Bioresonance therapy for allergies, atopic dermatitis, non-organic gastrointestinal complaints, pain and rheumatic diseases

Systematic Review



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Projektleitung:Dr. Claudia WildProjektbearbeitung:Katharina Hintringer, BA

#### CONTACT INFORMATION

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#### Responsible for Contents:



Ludwig Boltzmann Institute of Health Technology Assessment (LBI-HTA) Garnisongasse 7/20, A-1090 Vienna http://hta.lbg.ac.at/

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### Table of Contents

Тε	able of Contents	3
1	<ul> <li>Bioresonance therapy for allergy, atopic dermatitis, non-organic gastrointestinal complaints, pain and rheumatic diseases</li> <li>1.1 Background</li> <li>1.2 Description of treatment</li> <li>1.3 Indication and therapeutic aim</li> <li>1.4 Treatment costs</li> </ul>	5 5 6
2	Literature search and selection	7 7 8
3	Assessment of the quality of the studies	11
4	Data extraction         4.1       Presentation of the study results         4.2       Efficacy         4.2.1       Efficacy of bioresonance therapy in diagnosis and treatment of allergy         4.2.2       Efficacy of bioresonance therapy in atopic dermatitis         4.2.3       Efficacy of bioresonance therapy in non-organic gastrointestinal complaints         4.2.4       Efficacy of bioresonance therapy in rheumatic diseases.         4.2.5       Efficacy of bioresonance therapy in chronic low back pain         4.3       Safety	11 16 16 16 17 17 17
5	Strength of the Evidence	19
6 7	BICOM – commissioned report Discussion and Conclusion	
8	References	25

#### Figures

Figure 2.4-1: Depiction of the selection process (QUORUM tree)	Figure 2.4-1: Depiction of	the selection process	(QUORUM tree)		9
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#### Tables

Table 2.2-1: Inclusion criteria	7
Table 4.1-1: Study results	12
Table 5-1: Evidence profile of bioresonance therapy	20

## Bioresonance therapy for allergy, atopic dermatitis, non-organic gastrointestinal complaints, pain and rheumatic diseases

#### 1.1 Background

Bioresonance therapy was developed in the 1970's by the physician Franz Morell in cooperation with the electrical engineer Erich Rasche. Bioresonance therapy (BRT), or also called biophysical information therapy (BIT) derives from the electro-dermal testing according to Voll. BRT, as an alternative medical method is used for diagnosis and treatment of several diseases like allergy, acute or chronic pain, rheumatic diseases and psychosomatic disorders [1].

BRT is based on the theory that bioelectro-magnetic fields exist, which cause oscillations and waves at a low frequency [2]. Furthermore, it is estimated that these oscillations and waves are part of the information transmitting system within the human body [3]. Only hypothetical explanations exist for these physical and physiological interactions.

According to the proponents of the theory, the main purpose of BRT is to identify pathological waves within the human body and to give a strong impulse to spontaneous healing energies of the body for self-regulation [2]. BRT is based on the assumption that atopic diseases disturb the normal electromagnetic fields of the body and that, through application of BRT/ BIT, these disturbances can be reversed [2].

However, sceptics say that BRT is pure placebo, and that any effect must be caused by placebo or other non-specific effects [2, 4].

#### 1.2 Description of treatment

During the therapy there is a direct connection via two electrodes between the BRT apparatus and the patient. Depending on the purpose of the therapy different forms of electrodes like cylinder, container, ball etc. are used. One of those two electrodes serves as the inline-electrode (or brass-electrode) which takes up waves and oscillations from one part of the body and transmits them to the apparatus. Within the BRT machine there is a so-called "separator" which analyses the information from the brass-electrode and distinguishes supposedly between healthy and pathological waves. Then the separator reverses or "corrects" the pathological waves and oscillations into healthy ones and then they are transmitted back to the body via the secondelectrode, the "exit-electrode". Usually the electrodes are connected with the extremities of the patient – either left or right side for the brass-electrode and the other one for the exit-electrode.

The most widely used "bioresonance apparatuses" are the commercially available BICOM, MORA or Vegaselect machines [3].

Besides therapy, BRT is also used for diagnostic purposes, especially for diagnosis of allergies. There are up to 600 different allergens available for aldeveloped in the 70's

based on the thesis that BRT gives impulses to spontaneous healing

BRT is supported by apparatus that reverses/"corrects" pathological waves to healthy waves

for therapy or diagnosis

lergy-testing. These allergens are either as biological active substances in ampoules or as software, where the information of the biological substances is digitally saved – also called electronic homeopathy [5] – obtainable [4]. The diagnostic procedure is similar to the therapy. Usually a cylindrical brass container electrode (inline electrode) is used to capture magnetic waves which are allegedly produced by allergens or other substances which might cause atopy and are then transferred through the BRT apparatus into the human body [2-3, 5].

#### 1.3 Indication and therapeutic aim

allergy, atopic dermatitis, non-organic gastrointestinal complaints, pain and rheumatic diseases The indications covered in this review are pain, rheumatic diseases, atopic dermatitis, non-organic gastrointestinal complaints and allergies.

The therapeutic aim is the alleviation or cure of these conditions.

#### 1.4 Treatment costs

costs not reported

The costs of bioresonance treatment and diagnosis are not reported anywhere in the literature included in this review.

#### 2 Literature search and selection

#### 2.1 PICO question

Is bioresonance therapy effective in reducing pain, healing rheumatic diseases, atopic dermatitis and allergies and in improving non-organic gastrointestinal complaints, in comparison to placebo or standard therapy?

Is bioresonance therapy safe?

BRT effective in comparison to placebo or standard

#### 2.2 Inclusion criteria

Table	2.2-1:	Inclusion	criteria
1 4010	2.2 1.	menuoron	cincina

Population	Patients with pain.		
	Patients with rheumatic diseases.		
	Patients with non-organic gastrointestinal complaints.		
	Patients with allergies.		
	Patients with atopic derma- titis.		
Intervention	Bioresonance therapy and/ or diag- nosis.		
Comparison	Placebo or standard therapy.		
Outcomes	Reducing and healing:		
	😂 Allergy		
	Atopic dermatitis		
	Non-organic gastrointesti- nal complaints		
	😂 Pain		
	Rheumatic diseases.		
Study design	All prospective studies with a control group.		

#### 2.3 Literature search

search in 4 databases The systematic literature search was carried out on 08.01.2009 in the following databases:

- Medline via Ovid
- 🏶 Embase
- Cochrane library
- CRD

The search was limited to English and German language literature and covered the entire time span of the databases.

After removal of duplicates, 56 bibliographical references were available. The exact strategy can be requested at the LBI for HTA.

**57 references found, 6** By means of a hand search, 1 additional reference was identified, which raised the overall number of hits to 57.

The selection of the literature was carried out by two reviewers, independently of each other. Conflicting views were settled by means of discussion and consensus, or through the involvement of a third person.

#### 2.4 Literature selection

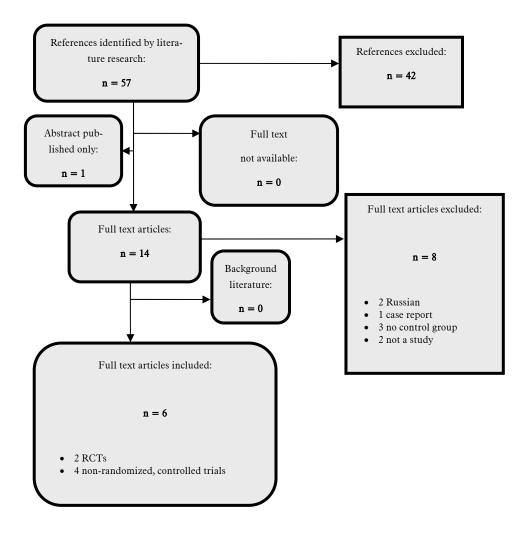


Figure 2.4-1: Depiction of the selection process (QUORUM tree)

#### 3 Assessment of the quality of the studies

The evaluation of the quality of the studies was carried out by two reviewers, independently of each other. Conflicting views were settled by means of discussion and consensus, or through the involvement of a third person. An exact list of the criteria that were used for the evaluation of the internal validity of the studies can be found in the internal manual of the LBI-HTA [6].

assessment of quality of studies carried out by two reviewers

#### 4 Data extraction

The extraction of data was carried out by one person. A second person checked the completeness and accuracy of the data.

#### 4.1 Presentation of the study results

Two RCTs and four non-randomized, controlled trials were included to answer the question as to whether BRT is effective in reducing or healing allergy, atopic dermatitis, non-organic gastrointestinal complaints, pain and rheumatic diseases and whether it is safe.

extraction of data by

one person

two RCTs and four non randomized trials included for review

#### Table 4.1-1: Study results

Author, Year, Ref- erence number	Kofler, H. et al. 1996 [4]	Schöni, M H. et al. 1997 [2]	Nienhaus, J. and Galle, M. 2006 [3]	Schuller, J. and Galle, M. 2007 [5]	Bonetti, M. et al. 2007 [7]	Arena, M. et al. 2008 [8]
Country	Innsbruck, Austria	Switzerland	Germany	Austria	Italy	Italy
Sponsor	Firma Medtronic, Friesenheim, Germany	supported by a grant provided by VOLG's program "best friends", Switzerland	not reported	not reported	not reported	not reported
Study design	non-randomized, con- trolled trial	RCT, sham-controlled, double-blind	RCT, placebo controlled, single-blind patients (pts)	non-randomized, pla- cebo controlled trial, single-blind (pts)	non-randomized con- trolled trial	non-randomized, con- trolled trial
Study quality	good	good	moderate	moderate	fair	fair
Number of patients	74 (intervention (I): 54, control (C): 20)	36 (l: 16, C: 16)	21 (l: 10, C: 10)	30 (not reported)	490 (l: 196, C: 294)	549 (A: 135, B: 139, C: 137, D: 139)
Lost to follow up	23	4	1	9	not reported	not reported
Study population	pts diagnosed with hay fever who refused treatment with a spe- cific hypo-sensitization therapy	children with atopic dermatitis	pts with non-organic gastro-intestinal com- plaints	pts with rheumatic dis- eases	pts with chronic uni- lateral or bilateral low back pain	pts with degenerative articular disease of the lumbar rachis with functional insuffi- ciency of the vertebral motor unit
Ø Patient age (years)	not reported	range 1.5-16.8	45.5 (range 13-82)	57.2 (range 40-82)	68 (range 55-87)	range 50-75
Indication for BRT	hay fever, pollinosis	atopic dermatitis	non-organic gastro- intestinal complaints	rheumatic disease	chronic low back pain	chronic low back pain
Intervention	biophysical allergy treatment with MORA bioresonance apparatus	supplementary to con- ventional medication 2 treatment sessions weekly for at least 4 weeks with bioreso- nance apparatus BICOM II	supplementary to con- ventional medication treatment with MORA bioresonance apparatus	treatment with MORA bioresonance apparatus	4 weekly paraverte- bral injections (10 cc of O <sub>2</sub> -O <sub>3</sub> gas mixture at 25 μg/ml; outpa- tient). BRT was given - supplementary - the month after infiltra- tion	comparison of 4 com- binations of interven- tions in back pain: A. TENS electro-sti- mulation and psycho- somatic postural re- habilitation B. magneto-therapy of

Author, Year, Ref- erence number	Kofler, H. et al. 1996 [4]	Schöni, M H. et al. 1997 [2]	Nienhaus, J. and Galle, M. 2006 [3]	Schuller, J. and Galle, M. 2007 [5]	Bonetti, M. et al. 2007 [7]	Arena, M. et al. 2008 [8]
Control	placebo	placebo	placebo	placebo	4 weekly paraverte- bral injections (10 cc of O <sub>2</sub> -O <sub>3</sub> gas mixture at 25 μg/ml; outpa- tient) only	bioresonance, TENS electro-stimulation and psychosomatic postural rehabilitation C. percutaneous paravertebral infiltra- tion of O <sub>2</sub> -O <sub>3</sub> , TENS electro-stimulation, psychosomatics pos- tural rehabilitation D. percutaneous paravertebral infiltra- tion of O <sub>2</sub> -O <sub>3</sub> , TENS electro- stimulation, psychosomatic pos- tural rehabilitation, magneto-therapy of bioresonance
Duration of treat- ment	4-6 weeks	4 weeks	3-6 weeks (6 treatment sessions per patient; 1-2 per week)	placebo: 2 weeks intervention: 4 weeks	18 months	11 weeks (15 sessions each — first eight ses- sions had a twice weekly schedule and weekly for the follow- ing 7 sessions
Main outcome measures	congruence of conven- tional allergological di- agnostic and diagnostic with bioresonance; rhinomanometry and nasal provocation tests; individual calendar of complaints (duration of complaints in eyes, nose, bronchi)	short term: clinical and skin scores (skin lesions/ Costa score/ itching/ pruritus score, sleep quality/ sleep score), blood cell activation marker	pts' and physicians' es- timation of the intensity and frequency of gastro- intestinal disorders; ex- amination results re- corded by the physician: stomach pain by palpa- tion, meteorism by per- cussion and intestinal noise by auscultation as- sessed pre and post treatment.	EAP(electro acupunc- ture)-40 value, subjec- tive/ perceived state of health, biochemical, physicochemical cellular parameters of blood	modified MacNab Method: <i>Excellent:</i> resolution of pain and return to regular daily activity before pain onset <i>good or satisfactory:</i> more than 50% reduc- tion of pain <i>mediocre or poor:</i> par- tial reduction of pain below 70%	scores of the VAS (Vis- ual Analogic Scale) – pain evaluation scale (o-10; o = "no pain" and 10 = "the utmost pain") Assessment times: prior/ after treatment, after 11 weeks of treatment & 1, 6 and 12 months, respec- tively.

Author, Year, Ref-	Kofler, H. et al. 1996 [4]	Schöni, M H. et al. 1997	Nienhaus, J. and Galle,	Schuller, J. and Galle, M.	Bonetti, M. et al. 2007	Arena, M. et al. 2008
erence number		[2]	M. 2006 [3]	2007 [5]	[7]	[8]
erence number Results	congruence only in 22%; repeated tests of rhino- manometry and nasal provocation could not demonstrate any bene- ficial effect compared to placebo	[2] change between scores prior treatment and af- ter 4 weeks (total Costa Score): 1: 39.8 $\pm$ 14.6 $\rightarrow$ 27.3 $\pm$ 13.1; C: 35.3 $\pm$ 16.4 $\rightarrow$ 26.6 $\pm$ 15.7; mean change 1: 12.5 $\pm$ 12.6; C: 6.7 $\pm$ 8.2. none of the differences between the groups was significant	M. 2006 [3] prior/ after treatment: significant changes in both groups (1:C) in all outcomes intensity/ frequency (pts' estimation) 1: 4.30 $\pm$ 0.30 $\rightarrow$ 2.20 $\pm$ 1.05/ 4.40 $\pm$ 0.43 $\rightarrow$ 2.50 $\pm$ 0.94 vs. C: 3.70 $\pm$ 0.59 $\rightarrow$ 3.40 $\pm$ 0.52/ 4.20 $\pm$ 0.64 $\rightarrow$ 3.80 $\pm$ 0.49 (statistically significant changes between groups, Mann-Whitney- U-Test, p<0.05); intensity/ frequency (physicians' estimation) 1: 3.30 $\pm$ 0.30 $\rightarrow$ 1.60 $\pm$ 0.78/ 3.20 $\pm$ 0.49 $\rightarrow$ 1.70 $\pm$ 0.83 vs. C: 3.60 $\pm$ 0.32 $\rightarrow$ 3.30 $\pm$ 0.42/ 3.70 $\pm$ 0.42 $\rightarrow$ 3.60 $\pm$ 0.32 (statistically significant changes between groups, Mann-Whitney- U-Test, p<0.01); significant changes also for stomach pain & me-	2007 [5] EAP-changes prior/ after treatment: 1: mean change of EAP- 40 -6.2 SkT (significant; p<0.05), C: -1.2 SkT (not signifi- cant; p<0.05) improvements in subjec- tive outcomes	[7] I: 60%/ 21% (excel- lent or good) vs. C: 52%/ 21% (excel- lent or good) I: after period of im- provement 21% par- tial return of pain	[8] week 11: A-B: group A had more improvements than group B; B-C: group C main- tained better thera- peutic effects com- pared to group B; C-D: group C and D are closely compara- ble; singular effects of BRT were not meas- ured
Adverse events	not reported	none	teorism, but not for in- testinal complaints none	not reported	symptoms worsened	not reported

Author, Year, Ref-	Kofler, H. et al. 1996 [4]	Schöni, M H. et al. 1997	Nienhaus, J. and Galle,	Schuller, J. and Galle, M.	Bonetti, M. et al. 2007	Arena, M. et al. 2008
erence number		[2]	M. 2006 [3]	2007 [5]	[7]	[8]
Conclusion of au-	no significant differ-	scientific background of	BRT has significant	limited number of pts	preliminary findings	the multi-disciplinary
thors	ences between interven-	BRT seems to be rather	mean effects, but big	involved, intervention	show association with	approach showed im-
	tion-group and placebo-	shaky, for medical and	variances in individuals'	and control group dif-	BRT, for pts with con-	provements in nearly
	group were found; the	ethical reasons, not pos-	reactions: pts react indi-	fered for ethical reasons,	traindications to drug	all groups; the inte-
	mean length of hay fe-	sible to renounce con-	vidually to an "all or	different length of	treatment or in addi-	gration of TENS, bio-
	ver complaints were less	ventional medicine, only	nothing" principle; re-	treatment, therefore	tion to medication,	resonance, postural
	in the placebo-group;	additional, no significant	sults of this trial confirm	placebo effect likely to	since no side effects	rehabilitation guaran-
	the trial gives evidence	influence on atopic	results of other trials	be underestimated, sin-	are likely to occur	tees a better mainte-
	that bioresonance is	dermatitis, no side ef-	when this effect (big	gle-blinded placebo ad-	caused by BRT	nance over time
	NOT suitable for diag-	fects, but unethical to	variances in reactions)	ministration a "subtle		
	nosis or treatment of	promise success	were observed	form of suggestion" can		
	pollinosis; the potential			not be out ruled; objec-		
	for placebo-effects is			tivity, reliability and va-		
	substantial; these pla-			lidity of EAP is under		
	cebo effects can be used			discussion		
	– on an individual basis –					
	as reasonable accompa-					
	nying measures					

Fair: placebo effect and reporting bias likely

Moderate: some trial data not reported, outcome measures imprecise/ subjective

Good: all patient data pre-/ post treatment reported, significant bias unlikely

#### 4.2 Efficacy

# **5 indication groups** The populations that can be treated with BRT/ BIT vary. This is reflected in the very different indications treated in the trials included in this review. In the following paragraphs the efficacy of BRT/ BIT is evaluated for all of the 5 indications listed in the PICO question – allergy, atopic dermatitis, non-organic gastrointestinal complaints, rheumatic diseases and chronic low back pain. Altogether, the trials included 1210 patients.

#### 4.2.1 Efficacy of bioresonance therapy in diagnosis and treatment of allergy

allergies

diagnosis in only 22% congruence with conventional test

no difference prior/ after therapy, nor between groups

**BRT not effective** 

One [4] non-randomized, controlled-trial of good quality (n=74) reported on the efficacy of bioresonance therapy compared to standard care in diagnosis and treatment of allergy. Pollinosis was the type of allergy of interest in this placebo-controlled trial. Kofler et al. (1996) observed that only 22% of the results of conventional allergic diagnostic and diagnostic with bioresonance match. To measure the efficacy of bioresonance therapy rhinomanometry and nasal provocation tests were used. After the bioresonance treatment neither a significant difference to the start of the therapy nor between the experimental and the placebo group could be found considering these outcomes.

Based on the big variances within the results Kofler et al. (1996) concluded that bioresonance therapy is not superior to placebo and therefore not adequate for diagnosis and treatment of allergic illnesses. Although, the methodological quality of the trial is good the strength of evidence is rated moderate, due to the small number of trials.

## 4.2.2 Efficacy of bioresonance therapy in atopic dermatitis

atopic dermatitis in One RCT children nance the controllec proved sig

mean: no difference; wide ranges between individuals

BRT only additional

small number of patients One RCT [2] of good quality (n=36) reported on the efficacy of bioresonance therapy in children with atopic dermatitis. The trial was shamcontrolled and double-blind. Whereas the skin lesions (costa score) improved significantly in both groups after 36 days, Schöni et al. (1997) found no significant difference between the experimental group and the placebo group. Similarly, the analysis of specific blood cell activation markers after the treatment period and the results of the questionnaire to assess long-term clinical outcomes 8 month after the therapy showed no significant changes in both groups.

Further RCTs of good quality are required to establish the effect of BRT in atopic dermatitis, thus, although the quality of the study is good, the strength of evidence is rated moderate, due to small number of trials.

#### 4.2.3 Efficacy of bioresonance therapy in nonorganic gastrointestinal complaints

One RCT [3] of moderate quality (n=21) reported on the efficacy of bioresonance therapy in patients with non-organic gastrointestinal complaints. The trial was placebo-controlled and patients were blinded. In six out of seven main outcome parameters significant changes were observed in both groups prior/ after bioresonance therapy. The mean differences between experimental and placebo group were statistically significant.

However, considerable variances within the intervention group were observed, which reflects the results of other trials that patients react very individually on the therapy.

Further RCTs of good quality are needed to determine, whether BRT is effective in the treatment of non-organic gastrointestinal complaints. The strength of evidence is low, due to the small number of trials.

## 4.2.4 Efficacy of bioresonance therapy in rheumatic diseases

One [5] non-randomized, placebo-controlled, single-blind trial of moderate quality (n=30) reported on the efficacy of bioresonance therapy in rheumatic diseases. The main outcome measure was the EAP (electro acupuncture)-40 value. Schuller & Galle (2007) found a significant improvement of the EAP-40 value in the intervention group (mean change -6.2 SkT) but not in the control group (-1.2 SkT).

Although, the size of effect was high (0.69; possible values: 0-1) considerable variances between patients in the intervention group led to a very low stability (0.16; possible values: 0-1) of the results within the group, which supports the findings of Nienhaus & Galle (2006). However, Schuller & Galle (2007) concluded that BRT is effective in the treatment of rheumatic diseases.

Due to flaws in the methodological quality, like different duration of therapy between placebo and experimental group of the study, results cannot be generalised. The strength of evidence is low, thus further RCTs of good quality are necessary to support the findings of this trial.

## 4.2.5 Efficacy of bioresonance therapy in chronic low back pain

Two [7-8] non-randomized, controlled-trials, both of fair quality (n=1039) and both conducted in Italy reported on the efficacy of BRT in chronic low back pain. Bonetti et al. (2007) and Arena et al. (2008) found the addition of BRT to therapy of chronic low back pain more effective than pain therapy alone.

Bonetti et al. (2007) showed that the combination therapy of  $O_2$ - $O_3$  paravertebral infiltration and BRT (experimental group) is more effective in treating chronic low back pain (81% excellent or good) compared to the control group (only oxygen-ozone therapy; 73% excellent or good).

non-organic gastrointestinal complaints

significant changes in both groups, but also between groups wide range between individual reactions

10 patients received BRT

rheumatic diseases

significant differences between the groups

wide range between individual reactions

small number of patients – strength of evidence is low

chronic low back pain

BRT shows additional effects but difference of questionable clinical relevance Arena et al. (2008) compared four different combinations of treatment options: percutaneous paravertebral infiltration of  $O_2$ - $O_3$ , magneto-therapy of bioresonance (BRT), transcutaneous electrical nerve stimulation (TENS) and psychosomatic postural rehabilitation. Results of group D (combination therapy of all four treatment options – including BRT) were closely comparable to the results of group C (not including BRT), which were both significantly better than the results of group A and group B. Twelve month after the therapy the increasing pain was evaluated, thus group D (36.63% anyvague; 27.72% considerable-grave) was superior to group C (28.57%; 43.88% respectively).

The strength of evidence is low, thus further RCTs of good quality are needed to support the findings of Arena et al. (2008) and Bonetti et al. (2007).

#### 4.3 Safety

side effects are not mentioned as did not occur Three [4-5, 8] out of the six included trials failed to make reference to the safety of BRT and two mentioned that no serious side effects occurred [2-3]. Bonetti et al. (2007) reported that the bioresonance therapy was generally well tolerated, whereas in nine patients symptoms worsened. Therefore they reduced the intensity of the treatment and concluded that the principle greater intensity results in greater efficacy is not always applicable in BRT.

According to Nienhaus et al. (2006) up to now no serious side effects were reported in published human trials [3].

#### 5 Strength of the Evidence

The GRADE system is used to evaluate the strength of the evidence. GRADE uses the following classifications and definitions to evaluate the strength of the evidence (see [9]).

GRADE system

- High: further research is very unlikely to change our confidence in the estimate of effect
- Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
- Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
- Very low: any estimate of effect is very uncertain

#### Table 5-1: Evidence profile of bioresonance therapy

Number of studies/ patients	Design	Methodological quality	Consistency of re- sults	Directness	Size of effect	Other modi- ficatory fac- tors	Strength of the collective evidence
		·	Outcome: a	llergy – pollino	sis (hay fever)		
1/74	non-randomized, controlled trial	good	not applicable <sup>*</sup>	yes	congruence of diagnosis in 22%; as the therapy is based on the diagnosis, the use of BRT cannot be effective	none	moderate
			Outcome:	atopic dermati	tis in children		
1/36	RCT, sham- controlled, double- blind	good	not applicable	yes	9.6 ± 10.8 (Wilcoxon signed rank test; p<0.001) mean reduction in Costa score, no significant dif- ferences between treatment and placebo	none	moderate
			Outcome: non-o	organic gastroii	ntestinal problems		
1/21	RCT, placebo- controlled, single- blind (pts)	moderate	not applicable	yes	significant changes prior/ after treatment in both groups (pts' estimation 1: 4.30 $\pm$ 0.30 $\rightarrow$ 2.20 $\pm$ 1.05 vs. C: 3.7 $\pm$ 0.59 $\rightarrow$ 3.40 $\pm$ 0.52); statistically (Mann-Whitney-U-Test) significant difference be- tween groups, but of questionable clinical rele- vance	none	low
			Outco	ome: rheumatio	c disease		
1/30	non-randomized, placebo-controlled trial, single-blind	moderate	not applicable	yes	I: -6.2 SkT mean reduction with very low stability between pts (range 3.8-18.4 SkT); statistically sig- nificant (p<0.05)	none	low
	(pts)				C: -1.2 SkT mean reduction; statistically not signifi- cant (p<0.05)		
			Outcon	ne: chronic low	back pain		
2/1039	non-randomized, controlled trial	fair	yes	yes	BRT in addition to other non-drug therapies shows additional benefit	none	low

\*applicable only if more than one study

#### BICOM – commissioned report 6

Additionally to the in Chapter 3 analysed trials we received two reports [10-11] summarizing trials evaluating the effectiveness of BRT. Most of the included trials are published in Chinese language, were a conference presentation or a research report in a language other than German or English, which didn't make it possible for us to critically appraise the originally published study reports.

Both reports on the clinical effectiveness of BRT were conducted as a commissioned work from Regumed GmbH, the producer of the BICOM bioresonance apparatus, by the biometrician Dr. Volker W. Ralphs (2005) and V. W. Ralphs in cooperation with the physician Dr. med. Andreas Rozehnal (2006). Their analysis included 15 trials provided to them by the company Regumed. They graded the "Level of evidence" according to the scheme of the American Heart Association (modified according to Dick 2000).

As our systematic review only included prospective and controlled trials we will only summarize the result of studies graded "evidence level 1-3" (8 evidence levels; 1=highest, 8=lowest).

Thus, we took the following five trials into consideration:

- \* Yang J and Zhang L., 2004 [12]. They examined whether treatment asthma in children of asthmatic patients with BRT is superior to conventional treatment with corticoids and antiallergics. Therefore, they designed a prospective and controlled trial with 300 patients (children) (I: 213; small effects in C: 87) and compared the outcomes differentiating between "healing", "improvement", "effective", "not effective" after six month. Whereas 43.8% of the intervention group reported "healing", 42.5% of the control group did so; "improvement" (I: 31.9%; C: 19.5%); "effective" (I: 11%; C: 13.8%) and "not effective" (I: 13.3%; C: 24.2%).
- Huang S. et al., 2005 [13]. Huang S. et al. conducted a RCT to find out whether BRT is effective in treating children with allergic asthma and allergic rhinitis. The 181 patients recruited were divided in 3 groups: (1) BICOM bioresonance treatment for children with first diagnosis of the disease, (2) BICOM bioresonance treatment in children who did not respond to prior medical treatment and (3, control group) children with first diagnosis, no prior treatment and medical treatment with glucocorticoids and antihistamine. After six month they evaluated the effectiveness with a threepoint-scale: "considerably effective", "effective" and "ineffective". The clinical effectiveness of BRT in allergic rhinitis (considerably effective and effective) in group 1 (85.4%) and group 2 (81.9%) is not significantly better than conventional medical treatment (group 3: 78.1%) (p>0.05); comparable results for allergic asthma – (1) 86.4%, (2) 78.1% and (3) 76%. Although the authors conclude that this therapy is considerably suitable for patients with chronic disease because they are equally effective as conventional therapy and do not cause severe adverse effects like some medications.
- Machowinski R. & Gerlach I., 1996 [14]. They examined whether **\***\* BRT is clinically effective in treating patients with impairment of hepatocytes in comparison not to do anything. According to the

additional source: **BICOM** commissioned report including mostly Chinese publications

only two controlled

trials

improvement

asthma/ rhinitis

equally effective to conventional therapy

impairment of hepatocytes

significant differences between groups – no data available

overload syndrome in top athletes

> BRT superior to ultrasound therapy

BICOM diagnosis vs. Prick-test

> specificity and sensitivity

BRT effective in treating allergy, impairment of hepatocytes and overload syndrome commissioned report differences between groups were statistically significant and clinically relevant. Unfortunately, no data to support these findings are provided in the commissioned report.

Papez B. and Barovic, n.a.[15]. According to Papez and Barovic's research paper the purpose of the trial was to examine whether treatment with BRT (I: 12 pts) is superior to ultrasound therapy (C: 12 pts) in overload syndrome in top athletes. The main clinical outcome measure was the VAS-pain score (0-10). The means of the intervention group improved significantly prior/ after therapy. Further, BRT was statistically significant and clinically relevant superior to ultrasound therapy (p<0.05).</p>

Giannazo E. et al., 2002 [16]. This trial was conducted to validate the allergy-diagnosis procedure with the BICOM apparatus compared to the standard test – the "Prick-test". Each of the 31 patients included was tested in the same four indications with both methods. The sensitivity of the BICOM-test was found to be 0.84 (95% CI: 0.72-0.91) and the specificity was 0.66 (95% CI: 0.53-0.78). Sensitivity and specificity of the "Prick-test" were not reported. Giannazo et al. (2002) concluded that BRT diagnosis is clinically relevant because it is superior to "guessing".

Due to considerable methodological flaws two of the provided trials were excluded from the summary of the evidence by the authors. Ralphs and Rozhenal (2006) concluded based on the other six trials – Huang S. et al. (2005) level 1-2, Yang J. and Zhang L. (2004) level 2-3 and the remaining 4 were graded with level 5 – that these findings clearly show that BRT is effective in allergy. Further, Ralphs (2005) concluded that BRT is also clinically effective in treating impairment of hepatocytes and top athletes with overload syndrome.

#### 7 Discussion and Conclusion

The evidence of Bioresonance therapy is very heterogeneous. Overall, trial results show big placebo effects and big variances between patients. Therefore, authors of the trials included suggest that BRT should only be provided additionally to standard of care and after detailed education on effectiveness of BRT of the patient.

As therapy bases on the right diagnosis, BRT is not suitable for diagnosis and not for therapy of allergy in patients with pollinosis. The placebo-effect in the treatment of children with atopic dermatitis is estimated high as treatment and placebo group show significant improvements while the differences between the groups were not statistically significant. Although the difference between means of placebo and intervention group was statistically significant in non-organic gastrointestinal complaints and in rheumatic diseases, high placebo-effects are assumed due to wide ranges between individual reactions. Using BRT in combination with other treatment options for chronic low back pain showed additional effect in the improvement of symptoms.

Finally, providing BRT to patients and promising unforeseeable results is also an ethical question. The wide possible variances between individuals have to be communicated to the patients. Thus, further RCTs of good quality are needed to clarify how BRT works and in which indications it is effective. heterogeneous evidence

high placebo effects and big variances between individuals

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