arm cohort studies were identified. 5 of 7 studies found substantial tumour remission in various cancers, one study reported remission of CIN, and 4 studies remission of malignant pleural effusion or ascites. Quality of reporting in cohort studies was mostly reasonably good. Mistletoe application was well tolerated.

CONCLUSIONS: Regarding quality of studies and consistency of results, the best evidence for efficacy of mistletoe therapy exists for improvement of QoL and reduction of side effects of cytotoxic therapies (chemotherapy, radiation). Survival benefit has been shown but not beyond critique. Tumour remissions are described in cohort studies that investigate the application of high dose or local mistletoe extracts. As several reasonably well-conducted studies indicate beneficial effects, further properly designed trials should be encouraged to investigate clinical efficacy and its possible dependency on the mode of application.


BACKGROUND: Viscum album L. extracts (VAE, European mistletoe) are a widely used medicinal plant extract in gynaecological and breast-cancer treatment.

METHODS: Systematic review to evaluate clinical studies and preclinical research on the therapeutic
effectiveness and biological effects of VAE on gynaecological and breast cancer. Search of databases, reference lists and expert consultations. Criteria-based assessment of methodological study quality. \textbf{RESULTS:} 19 randomized (RCT), 16 non-randomized (non-RCT) controlled studies, and 11 single-arm cohort studies were identified that investigated VAE treatment of breast or gynaecological cancer. They included 2420, 6399 and 1130 patients respectively. 8 RCTs and 8 non-RCTs were embedded in the same large epidemiological cohort study. 9 RCTs and 13 non-RCTs assessed survival; 12 reported a statistically significant benefit, the others either a trend or no difference. 3 RCTs and 6 non-RCTs assessed tumour behaviour (remission or time to relapse); 3 reported statistically significant benefit, the others either a trend, no difference or mixed results. Quality of life (QoL) and tolerability of chemotherapy, radiotherapy or surgery was assessed in 15 RCTs and 9 non-RCTs. 21 reported a statistically significant positive result, the others either a trend, no difference, or mixed results. Methodological quality of the studies differed substantially; some had major limitations, especially RCTs on survival and tumour behaviour had very small sample sizes. Some recent studies, however, especially on QoL were reasonably well conducted. Single-arm cohort studies investigated tumour behaviour, QoL, pharmacokinetics and safety of VAE. Tumour remission was observed after high dosage and local application. VAE application was well tolerated. 34 animal experiments investigated VAE and isolated or recombinant compounds in various breast and gynaecological cancer models in mice and rats. VAE showed increase of survival and tumour remission especially in mice, while application in rats as well as application of VAE compounds had mixed results. In vitro VAE and its compounds have strong cytotoxic effects on cancer cells.

\textbf{CONCLUSION:} VAE shows some positive effects in breast and gynaecological cancer. More research into clinical efficacy is warranted.

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\textbf{USEFUL LINKS:}

www.ivaa.info (International Federation of Anthroposophic Medical Associations)
www.medsektion-goetheanum.org (international conferences)
www.ahasc.org.uk (United Kingdom)
www.anthroposophischeaerzte.de (Germany)
www.nvaa.nl (Netherlands)
www.paam.net (USA)
www.vaoas.ch (Switzerland)
www.anthromedlibrary.com
www.ifaemm.de (research)
www.kikom.unibe.ch (University of Bern, Switzerland)
www.louisbolk.nl/companions (basic medical subjects)
www.misteltherapie.de (cancer therapy)