

Technique of Whole-Body Hyperthermia and the Fibromyalgia Syndrome—first Controlled Clinical Trials

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non-oncological Hyperthermia

Technique of Whole-Body Hyperthermia and the Fibromyalgia Syndrome

– first Controlled Clinical Trials

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Why Water-Filtered Infrared-A Radiation for Whole-Body Hyperthermia ?



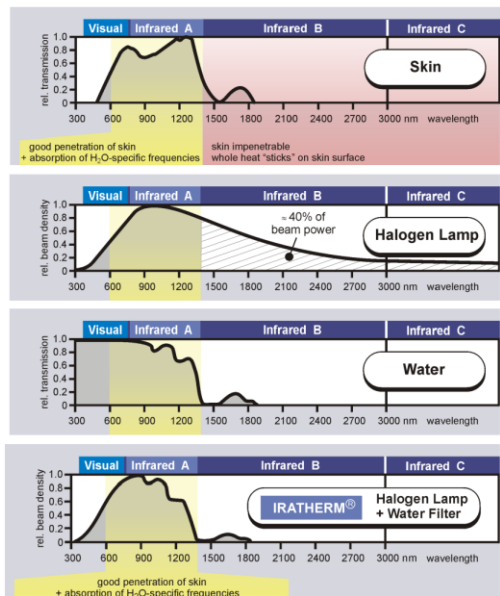
The spectral transmission of skin starts at a long wave visual light of about 600 nm wavelength (see "Visual") and passes the whole infrared-A until its upper long wave limit of about 1,400 nm wavelength. In contrast to that, the skin is nearly impenetrable to heat radiation from the spectral regions of infrared-B and infrared-C. Therefore one can speak of "deep-acting heat" in the case of infrared-A heat radiation, whereas with infrared-B and infrared-C radiation we speak only of "surface heat".

Red light lamps or halogen lamps are well-known and powerful heat radiators. The latter mostly operates on higher power. The following presentation of spectral distribution of a halogen lamp shows that its heat radiation contains 40% of the unwanted, skin-straining infrared-B and infrared-C radiation.

Water is the appropriate choice of filter to eliminate infrared-B and infrared-C radiation because water, similar to skin, has a selective transmission of infrared radiation. This property results from the fact that the skin of an adult consists to 75% of water. Just like skin, water is a good transmitter of infrared-A radiation. While infrared-B and infrared-C are nearly completely absorbed, only small absorption bands (near 950 nm and 1,150 nm) are given in the spectral region of infrared-A.

By placing a water filter in front of a halogen lamp, the result is a heat radiation, with a spectral distribution nearly equal to the spectral transmission of the skin.

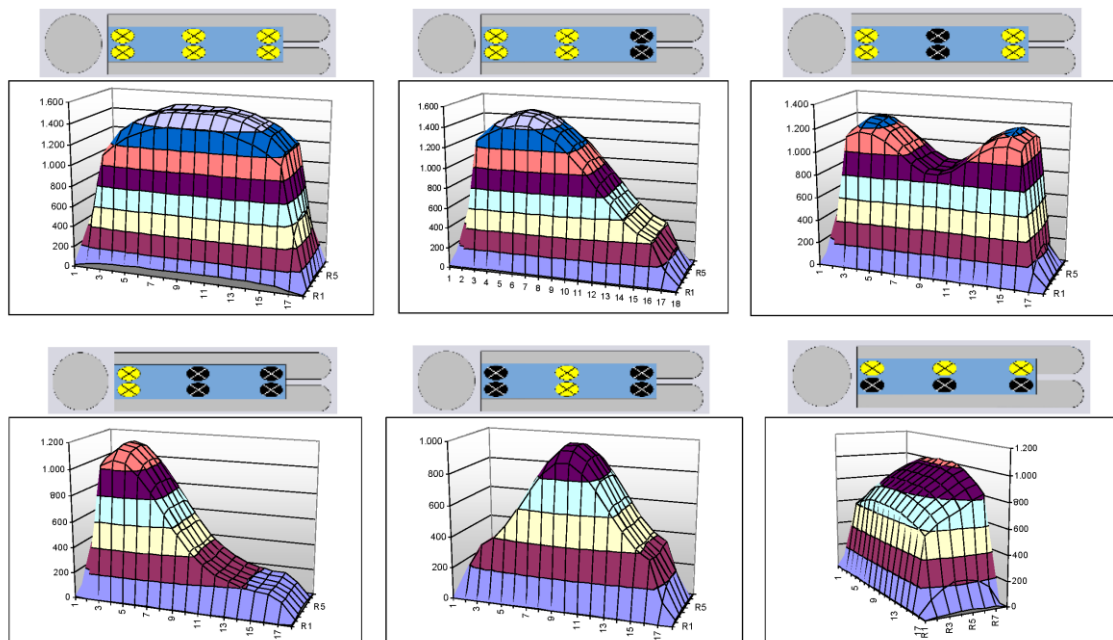
Using water-filtered infrared-A radiation the IRATHERM® allows a much higher irradiation level than that of commercial infrared or halogen lamps at same skin tolerance (Δ = factor 2.6). Water-filtered infrared-A is heat radiation similar to natural sun radiation because natural sun radiation is formed with the help of the humid atmosphere of the earth.



Whole-Body Hyperthermia Equipment „IRATHERM®1000“ with water-filtered infrared-A radiation for body-core temperature untol 40.5 °C and higher



Variation of Irradiance in Level of Patient Net (6 single controllable radiators)



The Three Levels of Whole-Body Hyperthermia (WBH)

	Mild WBH	Moderate WBH	Extreme WBH
Target Temperature body-core, T(rectal)	< 38,5 °C	38,5 °C - 40,5 °C	> 40,5 °C
Duration of Application in the given temp. region	≤ 30 min	> 30 min	usually ≥ 60 min
Load of Patient	sweating, no thermoregulatory stress	sweating, no thermoregulatory stress	thermoregulatory stress, deep intravenous anesthesia or general anesthesia
Supervision of Patient	without care	care by nurse T(axill) or T(rectal) or T(sublingual) or T(tympanal)	care by nurse with medical supervision continuously T(rectal) ± T(axill / tympanal) + HF/SpO2 ± ECG sporadic ± NIBP („±“ means optional)
Range of Indications (selection)	relaxation, wellness	rehabilitation, physiotherapy, rheumatology, orthopaedics	rheumatol., dermatol., oncology, psychiatry, immunology, environmental medicine

heckel-medizintechnik and Von Ardenne Institute 01/2018

Possible Indications of Moderate Hyperthermia

- arterial hypertension
- overstraining of musculature,
especially deep-lying muscles
of lumbar region
(adjuvant to massage treatment)
- chronic back pain
(after detailed establishing a diagnose)
- fibromyalgia syndrome
- therapy-resistant neuralgias
- migraine
- sub-acute, chronic inflammation
- rheumatic diseases
(degenerative and sub-acute inflammatory)
- ankylosing spondylitis
- systemic scleroderma
- allergic rhinitis
- bronchial asthma
- neurodermatitis
- depression / SAD
- cancerous diseases
(an adjuvant measure to standard therapies and
immune modulation)
- regeneration or rehabilitation
in sports medicine

acc. to K.L. Schmidt: Hyperthermie und Fieber,
M. Heckel: Ganzkörper-Hyperthermie
und Fiebertherapie a.o.

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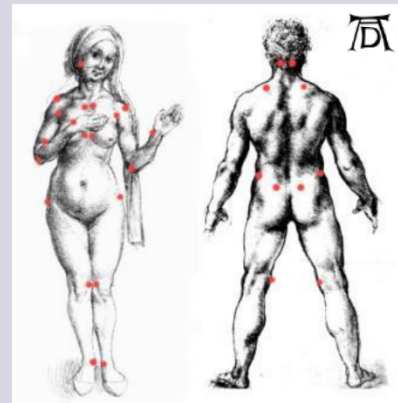
Necessity of interdisciplinary **S3-Guideline**: „Because of the incidence of FMS, the controversies about its classification and treatment as well as its inappropriate health care“

- **Definition**

Core symptoms of FMS are chronic pains in several body regions among other symptoms like sleep disturbances, none-relaxing sleep and fatigue (physically and/or spiritually).

- **Prevalence**

In western industrial nations in general adult population the prevalence is 0.7 – 3.3%.
Women are more frequent affected than males.
Women in **(D)** between 35 and 74 years: 5.5%.



from S3-Guideline 2012

S3-G.: Genesis of this disease is still unexplained.

Present state of studies doesn't allow a categorical statement about the etiology of FMS.

Risk indicators, Etiology and Pathophysiology (choice)

- Inflammatory-rheumatic diseases, Gene polymorphisms, lack of physical activity, sexual abuse, stress at workplace, ...
- Lack of vitamin D, Infection diseases, changed central pain processing, dysfunction of hypothalamus-hypophysis-adrenocortical axis, ...

Wolfe 2011, Weir 2006, Häuser 2011, Kivimäki 2004, McBeth 2010, Petzke 2010, McBeth 2007, Holliday 2010,

from S3-Guideline 2012

Effect of a Serial Whole-Body Hyperthermia with Water-Filtered Infrared-A Radiation on Fibromyalgia Pain

[Schleenbecker HG, Schmidt KL. Phys Rehab Kur Med 1998;8:113-117]



Pilot Study

Patients

11 female patients (53 ± 5 years)
fibromyalgia (established acc. to Wolfe 1990, Müller 1990, Yunns 1981), known for several month to 12 years

Method

serial mild infrared-A-hyperthermia, 3 x / week, over 3 weeks,
each 30 min duration with rise in T_{typ} of 1.3°C

- measurement of tenderness threshold on 24 tenderpoints with dolorimeter
- measurement of subjective pain intensity with pain score for 11 sections of the body
- measurement of subjective pain intensity with visual pain analog scala

Result

Treatment →	Before 1.	After 1.	Before Last	Significance
tenderness threshold	2.0 $\pm$ 0.3	2.3 $\pm$ 0.5	2.2 $\pm$ 0.4	n.S.
pain score	2.5 $\pm$ 0.9	1.3 $\pm$ 0.6	1.7 $\pm$ 0.5	S.
pain analog scala	68 $\pm$ 7	31 $\pm$ 5	37 $\pm$ 16	S.

A mild whole-body hyperthermia with water-filtered infrared-A radiation „has a significant analgesic effect in fibromyalgia, especially under repeated application“.

Clin J Pain 2007; 1: 67-75



A Randomized Controlled Trial on the Effectiveness of Mild Water-filtered Near Infrared Whole-body Hyperthermia as an Adjunct to a Standard Multimodal Rehabilitation in the Treatment of Fibromyalgia

Thomas Brockow MD, Andreas Wagner MD, Annegret Franke PhD, Martin Offenbächer MD MPH
and Karl L. Resch MD PhD

● Inclusion of 139 patients:

- fulfillment of ACR 1990 criteria for fibromyalgia¹⁾
- pain intensity of last week ≥ 40 mm on 100 mm pain intensity VAS
- physical-functioning subscale FIQ-G^{x)} ≥ 1.2 ²⁾
- age 18 ... 70 years

- Device: IRATHERM®1000, using exclusively water-filtered infrared-A heat-radiation

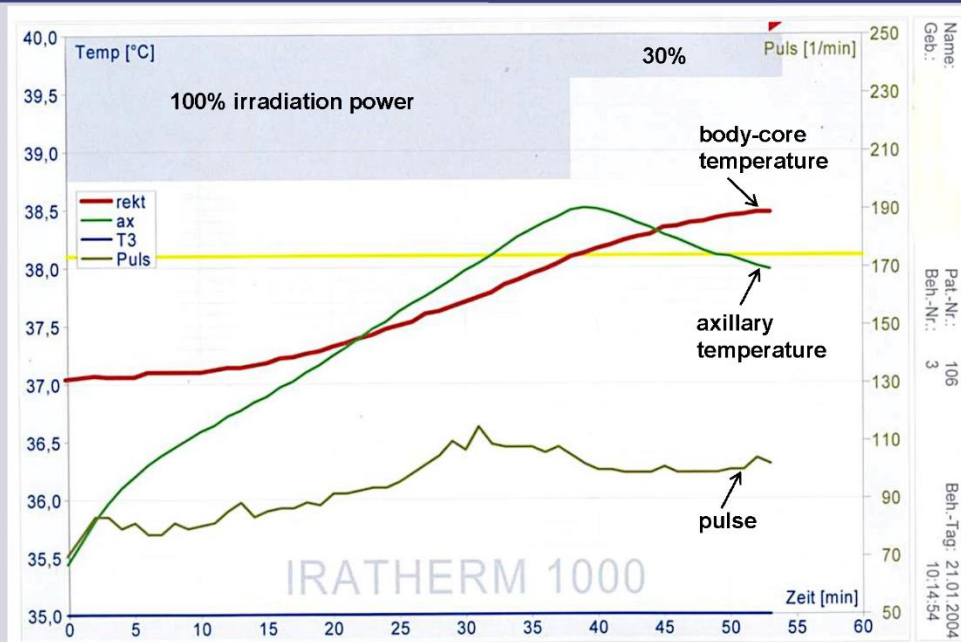


¹⁾ Wolfe et al. 1990,

²⁾ Offenbacher et al. 2000

^{x)} German Version of „Fibromyalgia Impact Questionnaire“

WBH Treatment with Water-Filtered Infrared-A Radiation



Efficacy of a serial Whole-Body Hyperthermia (WBH) as an Adjunct to a Standard Multimodal Rehabilitation (MR) in the Treatment of Fibromyalgia

[Brockow T, Wagner A, Franke A, Offenbacher M, Resch KL. The Clinical Journal of Pain 2007;1:67-75]

Multimodal Rehabilitation (MR)

5 x 60' pain management (relaxation techniques...)
 6 x 30' muscular cardiorespiratory and endurance training
 6 x 30' water-based exercises (34°C water temperature)
 6 x 30' flexibility training
 6 x 30' ergometer training (Pulse = 180-age)
 6 x Δt occupational therapy (group therapy)
 3 x 90' health education (self exercise programs ...)
 1 x 90' nutritional consulting
 Additive: indication related treatment of concomitant diseases

● Patients got **randomised**:

either a **standard multimodal rehabilitation (MR)**
 + a **mild water filtered infrared-A Whole-Body Hyperthermia (WBH)**
 (body-core target temperature 38.1°C; 6 sessions/3 weeks)

study group

or **exclusively**
 a **standard multimodal rehabilitation**

control group

NI-WBH + MR

MR

Efficacy of a serial Whole-Body Hyperthermia by wIRA (NI-WBH) as an Adjunct to a Standard Rehabilitation (MR) in the Treatment of Fibromyalgia

[Brockow T, Wagner A, Franke A, Offenbacher M, Resch KL. The Clinical Journal of Pain 2007;1:67-75]

● **Primary Objective Parameter**

- affective pain (McGill Pain Questionnaire,
 - sensory pain German version)

Secondary Objective Parameter

- pain intensity (pain scale of FIQ)
 - FM-related quality of life (FIQ2000, German version)

● **Clinical Instruments**

- total number tender points
 - mean tender point threshold
 - total tender point pain intensity

● **Measuring Points in Time**

- before and after intervention,
 3 and 6 month after end of intervention

Efficacy of a serial Whole-Body Hyperthermia by wIRA (NI-WBH) as an Adjunct to a Standard Rehabilitation (MR) in the Treatment of Fibromyalgia

[Brockow T, Wagner A, Franke A, Offenbacher M, Resch KL. The Clinical Journal of Pain 2007;1:67-75]



Results

NI-WBH + MR / MR	baseline	end of therapy	3 mon after	6 mon after	significance
affective pain	35,5 / 37,1	-11,4 / -6,2	-8,2 / -3,1	-6,2 / -2,1	P < 0,0005
sensory pain	22,3 / 22,0	-3,9 / -1,4	-3,7 / +0,4	-2,5 / +0,9	P = 0,001
pain intensity	6,4 / 6,2	-2,4 / -0,9	-1,6 / +0,1	-1,2 / +0,2	P < 0,0005
QOL	43,3 / 45,6	-17,5 / -11,6	-13,6 / -2,5	-9,5 / -0,4	P < 0,0005
pain intensity (TP's)	1036 / 1017	-139 / -32			P < 0,001

„NI-WBH + MR is superior to MR only in relation to pain control and amelioration of FM-specific QOL. These findings are remarkable because effectiveness of NI-WBH has been evaluated in addition to a multimodal rehabilitation program. ... all side effects were disappearing within 30 min after NI-WBH.“

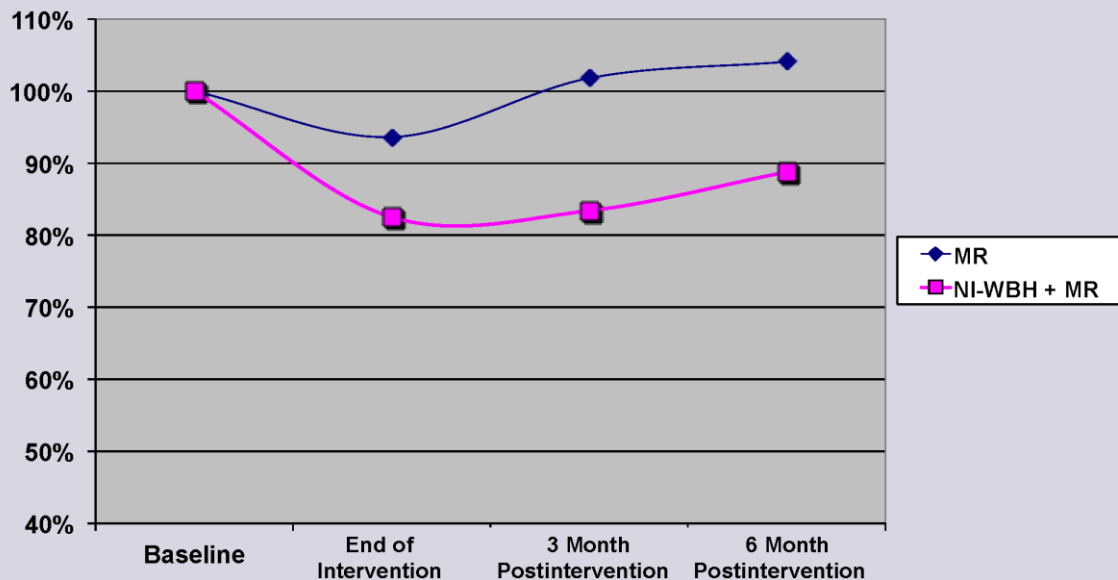
NI-WBH = Near-Infrared Whole-Body Hyperthermia
MR = Multimodal Rehabilitation

Efficacy of a serial Whole-Body Hyperthermia by wIRA (NI-WBH) as an Adjunct to a Standard Rehabilitation (MR) in the Treatment of Fibromyalgia

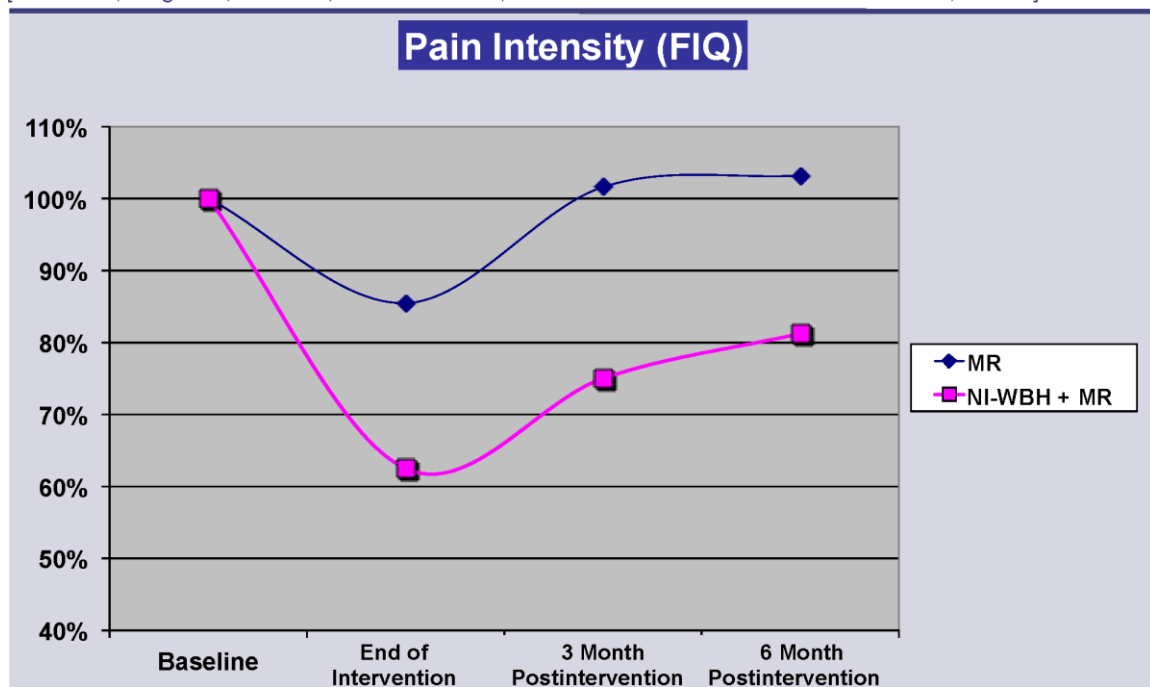
[Brockow T, Wagner A, Franke A, Offenbacher M, Resch KL. The Clinical Journal of Pain 2007;1:67-75]



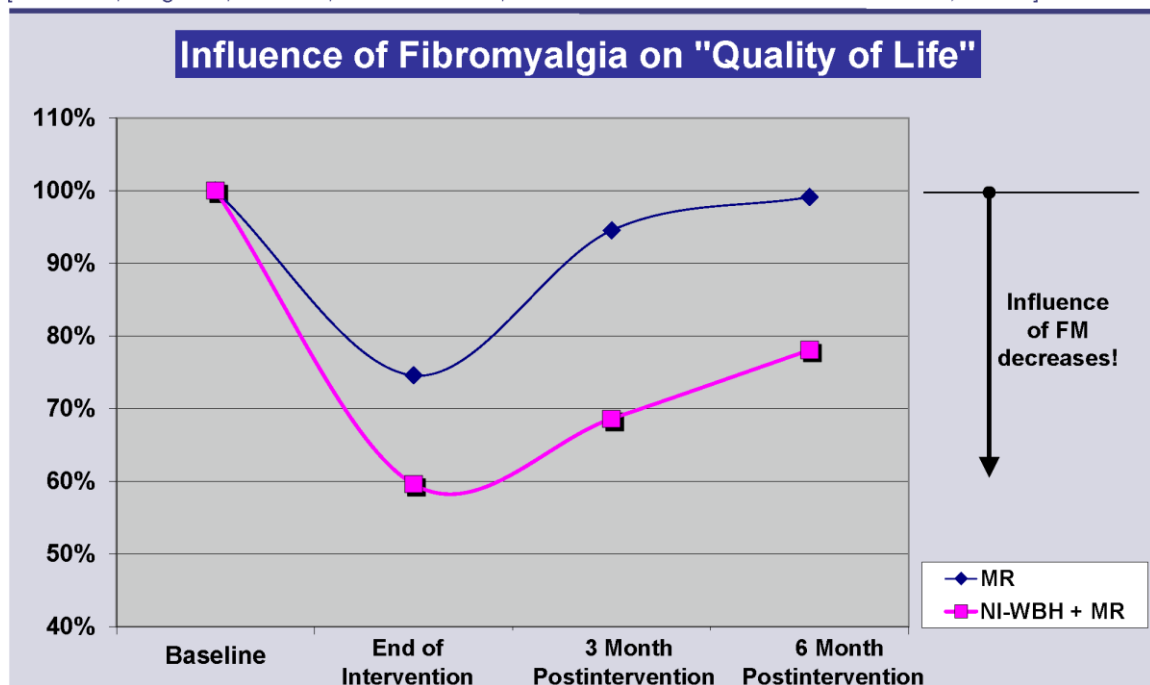
Sensory Pain



Efficacy of a serial Whole-Body Hyperthermia by wIRA (NI-WBH) as an Adjunct to a Standard Rehabilitation (MR) in the Treatment of Fibromyalgia [Brockow T, Wagner A, Franke A, Offenbaecher M, Resch KL. The Clinical Journal of Pain 2007;1:67-75]



Efficacy of a serial Whole-Body Hyperthermia by wIRA (NI-WBH) as an Adjunct to a Standard Rehabilitation (MR) in the Treatment of Fibromyalgia [Brockow T, Wagner A, Franke A, Offenbaecher M, Resch KL. The Clinical Journal of Pain 2007;1:67-75]



Efficacy of a serial Whole-Body Hyperthermia by wIRA (NI-WBH) as an Adjunct to a Standard Rehabilitation (MR) in the Treatment of Fibromyalgia
 [Brockow T, Wagner A, Franke A, Offenbaecher M, Resch KL. The Clinical Journal of Pain 2007;1:67-75]



Effect Sizes (95% Confidence Interval)	End of Therapy	3 Month after End of Therapy	6 Month after End of Therapy
affective pain	0.60 (0.26-0.94)	0.54 (0.20-0.88)	0.44 (0.10-0.78)
sensory pain	0.42 (0.08-0.76)	0.62 (0.29-0.96)	0.46 (0.12-0.80)
pain intensity	0.60 (0.25-0.94)	0.59 (0.25-0.94)	0.51 (0.16-0.85)
FIQ-G-shortened	0.41 (0.07-0.75)	0.72 (0.37-1.08)	0.60 (0.25-0.95)
FIQ-G		0.75 (0.40-1.10)	0.59 (0.25-0.93)
mean tender point threshold	0.53 (0.19-0.87)		
total tender point pain intensity	0.66 (0.31-1.00)		
total number tender points	0.44 (0.10-0.78)		

Efficacy of a serial Whole-Body Hyperthermia by wIRA (NI-WBH) as an Adjunct to a Standard Rehabilitation (MR) in the Treatment of Fibromyalgia
 [Brockow T, Wagner A, Franke A, Offenbaecher M, Resch KL. The Clinical Journal of Pain 2007;1:67-75]



Summary

Study group (NI-WBH + MR) showed:

- significant treatment effects for all study parameters
- superior pain reduction versus standard therapy alone
- clinically relevant mean effect sizes
- sustainability until 6-month-follow-up
- side effects in 20% of study patients (especially blood pressure dysregulations), short-lived and disappearing in < 30 min after NI-WBH



TOP TEN of Patients most beneficially perceived Therapies in Fibromyalgia

- whole-body heat therapy
- thermal bathes
- fibromyalgia education
- laying down and resting
- local heat therapy
- lymphatic drainage
- functional training
- bathes
- osteopathy
- dance therapy

Efficacy of a serial Whole-Body Hyperthermia by wIRA (NI-WBH) as an Adjunct to a Standard Rehabilitation (MR) in the Treatment of Fibromyalgia

[Walz J, Hinzmann J, Haase I, Witte T. Der Schmerz 2013;1:38-45]



Controlled Clinical Trial with 6 Month Follow-Up

Patients

Fibromyalgia (in acc. to ACR1990 criteria for FM, age 18...70 years)

67 pat., MR-group 21 Pat. (50 ± 11y) ↔ NI-WBH1 + MR-group 20 pat. (54 ± 8y) 1 x / week over 3 weeks
↔ NI-WBH2 + MR-group 26 pat. (57 ± 9y) 2 x / week over 3 weeks

Therapy

standard rehabilitation (MR) ± serial mild infrared-A hyperthermia (NI-WBH1 and NI-WBH2)
increase of body-core temperature within 40 min until $T_{rect} = 38.0^{\circ}\text{C}$ plus 18 min plateau phase

Prim. Outcome: measuring of pain intensity

by 11 stepped numerical rating-scale (NRS)

Sec. Outcome: measuring of affective pain

by 14 stepped items (emotional)

measuring of sensory pain

by 10 stepped items (body related)

measuring of FMS related quality of life

by German version FIQ-G (QOL)

measuring of depression

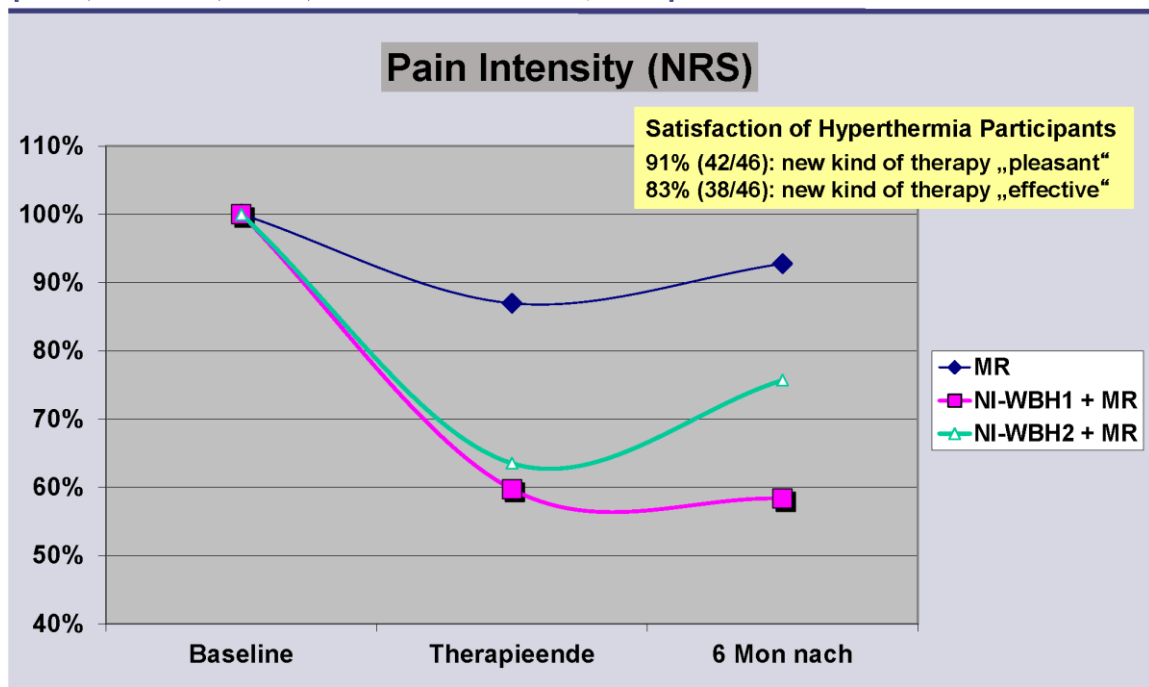
by subscale out of the Brief Symptom Inventory

Result

NI-WBH1 / NI-WBH2 / MR	baseline	end of therapy	6 mon post	significance
pain intensity (NRS)	7.2 / 7.4 / 6.9	-2.9 / -2.7 / -0.9	-3.0 / -1.8 / -0.5	P < 0.001
affective pain	37.2 / 41.3 / 36.8	-7.5 / -9.5 / -2.7	-9.0 / -3.8 / -0.9	P = 0.005
sensory pain	20.4 / 24.5 / 24.3	-0.7 / -2.5 / -1.6	-2.4 / -0.7 / -2.0	P = 0.462
QOL	54.6 / 53.4 / 47.3	-21.2 / -17.9 / -7.1	-14.7 / -8.1 / -3.1	P = 0.014
depression	2.5 / 2.4 / 2.3	-0.9 / -0.6 / -0.5	-0.6 / -0.3 / -0.2	P = 0.451

Efficacy of a serial Whole-Body Hyperthermia by wIRA (NI-WBH) as an Adjunct to a Standard Rehabilitation (MR) in the Treatment of Fibromyalgia

[Walz J, Hinzmann J, Haase I, Witte T. Der Schmerz 2013;1:38-45]



Microcirculation Abnormalities in Patients with Fibromyalgia

[Morf S, Vesti B, Forster A, Franzeck U, Koppensteiner R, Uebelhart D, Sprott H. Arthritis Res Ther 2005;7]



Unblinded Preliminary Case-Control Study

Patients 10 women (54,0 ± 3,7 years) with Fibromyalgia (FM), classified in accordance with criteria of ACR
 3 control groups: 10 healthy women
 10 women with Rheumatoid Arthritis
 10 women with Systemic Scleroderma } age-matched to FM

Method Observation of microcirculation by intravital capillary microscopy and laser-Doppler fluxmetry

Result

- FM-patients had compared with healthy controls:
 - significantly fewer capillaries in nail fold (P < 0.001)
 - significantly more capillary dilatations in nail fold (P < 0.05)
 - significantly more irregular capillary formations in nail fold (P < 0.01)
- Peripheral blood flow in FM patients was much less than in healthy controls (P < 0.001), but did not differ from that of Systemic Scleroderma patients (P = 0.73)

„The data suggest that functional disturbances of microcirculation are present in FM patients and that morphological abnormalities may also influence their microcirculation.“



Prospective Case-Control Study

Patients 25 patients (59, 50-70 years) with Fibromyalgia (FM), diagnosed according to 1990 ACR-criteria
10 patients (50, 39-75 years) with monopolar Depression without pain
control group: 55 healthy subjects matched for age and gender related to FM-group

Method quantification: intradermal nerve fibre density in skin punch biopsies of lower leg and upper thigh
examination: small fibre function by quantitat. sensory testing and pain-related evoked potentials

Result FM-patients compared with healthy controls:

- signif. **reduced total nerve fibres in skin** biopsies at lower leg and upper thigh (P < 0.001)
- signif. **increased neuropathic pain** (P < 0.001)
- signif. **impaired small fibre function** (P < 0.001)
with increased cold and warm detection thresholds
- signif. **reduced amplitudes of pain-related evoked potentials** (P < 0.001)
upon stimulation of face, hands and feet

„All three methods used (in this study) support the concept of impaired small fiber function in patients with fibromyalgia syndrome, **pointing towards a neuropathic nature of pain in fibromyalgia syndrome.**“

Our Hypothesis for the Cause of Fibromyalgia Syndrome



By living poor in exercise,
which is typical for the living style
of western industrial countries today,
the degeneration of microcirculation
is accelerated as one gets older.

abnormality of
microcirculation

[Morf S, et al. Arthritis Res Ther 2005]

Consequence

The more and more reduced supply
of the intercapillary region generates
a pathological milieu in the tissues.
Hence, also the small fibers degenerate
and some die off. Probably in this phase
before they die off they signalize pain.

small fiber
pathology

[Üceyler N, et al. Brain 2013]

2016



Message

A healthy microcirculation serves as **disease prevention** by securing of a healthy milieu in the intercapillary region.

by

- a proper supply of all cells and tissues with H_2O , O_2 , nutrients, immune cells, etc. but also
- a proper disposal of metabolic end products.

A healthy microcirculation is essential, to guide the humans healthy through the life until their old age.

The broad **action spectrum of whole-body hyperthermia**, based on sunlike heat radiation, can be a helpful instrument in the orchestra of the future Integrative Medicine.

www.iratherm.de

Thanks