Clinical Outcomes of Rhythmical Massage

A Prospective Cohort Study with Swiss Outpatients

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Abstract

Introduction: Rhythmical massage (RM) is a form of massage therapy extensively used in anthroposophic medicine (AM). Here, RM's use and impact on clinical outcomes was investigated in a prospective observational study performed with patients from a Swiss hospital and an associated group practice.

Methods: Patients (79 individuals) referred to the two hospital sites for RM for any indication were enrolled in the present study and received an average of nine RM sessions during a period of 3 months. Clinical outcomes were assessed with Disease and Symptom Scores, the Health-Related Quality-of-Life (HRQoL) questionnaire Short Form-36 (SF-36), and Goal Attainment Scaling (GAS). The treating physicians documented the Disease Scores, and other outcomes were documented by the patients. All outcomes were documented at the beginning of the therapy (baseline) and after the last therapy session; a follow-up took place 6 months after the first session.

Results: Fifty-nine patients completed the study per protocol. The most common indications were mental and behavioral disorders (36%; $n = 21$; primarily fatigue and depression), neoplasms (22%; $n = 13$; mainly breast cancer), and musculoskeletal diseases (14%; $n = 8$). The mean duration of the main symptoms at baseline was 4 years (range: 16 days to 43 years). There was a statistically significant improvement in all outcomes between baseline and the end of therapy. Improvements from baseline to therapy end were (mean $\pm$ standard deviation): 2.0 ± 2.47 (self-reported Symptom Score); 2.1 ± 2.20 (physicians' Disease Score); 2.9 ± 7.10 (SF-36 Physical Health Summary measure); 8.3 ± 12.74 (SF-36 Mental Health Summary measure); and 2.1 ± 1.15 (GAS). Subgroup analyses revealed improvements in patients with: (1) mental/behavioral disorders; (2)

neoplasms; (3) symptoms lasting longer than 6 months; and (4) patients who were treated exclusively with RM. Most improvements were maintained until follow-up.

Conclusions: Patients receiving RM for any indication in an anthroposophic medicine setting perceived reductions of symptoms accompanied by improvements of HRQoL. In addition, self-defined therapy goals were largely attained and the treating physicians observed a decrease in disease severity. Given the results of this study, the current authors encourage researchers to conduct future controlled studies on RM for specific indications.

Introduction

Anthroposophic Medicine

Anthroposophic medicine (AM) is an integrative multimodal treatment system that can be seen as an extension of conventional medicine and that is based on a holistic concept of the human organism and nature.¹ AM was founded in the early 1920s by the philosopher and reformer Rudolf Josef Lorenz Steiner, PhD (1861–1925 AD), and Ita Wegman, MD (1876–1943 AD); is currently established in 80 countries worldwide; and is practiced mainly in Central Europe. According to AM, human constitution and health are mostly dependent on the functioning and interplay of three systems: the nerve-sense system; the motor-metabolic system; and the rhythmical system. Whereas the first two systems are seen as polar to each other, the latter system, which is most present in the respiratory and circulatory organs, is thought to be intermediate. Various diseases are believed to be derived from disturbed activity of the rhythmical system.¹

Rhythmical Massage

Rhythmical massage (RM) is one type of AM therapy and was developed from Swedish massage by Dr. Wegman.² The term *rhythmical* applies both to the system of the human con-

stitution the massage addresses and to the rhythmical quality of the massage itself. RM is performed to restore the balance in rhythmical physiologic processes—such as respiration, circulation, sleeping and waking, digestion, and hormonal rhythms—that are often disturbed by modern lifestyles.

RM uses a gentle rhythmical touch with an element of suction rather than pressure that penetrates the tissues deeply. Characteristics of RM are rhythmically undulating movements including special movement patterns, such as circles, spirals, and lemniscates (figure eights). Massage oils are used sparingly as well as ointments containing metals, such as copper and iron. Both oils and ointments are applied not only as lubrications but also as medications and are chosen according to the AM concept of the human organism and nature.³ A specialty of RM is application of ointments close to defined body organs—the heart, liver, kidney, or spleen—to support their functions.⁴ RM can be used as a monotherapy or in conjunction with other therapies. RM is practiced by massage therapists who are trained in RM schools according to a standardized curriculum.⁵

Clinical Outcomes of Rhythmical Massage

RM is used not only for its relaxing effects on subcutaneous tissues and muscles, but also to achieve general effects (e.g., vitality, inner balance) and disease-specific effects.² Some applications for which RM can be supportive include circulatory, respiratory, digestive, and neurologic disorders; orthopedic conditions; insomnia, migraines; depression; and pain management.

Previously, the clinical effectiveness of RM has been investigated mainly in observational studies addressing AM as a whole system, especially in the context of the Anthroposophic Medicine Outcomes Study.⁶ This study focused on chronic diseases and revealed that use of AM—including, but not limited to, RM—was associated with symptom reduction and improvement of health-related quality of life (HRQoL) for the following indications: chronic depression⁷; anxiety disorders⁸; chronic low-back pain⁹; attention-deficit hyperactivity disorder (ADHD)¹⁰; migraine¹¹; and asthma.¹² When the data from the patients in the Anthroposophic Medicine Outcomes Study, who were treated with RM, were analyzed independently of their diagnoses, long-term reductions of symptoms and improvements in HRQoL were observed.¹³

The Present Study

The aim of the present study was to characterize the use of, and evaluate clinical outcomes of, a course of RM in outpatients in a small Swiss hospital and an associated medical center. The study included patients with both chronic and/or acute conditions in a real-world setting. Accordingly, all diagnoses were included, RM was prescribed and performed independently of the study, and other therapies and medications were permitted. In some patients, the effects of RM on surface temperature ($n = 9$) and on heart rate variability (HRV; $n = 11$)

were measured by infrared imaging and electrocardiography, respectively. RM produced an immediate increase in dorsal temperature and improved temperature distribution as well as increasing sympathetic activity.¹⁴ During various therapy sessions, RM produced a progressive improvement of warmth distribution and regulation of resting HRV.¹⁴ The results of the use and outcome of RM for the entire sample of patients are shown and discussed in this article.

Methods

This single-arm, prospective cohort study was performed at two hospital sites. Its primary objective was to study the effect of RM on clinical outcomes in patients with any diagnoses. The study was approved by the ethics committee of Canton Zürich and was conducted according to the Helsinki Declaration. Written informed consent for participating in the study was obtained from all patients prior to enrollment.

Outpatients referred to the Paracelsus-Hospital of Richterswil, Switzerland, or, since February 2012, to the Paracelsus Centre of Sonnenberg Zürich, Switzerland, with a medical prescription for RM for any indication, were consecutively enrolled in the study.

Exclusion criteria were:

- (1) RM treatment during the 12 months before enrollment in the study
- (2) Age < 18 or > 75
- (3) Infections with pathogens
- (4) Fever
- (5) Furuncles, eczema, and fungi
- (6) Burns and open wounds.

RM was performed by three different RM therapists, who have certification from the School for Rhythmical Massage of the Ita Wegman Hospital (Arlesheim, Switzerland) or from the Swiss EMR (Erfahrungs Medizinisches Register). At the beginning of the study, all therapists had at least 1 year of professional experience with RM after receiving specific certification.

The study patients received an average of nine RM sessions (range 5–16 sessions) at a frequency of usually 1–2 times per week. RM was performed as specified in the Introduction (in the Rhythmical Massage section) of this article.

The therapists were allowed to choose the body regions to be massaged, the massage movements, and the applied oils and ointments on an individual basis. RM was administered in a draft-free therapy room with the patient wrapped in sheets or towels and only the area to be treated left uncovered. Each session encompassed a 30-minute massage (which often included one or two ointment applications to body regions close to certain organs and typically lasting for 1–2 minutes each) and at least 20 minutes of therapeutic rest with the patient lying on his or her back.

The most frequently used oils were gold, rose (*Rosa* spp.), and lavender (*Lavandula angustifolia*) peat fiber oil (Torffaser

Atelier, Lenzburg, Switzerland), *Solum uliginosum* comp oil (Wala GmbH, Eckwälden/Bad Boll, Germany), and Arnica comp/copper oil (Weleda AG, Arlesheim, Switzerland). The two latter oils are registered at the Swiss Agency for Therapeutic Products (without indications); peat fiber oil is officially authorized in Switzerland. The three most frequently used ointments contain one of the metals tin, copper, or lead—at concentrations of 0.4 % or lower—and are produced in Switzerland (Weleda AG, Arlesheim).

Whereas the former two ointments are registered (without indications) at the Swiss Agency for Therapeutic Products, the latter ointment is sold in Switzerland as a magistral preparation. In this context, it is worth mentioning that the use of ointments containing lead and other metals in AM is most likely to be safe. In fact, a previous study showed that, after an exaggerated application of 0.4% lead-ointment, no increase of lead concentrations in whole blood, urine, and scalp hair were detected.¹⁵

Other therapies and medications were permitted during the study (from the first RM session until the follow-up assessment 6 months after the first session). Self-reported information on these therapies and medications was collected.

Clinical Outcomes

Main Outcomes

Disease and Symptom Score, and Physical and Mental SF-36 Summary measures were defined *a posteriori* as main outcomes. In addition, Goal Attainment Scaling (GAS) at therapy end was included as a main outcome.

Disease and Symptom Scores

Given that study patients presented different diagnoses, Disease and Symptom Scores were assessed uniformly for all diagnoses on numerical scales from 0 (= not present) to 10 (= worst possible) with the Disease and Symptom Scores questionnaire, as described previously.¹³ The referring physicians were asked to attribute a value to the global severity of the disease (main diagnosis) at each assessment. At the same time, each patient was asked to specify up to 6 symptoms in order of decreasing importance as the reasons that the patient visited a physician. Furthermore, each patient was invited to attribute a value to the severity of each symptom and specify the corresponding duration.

HRQoL

HRQoL was assessed with a questionnaire from the Short Form-36 (SF-36), a widely used, generic health survey with 36 items.¹⁶ The 36 items yield ten scores on a scale from 0 to 100: eight health scales (physical functioning, role limitations caused by physical problems, bodily pain, general health, vitality, social functioning, role limitations caused by emotional problems; and mental health) that aggregate 2–10 items each; and two health summary measures (physical health summary and mental health) that aggregate 4 scales each. In addition, a

single item addresses the perceived health change during the previous year (on a scale of 1–5). Normally, a healthy population has values close to 50% for both summary measures.¹⁶

Goal Attainment Scaling

Fulfillment of RM objectives during the study was assessed by GAS.^{17,18} GAS is a method originally developed in the mental health area as an evaluation tool that allows patient participation in the goal-setting process. The patients were asked during an interview before the start of therapy to define 1–4 personal health goals for RM. The goal first reported by the patient is

Patients with mental or behavioral disorders seemed to be particularly motivated to complete the study.

referred to in the text as the “first goal,” and the second goal as the “second goal.” For each goal specified, a 7-point numerical scale (–2 to +4) composed of a graded series of possible treatment outcomes was set, with 0 being the level at therapy start, positive values reflecting improvements, and negative values indicating deteriorations. In post-treatment interviews, patients were asked to define the level reached at the time of the interview. The interviews were conducted with one of the investigators, personally or by telephone.

Other Outcomes

Data on each patient’s personal situation (“Have you experienced any stressful personal situations in the 8 previous weeks?”), adjunctive therapy use (“Do you receive any adjunctive therapies for the same goals as RM?”), appreciation of RM compared to adjunctive therapy (“If yes, what is the significance of RM within the whole therapy concept?”), sleep and digestion (“Are you satisfied with your sleep quality?” and “Are you satisfied with your digestion quality?”) were collected. These data were considered as additional items in the Disease and Symptom Scores questionnaire.

Data Collection

Most clinical outcomes were documented by the patients in questionnaires (Symptom Scores, SF-36) and interviews (GAS) at the first RM session, after the last RM session and 6 months after the first session to evaluate the sustainability of the therapy effect (follow-up). Data on the additional items discussed in Other Outcomes were also collected from the patients at these three timepoints.

The referring physicians documented eligibility criteria, main indication for RM, and comorbid diseases (if relevant) at study entry; Disease Score at the first RM session, after the last RM session, and 6 months after the first session; and information on any serious adverse events throughout the study. The various single diagnoses for which RM had been prescribed were grouped *a posteriori*. The date of the therapy sessions,

the overall goals of therapy for the patients, the massage oils and ointments used, and the body organs treated were documented by the therapists.

Data Analysis

Patients fulfilling eligibility criteria and with available data for at least one of the main outcomes at baseline and at the end of therapy were considered. Data were entered into an Excel spreadsheet (Microsoft Office Excel 2003®; Microsoft, Redmond, Washington) and analyzed using IBM SPSS® Statistics, version 19 (Chicago, Illinois).

Self-reported Symptom Scores from the Disease and Symptom Scores questionnaire were analyzed in two different ways: (1) Only the scores of the symptoms initially reported at baseline were considered for analysis of the clinical outcomes, compared to the scores for the same symptoms if reported at therapy end and/or at follow-up (the *initial symptom score*, according to previous work¹³); (2) Scores of all symptoms reported by the patients at baseline, end of therapy, and follow-up were considered for analysis (the *all symptoms score*). In both analyses, when more than one symptom had been mentioned, the scores of the various symptoms were averaged; this was also done while analyzing GAS.

SF-36 data were analyzed as described in a corresponding manual.¹⁶ Statistical significance of differences between

measurements performed at two different timepoints was detected with a paired *t*-test (2-tailed significance); other tests are noted in the Results section. The results were considered significant if $P \leq 0.05$; statistical tendencies were defined as $0.05 < P < 0.15$. Unless otherwise specified, data are shown as mean $\pm$ standard deviation (SD).

Results

Patient Recruitment and Follow-Up

From August 2008 (the first patient was seen on August 23, 2008) to June 2012 (the last patient was seen on June 1, 2012, and finished the study on November 16, 2012), a total of 79 patients fulfilled all eligibility criteria and were enrolled in the study. This corresponds to ~40% of the potentially recruitable patients whose information was retrieved from the hospital's electronic register during the study recruitment period. Reasons for not considering all recruitable patients were limited personnel and administrative resources; no active patient selection was performed.

Of the 79 enrolled patients, 7 patients did not fulfill the eligibility criteria and 13 patients discontinued the study before the end of the therapy. Fifty-nine (59) patients completed the therapy course per protocol. Follow-up data were available from 53 (90%) of these 59 patients.

Table 1. Baseline Characteristics of Patients and Main Therapy Features (N = 59)^a

Baseline characteristics	n/N	% or mean $\pm$ SD (range)
Age		49.4 $\pm$ 12.5 years (23–73 years)
Female gender	50/59	85
Diagnosis groups (ICD-10)		
Mental & behavioral disorders (F0-F99)	21/59	36
Neoplasms (C00-D48)	13/59	22
Musculoskeletal diseases (M00-M99)	8/59	14
Circulatory diseases (I00-I99)	6/59	10
Main diagnoses		
Fatigue	12/59	27
Breast cancer	5/59	9
Depression	5/59	9
Arterial hypertension	4/59	7
Comorbid diagnosis groups (ICD-10) ^b		
Musculoskeletal diseases (M00-M99)	10/59	17
Mental & behavioral disorders (F00-F99)	8/59	14
Nervous system disorders (G00-G99)	5/59	9
Comorbid single diagnoses		
Back & neck pain	7/59	12
Headache	4/59	7
Fatigue	4/59	7

(Continued)

Table 1. Baseline Characteristics of Patients and Main Therapy Features (N = 59)^a (Continued)

Main therapy features	n/N	Mean ± SD (range)
<i>Main goal of rhythmical massage (as stated by therapists)</i>		
Relax and calm down	16/59	27
Fortify	15/59	25
Relieve pain	10/59	17
Increase body awareness	8/59	14
Support rhythmical physiologic processes	7/59	12
<i>Duration of self-reported symptom</i>		4 ± 8.0 years (16 days to 43 years)
Back and/or articulations pain	39/160	24
Fatigue and/or depression	29/160	18
<i>First therapy goal (defined by patients)</i>		
Reduction of fatigue	14/58	24
Relief of back pain	8/58	14
<i>Second therapy goal (defined by patients)</i>		
Sleep improvement	4/23	17
Relief of neck tensions	3/23	13
<i>Massage oils</i>		
Peat-fiber oil	32/59	54
<i>Solum uliginosum</i> comp oil	15/59	25
Arnica comp/copper oil	7/59	12
<i>Ointments</i>	52/59	88
<i>Diagnosis-related adjunctive therapies^c</i>	37/55	67
Therapeutic eurythmy	9/37	24
AM-medications including mistletoe therapy	7/37	19
Acupuncture/TCM	5/37	14
Psychotherapy	4/37	11
Homeopathic medications	3/37	8

N, number of participating patients for which information on a given characteristic is available.

n, number of participants ascribed to each subgroup within a given characteristic.

^aCategories corresponding to < 3 patients are not shown.

^bThis is shown if reported.

^cAs mentioned at beginning of rhythmical massage.

SD, standard deviation; ICD, International Classification of Diseases; AM, anthroposophic medicine; TCM, Traditional Chinese Medicine.

The reasons for study discontinuation/completion are not known. Patients who completed the study were compared with those who did not. Age and gender did not influence study completion. However, patients with mental or behavioral disorders seemed to be particularly motivated to complete the study, compared to others; only 3 of 21 patients with such conditions did not complete the study, and a statistical tendency was detected ($P = 0.099$; Chi-square test).

Study discontinuation was significantly more frequent in the first part of the study—when patients concomitantly authorized infrared imaging and electrocardiography¹⁴—than afterward (10 discontinuations among 21 patients in the first part of the study versus 10 discontinuations among 48 patients in the second part of the study, $P = 0.009$; Chi-square test). This finding suggests that the study participants might have been upset by the high number of procedures used in the first part of the study.

Participating Physicians and Therapists

RM was prescribed to study patients by 25 different physicians. Most prescriptions were from gynecologists (29%; 17/59), internists (27%; 16/59), and general practitioners (19%; 11/59). Therapy was given by 3 different RM therapists, each treating 25 (45%); 21 (39%); and 9 (16%) patients, respectively.

Baseline Characteristics

The patients were, on average, age 49.4 ± 12.5 (mean ± SD; range: ages 23–73); and in most cases, were female (85%; 50/59). The most frequent main diagnosis groups and indications for which RM had been prescribed are shown in Table 1. Thirty-four patients (58%; 34/59) had comorbid conditions, which varied widely. Most self-reported symptoms at therapy start were back and/or joint pain (24%; 39/160) as well as fatigue and/or depression (18%, 29/160). The mean dura-

Figure 1. Symptoms (self-reported) and Disease (physician's assessment) Scores of the study patients at baseline, therapy end (average 3 months after baseline), and 6-month follow-up. SD, standard deviation.

tion of the first self-reported symptom at baseline was 4 ± 8.0 years (median: 300 days; range: 16 days to 43 years). Personal goals of the patients mentioned in the GAS interviews are also shown in Table 1.

Therapies

RM administration was documented for each patient from the first RM session until follow-up assessment 6 months later. The mean number of therapy sessions was 9.0 ± 0.23 (median: 9.0; range: 5–16) and the mean therapy duration was ~ 3 months (95 ± 5.5 days; median: 91 days; range: 27–205 days). After the last study RM session (second assessment), additional RM sessions were scheduled for 18 of the 59 (31%) patients. For 4 patients (7%), the second assessment (after the last RM session) coincided with the follow-up assessment; because of these patients' private reasons, their study therapy lasted 6 months.

The main goals of RM as stated by the therapists, as well as the most frequently used massage oils are also shown in Table 1. Ointments were applied to the large majority of the patients; most often, the treated regions were those close to the liver, kidney, and spleen, and the ointments contained tin, copper and lead, respectively (data not shown).

At baseline, 37 of 55 evaluable patients (67%) reported receiving at least one diagnosis-related adjunctive therapy (therapeutic eurythmy, anthroposophic medications, including mistletoe (*Viscum album*), or acupuncture/Traditional Chinese Medicine). RM administered immediately before mistletoe infusion was explicitly reported by 2 patients to support the effect of mistletoe.

Disease and Symptom Scores

The number of symptoms reported by each patient decreased from 2.7 per patient at therapy entry (160/59) to 1.8 at therapy end (102/56) and to 1.6 at follow-up (86/53). Figure 1 shows that there was a statistically significant improvement in Symptom Scores as reported by the pa-

tients and in Disease Scores as reported by the physicians from baseline to the end of the therapy. The improvements were highly significant and long-lasting, given that the scores at follow-up were still significantly reduced, compared to baseline.

As mentioned in the Methods section, the Disease and Symptom Scores questionnaire was analyzed in two different ways. When the scores of only the symptoms reported by the patients at baseline were considered (initial symptoms), a Symptom Score reduction from 6.0 ± 1.72 at baseline to 2.8 ± 2.25 at therapy end was noted (Fig. 1). When all symptoms reported spontaneously by the patients at any timepoint were considered (even if the symptoms were first mentioned at assessments 2 or 3), the average Symptom Score decreased only to 4.0 ± 2.47 (Table 2). As shown in Figure 1, the physicians' Disease Score for the patients decreased likewise from baseline to the end of therapy and from baseline to follow-up.

HRQoL (SF-36 Questionnaire)

HRQoL improved statistically significantly from baseline to the end of therapy and from baseline to follow-up (Fig. 2; Table 2). In Table 2, all subscales of the SF-36 questionnaires at baseline, end of therapy, and at follow-up are shown. All scores improvements were statistically significant at therapy end, and, with the exception of the General Health score, from baseline to follow-up.

GAS

The therapy goals most frequently defined by patients during the first GAS interview comprised improvement of fatigue and relief of back pain as the first health goal, and sleep improvement and relief of neck tension as the second health goal. Treatment outcomes of the first two personal health goals were positive in a highly statistically significant manner, both at the end of therapy and at follow-up, compared to baseline (Fig. 3). Also, when all mentioned goals were considered together, highly statistically significant improvements were also noted (2.2 ± 1.46 and 2.6 ± 1.12 from baseline toward therapy end and from baseline toward follow-up, respectively).

Subgroup Analyses

Subgroup analysis of the main clinical outcomes was performed for the two most frequent main diagnosis groups, namely mental and behavioral disorders ($n = 21$) and neoplasms ($n = 13$). In both subgroups, improvements in self-reported symptom scores, HRQoL (Physical and Mental Health Summary measures), and GAS personal health goals were observed. In addition, Disease Scores, determined by the treating physicians, markedly improved in these two diagnosis subgroups (Table 3). As expected, in the subgroup with mental and behavioral disorders, the improvements of mental health-related scales were greater. In the subgroup of patients with cancer, most improvements attained statistical significance. What is more, for these diseases, the increases in the Physical Health Summary measure was the most modest.

Table 2. Clinical Outcomes of Patients Before RM (Baseline), at End of Therapy,^a and at 6-Month Follow-Up

Item	Baseline				End of therapy					Follow-up				
	Mean	±	SD	n	Mean	±	SD	n	P	Mean	±	SD	n	P
Initial Symptoms score (0–10) ^b	6.0	±	1.72	56	2.8	±	2.25	56	< 0.001	2.5	±	2.11	50	< 0.001
All Symptoms score (0–10) ^c	6.0	±	1.72	56	4.0	±	2.47	56	< 0.001	3.8	±	2.37	51	< 0.001
Disease Score (0–10)	5.8	±	1.97	45	3.7	±	2.01	45	< 0.001	3.7	±	2.52	35	< 0.001
SF-36 scores (0–100)														
Physical Functioning	79.7	±	21.35	58	84.6	±	21.90	58	0.006	85.4	±	21.31	54	0.032
Role Physical	45.4	±	42.36	54	72.7	±	38.01	54	< 0.001	71.9	±	39.06	53	< 0.001
Bodily Pain	59.5	±	28.96	57	70.4	±	26.79	57	0.005	75.3	±	23.43	53	0.001
General Health	59.2	±	19.43	57	64.1	±	18.77	57	0.022	62.4	±	18.19	54	0.243
Vitality	39.7	±	21.41	58	54.0	±	18.98	58	< 0.001	53.8	±	19.55	54	< 0.001
Social Functioning	61.9	±	30.02	58	79.3	±	22.03	58	< 0.001	78.2	±	25.02	54	< 0.001
Role Emotional	45.5	±	45.75	52	76.9	±	37.07	52	< 0.001	76.5	±	36.08	51	< 0.001
Mental Health	59.5	±	21.05	58	68.41	±	15.30	58	0.001	69.2	±	15.04	54	0.001
SF-36 Physical Health Summary	45.8	±	10.32	51	48.7	±	10.35	51	0.005	49.1	±	9.77	51	0.008
SF-36 Mental Health Summary	39.0	±	14.19	51	47.3	±	9.82	51	< 0.001	47.2	±	9.64	51	< 0.001
SF-36 Health Change ^d	3.4	±	1.34	55	2.4	±	1.21	55	< 0.001	2.2	±	1.07	53	< 0.001
GAS first goal	0.0	±	0.00	58	2.1	±	1.35	58	< 0.001	2.7	±	1.41	38	< 0.001
GAS second goal	0.0	±	0.00	23	2.3	±	2.28	23	< 0.001	2.2	±	2.20	20	< 0.001

^aEnd of therapy was an average 3 months after baseline.^bSymptom score analyzed considering only the symptoms reported at baseline.^cSymptom score analyzed considering all symptoms reported during the study.^dHealth change (compared to 1 year ago, with 1 = much better now and 5 = much worse now).

RM, rhythmic massage; SD, standard deviation; SF-36, Short Form-36; GAS, Goal Attainment Scaling.

To investigate the likelihood of natural recovery explaining these improvements, the subgroup of patients with long-term symptoms (≥ 6 months) was considered in an additional analysis. To study if RM per se (i.e., in the absence of adjunctive therapies) led to some improvements, the data of the patients without adjunctive therapies were also considered independently. The data of these subgroups are shown in Table 3.

In additional analyses (analyses of variance), the improvements of the various main outcomes were compared: (1) in patients with symptoms lasting for ≥ 6 months versus < 6 -months; and (2) between patients receiving adjunctive therapies and those who received RM only. Whereas in the latter case (2), no statistically significant difference—nor tendency—was detected, in the former case (1), a few differences were noted. Apparently, the improvements reported by patients with symptoms appearing in the last 6 months were slightly higher than those of patients with long-term symptoms. However, for the Mental Health Summary measure only, a statistically significant difference was noted at the end of therapy (and a tendency was noted at follow-up).

Other Outcomes

To the question “Have you experienced any stressful personal situation in the 8 previous weeks?” 21 of 57 patients (37%) answered positively at therapy start, 11 of 54 patients (20%)

Figure 2. Short Form-36, Physical and Mental Health Summary scores of the study patients at baseline, therapy end (average 3 months after baseline), and 6-month follow-up. SD, standard deviation.

answered positively at the end of therapy, and 8 of 51 patients (16%) answered positively at follow-up. Use of diagnosis-related adjunctive therapies was reported by 38 of 55 patients (69%) at RM start, 30 of 54 patients (56%) at RM conclusion, and 25 of 50 patients (50%) at follow-up. Most patients rated RM's relevance as high with respect to the adjunctive therapies (20 of 40 patients at therapy start [50%]; 16 of 31 patients at therapy end [52%], and 16 of 24 patients at follow-up [67%]).

Figure 3. Goal Attainment Scaling (GAS) scores of the study patients at therapy end (average 3 months after baseline), and 6-month follow-up. (Per definition, the score value at baseline was 0, at therapy end and follow-up, possible values varied between -2 and +4). SD, standard deviation.

Patients' satisfaction with their sleep quality appeared to improve during the course of the therapy (14 of 53 patients [26%] were very satisfied at the start of therapy, compared to 19 of 54 patients [35%] at the end of therapy), but this improvement was not maintained until follow-up (13 of 50 patients [26%] were very satisfied at follow-up). Patients' satisfaction with their digestion, however, appeared to improve continuously from the start of RM the end of therapy to follow-up (27 of 54 patients [50%] at the start of RM, 33 of 54 patients at the end of RM [61%], and 33 of 51 patients [65%] at follow-up were very satisfied).

Two patients presented with serious adverse events during their study participation. One patient was hospitalized after the end of the RM course, because of bone fractures caused by metastatic osteosarcoma. One patient was hospitalized after the second assessment because of a bronchial carcinoma and died 13 days later. These serious adverse events were not related to RM; both cancer diagnoses were known at recruitment.

Table 3. Main Clinical Outcomes of Patients' Subgroups Corresponding to the Most Frequent Diagnosis Groups Before RM (Baseline), at End of Therapy,^a and at Follow-Up^b

Item	Baseline				End of therapy					P	Follow-up				P
	Mean	±	SD	n	Mean	±	SD	n	Mean		±	SD	n		
Mental and behavioral disorders															
All Symptoms score (0–10) ^c	5.9	±	1.51	21	3.2	±	2.44	21	< 0.001	3.0	±	2.20	19	< 0.001	
Disease Score (0–10)	6.1	±	1.68	15	3.1	±	1.67	15	< 0.001	3.4	±	2.51	9	0.021	
SF-36 Physical Health Summary	48.0	±	8.88	18	52.6	±	6.44	18	0.041	52.2	±	6.60	19	0.045	
SF-36 Mental Health Summary	34.3	±	16.29	18	43.5	±	11.81	18	0.032	44.5	±	8.31	18	0.034	
GAS average	0.0	±	0.00	21	2.5	±	1.06	21	< 0.001	2.9	±	1.09	15	< 0.001	
Neoplasms															
All Symptoms score (0–10) ^c	6.6	±	1.36	11	4.6	±	2.23	11	0.022	2.6	±	0.87	9	0.043	
Disease score (0–10)	5.5	±	2.02	11	4.3	±	2.45	11	0.014	3.9	±	2.77	10	0.082	
SF-36 Physical Health Summary	40.8	±	9.65	12	41.3	±	11.78	12	0.772	43.6	±	10.69	11	0.302	
SF-36 Mental Health Summary	45.8	±	11.13	12	50.2	±	8.38	12	0.076	49.7	±	9.86	11	0.248	
GAS average	0.00	±	0.00	13	1.7	±	1.38	13	0.001	2.0	±	1.31	10	0.001	
Long symptoms duration (≥ 6 months)															
All Symptoms Score (0–10) ^a	6.2	±	1.52	33	3.9	±	2.56	33	< 0.001	3.7	±	2.46	31	< 0.001	
Disease score (0–10)	5.5	±	1.98	27	3.7	±	1.93	27	< 0.001	3.7	±	2.44	21	0.005	
SF-36 Physical Health Summary	46.1	±	11.31	29	48.6	±	10.39	29	0.074	49.0	±	11.00	29	0.066	
SF-36 Mental Health Summary	43.1	±	13.36	29	47.9	±	9.74	29	0.026	48.0	±	10.06	29	0.047	
GAS average	0.0	±	0.00	33	2.1	±	1.06	33	< 0.001	2.5	±	1.01	22	< 0.001	
Without adjunctive therapies															
All Symptoms Score (0–10) ^a	6.4	±	1.47	16	3.3	±	2.40	16	< 0.001	3.9	±	2.71	14	0.002	
Disease score (0–10)	4.9	±	2.39	11	2.7	±	1.19	11	0.020	3.1	±	2.85	8	0.258	
SF-36 Physical Health Summary	47.8	±	10.68	17	50.4	±	8.73	17	0.220	50.1	±	10.90	16	0.638	
SF-36 Mental Health Summary	36.8	±	16.41	17	49.3	±	9.29	17	0.002	47.0	±	10.28	16	0.032	
GAS average	0.0	±	0.00	17	2.7	±	0.91	17	< 0.001	3.05	±	0.76	14	< 0.001	

^aEnd of therapy was an average 3 months after baseline.

^bData at 6-month follow-up are also shown to enable comparisons.

^cPer Goal Attainment Scoring.

RM, rhythmical massage; SD, standard deviation; SF-36, Short Form-36; GAS, Goal Attainment Scoring.

Discussion

The effectiveness of RM is widely recognized in AM, based on clinical observations, but this is still documented scarcely. The present study was designed to investigate RM's effect on clinical outcomes as a primary therapy in a centralized setting under routine conditions. Outpatients with an RM prescription for any diagnosis were included without restricting use of concomitant therapies and medications. At the end of the RM therapy (i.e., an average of 3 months from start of therapy), substantial reductions of in disease symptoms and improvements in quality of life (QoL) were reported. In addition self-defined therapy goals were attained. These improvements were partially maintained 6 months after therapy was initiated.

The data generated from the current study corroborate previous observations on the effectiveness of RM¹³ and increase the number of diagnosis for patients who are likely to benefit from RM. The most frequent indications were mental and behavioral disorders, and cancer. Specifically, the considerable group of patients with cancer deserves particular attention because this group was not represented in the previous study.¹³

Clinical outcomes and their evolution were comparable in both the current and the previous study,¹³ with a few exceptions. The averaged initial Symptom Score was 6.0 at baseline and 2.5 at follow-up; the Disease Score was 5.8 at baseline and 3.7 at follow-up. In the previous study,¹³ the Symptom Score decreased from 5.7 at baseline to 3.3 at 6 months and the Disease Score diminished from 6.2 at baseline to 3.6 at 6 months.¹⁹ Thus, Symptom and Disease Scores at baseline are comparable in the two studies, as is the reduction of symptoms.

With respect to the SF-36 questionnaire, improvement of the General Health score was considerably larger in the previous study than in the current study. However, the scores for Role Limitations caused by emotional problems improved from 46.4 at baseline to 76.5 at follow-up in the current study, whereas it had changed from 48.2 to 66.1 in the previous study. Furthermore, the Mental Health Summary measure as well as the scores Mental Health and Social Functioning were markedly more improved in the current study.

The marked improvements in scores related to mental health reported in this article are probably related to their relatively low average values at baseline (i.e., to the more severe impairments of the patients in terms of mental health). For example, the improvement in the Mental Health Summary measure was more evident than that in the Physical Health Summary measure, which is likely to be related to the corresponding different baseline values.

To the current authors' knowledge, the present study included, for the first time, the GAS as a clinical outcome measure in the research on complementary medicine. The GAS was originally developed to assess the outcomes of personalized psychosocial interventions in the mental health and educational areas.¹⁷ The GAS has since then been used extensively in physical and neurologic rehabilitation settings.

The GAS allows a semiquantitative (ordinal) assessment of the attainment of individually set goals and offers potentially useful qualitative information regarding patients' priority goals for treatment. It was decided to include the GAS as a clinical outcome, in addition to the Disease and Symptom Scores and SF-36, to evaluate the therapeutic benefits of RM from the patients' perspective.

As expected, the primary therapy goals indicated by the study patients at baseline (reduction of fatigue and relief of back pain) corresponded to the first and third most frequent indications reported by the treating physicians (mental and behavioral disorders and musculoskeletal diseases, respectively); these goals also partially overlapped with the main goals of RM as defined by the therapists (relaxation, calming down, and relief of pain). Given that the treatment outcomes from GAS were consistent with the outcomes obtained with the two other instruments used, the current authors believe that GAS constitutes an appropriate and promising assessment method for holistic medicine research.

Generally, the outcomes of the present study confirmed the previous results on the effectiveness of RM,¹³ as well as other reports on the effectiveness of AM as a whole (see the Introduction and the references therein), especially those related to mental and behavioral disorders, and cancer. AM including RM has repeatedly been found to influence various mental and behavioral disorders favorably, such as chronic depression, anxiety, and ADHD.^{7,8,10} Likewise, patients with cancer who had received anthroposophic care (including RM) experienced improvement of QoL, particularly with regard to emotional and social levels, during the first 4²⁰–12 months.²¹

The observed beneficial effects of RM on mental and emotional health parallel the recently shown long-term physiologic effects of RM on surface temperature and on HRV in a subgroup of patients from the present study. During RM therapy, the difference between temperature extremes after therapy become smaller and a progressive regulation of the resting HRV occurred.¹⁴ Over the short-term, RM has been shown to lead to an increase in the patient's dorsal surface temperature as well as to increased HRV and sympathetic stimulation. Therefore, RM can lead to an immediate empowerment of patients that might contribute to long-term regeneration, and to reductions of their disorders, as was observed in the present study.

Study Limitations, Strengths, and Recommendations for Future Research

The limitations of the present study include the absence of a control group and the lack of restrictions on use of RM and adjunctive therapies and medications during the study. Patients' expectations, overstatement of their improvements because of thankfulness and spontaneous self-healing could have contributed to the perceived improvements in clinical outcomes. In addition, a possible effect of the observed decrease of stressful

personal situations in the weeks before assessment, at baseline, end of therapy, and follow-up is conceivable. Finally, a frequent cause of pre–post improvements seen in treatment studies is regression to the mean from self-selection of patients to study inclusion at symptom peaks, followed by return/regression to average symptom levels unrelated to treatment. For these reasons, the observed improvements in clinical outcomes cannot be causally attributed to RM.

Patients were permitted to mention new symptoms at the end of therapy and at the 6-month follow-up. When analyzing the data regarding all of these symptoms during the study, the improvements were observed to be less marked than those observed when confining the analysis to the initially mentioned symptoms. This might have led to an underestimation of the therapeutic effect of the intervention.

The dropout analysis revealed that patients with mental and behavioral diseases did complete the study more often than the other patients. Other parameters, such as age or gender, did not influence study completion. This might have led to a relative enrichment of the study in patients with mental and behavioral diseases; other indications for selection bias were not found.

Considering the long duration of the disease symptoms reported by most patients as well as the significant improvements observed in the subgroup of patients with only long-term symptoms, a positive influence of RM on the clinical outcomes is likely. This point is strengthened by positive data in the subgroup of patients without adjunctive therapies. In addition, patients seemed able to distinguish between stronger and less-strong improvements in their different SF-36 scores. That this difference related to the most frequent diagnosis group (mental and behavioral diseases) can be seen as an argument against confounding study results by observation bias.

Finally, the design of the present study has the advantage of reflecting clinical practice. The outcomes obtained correspond to an unselected patient population.

Conclusion

Patients treated with RM for any indication in an AM setting had substantial long-term reduction of (mostly durable) symptoms and disease scores accompanied by improvement of HRQoL. Self-defined therapy goals were attained at the end of the therapy and were maintained for at least 6 months. The study design did not allow for conclusions on the efficacy of RM. However, on the basis of the present results, using RM can be encouraged, especially for patients who have mental or behavioral disorders and cancer. Future controlled studies on RM for specific indications are needed.

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Disclosure Statement

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