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Rhythmical einreibung [embrocation] with Solum Oil® for patients with chronic pain – a prospective observational study

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Rhythmical einreibung with Solum Oil® for patients with chronic pain – a prospective observational study

■ **Abstract**

Background: Pain is a complex physical and psychological occurrence, treatment of which in modern pain relief therapy involves the use of a diverse range of procedures. Increasingly, complementary medical procedures are in demand in this context, and offer either direct or indirect pain relief. The aim of the present study is to evaluate the therapeutic effects of rhythmical einreibung with Solum Oil® in patients suffering from chronic pain. *Material and methods:* In a prospective observational study, 100 patients with chronic pain were treated three times (T_1 -T_3) within 24 days with a rhythmical einreibung with Solum Oil®. The main active constituents per 10g of Solum Oil® are: aqueous peat extract (1.5) 1.96 g and Lavandulae aetheroleum 0.5 g. The Mood Scale (Bf-S) and Pain Perception Scale (sensory PPS, affective PPS) were measured before the first and after each of the three follow-up treatments. To measure the therapeutic effect, effect sizes were calculated and regression to the mean analysis was performed. *Results:* Patients were mainly female (89%), mean duration of chronic pain (low back pain): 8.8 years; one drop-out due to urticaria. Bf-S was reduced from 25.8 (22.8; 28.1) 95% CI) before T_1 to 13.3 (11.7; 15.0) after T_3; sensory PPS from 18.8 (17.7; 19.8) to 15.2 (14.1, 16.4), affective PPS from 29.8 (27.9; 31.7) to 21.3 (19.4; 23.0) (all $p< 0.01$). Effect sizes (d): Bf-S: $d = 0.81$; affective PPS: $d = 0.85$; sensory PPS: $d = 0.55$. *Conclusion:* The high effect sizes indicate that repeated rhythmical einreibung with Solum Oil® has a very beneficial impact on sense of wellbeing and in particular the affective aspects of pain perception in patients suffering chronic pain, whereas the effect on the sensory aspects is somewhat less. Further investigations in the context of controlled clinical studies are recommended.

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■ **Key words**
Chronic back pain
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Solum Oil
Observational study
Regression to the mean

Diagram 1:
Rhythmical einreibung according to Wegman/Hauschka (4)

Introduction

Pain is a complex physical and psychological occurrence, treatment of which in modern pain relief therapy involves the use of a diverse range of procedures. In the case of chronic pain, however, the therapeutic effect is not always satisfactory, leading to patients frequently seeking interdisciplinary pain relief treatments. In this context, natural and complementary medicine procedures are in demand, such as acupuncture, homeopathy, phytotherapy, neural therapy, physiotherapy and relaxation techniques, offering either direct or indirect pain relief (1).

In anthroposophic medicine, a series of pain relief procedures exist, some of which are presented in this special issue. Non-pharmacological therapy methods have not often previously been the focus of clinical research projects. Thus, while favourable empirical reports exist for oil dispersion baths – as documented for instance in the treatment of neuropathies in the context of a field study by Rimpau (1996) - no systematic analysis of the mode of action and efficacy currently exists (3). Likewise, according to the recent survey of the literature by Bertram (4), only marginal results exist for rhythmical einreibung, a therapy developed in the 1920s by Ita Wegman and Hauschka, in which specific elements of rhythmical massage were further differentiated and elaborated.

The characteristic element of this therapy are special rhythmical strokes such as syncopated circles and spirals used for certain parts of the body (e.g. back, leg, foot, arm and hand) (*diagram 1*). In order to elaborate the available empirical knowledge of rhythmical einreibung experts and make it publicly available, and at the same time to systematically record the modes of action and effects in pain reduction as experienced by patients receiving therapy, a study concept was developed which aimed to answer the following questions:

- Which therapeutic response models are intersubjectively recognised by rhythmical einreibung experts and regarded as significant?
- How do rhythmical einreibung procedures work on the wellbeing, pain intensity and pain perception of patients?

Material and methods

Setting

For this research, the setting of an uncontrolled, prospective observation study was chosen, with 3 defined measurement points (start of therapy, interim point, end of

therapy. The study was carried out from 1.9.2000 to 31.3.2002 at the natural medicine department of Bonn University's medical policlinic. Participants were in- and out-patients of both genders aged between 20 and 70, with chronic, non-radicular pain symptoms in the lower back region. Patients with acute vein thrombosis, open wounds in the skin region due to receive the procedure, or skin allergies that contra-indicate use of Solum Oil were excluded from the study. Likewise excluded were patients concurrently receiving treatment with other pain-relieving external or internal applications (e.g. oils or ointments).

A total of 105 patients were included in the study. Five patients could not be included for organisational reasons, and the study was therefore carried out with 100 patients. The socio-demographic data of the patient group are listed in *table 1*.

In accordance with the non-intervening character of the observational study, therapy dates were individually determined. The time between applications was set at 12 days (95% confidence interval: 9-16 days). The following outcome parameters were investigated at each attendance:

Wellbeing/mood

Patient wellbeing was measured using the Bf-S mood scale. This is a fully standardised test instrument for patient self-evaluation (6), which records the extent of current impairment of subjective wellbeing in a list of 28 qualitative word pairs (e.g. "fresh-weary") from which the patient chooses the one he finds most applicable for him or remains neutral (neither/nor). The Bf-5 scale is primarily used to record changes in wellbeing in relation to interventions, and is therefore especially suited to pre-post comparisons. To arrive at the score, the negative words chosen from mood pairs are given 2 points, neutral ones 1 point and positive states 0 points. The state of wellbeing is recorded before the start of therapy and then after each therapy session.

Table 1: Socio-demographic data of the patient group (n=100)

	Male	Female	Total
Gender	**11%**	**89%**	
Age			
• **Average**			
(95% confidence interval)	**46.9 (36.9; 56.9)**	**47.3 (44.4; 50.2)**	**47.3 (44.5; 50.1)**
• **Standard deviation**	**17.0**	**13.6**	**13.9**
• **Median**	**43**	**48**	**48**
Body mass index			
• **Average**			
(95% confidence interval)	**25.3 (23.7; 26.9)**	**24.5 (23.7; 25.3)**	**24.6 (23.9;25.3)**
• **Standard deviation**	**2.8**	**4.0**	**3.9**
• **Median**	**25.1**	**23.8**	**23.8**
Pain duration (years)			
• **Average**			
(95% confidence interval)	**8.0 (4.1; 11.9)**	**8.9 (6.3;11.5)**	**8.8 (6.5; 11.1)**
• **Standard deviation**	**6.7**	**12.0**	**11.4**
• **Median**	**7**	**4**	**4.5**
Pain type			
• **Long-term**	**72.7%**	**47.7%**	**50.5%**
• **Pain attacks**	**27.3%**	**43.3%**	**41.5%**
• **Long-term with episodic interruptions**		**4.5%**	**4.0%**
• **No answer**		**4.5%**	**4.0%**
Maximum pain (multiple answers possible)			
• **Morning**	**45.5%**	**38.4%**	**39.2%**
• **Midday**	**9.1%**	**20.9%**	**19.6%**
• **Afternoon**	**36.4%**	**33.7%**	**34.0%**
• **Evening**	**9.1%**	**44.2%**	**40.2%**
• **Night**	**9.1%**	**22.1%**	**20.6%**
• **No circadian differences**	**9.1%**	**26.7%**	**27.8%**
Daily impairment due to pain in the last 6 months			
• **Very great**	**-**	**8.0%**	**7.1%**
• **Great**	**18.2%**	**30.7%**	**29.3%**
• **Average**	**54.5%**	**52.3%**	**52.5%**
• **Low**	**27.3%**	**9.1%**	**11.1%**

Pain perception and intensity

The pain perception scale PPS comprises 24 items that reflect both affective and sensory aspects of pain sensitivity (7). In line with this general distinction (affective and sensory), the form is divided into two sections of, respectively, 14 and 10 items. To every statement there are four possible answers: “applies exactly”, “applies largely”, “applies a little”, “does not apply”, on a scale from 4 to 1. The PPS can be used for all pain in connection with inflammatory or degenerative diseases of the postural and movement

system, as well as in pain with a muscular cause. Pain perception, like mood/wellbeing, is recorded before the start of treatment and after each treatment session.

Pain intensity is measured by means of a visual analogue scale (VAS) on a scale from 0 –10. At the start of the study the VAS was also used to quantify pain intensity individually formulated by the patient as bearable, in order to be able to generate statements relating to individual attainment of the therapy objective. Pain intensity was recorded in each case before and after every rhythmical einreibung session.

As further parameter, efficacy and tolerance were also evaluated by patient and therapist on a scale from 1 = very good to 4 = very bad.

Statistical evaluation

At the various data recording points, average values for the respective questionnaire scores were calculated and descriptively presented by means of boxplots. To quantify the therapeutic effect, the effect measure d according to Cohen was modified in line with McGaw & Glass (8) as quantitative parameter for the strength of the effect. Here the following categorisation applies: d< 0.5: weak effect; d between 0.5 and 0.8: medium effect; d> 0.8: strong effect. In order to exclude the possibility that a measured effect might solely be a statistical artefact in the sense of a regression to the mean (RTM), the results were tested - with the aid of the modified t test developed by Mee & Chua (9)- for significant change in the score with regard to a regression effect. In this method, a "true" average μ of the outcome parameters must initially be defined in order to then test for significance the values after therapy (here after T_3) with the baseline values at T_1 corrected by μ, based on a modified t test (10). Based on the test manual, the following values were chosen here for μ: affective pain perception: $\mu_{aff} = 20$; sensory pain perception: $\mu_{sens} = 13$; mood/wellbeing: $\mu_{mood} = 13$. This choice is governed by the reference values of a healthy random sample and therefore will tend to be a conservative estimate for chronic pain patients. The significance level p=0.05 was chosen.

Expert interviews

Alongside the quantitative study, 13 expert interviews were carried out to clarify key typical therapy configurations. To meet the requirements for this, each interview partner had to have: basic nursing training, many years of therapeutic experience in the nursing profession, and proven competence in rhythmical einreibung. The interviews followed a lightly structured thread. The emphasis of interviews was on narrative descriptive aspects (11) and proximity to the research subject was assured by means of episodic interviews (12). The prime focus was on reports of personal experiences in relation to therapeutic effects subjectively assessed as significant. The form of data analysis developed for this study is based on a combination of heuristic finding strategies (13) with methods of phenomenological reduction in the sense of a search for "intrinsic forms and laws" (14).

Results

Qualitative part

Although very varied patient responses to rhythmical einreibung were reported, it was possible to find three typical response models in the context of the qualitative part of the study: *release*, *being whole again* and *new capacity*. These related to both the physiological-vegetative and psychological domain (*diagram 2*). *Release* means, here, a

sense of liberation from a habitualised type of vegetative, sensory-motor affective or cognitive fixity that has been acquired in the past. *Being whole again,* in contrast, refers to experiences that, following release, lead to a sense of altered self-perception. On this basis, rhythmical einreibung procedures can also open up new possibilities for engaging with life. This *new capacity* can express itself in a new interest in one's own body or in a new commitment to the treatment which then, instead of merely being endured, is supported wholeheartedly. A detailed presentation of this part of the study can be found in (15,16) (*diagram 2*).

Quantitative part

Diagram 3 shows progression of pain perception at points T_1 (start) to T_3 (end), measured by means of a visual analogue scale (scaling from 0 = no pain to 100 = extremely severe pain). Presented here are median (black line), 2^{nd} to 3^{rd} quartile (box) and range (error bar).

In *diagram 3* we see an immediate decline of pain intensity, always immediately after treatments. At the same time, a declining trend is apparent from before points T_1 (start) to before T_3 (end). In the middle, pain intensity after the first treatment session stood 7.2 scale points above the pain intensity cited as bearable for the patient; after the second session 4.2 scale points above this; and after the third treatment session 3.2 scale points above the pain intensity cited as bearable for the patient.

With a value of 17, the median for pain intensity after the third treatment lies almost within the 95% confidence interval of pain intensity of 13.9 (11.1; 16.8) cited as bearable by the patients before treatment. This interval is marked by lines in *diagram 3*. A total of 37 patients achieved better VAS values after conclusion of treatment than the pain intensity cited by them as bearable.

Diagrams 4 and 5 show the progression of sensory and affective pain perception (PPS scale) and mood/wellbeing (BF-S scale) both before point T_1 (baseline) and after points T_1 (start) to T_3 (end). Median (black line), 2^{nd}-3^{rd} quartile (box) and range (error bar) are presented.

Diagram 2: Therapeutic models following rhythmical einreibung (5,6)

Therapeutic effect	Rhythmical einreibung	New capacity
		Practising new realisation potential
		Being whole again Bodily actualisation of relation to reality
		Release Letting go of past bodily fixity

Diagram 3

before after before after before after

Diagram 4

Affective pain perception Sensory pain perception

before after before after before after before after

Diagram 5

before after before after

Diagram 3
Progression of pain perception on the visual analogue scale (the lines represent the 95% confidence interval of the pain intensity formulated as therapy goal by the patient).

Diagram 4
Changes to affective and sensory pain perception over the course of the study

Diagram 5
Change to wellbeing over time

Table 2: Effect levels and results of the RTM analysis

	d ($T_0 - T_1$)	**d ($T_0 - T_2$)**	**d ($T_0 - T_3$)**	**p-value**	**Therapeutic effect**
Wellbeing/mood	**0.92**	**0.72**	**0.025**	**0.025**	**Positive**
Affective pain perception	**0.79**	**0.83**	**0.86**	**0.026**	**Positive**
Sensory pain perception	**0.73**	**0.61**	**0.55**	**0.216**	**Negative**

Diagram 6

Efficacy (therapist) Efficacy (patient) Efficacy (comparison) Tolerance (therapist) Tolerance (patient)

Diagram 6
Assessment of efficacy and tolerance by patient and therapist at points T_1 (start) to T_3 (end). Average and standard deviation of the scale values are presented, from 1= very good to 4= bad. The efficacy comparison relates here to the question of how the effect of Solum Oil is evaluated by comparison with other pain therapies known to patients.

Effect levels

The effect levels were calculated for the scale totals of surveys BF-S and PPS. In the PPS a distinction was still made between the subscales of affective and sensory pain perception. This produced the effect levels presented in *table 1 (table 2)*.

These effect levels must be categorised as medium to very strong effects between the points of start (T_0), interim test (T_1) and end test (T_2). The RTM analysis, in addition, was able to exclude the possibility that improvements in the wellbeing domain and in affective pain perception are merely regressions to the mean.

Treatment evaluation

The efficacy and tolerance evaluation gave rise to the results presented in *diagram 6*.

In all categories and at all points in time, average values occur here between "very good" and "good". Only in 5 cases at points T_1 and in 6 cases each at points T_2 and T_3 did patients assess the efficacy of rhythmical einreibungen with Solum Oil as "satisfactory". Over the course of the study, in addition, a significant improvement in efficacy evaluations can be detected between T_1 and T_3 (t test, $p< 0.05$). This effect is not as decisive in the therapist's estimate (t test, $p= 0.07$).

Discussion

In the present study on patients treated during its course, who on average suffered pain for 8.8 years, highly significant changes occur during treatment in relation both to sensory and affective pain perception (measured on the PPS scale). Pain intensity also, as measured on a visual analogue scale, shows similarly significant improvements. Here around 40% of study patients achieved, after the last treatment session, a pain level which they had individually formulated as bearable prior to the start of treatment.

The high efficacy also apparent in the graphs (effect levels for wellbeing and affective pain perception: $d = 0.8$) give a tangible demonstration that repeated rhythmical einreibung with Solum Oil has a very beneficial effect on the wellbeing and in particular the affective aspects of pain perception in patients suffering from chronic pain. Around 40% of the study patients achieved, after the last treatment session, a pain level which they had individually formulated as bearable prior to the start of treatment.

Alongside the quantitative study, 13 expert interviews were analysed to clarify key typical therapy configurations, giving rise to the categories of "release", "being whole again" and "new capacity". These were able to broaden both the physiological-vegetative and psychological dimension of the effects of rhythmical einreibung treatments.

Limitations

Despite the multi-perspective approach chosen here, there are certain limitations on general applicability of the results obtained from the chosen study design. Due to lack of follow-up, only short- to mid-term effects of rhythmical einreibung treatments could be demonstrated here. Given the ongoing symptoms of pain cited by patients with a duration of 8.8 years on average, it is highly probable that a natural pain graph can be excluded as cause of the measured effect levels. Nevertheless, possible non-specific effects will be discussed here, as these are for instance described in (17) for uncontrolled, single-arm studies.

On the one hand, the patient usually seeks help from the therapist at the point of maximum pain. In this context, therefore, the statistical effect of the regression to the mean plays an important role. In the present study, this effect could be excluded, with the modified t test developed by Mee and Chua, for affective pain perception and the patient's sense of wellbeing.

Alongside this statistical effect, according to Fine et al (18) all body-oriented therapy forms give rise to a range of unspecified effects. In connection with the present study, patient self-selection and the expectations related to it, primarily, alongside the study setting in a university clinic, can be cited as "meaning response". Further bias factors not investigated in the present study design can be added, such as changes of lifestyle, giving an expected answer and failure to mention co-interventions. Nevertheless, the typical treatment trajectory for placebo effects described in (18) can be excluded for this study.

Since blinding is not practically possible in the case of manual therapies, the non-specific effects described here must also be expected in randomised studies. In planning future clinical studies on rhythmical massage techniques therefore, a control therapy should be carried out which induces the same non-specific effects. Alternatively, a factorial study design can be chosen that encompasses diverse patient expectations as setting factor (19).

Summary

Overall it can be established that pain experienced over many years does not usually disappear following einreibung with Solum Oil, but that, rather, a change of perception occurs in the sense of more precise definition of the pain experience. This can be expressed for instance in the fact that certain (sensory) pain qualities are accentuated while other (especially affectively experienced) ones tend to diminish. For the patient this means that, in his subjective experience, pain can be better controlled, which also explains measured improvements in mood/wellbeing. This is also confirmed by the categories of "release" and "being whole again" found in the qualitative study arm.

The results found here can therefore form the basis for subsequent studies, in order to obtain further insights into a very promising but (as yet) insufficiently researched form of external application. Alongside methodological aspects, future studies should also more precisely investigate some of the active physiological principles of rhythmical massage described in (20) and the pharmacological effects of the oil.

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