

## **Author's response to reviews**

**Title:** Health costs in anthroposophic therapy users: a two-year prospective cohort study

### **Authors:**

Harald J Hamre ([harald.hamre@ifaemm.de](mailto:harald.hamre@ifaemm.de))  
Claudia M Witt ([claudia.witt@charite.de](mailto:claudia.witt@charite.de))  
Anja Glockmann ([anja.glockmann@ifaemm.de](mailto:anja.glockmann@ifaemm.de))  
Renus Ziegler ([ziegler@hiscia.ch](mailto:ziegler@hiscia.ch))  
Stefan N Willich ([stefan.willich@charite.de](mailto:stefan.willich@charite.de))  
Helmut Kiene ([helmut.kiene@ifaemm.de](mailto:helmut.kiene@ifaemm.de))

**Version: 2 Date:** 19 April 2006

**Author's response to reviews:** see over

## MS: 1197590162945830 - Health costs in anthroposophic therapy users: a two-year prospective cohort study

### Response to comments from reviewers and from editorial team

<b>Reviewer Peter H. Canter</b>		
<b>Reviewer's comments</b>	<b>Our response</b>	<b>Manuscript changes</b>
The main limitation of the study is the lack of a control group which means that the health benefits mentioned in the introduction cannot be attributed with any confidence to the AM intervention...	We have nowhere in the manuscript attributed the health benefits to the AM intervention. We feel, however, that the reader of this cost analysis should have a minimum of information on clinical outcomes reported elsewhere.	See below.
... and also that the significance of the observed cost changes over the three years of the study cannot be assessed.	We agree that according to the design no conclusions about the cause of the cost changes can be made. It is possible, however, to assess possible causes. We have discussed five alternative explanations for the hospital reduction, which was the major determinant of cost changes: a) successful therapies, b) spontaneous clinical improvement, c) spontaneous reduction of hospitalisation rates, d) changes in health-care implementation in Germany, e) healthcare policy of AM general practitioners.	See below.
<b>Major Compulsory Revisions</b>		
1. The conclusion should be something like: "There was a reduction in costs in the second year but whether or not this was the result of the treatment given cannot be ascertained from the uncontrolled study design employed"	We are happy to revise our conclusion, but we do not find it appropriate to focus a conclusion section on what a study does not say, but rather on what a study, withstanding its limitation, says. We would like to refer to the conclusion section of a paper recently published in BMC Health Service Research, also with a pre-post design without comparison group ( <a href="http://www.biomedcentral.com/1472-6963/5/48">http://www.biomedcentral.com/1472-6963/5/48</a> ).	Revised conclusion with [added text] and (text shifted from end of discussion): "In patients starting anthroposophic therapies for chronic disease, costs did not increase in the first year, in spite of the intensified therapy. In the second year, a reduction of costs was observed. [This reduction was largely explained by a decrease of inpatient hospitalisation. Within the limits of a pre-post design], (our findings suggest that anthroposophic healthcare in Germany is not associated with a relevant increase in total health costs.)"
2. The discussion of strengths and limitations fails to adequately address the absence of a control group. It should explicitly state that this as a	We had a sentence stating that our design does not allow for comparative cost-effectiveness, but we see no problem in expanding this section.	We have inserted the following phrase: "A limitation of the study is the absence of a comparison group. We do not know if in similar patients in similar settings receiving conventional or no treatment,

<p>limitation to the study and spell out that similar or even lower costs might have been observed with conventional or no treatment.</p>		<p>costs would have increased, been stable, or been reduced.”</p>
<b>Minor Essential Revisions</b>		
<p>1. In abstract "reduced by -416 euros" is a double negative remove -. Also recurs at the end of the discussion</p>	<p>Logically, this criticism is correct. We had used the “-“ sign to promote clarity in the interpretation of the associated 95% confidence intervals (in abstract and also in the results section), but we realise this double negation can lead to ambiguity.</p>	<p>“reduced by -“ has been changed to “reduced by” in abstract, results, and discussion sections, and the corresponding 95% confidence intervals have been reversed as appropriate.</p>
<p>2. In methods exclusion criteria: the meaning of "&gt;30min for main diagnosis respectively" eludes me</p>	<p>We have modified this sentence to improve clarity.</p>	<p>“Exclusion criteria: previous art / eurythmy / rhythmical massage therapy / AM-related consultation ≥ 30 min for main diagnosis, respectively.” has been changed to “Exclusion criteria: previous AM therapy (art / eurythmy / rhythmical massage / AM-related consultation ≥ 30 min) for main diagnosis, respectively.</p>
<p>3. Data analysis. How can this be an intention to treat analysis if inclusion of data depended on obtaining at least 3 of 5 questionnaires and n=94 were excluded for this reason?</p>	<p>We used the “intention to treat analysis” concept in the narrow sense of “analysis of all patients referred to or starting AM therapies, regardless if they actually received their planned therapy”, analogous to e.g. Cochrane Handbook for Systematic Reviews of Interventions 4.2.5, paragraph 8.4.1., first criteria, first part. (E. g. 7% of patients referred to AM art, eurythmy or massage therapy did either not receive the planned therapy or therapy documentation is incomplete. These patients were included in the cost analysis if other eligibility criteria were fulfilled.)</p>	<p>“Data analysis followed the intention-to-treat-principle” has been changed to “Data analysis was performed on all patients fulfilling eligibility criteria”</p>
<p>4. Discuss the issue of health status determination by the AM physicians in a study designed to assess costs for a health insurance company</p>	<p>The reviewer is probably alluding to potential documentation bias by AM physicians with vested interests in AM therapy refunding within healthcare budgets. This was a serious concern when planning this open study, wherefore the study documentation by AM physicians was kept at a minimum (referral to non-AM-physicians was not feasible). See added discussion:</p>	<p>Added to discussion section: “Since patients were treated by AM physicians who could possibly have an interest in AM therapies having favourable outcomes, study data were largely collected by patients and not physicians. For this analysis, any bias affecting physician’s documentation would not affect outcomes (resource utilisation), since these outcomes were documented by patients. Also, physicians’ documentation of baseline health status (main and comorbid diagnoses) did not affect patient recruitment, since patients were enrolled regardless of diagnoses.”</p>

<b>Discretionary revisions</b>		
None		
<b>Reviewer Gene Feder</b>		
<b>Reviewer's comments</b>	<b>Our response</b>	<b>Manuscript changes</b>
None necessitating response		
<b>Major Compulsory Revisions</b>		
None		
<b>Minor Essential Revisions</b>		
1. Flow diagram of recruitment and follow up would be a better way of conveying that information than the paragraph on pp. 7&8	We have included a flow diagram with the categories "screened patients", "included patients", "not included patients", and "reasons for "non-inclusion". We would however advise against the solution suggested by this reviewer (full flow diagram presenting follow-up rates at each follow-up). The reason is that the inclusion criterion "patients must have three out of five follow-ups available" produces artificially inflated follow-up rates for included patients, which could be misleading to the readers. If the editor insists, we will of course provide such a flow diagram.	A flow diagram has been included (Figure 1) and the corresponding text in the results section shortened.
2a. I think the term "favourable" in relation to occupation is wrong. Why are some jobs more favourable than others?	The term "favourable" in relation to occupation referred to the average income of each occupational category, as alluded to in the methods section ("Sick-leave costs were calculated from national average gender-specific earnings for civil servants, salaried employees, and wage earners", see also Table 1, "sick leave"), in particular to the higher incomes of salaried employees vs. wage earners (year 2000: males 113 € vs. 80 € per day, females: 80 € vs. 59 €).	We have re-written this sentence: "Compared to the German population, patients had higher educational and occupational levels, had less daily alcohol consumers and regular smokers, and were less overweight; patients' socio-demographic status was similar to the population regarding low-income, living alone, severe disability status, and sport; and less favourable for work disability pension and sick-leave."
2b Also I don't understand the difference between wage earners and salaried employees (table 2)	These terms are the official English translations of the German terms "Arbeiter" (wage earners) and "Angestellte" (salaried employees), used by the Statistisches Bundesamt Deutschland (Federal Statistics Office Germany). See also 2a, above.	We have included the German terms "Beamter" (civil servants), "Arbeiter", and "Angestellte" in Table 2
<b>Discretionary revisions</b>		
None		
<b>Corrections unrelated to reviewers' / editors'</b>		

<b>comments</b>		
	We found a minor error in the methods section.	“(statutory health insurance: direct costs and sick-leave costs for first six weeks; employer: sick-leave costs beyond first six weeks)” has been corrected to “(employer: sick-leave costs for first six weeks; statutory health insurance: direct costs and sick-leave costs beyond first six weeks)”
	We found a minor error in the discussion section.	“This reduction of 0.08 days per two years corresponds to only 5% of the observed reduction of 1.78 days per two years in our study patients.” has been corrected to “This reduction of 0.11 days per two years corresponds to only 6% of the observed reduction of 1.78 days per two years in our study patients.”
<b>Editorial Team</b>		
<b>Requests</b>	<b>Our response</b>	<b>Manuscript changes</b>
The background section in your original abstract could be expanded to put the work into context	We have expanded the background sections of abstract and text.	Addition to abstract: “Anthroposophic therapies (counselling, special medication, art, eurythmy movement, and rhythmical massage) aim to stimulate long-term self-healing processes, which theoretically could lead to a reduction of healthcare use.”  Further addition to text (taken from the covering letter and referenced): “Complementary therapies are popular and extensively used. In Germany and Switzerland some complementary therapies are reimbursed within health care budgets. In these countries there has been a debate as to whether reimbursement of complementary therapies may lead to increased overall health expenditures [1].”
Please could you expand the conclusions section of your abstract...	We have done this.	Addition: “This reduction was largely explained by a decrease of inpatient hospitalisation. Within the limits of a pre-post design, study findings suggest that anthroposophic therapies are not associated with a relevant increase in total health costs.”
...and please structure your abstract according to the guidelines	We have checked the guidelines and believe the abstract now conforms to these.	
Could you also please go through the manuscript formatting checklist... and	We have done this.	

ensure that your revised manuscript conforms to all of the points.		
--	--	--