Homeopathic RCT embedded in an observational study of children with ADHD – a successful model of whole systems CAM research

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European Congress for Integrative Medicine
Berlin, 7-8 November 2008
Homeopathic treatment of inattentive children
Four Questions

△ Is homeopathic treatment effective in children with ADHD?

△ Is there an efficacy of homeopathic remedies?

△ Is homeopathic therapy in children with ADHD economical?

△ Is the clinical effectiveness stable over 5 years?
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Study Requirements HOM and CON

homeopathic (HOM): individual prescription
law of similars
single remedy
set-up of individual reaction
following prescription

conventional (CON): prospective
controlled
randomized
double-blind
control group
Homeopathic treatment of inattentive children
Study Design: Three Phases including RCT

(modified Bönninghausen’s method, Q-(LM)-potencies)

Diagnosis
- Stratification and Randomisation -

Evaluation

Pilot-Study

CGI

Verum (V)  Placebo (P)

Arm B (PVV)

Arm A (VPV)

Time →

(0)  (6)  (7.5)  (9)  (10.5)  (60)

Screening Phase
(Observational Study)

Crossover Phase
(Randomised Clinical Trial, RCT)

Follow-up
(Open Label Extension Study)

Long-term FU

Period 1

Period 2


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Patient Flow and Unrestricted Medication

140 patients are interested to participate, recruited by lectures

83 fulfill ADHD diagnosis and screening phase inclusion criteria

70 (84%) fulfill RCT inclusion criteria (+ 3 short after deadline [→90%])

-5 (7%) refuse to participate in RCT

-3 fulfill RCT criteria after deadline

62 children participate in RCT

-4 drop-outs (behavioural problems (2), depression, and tics)

58 children finish RCT and undergo long-term therapy with

medication of 17 different remedies in Q-(LM-) potencies
(calc [n=15], sulph [8], cham, lyc, sil [5 each], hep, nux-v [4 each], chin, ign, merc [3 each], caps, caust, hyos, phos, ph-ac, sep, staph [1 each])

60 children available for long-term follow-up (2008)

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CGI from Diagnosis to Long-term Follow-up

diagnosis n=62
before crossover n=62
6 weeks after crossover n=59
14 weeks after crossover n=48
18 months follow-up n=53
5 years follow-up n=60

x = MPH therapy
y = no therapy
z = homeopathy

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Conclusions Homeopathic Therapy

Homeopathy is especially suitable for
- infants, nursery and primary school children:

Highly Significant Amelioration (CGI) of
- intensity of ADHD
- emotional, social and behaviour in school

Highly Significant Amelioration (Neuropsychology) of
- visual perception
- impulsivity and attention

Significant Difference between Placebo and Remedy (RCT)

Frei H, Everts R, von Ammon, K et al. Homeopathic treatment of children with attention deficit hyperactivity disorder: a randomised, double blind, placebo controlled crossover trial
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Mean Cost Comparison for Long-term ADHD Therapy

![Graph showing mean cost comparison for long-term ADHD therapy using different treatments. The graph compares homeopathy, methylphenidate (MPD), and the equivalent cost in Swiss francs (CHF). The y-axis represents drug cost per day (€), and the x-axis shows the dosage in mg. The graph indicates that homeopathy is generally less costly than methylphenidate treatments.]

2005: 1 € = 1.50 CHF
Homeopathic treatment of inattentive children
Four Answers

Summary

Homeopathic therapy in treating children with ADHD comprises remedies with a specific efficacy,
is clinically and neuropsychologically effective,
for a duration of at least five years,
is economically a valuable option, due to being at least as cost effective as low dose stimulants.
Homeopathic treatment of inattentive children: Factors for success

Appropriate study design combining homeopathic (HOM) and conventional (CON) requirements

HOM: optimized repertorization method using specific questionnaire, perception symptoms, and operationalized materia medica comparison (polar symptoms)

CON: randomisation, stratification, blinding after successful therapy: willingness to participate, compliance, and low drop-out rate
Homeopathic treatment of inattentive children
Expenditure

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1998-2005 8 years

Frei H, Thurneysen A
Brit Hom J 2001; 90:183-188
Treatment for hyperactive children: homeopathy and methylphenidate compared in a family setting.
Homeopathic treatment of inattentive children

Thanks

children and families
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Homeopathic treatment of inattentive children
Expenditure

Timetable

- Pilot Study (Brit Hom J 2001)*: 1998-2001, 3 years
- Design and Team Formation: 2000-2001, 1 year
- Gesuchstellung (Ethic Commissions, IKS): 2001, 0.5 year
- Implementation: 2001-2004, 2.5 years
- Assessment, Writing, Publication: 2004-2005, 1 year

Time: 1998-2005, 8 years

Budget: 250’000 CHF, approx. 185’000 EUR

*Frei H, Thurneysen A
Brit Hom J 2001; 90:183-188
Treatment for hyperactive children: homeopathy and methylphenidate compared in a family setting.
Optimising diagnosis through questionnaire, polarity analysis and perception symptoms

Increase in efficiency of homeopathic treatment in children with ADHD with stepwise introduction of a general questionnaire (GQ), the analysis of polar symptoms (PA) and the inclusion of perception symptoms (PS)

Graph showing the increase in Conners Global Index scores with prescriptions.
Optimised randomisation after successful therapy differentiates verum from placebo after 6 months.
Homeopathic treatment children with AD(H)D
Textbook - English Translation in Preparation
Homeopathic in AD(H)D - Publications concerning methodology

H. Frei, K. von Ammon, A. Thurneysen
Treatment of hyperactive children: Increased efficiency through modifications of homeopathic diagnostic procedure
Homeopathy (2006), 95, 163-170

H. Frei, R. Everts, K. von Ammon et al.
Randomised controlled trials of homeopathy in hyperactive children: treatment procedure leads to an unconventional study design
Homeopathy (2007) 96, 35-41
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CGI  Crossover Phase