

**Anthroposophic Medicine  
and Clinical Research**  
*Past - Present - Future*

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# AM research: History

1920.. Pre-clinical and clinical studies  
1930.. according to contemporary standards

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1950.. Rebuilding AM in post-war Europe  
1960..

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1970.. Struggling with double-blind  
1980.. randomised trial paradigm

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1990.. RCTs, NRCTs, cohort studies  
2000.. Methodology, technical standards

# Research in AM settings

## Randomisation often rejected

- Ethical reasons
- Physician-patient-relationship disturbed
- Therapy preference

→ Slow recruitment into RCTs

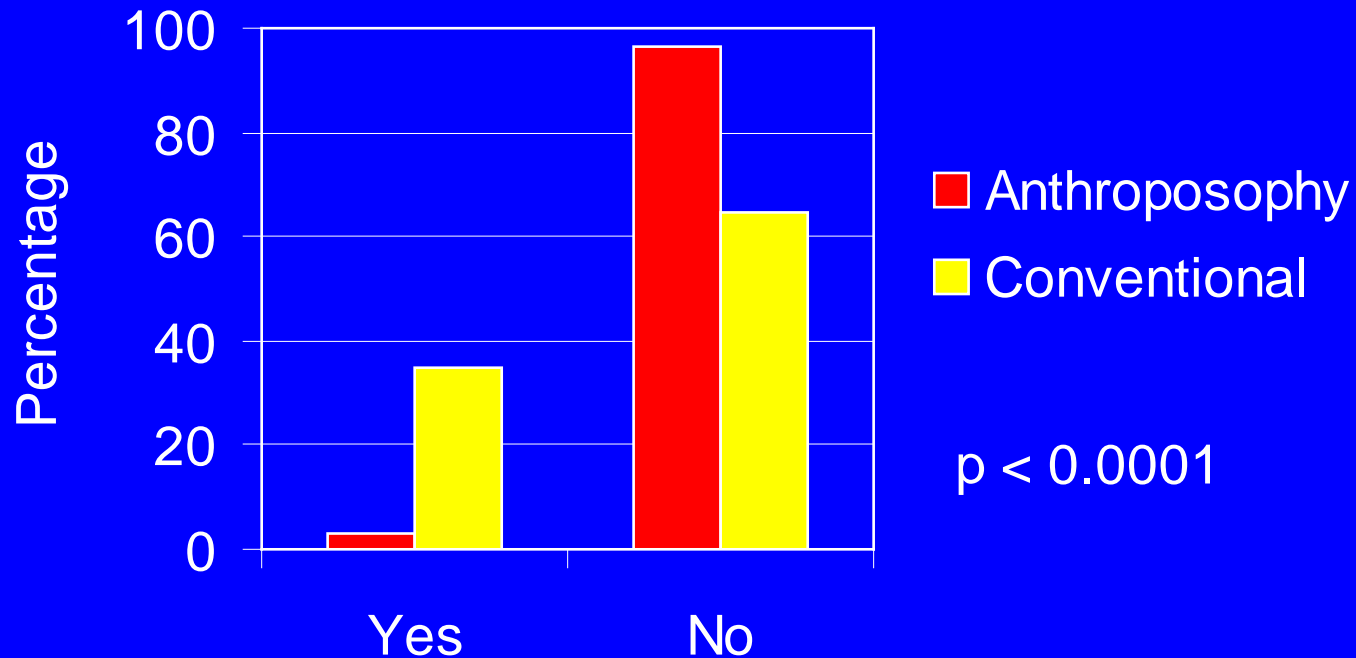
→ RCTs terminated prematurely

*Burkhardt G, Kienle G, Lancet 1978*

*Hamre HJ et al, Wien Klin Wochenschr 2005*

*Ziegler R, eCAM, 2007*

# “Is the patient willing to be randomised if treatment is part of a clinical trial?”



*Hamre HJ et al, Wien Klin Wochenschr 2005*

# Blinding in anthroposophic medication studies?

## Blinding is often unmasked

- E.g. local reactions from injections

*Rostock M et al, Forsch Komplementarmed 2004*

## Blinding can induce performance bias

- Cancer patients willing to participate in double-blind trials: worse outcome of AM therapy

*Grossarth-Maticek R et al, Altern Ther Health Med 2001*

# Anthroposophic medical products Distribution

> 2,000 products

> 7,000 concentrations / pack sizes

– 88%: <1,000 packs per year

*Hamre HJ et al, Drug Safety 2006*

Not enough money and manpower to conduct clinical trials for each product and concentration

# Therapy with AM products

## Standardised

- One AM product for one indication

## Individualised

- Tailored to individual needs
- One or several AM products  
+ artistic or physical AM therapies

*Hamre HJ et al, Drug Design, Development and Therapy 2008*

# **Health Technology Assessment Report on AM**

**Commissioned by the  
Swiss Federal Social Insurance Office**

***Anthroposophic Medicine***

***Effectiveness, Utility, Costs, Safety***

***Kienle GS, Kiene H, Albonico HU***

***Schattauer Verlag 2006, 360 pp.***

# HTA report on AM

## 188 clinical studies of AM products

- 18 randomised controlled
- 20 non-randomised controlled
- 150 single-arm cohorts

*High external validity*  
*Variable study quality*

# HTA report on AM Results

- 179 studies: positive result for AM
- 8 studies: no benefit
- 1 study: negative trend

*Kienle GS et al, Anthroposophic Medicine, 2006*

# Study example: Individualised therapy for acute respiratory and ear infections

- Conducted in A, D, NL, UK, US
- 1,016 patients from 36 primary care practices
- Chief complaint: cough, ear pain, rhinorrhoea, sore throat, or sinus pain
- Seeing anthroposophic or conventional physicians

*Hamre HJ et al, Wien Klin Wochenschr 2005*

# Respiratory infections study

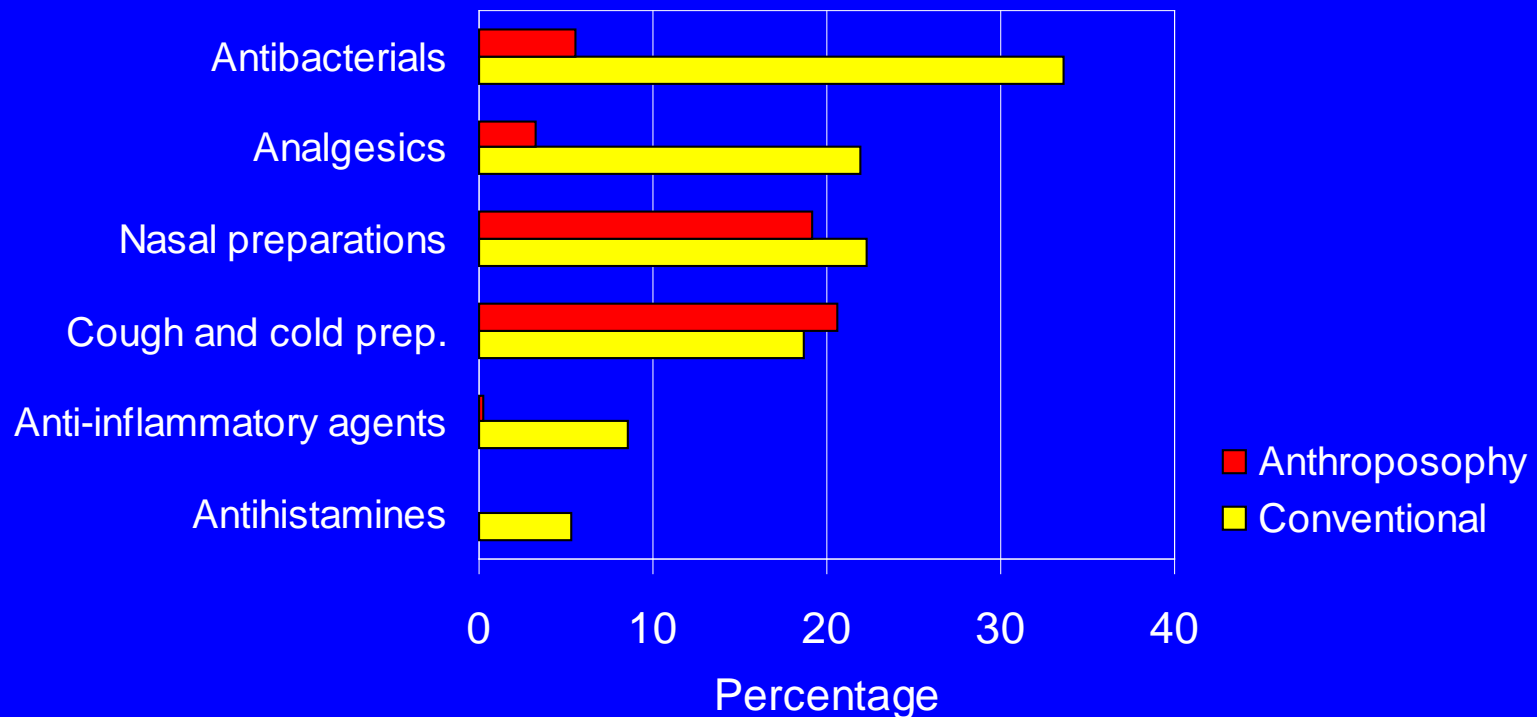
## Treatment

- Treatment at physicians' discretion
- Highly individualised therapy:
  - 265 different AM products prescribed
- AM vs. conventional treatment evaluated as whole systems

*Hamre HJ et al, Wien Klin Wochenschr 2005*

# Respiratory infections study

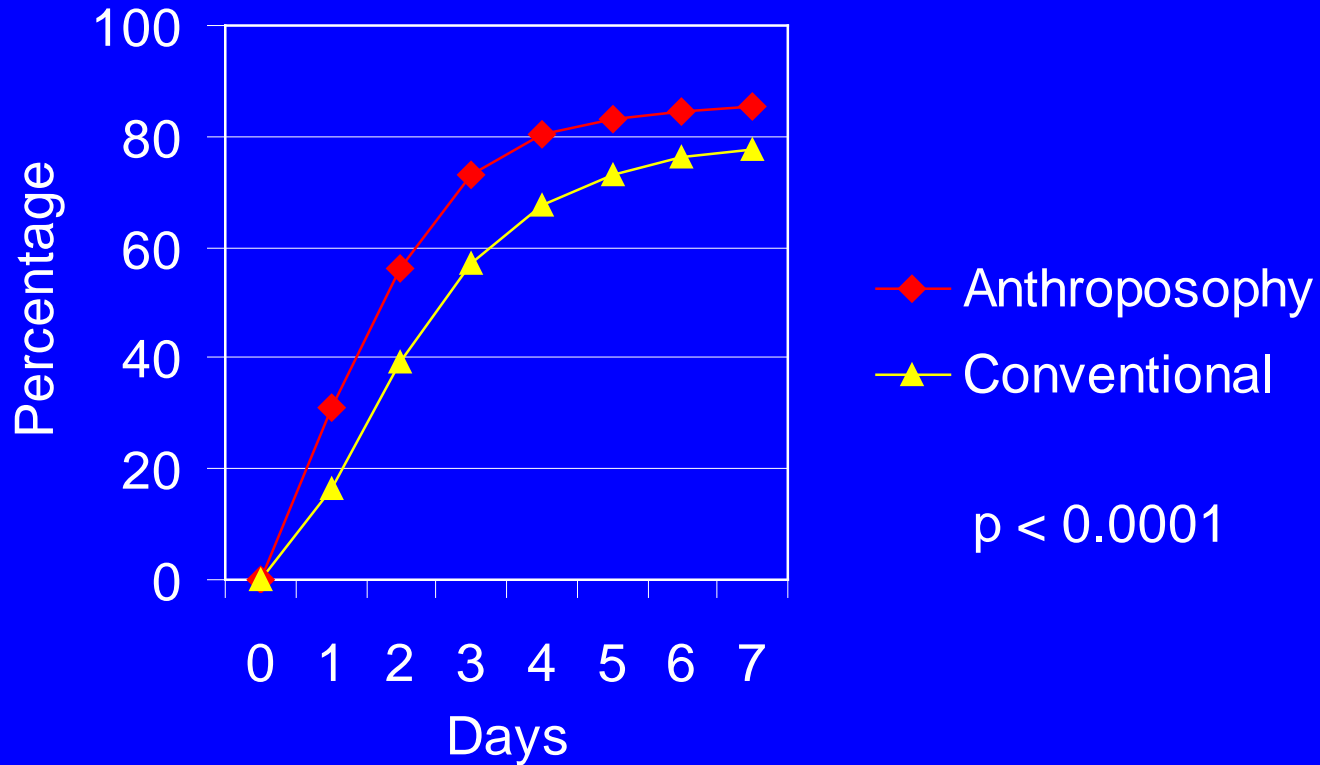
## Prescription by ATC group Day 0-28



*Hamre et al, Wien Klin Wochenschr 2005*

# Respiratory infections study

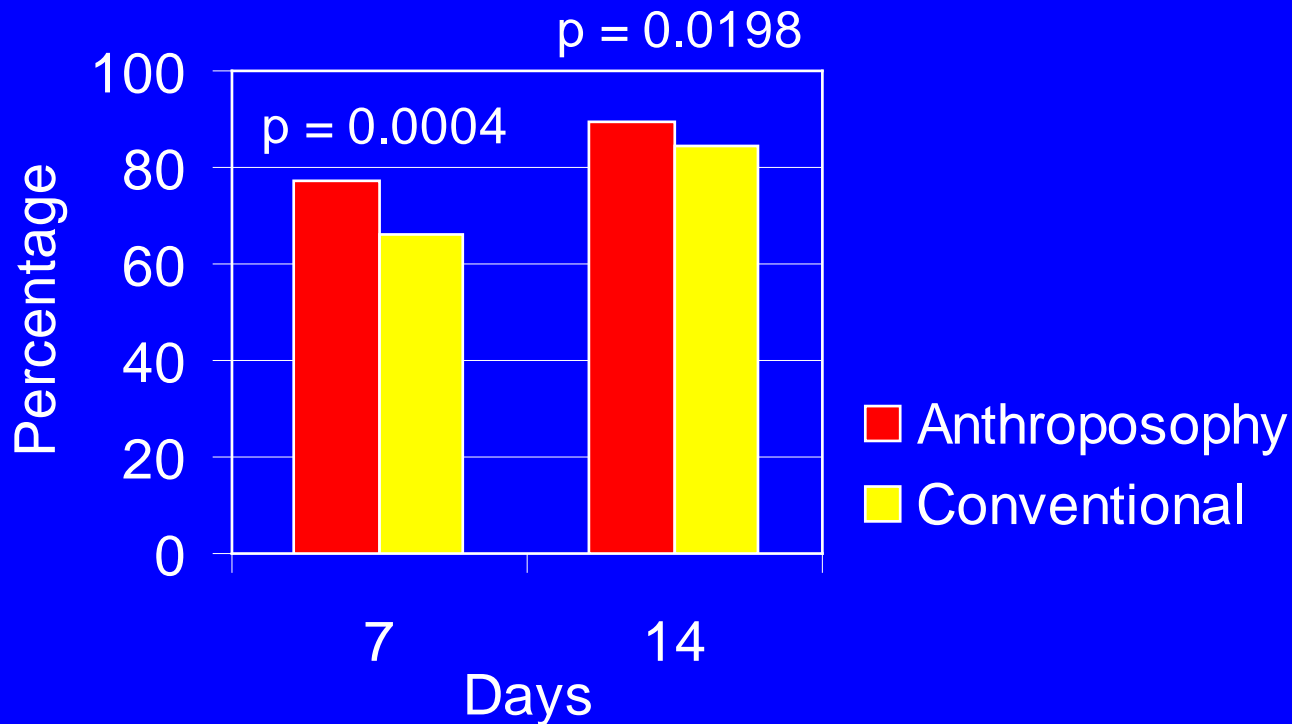
## Time to first improvement



*Hamre et al, Wien Klin Wochenschr 2005*

# Respiratory infections study

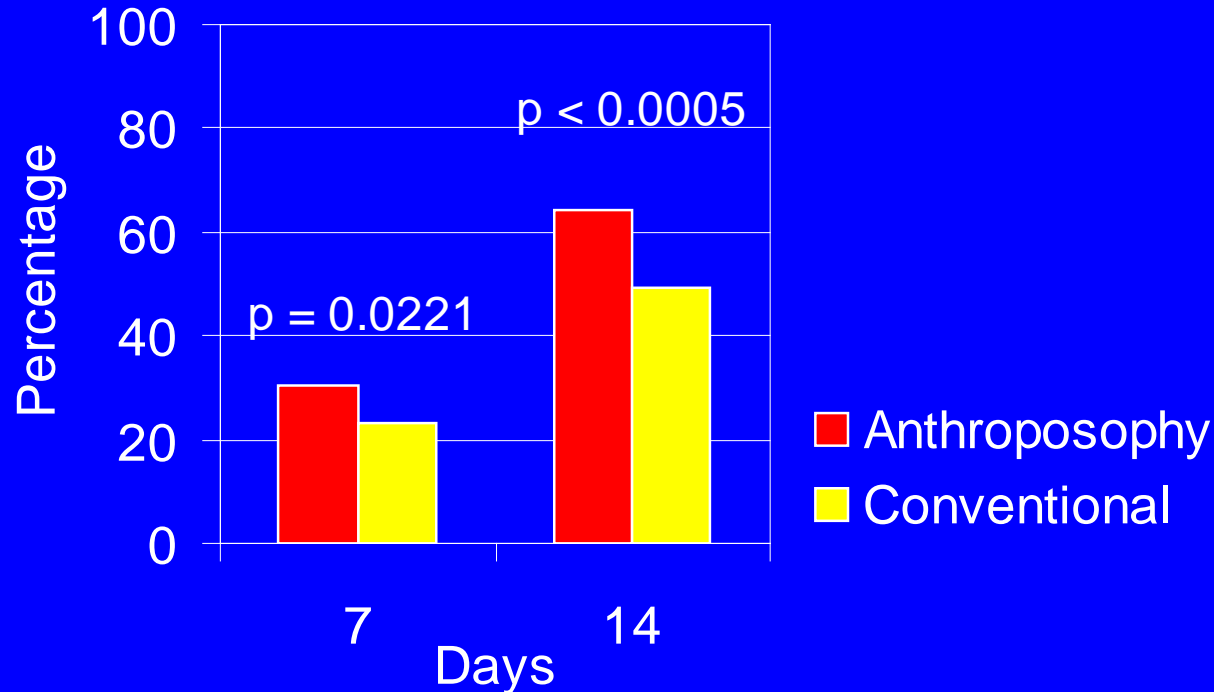
## Major improvement



*Hamre et al, Wien Klin Wochenschr 2005*

# Respiratory infections study

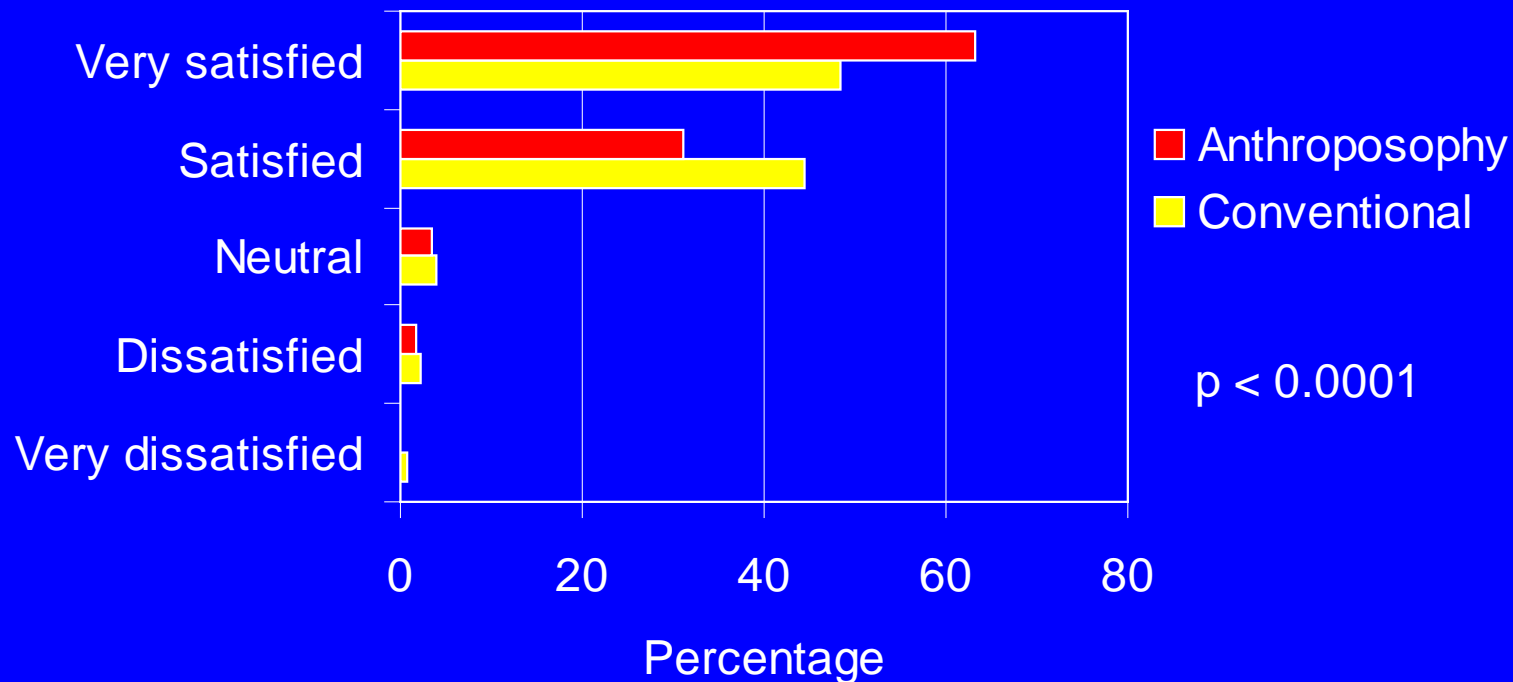
## Complete recovery



*Hamre et al, Wien Klin Wochenschr 2005*

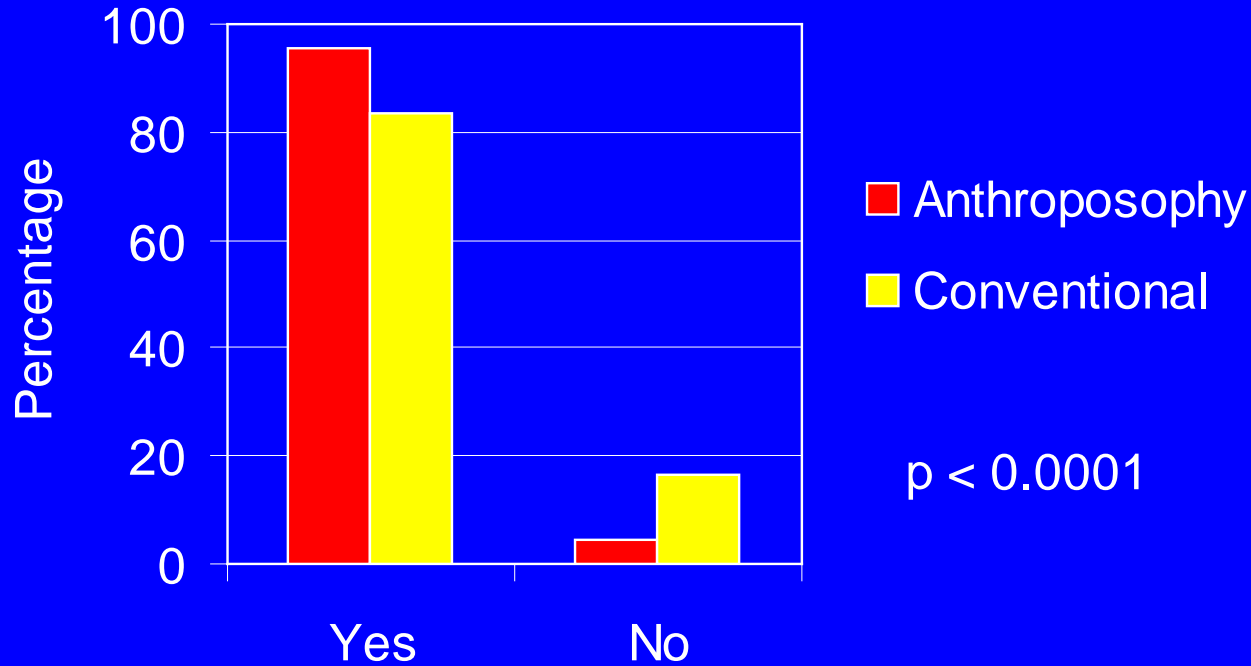
# Respiratory infections study

## Patient satisfaction with treatment



*Hamre et al, Wien Klin Wochenschr 2005*

# “Would you choose this therapy again for your problem?”



*Hamre et al, Wien Klin Wochenschr 2005*

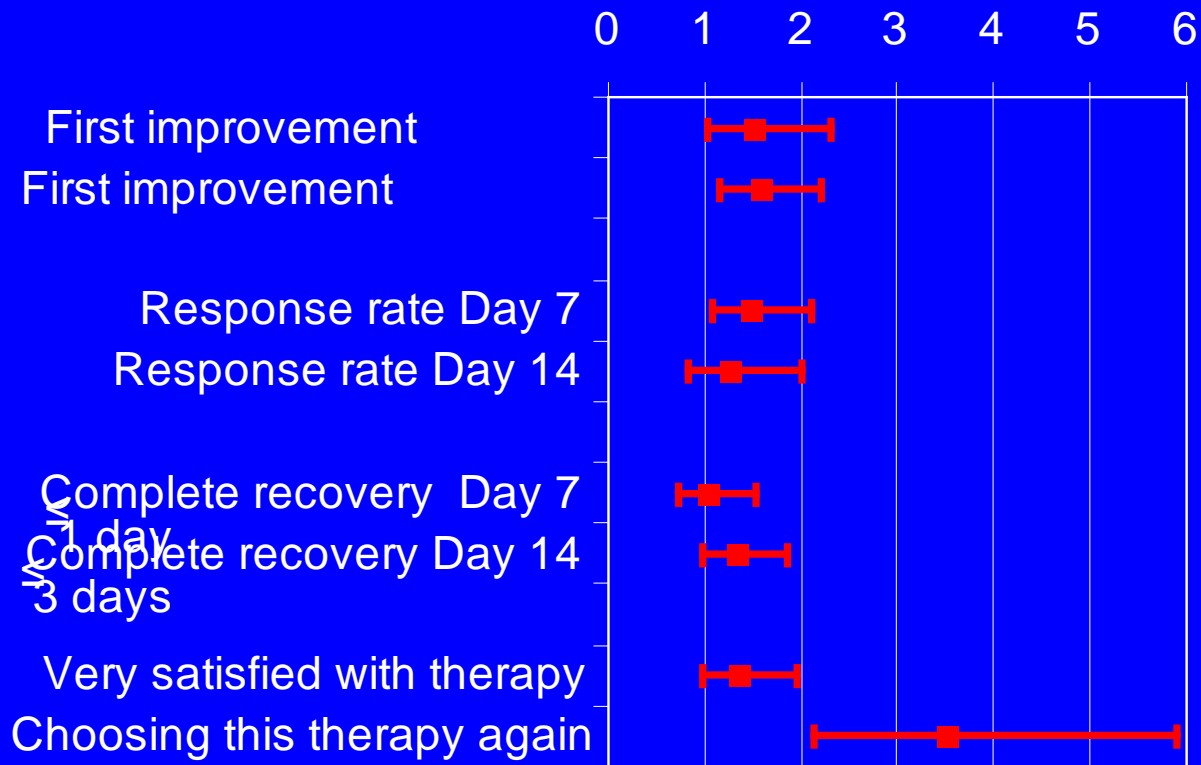
# Respiratory infections study

## Adjustment for baseline differences

- Country
- Gender
- Age
- Chief complaint
- Duration of chief complaint
- Previous episode of chief complaint
- Baseline symptom severity

*Hamre et al, Wien Klin Wochenschr 2005*

# Adjusted odds ratios



**Odds ratio > 1 indicates more favorable outcome in Anthroposophy Group**

*Hamre et al, Wien Klin Wochenschr 2005*

# Safety of AM Medications

- Studies: Generally well tolerated
- ADR infrequent, mild/moderate severity
  - Local reactions from topical application
  - Systemic hypersensitivity
  - Aggravation of pre-existing symptoms

*Kienle GS et al, Anthroposophic Medicine, 2006*

*Hamre et al, Drug Safety 2006*

# Risk from avoidance of necessary conventional treatment in AM settings?

Comparative studies: AM treatment had similar or lower adverse event rates than conventional treatment

*Hamre HJ et al, Wien Klin Wochenschr 2005*

*Plangger N et al, Eur J Obstet Gynecol Reprod Biol 2006*

*Hamre HJ et al, Eur J Med Res 2007*

# 2-year prospective safety analysis

- 662 outpatients
- 949 AM products used for chronic indications
- Confirmed ADR to AM products
  - 3.0% of users
  - 2.2% of products
  - 1 ADR per 382 patient-months
  - No serious ADR

*Hamre HJ et al, Drug Safety 2006*

# Future research on AM products

- Randomised trials
  - Selected products and indications
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    - Kiene H, Springer-Verlag 2001*
    - Hamre HJ et al, J Eval Clin Pract, in press*

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*Kiene H, Springer-Verlag 2001*  
*Hamre HJ et al, J Eval Clin Pract, in press*
- Whole system research
  - Evaluation of individualised AM therapy  
*Boon H et al, eCAM 2007*