Does even a single treatment with Alpha Cooling® Professional (ACoP) affect the quality of life?

A brief analysis of the influence of subjective resilience, satisfaction and feeling of health after a single treatment using Alpha Cooling® Professional

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Summary:

Background: In December 2022, the author conducted an observational study on the short-term development of pain after a single treatment with Alpha Cooling® Professional. In this context, the participants were also asked to give a before-and-after assessment of the parameters "resilient", "satisfied" and "feeling healthy". The current study evaluates these results.

Method: A total of 150 patients from an orthopaedic practice underwent treatment using Alpha Cooling® Professional. They assessed their subjective resilience, general satisfaction and feeling of health immediately before and after the treatment and on the morning of the following day. The significance test was carried out using the dependent t-test, the effect size was calculated using the Cohen value.

Results: A statistically significant improvement in all the parameters examined was confirmed. A strong effect was seen immediately after the single cold treatment with Alpha Cooling® Professional. An improvement was still measurable on the following day.

Conclusion: Even a single application of Alpha Cooling® Professional can achieve a subjective improvement in general resilience. This effect appears to last for several hours and was still measurable the morning after the treatment.

1. Introduction and objectives

In December 2022, the author conducted an observational study on the effect of Alpha Cooling® Professional on pain intensity after a single application [1]. A significant pain relief was shown here, which was recognizable both immediately after the treatment and with even greater effect strength the morning after the application. In this context, patients were also asked to provide a before-and-after assessment of the parameters "resilient", "satisfied" and "feel healthy".

The present study supplements the aforementioned study with these parameters.

Alpha Cooling® Professional is a device manufactured by ALPHA Industries AG (formerly DEUSSL Manufaktur GmbH) in 88260 Argenbühl / Germany. According to the company's own information, this achieves a whole-body cold treatment by cooling the palms of the hands [2]. For treatment, the hands are placed in two cooling chambers. Through 3-5 cooling cycles of two minutes each, a specially developed vacuum system is used to gently cool the blood throughout the body.

More and more users are reporting personally and in various media about relief from various complaints and an improved quality of life.

However, apart from the observational study mentioned at the beginning, no structured data exists in this regard. This evaluation is therefore intended to determine the extent to which a single use of this device can achieve a subjective improvement in resilience, satisfaction and feeling of health.

The aim here is to check whether the mean values of the parameters mentioned are unchanged before and after treatment (null hypothesis H_0).

The following alternative hypotheses H_1 are put forward:

Alternative hypothesis H_{1A}: Participants feel more resilient, happier and healthier immediately after treatment than before.

Alternative hypothesis H_{1B}: The subjective resilience, satisfaction or feeling of health is better the morning after treatment than before.

The present study is an observational study without a control group. There is also no restriction of the group of people studied with regard to illnesses or previous treatments.

This analysis serves as an initial assessment of whether a positive effect is possible through treatment with Alpha Cooling® Professional. Further clinical studies may be conducted to further demonstrate this effect in the future.

2. Material and methods

A total of 150 patients from an orthopaedic specialist practice were included in the period from July 2022 to February 2023. The only requirement for participation was the exclusion of consensual contraindications [3].

The Alpha Cooling® Professional device from DEUSSL Manufaktur GmbH was used as the treatment device, as of May 2021, was used. A single application of 5 cycles of two minutes cooling each was used.

Participants were asked to provide an assessment of the parameters

- resilient or ready to use
- satisfied or dissatisfied
- feel healthy or ill (Figure 1).

Based on the Visual Analog Pain Scale (VAS), the current situation was to be assessed on a 100 mm long line. The positive aspect, i.e. " resilient", was always on the far left, "satisfied" and "healthy". On the far right were the negative extremes of "exhausted", "dissatisfied" and "sick" anchored.

The assessment should be carried out three times:

- before the treatment
- Immediately after treatment
- the next morning.

Conscious changes to everyday life should be avoided during this time, as should taking additional medication or undergoing further treatments, e.g. physiotherapy.

Using a ruler, the parameters were measured in millimeters, i.e. using the load capacity as an example: from 0mm = "loadable" to 100mm = "fixed and finished".

The present evaluation is part of a comprehensive application observation. The questionnaire completed by the participants covered the four parameters " healthy" and " satisfied",
"resilient" and "pain". Not all of these parameters were always relevant for the participants at the time of treatment.

Inclusion in this study therefore only took place if a measurable restriction of the respective parameters was recognizable before the application and was marked accordingly on the 100 mm long line. A value of at least 5mm measured from the left was defined by the author as the limit value for inclusion.

At the start of the study, only the assessment before and immediately after the

Application. In the course of the study, the assessment was extended to include the morning after treatment due to repeated positive feedback. All other parameters remained unchanged. However, this resulted in the different number of patients included to test the two alternative hypotheses mentioned at the beginning.

Statistical processing was carried out using the t-test for dependent samples with a significance level of alpha = 0.05 [4]. The first measurement point was always the value measured before the treatment. The second measurement point for alternative hypothesis H1A was the measured value immediately after treatment, for alternative hypothesis H1B the measured value the morning after.

The effect size was measured using the Cohen value d.

A value between 0.2 and <0.5 is defined as a small effect, 0.5 to <0.8 as a medium effect and 0.8 and greater as a strong effect [5].

The statistical calculation was carried out using the online Datatab" software at https://datatab.de/statistik-

rechner/hypothesentest.

In addition, the office software LibreOffice/Calc was used. The "Descriptive statistics" and "Dependent t-test" functions were used for statistical processing.

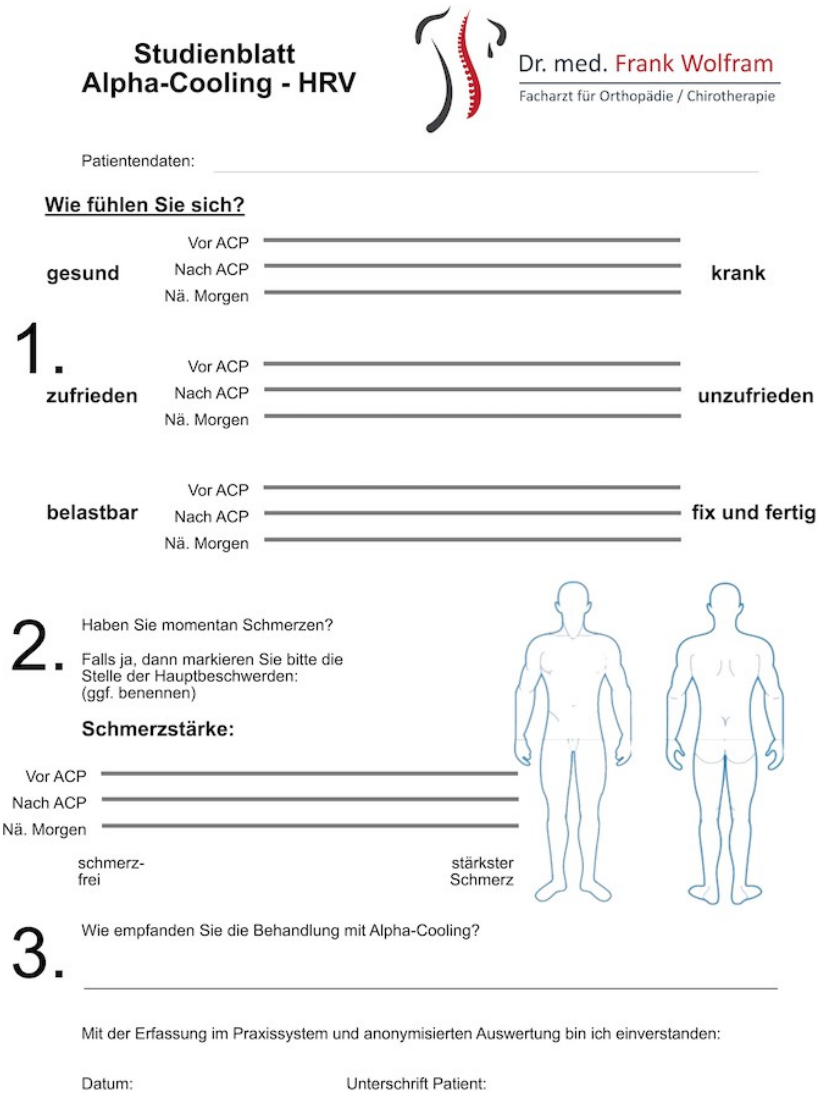

Fig. 1: Study sheet for recording the parameters before and after application of Alpha Cooling® Professional

3. Results

3.1 Parameters "resilient" to "ready to go"

A total of n=142 patients could be included in this observational study, taking into account the above-mentioned conditions and correctly completed questionnaires.

In terms of gender, there was a clear female dominance: n=107 female, n=34 male, n=1 without gender information.

Of these participants, n=140 compared their resilience immediately before and after treatment (n=106 female, n=33 male, n=1 without gender information).

A total of n=111 patients provided an assessment of their resilience the morning after treatment (n=79 female, n=31 male, n=1 without gender information).

For the two alternative hypotheses H1A and H1B mentioned, separate data preparation and evaluation is presented below.

3.1.1 Alternative hypothesis H1A: Subjective resilience is better immediately after treatment with Alpha Cooling® Professional than before.

The self-assessment of subjective resilience before treatment resulted in a mean value of 49.92 mm with a standard deviation of 26.82 mm. It ranged from 5mm to 100mm, whereby the lower limit for inclusion in the evaluation was set by the author at 5mm (see explanations in Section 2).

Immediately after treatment, load-bearing capacities between 0mm and 100mm were marked. The mean value was 42.14mm with a standard deviation of 25.81mm (Figure 2).

Resilience was therefore assessed as lower before treatment than immediately afterwards.

t-test for dependent samples

In the t-test for dependent samples, the null hypothesis is used to test whether the measured differences are statistically significant. The null hypothesis is that treatment with Alpha Cooling® Professional has no influence on the resilience of the participants.

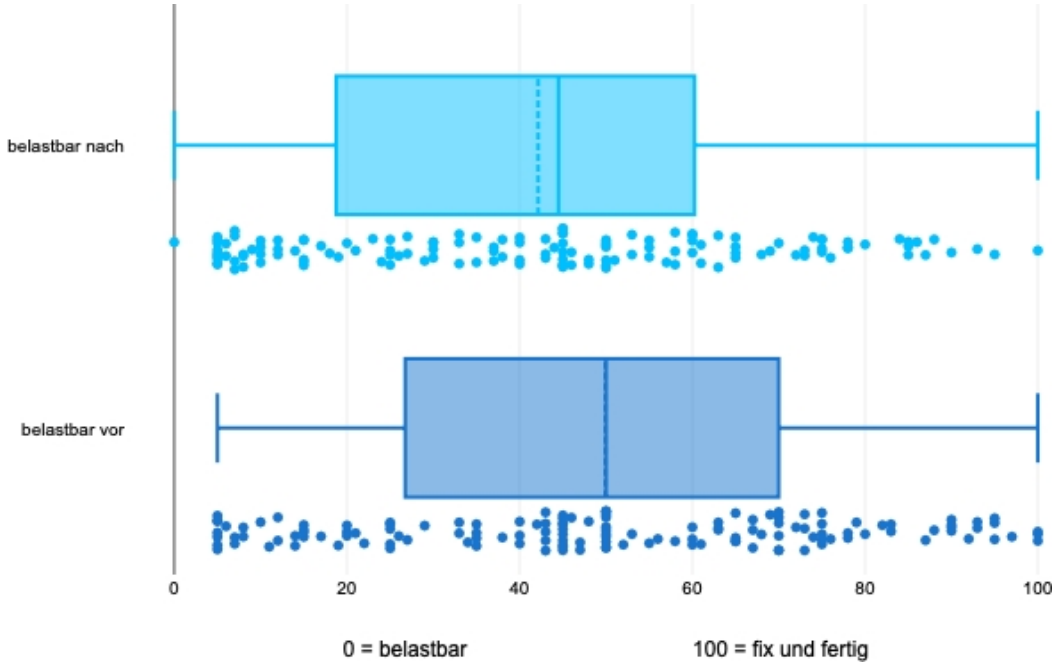

Figure 2: Subjective resilience and mean values immediately before and after Alpha Cooling® Professional treatment, n=140 people

At a fixed significance level of 5%, the null hypothesis is rejected if the calculated p-value is less than 0.05.

Based on the documented pain levels, a one-sided p-value (T<=t) of <0.001 (1.53E-08) was calculated.

The p-value of <0.001 is therefore below the specified significance level of 0.05. The t-test result is therefore significant for the available data and the null hypothesis is rejected. Treatment with Alpha Cooling® Professional therefore led to a significant improvement in the subjective resilience of the participants immediately after use.

Measurement of the effect strength

The effect size for the alternative hypothesis H1A is measured using the Cohen value d.

The effect size d is 0.83 and can therefore be regarded as a large effect.

3.1.2 Alternative hypothesis H1B: Subjective resilience is better in the morning after treatment with Alpha Cooling® Professional than before.

A total of n=111 patients also assessed their subjective resilience the morning after using Alpha Cooling® Professional. The documented value before treatment ranged from 5mm to 100mm. The mean value was 48.92mm with a standard deviation of 27.12mm.

On the morning after the treatment, the users marked their load capacity from 0mm to 95mm with a mean value of 37.37mm. The standard deviation was 24.64mm.

t-test for dependent samples

The restriction of exercise tolerance before the application of Alpha Cooling® Professional shows higher values than the morning after. Once again, the t-test for dependent samples is used to test the null hypothesis. Once again, the null hypothesis is defined as the treatment having no effect on exercise tolerance. The significance level is again set at 5%.

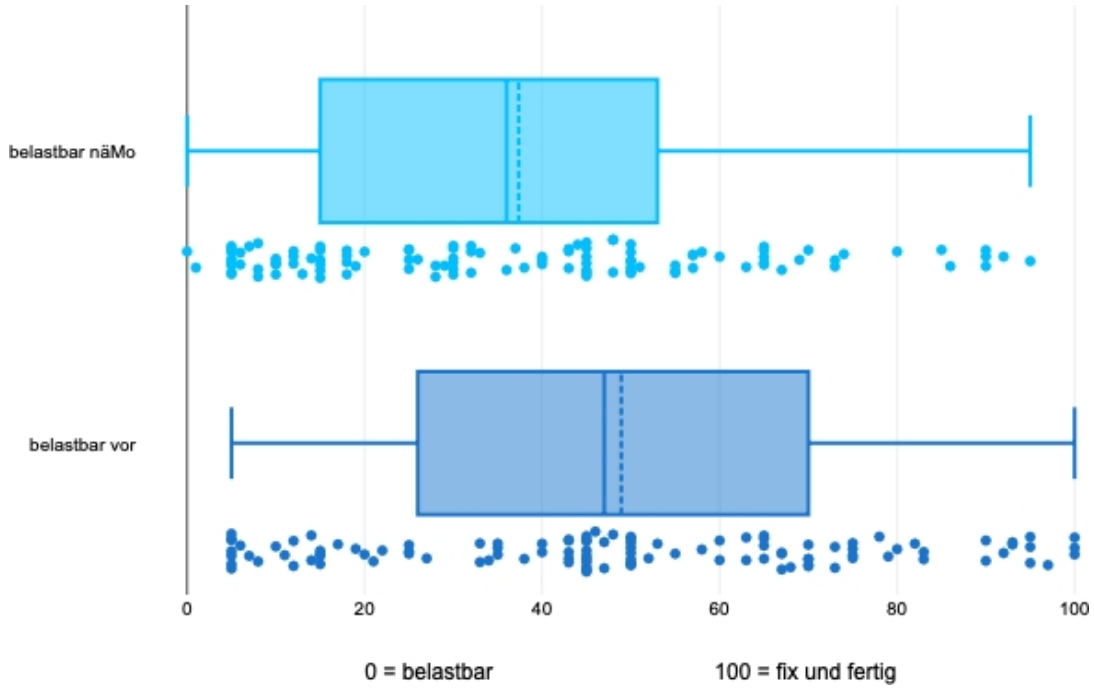

Figure 3: Subjective resilience and mean values immediately before and in the morning after (näMo) treatment with Alpha Cooling® Professional, n=107 people

Based on the documented measured values, a one-sided p-value (T<=t) of <0.001 (4.28E-10) is calculated. The p-value is therefore also below the specified significance level of 0.05, so that the null hypothesis is rejected. The effect of improved resilience is therefore statistically significant.

Measurement of the effect strength

The calculated effect size via the Cohen value d is 0.67 and corresponds to a medium effect.

For n=128 people, satisfaction was assessed immediately before and after treatment with a gender distribution of n=99 female, n=28 male, n=1 without gender information.

The assessment of satisfaction in the morning after treatment was made by 100 test subjects (n=72 female, n=27 male, n=1 without gender).

For the two alternative hypotheses H1A and H1B mentioned, the data is again processed separately.

3.2 Parameter "satisfied" to "dissatisfied"

Of all participants, satisfaction before and after treatment was analyzed for a total of n=130 patients according to the criteria defined in section 2.

In terms of gender distribution, women were again in the majority: n=100 participants marked "female", n=29 "male", once no gender was specified.

3.2.1 Alternative hypothesis H1A: Participants are more satisfied immediately after treatment with Alpha Cooling® Professional than before

Taking into account the aforementioned inclusion criteria, the participants' satisfaction before treatment ranged from 5mm (fairly satisfied) to 100mm (dissatisfied). The mean value was 51.11mm with a standard deviation of 30.96mm.

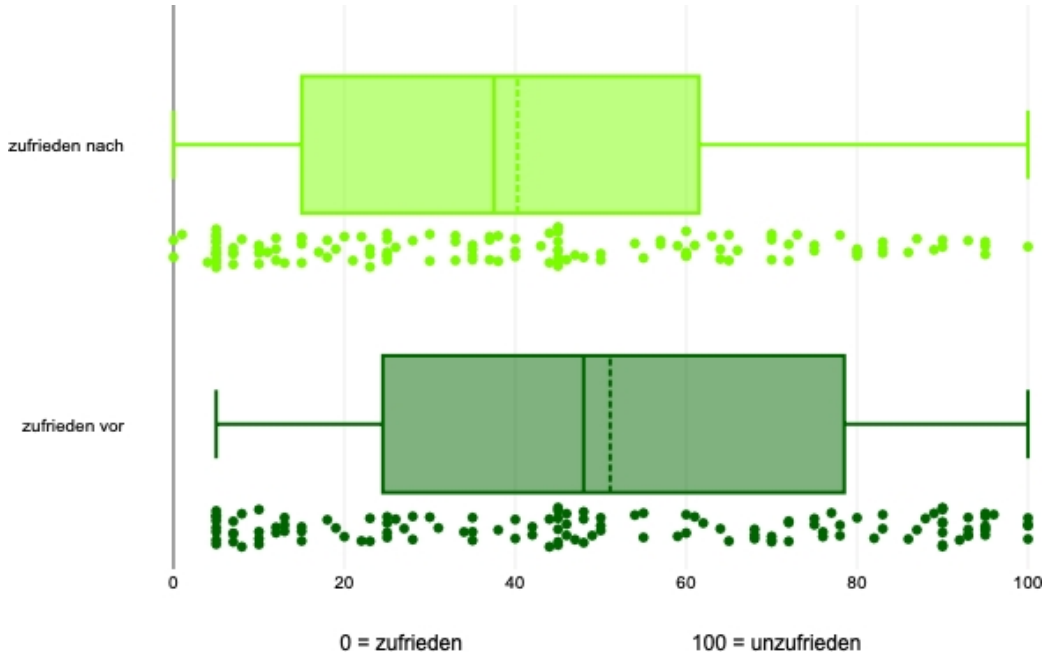

Figure 4: Subjective resilience and mean values immediately before and after Alpha Cooling® Professional treatment, n=128 people

Immediately after treatment, the mean value improved to 40.28mm (standard deviation of 27.78mm) with a variance of 0mm to 100mm (Figure 4). Thus, greater satisfaction was observed immediately after treatment with Alpha Cooling® Professional.

t-test for dependent samples

The statistical assessment is again carried out by setting the significance level at 5%. Based on the documented pain levels, a one-sided p-value (T<=t) of <0.001 (1.12E-10) is calculated, which is below the specified significance level. The t-test result is therefore significant for the available data. Treatment with Alpha Cooling® Professional resulted in the participants feeling more satisfied immediately after the application.

Measurement of the effect strength

The Cohen value d is again used to measure the effect size. It is 1.02 and thus defines a large effect.

3.2.2 Alternative hypothesis H1B: Subjective satisfaction is better the morning after treatment with Alpha Cooling® Professional than before

Of the n=100 participants included (n=72 female, n=27 male, one without gender), subjective satisfaction was reported on the entire spectrum from 100mm (dissatisfied) to 0mm (satisfied) for the morning after the application of Alpha Cooling® Professional. The mean value of 38.14mm (standard deviation 28.46mm) mm indicated improved satisfaction compared to before the treatment: here the mean value was still 49.88mm with a standard deviation of 31.55mm (Figure 5).

t-test for dependent samples

In the statistical calculation using the t-test for dependent samples, a one-sided p-value (T<=t) of <0.001 (4.33E-07) is calculated. The p-value is therefore also below the specified significance level of 0.05, meaning that the effect of improved satisfaction is also statistically significant the morning after treatment with Alpha Cooling® Professional.

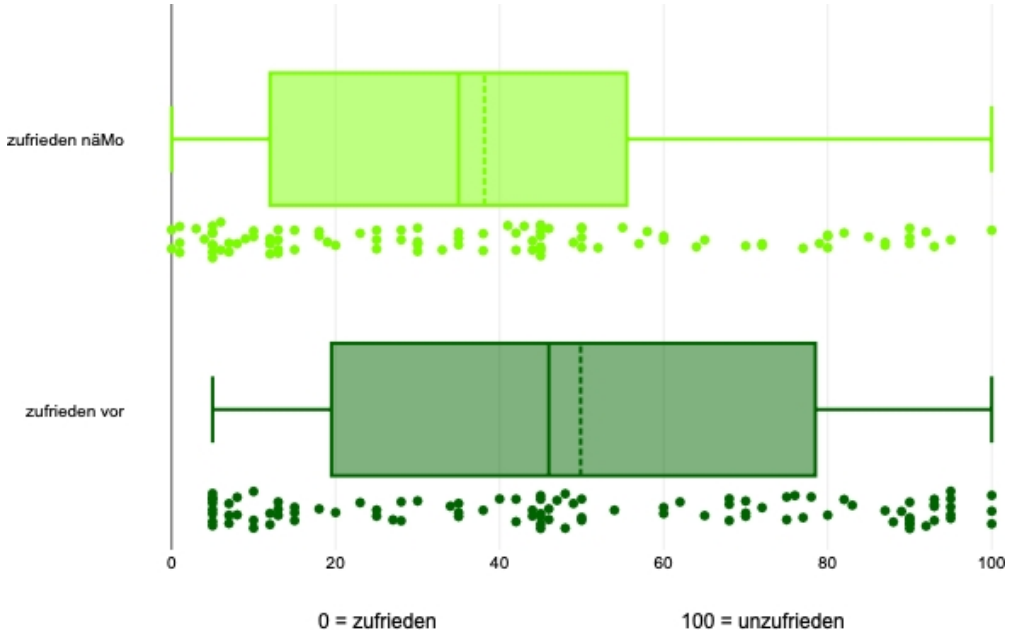

Figure 5: Subjective resilience and mean values immediately before and in the morning after (näMo) treatment with Alpha Cooling® Professional, n=100 people

Measurement of the effect strength

With regard to the effect size, the Cohen value d is calculated as 0.71. By definition, it is to be regarded as a medium effect.

3.3 Parameters "healthy" to "sick"

The third parameter included in this analysis is the participants' assessment of the extent to which they feel feel "healthy" or "ill".

A total of n=131 test subjects were included in the test of the alternative hypothesis H1A (feeling healthier immediately after treatment than before). The gender distribution was n=100 male, n=30 female, n=1 not specified.

As expected, the number of participants in the analysis for the morning after treatment was again somewhat lower. Of the 105 participants, n=74 defined themselves as female, n=30 as male, and one participant did not specify their gender.

3.3.1 Alternative hypothesis H1A: Participants feel healthier immediately after treatment with Alpha Cooling® Professional than before

Participants used the entire bandwidth on the specified scale from 0mm ("healthy") to 100mm ("ill"). By definition, only those who set their marker at 5mm or greater before treatment with Alpha Cooling® Professional and also set a marker for the time immediately after application were included in the analysis.

The evaluation of the n=131 persons before treatment resulted in a mean value of 51.56mm, the standard deviation was 28.67mm.

Immediately after treatment, the subjective perception of "healthy" was noticeably better with a mean value of 44.03mm (standard deviation: 26.76mm). Figure 6 shows this graphically.

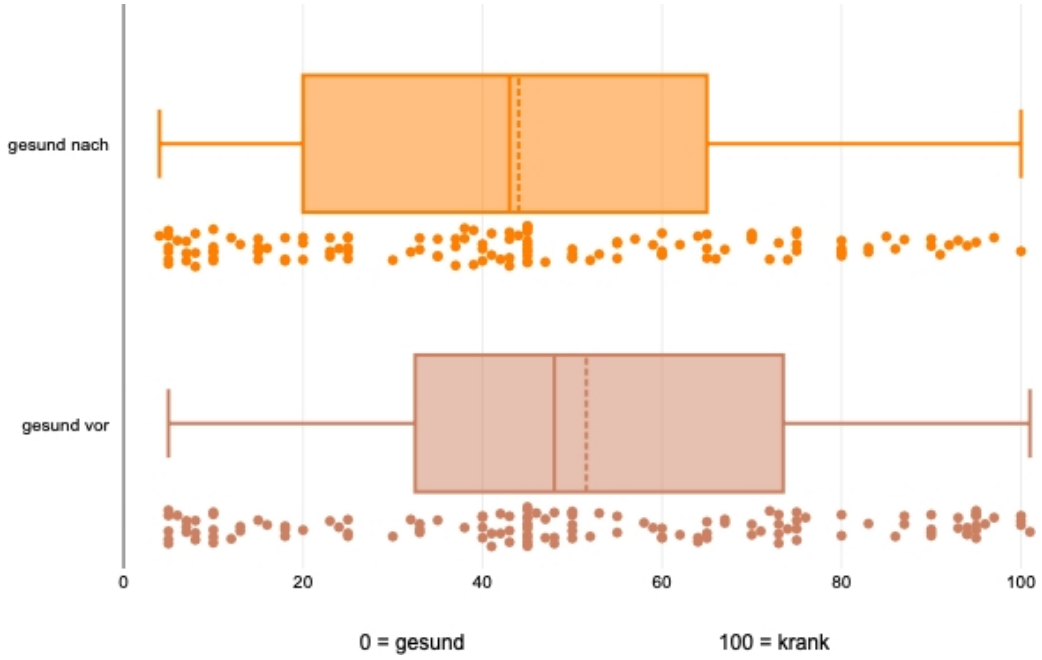

Figure 6: Feeling of health and mean values immediately before and after treatment with Alpha Cooling® Professional, n=131 people

t-test for dependent samples

Calculating the significance using the t-test for dependent samples with a significance level of 5% results in a one-sided p-value (T<=t) of 6.45E-08, which is below the specified significance level. The result is therefore significant for the available data. The treatment with Alpha Cooling® Professional therefore resulted in the participants feeling healthier or less ill immediately after the application.

Measurement of the effect strength

The Cohen value for analyzing the effect size showed a large effect of 0.88.

3.3.2 Alternative hypothesis H1B: In the morning after ACoP treatment, the "healthy" parameter is better than before treatment

A total of 105 participants still marked a "healthy - sick" parameter before treatment.

value of 5mm or greater and also gave an estimate for the morning after.

Here the mean value before treatment was 48.5mm, the standard deviation was 29.28mm. Immediately after the treatment, the mean value shifted away from "sick": at 38.9mm, it was almost 10mm further on the "healthy" side (standard deviation: 27.62mm).

Figure 7 shows the graphical representation.

t-test for dependent samples

The statistical evaluation using the t-test for dependent samples calculates the p-value at 1.39E-06 below the specified significance level of 0.05. The observed effect that the participants also feel healthier the morning after treatment with Alpha Cooling® Professional than before is therefore statistically significant.

Measurement of the effect strength

A Cohen value d of 0.70 is calculated for the assessment of the effect size, meaning that a medium effect can be assumed.

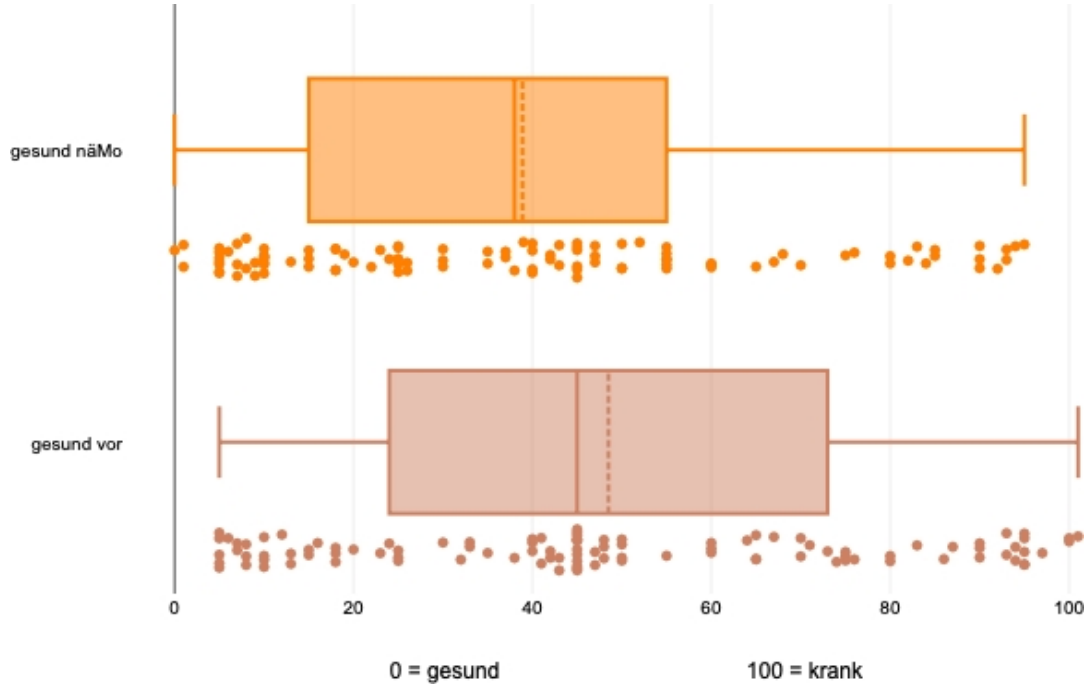

Figure 7: Feeling of health and mean values immediately before treatment with Alpha Cooling® Professional and the next morning (näMo), n=105 people

4. Discussion and interpretation

The results described here on cold therapy using Alpha Cooling® Professional provide further insights into the effectiveness of this method. They supplement the observational study on pain development published by the author in December 2022. The available data show a significant improvement in the parameters of resilience, satisfaction and feeling of health after a single application of cold therapy using Alpha Cooling® Professional.

The dependent t-test and the Cohen value were used for significance testing and effect size calculation, which provides a solid methodological basis for the results. The fact that the improvement in the parameters was statistically significant immediately after the application of Alpha Cooling® Professional and that this was still demonstrated on the following day is an important indication that the method can have a longer-lasting effect.

However, it should be noted that only a short period of time was considered here. This means that no statement can be made about the long-term effect of Alpha Cooling® Professional. It remains to be investigated whether the observed improvements last over a longer period of time and whether regular use of cold therapy with Alpha Cooling® Professional can achieve a long-term effect. It is also important to consider the safety and possible side effects of this method.

Overall, however, the data collected shows important findings on the effectiveness of Alpha Cooling® Professional as a cold therapy for improving resilience, satisfaction and feelings of health.

This method could therefore represent a promising option for the treatment of pain and health complaints and should be investigated in more detail in further studies.

5. Summary:

This study expands on the observational study published by the author in December 2022, which focused on the development of pain at the time. The present analysis evaluates further subjective perceptions. The participants were asked to assess whether they felt more resilient, happier and healthier after the one-off cold treatment with the Alpha Cooling® Professional (ACoP) device.

Statistical significance of the improvements was also demonstrated for these parameters.

A strong effect can be seen immediately after treatment. The improvement is still measurable the morning after the treatment. A medium effect strength was calculated for all three criteria.

Conflict of interest

The author, Dr. med. Frank Wolfram, was commissioned and paid as a medical consultant by the company ALPHA Industries AG, Geranienweg 19, 88260 Argenbühl, Germany, to carry out this study.

Manuscript data:

published on 29.05.2023

LITERATURE

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