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A Prospective “Study by Correspondence” on the Effects of Kneipp Hydrotherapy in Patients with Complaints due to Peripheral Neuropathy

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Paresthesia and other malfunction of sense are typical complaints of peripheral neuropathy (PNP) which are most often located symmetrically in the lower limbs. In more severe forms, there are also paresis, muscular atrophy and trophical changes of the skin. The prevalence of PNP is estimated at 1:2500 inhabitants in Germany. Etiologic relations include metabolic diseases, intoxications, infections and immunological diseases, yet in many patients their etiology remains unclear. The diagnosis is based on anamnesis, neurological examinations, particularly on nerve conduction velocity [1].

The therapy focusses on the underlying disease, provided there is one, and consists of supplementation of neurotrophic vitamins and α -lipoic acid, the latter mainly for patients with diabetes mellitus [2]. Other symptomatic treatments with drugs include calcium channel blockers in patients with muscle cramps, antiphlogistics, analgetics and antidepressants as well as topically applied capsicum extract standardized to capsaicin [3].

Various methods of physiotherapy are also used for the treatment of the symptoms of polyneuropathy, also hydrotherapy is recommended. There are no systematic investigations about hydrotherapy. Hydrotherapeutic applications in the tradition of Sebastian Kneipp (1821–97) are administered locally as cold stimulus with short duration, thereby inducing a local reactive hyperemia, involving neuronal, vegetative, endocrinal and immunological systems [4]. Long-term treatment with a series of hydrotherapeutic measures

Background: Kneipp hydrotherapy is often recommended to reduce symptoms of peripheral neuropathy on the basis that the cold stimulus could influence neuronal networking and that improvement of circulation and metabolism could improve local neuronal function. However, no data on clinical effectiveness are available. **Aim of the Study:** To evaluate the effectiveness of and compliance with hydrotherapeutic self-treatment in patients with peripheral neuropathy (PNP). **Design of the Study:** Preliminary open prospective observational “study by correspondence”: Patients received written information, instructions and questionnaires without direct contact with the study physician. **Methods:** Patients with interest in participation were enrolled from self-help groups and by TV and internet and were given instructions. They were asked to self treat at home daily using at least two out of four Kneipp hydrotherapeutic applications (knee affusion, cold foot-bath, alternating foot-bath, wet socks). After 8 weeks of treatment, patients returned their diaries with self-ratings of complaints before and after each application as well as their judgments before the cure and at its end. **Results:** We received completed forms from 27 patients (15 females, 12 males; mean age 68.2 years). Patients reported a significant decrease in dysesthesia from a mean of 3.4 (baseline) to 2.9 (t-test, $2p < 0.04$) after the cure. Hypoesthesia (numbness) improved from 3.5 to 3.1 ($2p < 0.12$). There were no significant changes for total pain (2.6 to 2.5) and paresis (0.8 to 0.8). Acute relief of symptoms was reported after 30–62% of applications with an increasing trend during the cure versus acute impairments only after 5 to 9% of applications. **Conclusions:** Our results give hints for effectiveness of self-treatment with hydrotherapy in patients with PNP – at least in a subgroup of them. Yet, there are limitations of the interpretation of the results of this uncontrolled study. Efficacy might be better after detailed and personal instruction on the hydrotherapeutic procedures. Conducting a prospective “study by correspondence” seems to be appropriate at least for generating preliminary data for natural healing self-treatments under realistic everyday conditions.

Keywords: Kneipp, hydrotherapy, peripheral neuropathy, study by correspondence

Eine prospektive „Fernstudie“ (Study by Correspondence) über die Wirkung der Kneipp Hydrotherapie bei Patienten mit Beschwerden infolge einer Polyneuropathie

Hintergrund: Kneippsche Hydrotherapie wird zur Symptomlinderung im Rahmen von Polyneuropathie empfohlen. Der Kältestimulus könnte die Funktion der neuronalen Netze beeinflussen und die Anregung der Durchblutung könnte die neuronale Funktion lokal verbessern. Allerdings sind keine Daten über die klinische Wirksamkeit bekannt. **Studienziel:** Untersuchung von Wirksamkeit und Compliance einer hydrotherapeutischen Selbstbehandlung bei Patienten mit Polyneuropathie (PNP). **Studiendesign:** Preliminäre offene prospektive Beobachtungsstudie („Fernstudie“, “Study by correspondence”): Die Patienten erhielten schriftlich Informationen, Anleitungen und Fragebögen ohne direkten Kontakt mit einem Prüfarzt. **Methoden:** Patienten mit Interesse an der Teilnahme wurden über Selbsthilfegruppen sowie über TV und Internet angesprochen und erhielten die Unterlagen. Sie sollten mindestens zwei von vier Kneippanwendungen täglich zu Hause durchführen (Knieguss, kaltes Fussbad, Wechselfussbad und nasse Socken). Nach 8-wöchiger Behandlung schickten die Patienten ihre ausgefüllten Fragebögen und Tagebücher mit Bewertungen der Beschwerden vor und nach jeder einzelnen Anwendung ein sowie ihre Gesamtbeurteilung ihrer Beschwerden vor und nach der Kur. **Ergebnisse:** Wir erhielten ausgefüllte Fragebögen von 27 Patienten (15 Frauen und 12 Männer, durchschnittliches Alter 68,2 Jahre). Nach Abschluss der kurmässigen Anwendungen berichteten die Patienten eine signifikante mittlere Abnahme der Dysaesthesie von 3,4 (Baseline) auf 2,9 (t-test, $2p < 0,04$). Hypoästhesie (Taubheit) verbesserte sich von 3,5 auf 3,1 ($2p < 0,12$). Es gab keine signifikanten Änderungen für Gesamtschmerz (2,6 auf 2,5) und für Parese (0,8 auf 0,8). Eine akute Symptomlinderung wurde nach 30–62% der Anwendungen berichtet mit einer Zunahme während der Kur, während akute Verschlimmerungen nur nach 5–9 % der Anwendungen berichtet wurden. **Schlussfolgerungen:** Unsere Ergebnisse geben Hinweise auf eine Wirksamkeit von Selbstbehandlung mit Hydrotherapie bei Patienten mit PNP – mindestens in einer Untergruppe. Es gibt Limitierungen für die Interpretation der Ergebnisse in dieser speziellen unkontrollierten Studie. Die Wirksamkeit könnte jedoch besser ausfallen nach einer detaillierten persönlichen Schulung über die Wasseranwendungen. Die Methode einer „Fernstudie“ erscheint wenigstens zur Erhebung preliminärer Daten über naturheilkundliche Selbstbehandlungen angemessen und zeigt ein realistisches Bild unter Alltagsbedingungen.

Schlüsselwörter: Kneipp, Hydrotherapie, Wassertherapie, Polyneuropathie, Fernstudie

is expected to train sensory feeling, circulation and metabolism in skin and the peripheral muscle. In addition, a series of hydrotherapy induces an adaptation to stressor stimuli [5] and influences local and systemic immunological functions (“hardening”).

There is a marked hyperemia for about 1 hour after a short cold stimulus in the affected skin region [6]. A general improvement of peripheral circulation after serial application of Kneipp hydrotherapeutic measures has been shown in several studies [7]. A better circulation should improve the impaired neuronal function in PNP. Furthermore, there are many complex physiologic and psychologic aspects of self-treatment with cold water applications which might be relevant for perception and reporting of neuropathic symptoms.

In order to investigate the efficacy of Kneipp hydrotherapy, we performed a first preliminary study as prospective intervention study in outpatients without personal contact to the study physician. The patients were given written information and instructions, were asked to complete questionnaires and to document in a diary symptoms and applications over a study period of 8 weeks under self-treatment. This type of study setting is new and was named ‘study by correspondence’. The only difference to normal open observational clinical studies is that there is no direct contact between patient and study physician. There is no reason why a patient could not document his history and his symptoms in well-explained questionnaires. Kneipp Hydrotherapy with several daily applications, on written or personal instruction, is normally a self-treatment anyway.

Materials and Methods

Patients

This was an open prospective study on the effects of Kneipp hydrotherapy in patients with complaints due to PNP. Study information material had been distributed to approximately 100 interested patients (most of them by patients’ self-help groups, some patients had become aware of this study on TV

and internet); only 27 patients, however, returned completed questionnaires.

There was no inclusion limitation with regard to severity of complaints, yet, we did not advise to apply hydrotherapy in more severe cases of paresis. There were also no limitations regarding etiology and status of diagnosis but we asked in our questionnaires for all available respective information.

Intervention

The intervention consisted of a series of hydrotherapeutic applications according Kneipp to be applied by the patients themselves. They were advised to continue with any prior therapies. They were given extensive written instructions how to apply the following four Kneipp applications: cold “knee affusion”, cold “wet socks”, “footbath” (= cold bath of lower limbs), alternating foot bath. These applications have in common that they provide a short but intensive cold stimulus by using water as cold as available (appr. 15° C). Patients were informed that the applications should induce local physiological reactions (initial vasoconstriction, followed by a longer lasting hyperemia) as well as systemic vegetative reactions including neurohormonal and circulatory reactions. As partial applications on the lower limbs, they should lead to moderate reactions and should usually be well tolerated.

A knee affusion is applied by means of a wide-lumen (3/4”) water hose with a steady low-pressure flow of cold water in order to avoid mechanical stimulation of the skin. It starts at the right fore-foot, is then directed upwards the calf to a few inches above the hollow of the knee, remains there for about 10 seconds and goes down at the inner side of the calf. Then the procedure is repeated in similar manner at the front side and afterwards the other leg is treated. The affusion is terminated with a short affusion of the soles. The whole procedure takes no longer than one minute.

For the foot-bath, a bucket filled with cold water – its surface reaching some inches below the knee – is required. The foot-bath lasts 10 to 30 seconds and is terminated immediately as soon as a cold pain is felt.

For the alternating foot bath, two buckets, one with cold (ca. 15° C) and one with warm water (ca. 36° C) are used. After having started with the warm foot bath for 3 minutes, one changes to the cold water bath for approx. 20 seconds. This procedure has to be repeated immediately and has always to be finished with the cold bath in order to induce the reactions after the cold stimulus as described above.

Wet socks of cotton are moistened with cold water and then applied. Having warmed-up after approximately 30 minutes, they are taken off before onset of sweating

Patients were asked to apply two to four of these Kneipp applications each day. Patients were free to choose the time of day and the type of each application.

Questionnaire and diary

The questionnaire sent to the patients asked for demographic data, general feeling, physical activities, use of nicotine and alcohol, history and etiology of PNP, former therapies and the symptoms (pain, paresthesia, numbness, paresis, other complaints, general impairment and feeling). These symptoms were to be rated in Likert scales from zero (none) to six (most severe complaints) before and after 8 weeks of treatment.

Patients were asked to record in the diary time and type of each application, the complaints before administration (from 0 to 6) and the immediate change of pain, hyperaesthesia, and paresthesia (unchanged, plus or minus) after each water application. Intake of analgetics was also recorded.

Statistics

Data were analysed descriptively; t-test was used, paired if appropriate. The outcome parameters were symptom scores before and after the treatment period, course of symptoms recorded in the diary, number of applications and initial changes of symptoms after each hydrotherapeutic measure. Compliance (frequency of applications) and questions regarding tolerability were used as a measure for practicability.

Ethic Comitee

There was no need for an approval by an ethic committee since it was an observational study with an intervention which is usually recommended as self-treatment in media and advisory books for patients [8]. Consent for anonymous data processing was given by the participants.

Results

Patients

We received completed questionnaires from 27 patients (12 male, 15 female). The patients' mean age was 68 years, their mean height 172 cm and mean weight 75.5 kg. Two patients out of 27 stopped treatment after 3 weeks, four patients reported intermediate discontinuation of the hydrotherapy within the first few days due to "worsening of complaints".

On the scale for physical activity (from 0 = bed rest to 6 = practising sports several times per week), the mean value was 3.6 before the study. Five patients reported that they could walk only with the aid of sticks. Twelve patients were smokers and 9 patients ingested moderate amounts of alcoholic beverages. In 12 patients, the etiology of PNP was unknown, the others reported: diabetes (2), cancer resp. cancer treatments (2), arteriosclerosis (2), rheumatic disease (2), neuroborreliosis (2), hormonal disease (1), metabolic disorder (1), vitamin deficiency (1), genetic disease (1), neuronal muscle atrophy (1), "other etiologies" (10). 23 patients were under observation of a neurologist, 13 patients of their general practitioner; 5 patients saw other medical specialists and 14 patients reported previous hospital treatments related to their PNP.

Twenty patients knew test results of their glucose levels, 15 patients of their lipids, 14 patients of levels of vitamin B₁₂ and folic acid. Seven patients reported prior biopsies of muscle and nerve; 6 patients remembered tests of cerebral spinal fluid or NMR.

Concomitant therapy was reported: 18 patients took supplementations of vitamins; 7 patients received infusions and 11 patients orally applied α -lipoic

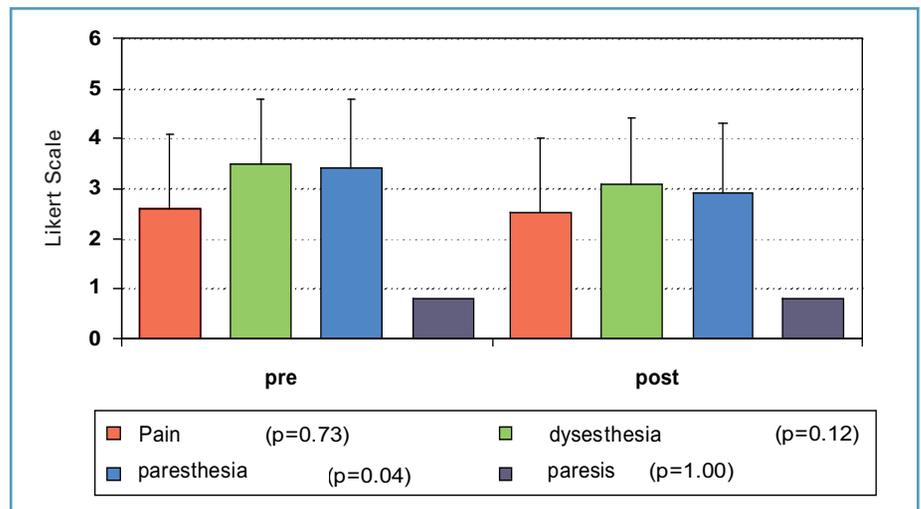


Fig. 1. Primary outcome parameters (mean on Likert Scale from 0=none to 6=most severe) before (pre) and after 8 weeks treatment (post).

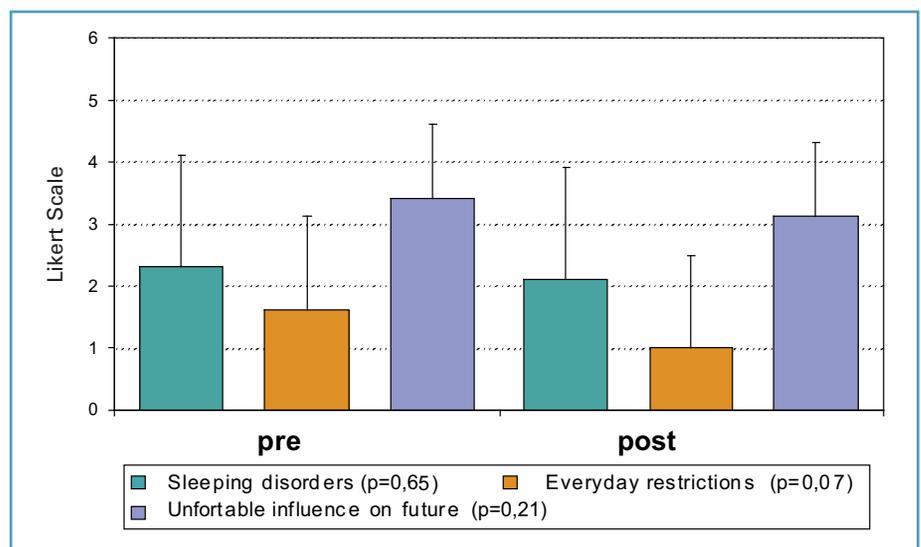


Fig. 2. Further outcome parameters (mean on Likert Scale from 0=none to 6=most severe) before (pre) and after 8 weeks treatment (post).

acid. 13 patients took analgetics and 11 patients received physiotherapy.

23 and 22 patients had symptoms of their right or left toes respectively. Involvement of the right or left lower limbs was recorded each in 15 patients. Eleven and 10 patients had also symptoms at the right or left hand respectively.

Therapy/Compliance

The most-favored Kneipp application was the knee affusion which was used about 11 times per patient and per week within the first week of treat-

ment. Towards the end of the treatment period, this practice was reduced to 9 times per week and per patient on average. There was a wide variation in the number of applications from patient to patient, e.g. a total of 8 to 179 knee affusions within 8 weeks. Cold foot-baths were used between 0 to 152 times per patient, giving a mean of 2 foot-baths per week per patient. Alternating foot-baths were used about 2 times per week and per patient. Wet socks were used 14 times in 8 weeks on average.

Symptoms before/after treatment

All patients suffered from pain with a mean score value of 2.6 at the beginning of the study. Twenty-three patients gave their rating after 6 weeks' therapy with a mean of 2.5 score points. The mean intra-individual change was 0.07 which means that there was a minimal alleviation of pain during the study which showed no significance (Fig. 1). An intra-individual improvement of 0.25 score points on average (from an average of 3.5 at baseline to 3.1 at termination) was analysed for the change of sensibility (numbness). This change in sensibility failed significance (t-test: $p = 0.12$). Paresthesia improved from a mean of 3.4 to 2.9 score points. The mean intra-individual difference was 0.58 score points ($p = 0.04$). Paresis was not very strongly pronounced, with an average of 0.8 score points and showed no changes during the study.

The symptoms sleep disorders, disability in daily activities and anxiety showed slight improvements. The impairment of daily activities was improved with an average intra-individual change of 0.38 score points ($p = 0.07$) (Fig. 2).

Symptoms recorded in diary

A completed diary was obtained from 23 patients. There was a very small increase of pain in the first 2 weeks with no clear relation to time of application. Overall, there is no effect to the pain in the time course (Fig 3). Similarly, there are no clear effects neither on sensibility nor on paresthesia.

Immediate effects after hydrotherapeutic applications

Overall, 49.9% of the Kneipp applications were reported to have led to acute improvements of pain; in 42.6% of the applications no acute changes of pain were observed. A worsening of pain was reported after 7.5% of the applications. The improvement rate rose during the study, with 40% improvement during the first week, 43.6% in week 2 compared to 62.4% in week 8. This change, however, is to be seen in coincidence with fewer applications used during the time course. Some patients did not proceed with ineffective

Kneipp applications and continued only the beneficial ones during the treatment period (Fig. 4).

Overall, most applications (61.8%) did not induce an acute change in sensibility. However, 32.7% of the Kneipp applications induced acute improvements and only 5.6% impairments. The improvement rate increased slightly during the first 5 weeks and then reached a plateau at about 35%.

In a similar manner, the rate of acute reductions of paresthesia increased from 30% of applications dur-

ing the first week to 41% at the end of the treatment period, resulting in a mean value of 33.7%. Only 9.5% of the applications caused an acute worsening, the remaining Kneipp applications did not lead to acute changes.

Analgetics' consumption

Eleven patients reported use of oral analgetics. During the first week, analgetics were taken 9.4 times per patient. This number decreased to 8 during week 3 until week 5 and afterwards to 6.5.

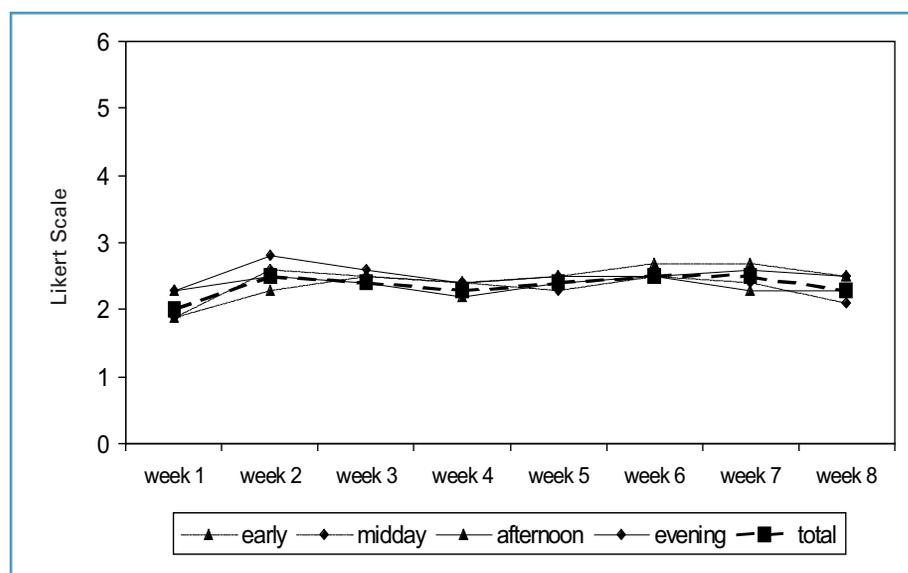


Fig. 3. Mean values of pain (Likert Scale from 0=none to 6=most severe) over time reported in patients' diaries.

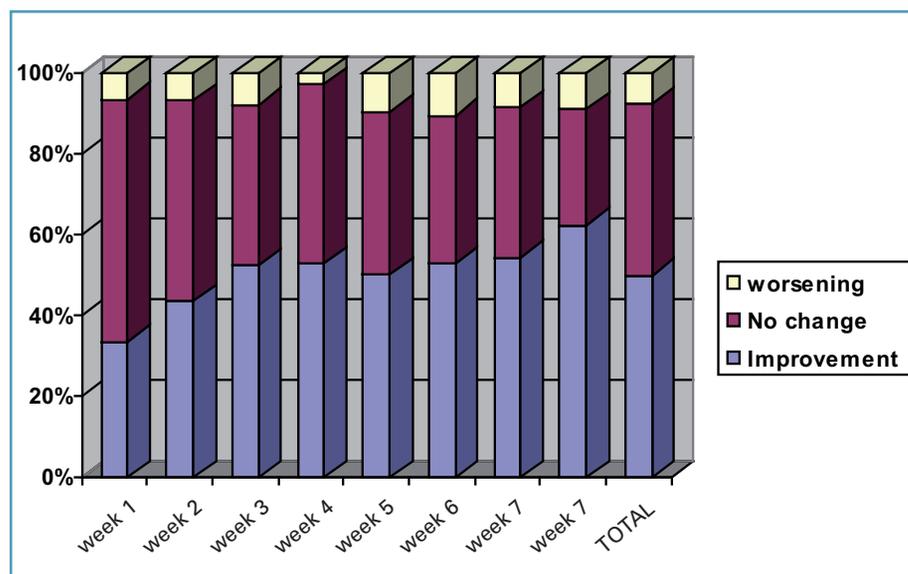


Fig. 4. Acute change of pain after Kneipp applications.

Discussion

Due to the small number of 27 patients, the analysis of the study parameters was limited. There are no apparent changes in the overall judgements of pain before and after 8 weeks of self-treatment using Kneipp hydrotherapy; which is in line with the mainly unchanged basic values of complaints before administrations recorded in the diaries during the time course. However, there was a significant decrease of paresthesia after 8 weeks. This moderate decrease could possibly be explained by spontaneous course, regression to mean, reporting bias; one could argue, however, that other symptoms should then also have been changed by this study-immanent factors.

There are relevant percentages (30–62%) of patients who reported in their diaries acute improvements of pain, sensibility and paresthesia after each single water application versus only 5–9% acute impairments. This percentage of Kneipp applications with acute improvements increased during the time course. However, it seems probable that many patients who did not experience acute improvement stopped the participation in the study or reduced the frequency of water applications during the 8 weeks. Therefore, the increasing acute response rate during the course of the study might be due to the “withdrawals” and not due to an adaptation process.

On the other hand, acute improvements after more than a third of applications (in those who had finally participated in the study) are reason enough to consider cold water applications as probative therapy in patients with PNP. Acute effects of a cold water application are plausible and could be explained by increased local circulation; on the other hand, vasoactive substances showed no improvement of symptoms in patients with diabetic polyneuropathy [9]. Hydrotherapeutic measures might also stimulate the same neurophysiologic mechanisms which are relevant in manipulative therapies including acupuncture for pain relief.

A further limitation of the study results lies in the procedure “study by

correspondence”. The exact diagnosis and etiology of this complex indication was only rated by questionnaires and is less accurate than a diagnosis by a neurologist. The number of patients is too small to look into subgroups with different etiology of their PNP which might respond in different manner to Kneipp therapy.

Judging by some of the telephone calls received during the study, it appears that many patients were not able to fully understand the written instructions and, consequently, some more patients did not return their questionnaires due to adverse reactions (they had no reactive hyperemia due to a prolonged cold application) and side effects (common colds).

The “study by correspondence” is a low-cost method to collect preliminary data about self-treatments and therefore a suitable instrument in the field of natural healing methods and some of CAM. It would be preferable, however, to handle inclusion or registration of patients more restrictively in order to obtain a more exact description of convenience sample and exact figures of drop-outs. This could be achieved by a two-step procedure where patients would submit their baseline data before receiving detailed instructions for the intervention and questionnaires for the course of the intervention.

On the basis of these results, we plan to conduct a further clinical study with personal instruction, anamnesis, controlled documentation as well as with a control group (waiting group), focussing on dysesthesia and paresthesia as primary outcome variables. Physiologic studies in patients with PNP versus healthy volunteers about acute effects on local circulation and metabolism could clarify the mode of action of a cold stimulus in PNP.

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Disclosure Statement

The authors declare that no financial or other conflict of interest exists in relation to the content of this article.

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