

A Mixed Methods Exploration of Homeopathy for Attention Deficit Hyperactivity Disorder: Comparing Research Evidence and Clinical Practice

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January 2012

Abstract

Background: Complementary and alternative medicine is increasingly evaluated from an evidence-based medicine perspective which includes clinical trials. It was unclear to what extent these trials represented clinical practice and assessed treatments as given in the real world. Attention deficit hyperactivity disorder (ADHD) and homeopathy were explored as an exemplar comparing clinical trials versus daily practice. **Objectives:** Evaluate, contrast and compare the homeopathy as practiced within research trials with the approach adopted by practitioners in their daily practice as a treatment for children diagnosed with ADHD. **Methods:** An explicitly mixed-methods approach based in Grounded Theory spanning quantitative and qualitative research techniques was adopted for this project. Data elements included a systematic review, individual patient data meta-analysis, practitioner survey, in-depth interviews and participant-observation. Each method was rigorously implemented and analysed according to best practice; the results were then synthesised to develop an explanatory model. **Results & Conclusions:** Although meta-analyses suggest there is little reliable evidence in favour of homeopathy for the treatment of ADHD, the trials conducted to date do not appear to have reflected clinical practice within the UK. The diversity of practice observed presents unique challenges for researchers who wish to improve the evidence base. A model of homeopathy as a process of individualisation is offered as a starting point for documenting observational studies and developing realistic evaluations, and an outline of a future comparative trial is provided.

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Glossary

Abbreviation	Term	Definition/notes
AMED		Allied and Complementary Medicine Database
ADHD	Attention Deficit Hyperactivity Disorder	A persistent pattern of inattention and/or hyperactivity-impulsivity that is more frequently displayed and is more severe than is typically observed in individuals at comparable level of development.
AIC	Akaike's Information Criteria	AIC values test competing models when explaining a particular data set and attempt to trade-off accuracy of prediction and complexity in terms of the number of variables required
	Allopathy or allopathic	An expression commonly used by homeopaths and complementary therapists to refer to Western or bio-medicine where pharmacologically active agents are used to treat or suppress symptoms. Originally used by Samuel Hahnemann.
APA	American Psychological Association	A scientific and professional organization that represents psychologists in the United States of America.
ARH	Alliance of Registered Homeopaths	One of the main professional bodies for homeopaths in the UK.
	Axial coding	Focused or axial coding refers to the more abstract coding that develops links between categories generated during open coding, illustrating dimensions and properties. Axial coding begins to reassemble the data which was fragmented during open coding and should provide precise explanations of phenomena.
	Bönninghausen	A homeopath from the 19th Century who produced the "Therapeutic Pocketbook" repertory. Symptoms are categorised and dealt with in a style unique among homeopathic texts.

Abbreviation	Term	Definition/notes
C	C potency	A homeopathic remedy prepared to the 1/100 dilution scale. For example a 2C dilution requires a substance to be diluted to one part in 100, and then some of that diluted solution diluted by a further factor of 100.
CAM or CAMs	Complementary and Alternative Medicine(s)	Systems of medicine or individual therapies which are largely provided out with conventional medical systems and may use alternative explanatory frameworks to that of biomedicine
CCT	Childrens' Checking Task	A cancellation task for children intended to assess attention and accuracy
CDPLP	Cochrane Developmental, Psychosocial and Learning Problems Group	Cochrane review group
CI	Confidence interval	Shows the range within which the true treatment effect is likely to lie, giving the range of possible effect sizes.
Conners CPT	Conners Continuous Performance Test	A neuropsychological test that assesses attention, impulsivity and activity control delivered through a computer.
CRS(-R) <ul style="list-style-type: none"> • CPRS • CGI-P/T 	Conners Rating Scales (Revised) Conners Parent Rating Scales Conners Global Index (parent or teacher rated)	An extensive package of questionnaires intended to evaluate the presence and severity of ADHD, including versions for completion by parents, teachers and adolescents in both short and long forms.
CONSORT	Consolidated Standards of Reporting Trials	A statement providing detailed guidance for best practice in the reporting of trials.
	Cook's Distance	Cook's Distance values indicate data points that may be outliers, where there may be missing data, and the impact of deleting some observations
CORH	Council of Organisations Registering Homeopaths	An organisation which attempted to review the regulation of homeopaths in the UK, disbanded in 2007.
CPD	Continuing Professional Development	A requirement for many professional bodies and often met through attending seminars/workshops.
CYP	Child or young person	
DoR	Date of randomisation	

Abbreviation	Term	Definition/notes
DSM-IV/III	Diagnostic and Statistical Manual of Mental Disorders version III or IV	Published by the APA as a standard criteria for the classification of mental disorders.
	Dynamisation	A homeopathic term describing a substance which is diluted with alcohol or distilled water and then vigorously shaken in a process called "succussion".
EBM	Evidence Based Medicine	Integrating individual clinical expertise with the best available external evidence from systematic research.
EMBASE		A biomedical and pharmacological database with more of a European focus than MEDLINE, and considerable drug and pharmaceutical research coverage.
EQ-5D		A standardised instrument for use as a measure of health outcome which produces a health state for each person that completes it
	Feingold Diet	An elimination diet focused on synthetic food additives and synthetic sweeteners. http://www.feingold.org/
FIH	Foundation for Integrated Health	A charity heavily involved in the promotion and evaluation of complementary medicine in the UK, patron HRH Prince of Wales.
	Flower essences	For example Bach Flower Remedies. Plants are soaked in water and either left in the sun or boiled, the solution is then diluted with brandy to make the mother tincture. Further diluted with brandy before sale, and taken as drops in water for emotional problems
	Generals	A homeopathic term referring to any symptom or modality that refers to the patient as a whole, not just one part.
	Grounded Theory	An approach to data collection and analysis that emphasises the generation of theory from data
	Hahnemann	Samuel Hahnemann (1755-1843) a German physician and pharmacologist who developed homeopathy as a medical system.

Abbreviation	Term	Definition/notes
HKD	Hyperkinetic Disorder	A group of disorders characterized by: early onset; a combination of overactive, poorly modulated behaviour with marked inattention and lack of persistent task involvement; and pervasiveness over situations and persistence over time of these behavioural characteristics. Similar to ADHD but with narrower diagnostic criteria.
	Homeopathy	A system of medicine based on the treatment of 'like with like': any natural or man-made substance capable of causing specific disease states and symptoms in healthy individuals may be used to treat the same symptoms when they occur as part of sickness. Remedies are made from a source material, shaken and serially diluted.
	Homeopathy (classical or constitutional)	This version involves an in-depth consultation and individualized analysis regardless of the condition being treated Chapman, Weintraub, Milburn, Pirozzi et al. (1999)
	Homeopathy (clinical)	Clinical homeopathy provides a standardized prescription for a predefined condition, based either on traditional recommendations, or new analysis of symptoms Clark and Percivall (2000)
	Homeopathy (complex)	Complex homeopathy combines several clinical medicines into a single formula Weiser, Strosser and Klein (1998).
	Homeopathy (isopathic)	Isopathic medicines are prepared from known or presumed aetiological agents Taylor, Reilly, Llewellyn-Jones, McSharry et al. (2000).
HomInform		A database of searchable references to journal articles and books on homeopathy hosted by the Glasgow Homeopathic Hospital.
HSR	Health Services Research	
	I^2	Describes the variation of effects that may be due to heterogeneity rather than sampling error
ICD-10	International Classification of Diseases (version 10)	The standard WHO diagnostic tool for epidemiology, health management and clinical purposes.
ICPC	International Classification of Primary Care	Used by the WHO to classify encounters with medical practitioners and treatment delivered.

Abbreviation	Term	Definition/notes
IPD	Individual Patient/Participant Data	Usually refers to the patient-level data sets used in IPD meta-analysis.
ITT	Intention To Treat	Analysis technique used in clinical trials where participant data is analysed according to treatment allocation.
	Kent or Kentian homeopathy	James T Kent (1849 - 1916), an American doctor who was active in the promotion and development of homeopathy. Kent was linked with Swedenborgian beliefs about the spiritual causes of illness. Wrote one of the most commonly used repertories.
	Lac	The name given to a family of homeopathic remedies made from the milk of various animals e.g. lac caninum
LM	LM potency	LM is the Roman numeral for 50,000 and these remedies are prepared on a dilution scale of 1/50,000. LM's are usually given as liquids and must be shaken and further diluted by patients before being taken.
	materia medica	A Latin medical term for the body of collected knowledge about the therapeutic properties of any substance used for healing. Now used mostly in homeopathy and herbal medicine rather than in conventional medicine.
MD	Mean Difference	A standard statistic that measures the absolute difference between the mean value in two groups in a clinical trial. It estimates the amount by which the experimental intervention changes the outcome on average compared with the control. It is used as a summary statistic in meta-analysis when outcome measurements in all studies are made on the same scale.
MEDLINE		MEDLINE is the U.S. National Library of Medicine's® (NLM) bibliographic database
	miasm	Homeopathic term for the three influences held to be responsible for all disease of a chronic nature and to form the foundation or basis for all disease in general according to Hahnemann. These are insidious influences present throughout the population, named as sycosis, psora and syphilis.
MRC	Medical Research Council	

Abbreviation	Term	Definition/notes
MTA	Multimodal Treatment Study of ADHD	The MTA cooperative group was responsible for a 14-month randomised trial comparing carefully managed medication versus intensive behaviour therapy versus a combination of the two approaches for children with ADHD. A control group of usual community care was also included.
MYMOP MYCAW	Measure Your Own Medical Outcome Profile; Measure Yourself Concerns and Wellbeing	A validated patient-generated, or individualised, outcome questionnaire. MYCAW was designed for use in cancer support services in particular, and those offering complementary therapies.
NAFKAM	Nasjonalt forskningscenter innen komplementær og alternativ medisin	Norwegian National Research Center in Complementary and Alternative Medicine
NCCRC	National Coordinating Centre for Research Capacity Development	The Research Capacity Development programme funded pre and post doctoral researchers in ring-fenced areas of interest that were expected to be of value to the NHS and UK health service.
NHS	National Health Service	National Health Service in the UK
NICE	National Institute for Clinical Excellence	A central organisation providing evidence-based guidance, quality standards and information for commissioners, practitioners and managers across health care in the UK (now renamed as the National Institute for Health and Care Excellence).
NMQ	Non-Medically Qualified	Used in relation to homeopaths who are not also medically qualified, the term “professional homeopath” is also often used.
	nosode	A family of homeopathic remedies made with substances derived from disease products, tissue samples, mucus, pus from discharges, or pure cultures of microorganisms.
NVivo		A qualitative data analysis computer software package produced by QSR International.

Abbreviation	Term	Definition/notes
	open coding	A technique used in Grounded Theory in the early stages of analysis where data are considered line-by-line or in discrete incidents. Descriptive labels are used as codes, which may be abstractions from the researchers own conceptual framework, taken from the known literature or in-vivo - actual words from participants.
PedsQL	Pediatric Quality of Life Inventory	A family of health related quality of life scales designed for use with and by children. A core module can be administered alongside disease-specific modules
	placebo	A control which is indistinguishable from the real treatment. Homeopaths also use "blank" Sac Lac remedies which are milk sugar pills without any added remedy for various therapeutic reasons
	polarity analysis	A method of homeopathic repertorisation developed from Bönninghausen that focused on opposing symptoms.
	polycrest	Refers to a very commonly used homeopathic remedy e.g. arnica or belladonna
	potency	The strength of a homeopathic remedy, usually denoted according to the Centesimal or LM scale.
	potentisation	as for dynamisation
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses	An agreed minimum set of items for reporting in systematic reviews and meta-analyses.
	proving or prufung	A homeopathic term referring to the way in which homeopathic remedies are tested on healthy individuals in order to establish what symptoms the remedy might be able to cure in the sick.
PsycINFO		Bibliographic database focusing on peer-reviewed literature in the behavioral sciences and mental health.
RADAR		A homeopathic computerised repertory which is based around the Complete Repertory, Synthesis and Bönninghausen's PocketBook, additional repertories and materia medica can be purchased and added on. Other programs include ISIS and MacRepertory.

Abbreviation	Term	Definition/notes
RCT	Randomised Controlled Trial	Research design which compares two or more groups that have been randomly allocated to treatment/control.
	Reiki	A type of hands-on healing which claims descent from Japanese traditions.
	remedy	Term often used to denote a homeopathic remedy
	remedy picture	The description of the symptoms or the type of person that a homeopathic remedy is expected to cure.
	repertory	Repertories are detailed listings of symptoms and their associated remedies. There are a variety of repertories around, some of which are very comprehensive and include classical works (such as those written by Kent) as well as more modern information e.g Synthesis. Some methods within homeopathy use particular repertories or sources in preference to others.
	Sankaran	Rajan Sankaran (1960-) an Indian homeopath who has pioneered the Sensation/Bombay style of case taking and prescribing in homeopathy
SD	Standard Deviation	A measure of variance in a data set
SF-36	Short Form (36) Health Survey	A validated health related quality of life scale in various versions (36, 12 and 6 items)
SMD	Standardised Mean Difference	A summary statistic in meta-analysis when the studies all assess the same outcome but measure it in a variety of ways. The standardized mean difference expresses the size of the intervention effect in each study relative to the variability observed in that study.
SoH	Society of Homeopaths	One of the main registering bodies for homeopaths in the UK.
SPSS		Software package for statistical analysis.
	succussion	Homeopathic term for shaking a remedy, used during the dilution process and before taking LM potencies.
	trituration	When a homeopathic remedy is to be made from insoluble solids, such as quartz and oyster shell, these are diluted by grinding them with lactose before being added to water.

Abbreviation	Term	Definition/notes
TAP	Test Battery for Attention Performance	A German language software package that tests attention, focus, and other abilities in relation to ADHD.
	T-score	A standardised score which uses population values and always has a mean of 50.
	verum	A homeopathic term used to describe an active remedy rather than a placebo.
	vital force	The spirit-like power which animates the human body according to Hahnemann and is disturbed in illness.
WHO	World Health Organisation	

Dedications

Like all explorers, we are drawn to discover what's out there without knowing yet if we have the courage to face it. — Pema Chödrön

Dedicated to those amazing people, and animals, in my life who have patiently endured the evolution of this thesis. Thank you for putting up with the early mornings, late nights, missed celebrations and other features of a doctoral student's life. Especial thanks to my family who forgave me for missing Christmas this year.

Supervision is without a doubt one of the key factors in finishing a Ph.D. and, without Joy Adamson, this thesis might not have made it onto these pages - thank you for taking on yet another student in need. My research mentors (Joanne Reeve and John Hughes), members of the Alternative Complementary Health Research Network, and generous colleagues from the Centre for Reviews and Dissemination have provided guidance and help when it was needed most.

The researchers and practitioners I have met in the six years of this project have been generous with their time and data. Without them this research could not have been carried out, and I hope they will find the results useful.

Author's Declaration

Note on author name: Morag Heirs (maiden name) before 2002 and after 1999; Morag Coulter (married name)

Systematic Review

This review was carried out by Morag Heirs (was Coulter) and Mike Emmans Dean with advice and support from Prof Trevor Sheldon, Dr. Simon Gilbody (University of York), Jane Dennis and Dr. Julian Higgins (Cochrane Developmental, Psychosocial and Learning Problems Group). The review was originally conceived of by Mike Emmans Dean. The first draft of the protocol was written by Morag Heirs and revised for submission to the Cochrane DPLP Group with Mike Emmans Dean. Searches were carried out by Morag Heirs, Mike Emmans Dean and the CDLPG librarians as indicated in the text. Data extraction was performed by Morag Heirs and checked for accuracy by Mike Emmans Dean. Data entry, analysis and write-up was carried out by Morag Heirs.

First published in the Cochrane Library as Coulter MK, Dean ME (2007) Homeopathy for attention deficit/hyperactivity disorder or hyperkinetic disorder. *Cochrane Database Syst Rev.* Oct 17;(4):CD005648.

Coulter, M., Dean, ME., Gilbody, S. (2006) Homeopathy for Attention Deficit Hyperactivity Disorder: A systematic review of effectiveness and safety (abstract), *Focus on Alternative and Complementary Therapies*, 11.

Heirs M (2007) Homeopathy for Attention Deficit Hyperactivity Disorder: A systematic review of effectiveness and safety. Presented at the Child Mental Health Research Network Conference, York Hospital

Dean ME, Coulter MK, Fisher P, Jobst K, Walach H. (2007) Reporting data on homeopathic treatments (RedHot): a supplement to CONSORT. *The Journal of Alternative and Complementary Medicine.* 13(1):19-24

Individual Patient Data Analysis

This section of the project was conceived of by Professor Trevor Sheldon and Morag Heirs, with advice from Dr Susan O'Meara (University of York). The protocol was developed and written by Morag Heirs. Statistical advice was provided by Dr Gavin Stewart (University of York). Data were extracted, analysed and written up by Morag Heirs.

Mixed-Methods

The mixed-methods data collection and grounded theory analysis components were devised by Morag Heirs with advice from Dr Joy Adamson (University of York), Dr John Hughes (University College London) and Dr Joanne Reeve (University of Liverpool). Data collection, analysis and write-up were carried out by Morag Heirs.

Heirs M (2007) Locating children and young people within homeopathic treatment. Presented at the 4th ACHRN Conference: Power and Autonomy in Complementary Medicine, University of Nottingham.

Heirs M and Hall A (2009) An interview with Didier Grandgeorge. *Homeopathic Links*, 22, 1-4

Heirs M (2009) Research versus Practice: a mixed methods exploration of homeopathic treatment for ADHD in children. Presented at the 5th ACHRN Conference: Valuing Qualitative Research, University of York

Discussion

Ideas presented in the Discussion chapter have been partially presented as follows.

Heirs M (2007) Person-centred outcome measures for attentional difficulties. Presented at the 4th Annual Hull York Medical School Research Conference, York Racecourse.

Heirs M (2009) Developing critical thinking in medical students – an example from a module around complementary medicine. Presented at The Annual Learning and Teaching Conference: Critical Thinking and Academic Skills, University of York.

Heirs, M. (2009) Further research required. *The Homoeopath*, 28, 9-12.

Heirs M (2010) Reflecting on the contributions of a mixed-method research project. Presented at EUROQUAL: International Perspectives on Qualitative Research in the Social Sciences

Heirs M (2010) Heterogeneity in Research and Practice: Homeopathy for Attention Deficit Disorder in Children. Presented at the 3rd Annual HomeoNet Research Forum (Homeopathic Health Care: Methodological, Theoretical and Practical Issues), Vancouver: Canada.

Chapter 1

Introduction and Background

This thesis is concerned with the relationship between research evidence and clinical practice in the setting of homeopathy for attention deficit hyperactivity disorder in children. In this chapter I will outline the origin and principles of evidence based medicine, and their relationship to complementary and alternative medicine. The extent to which evidence based medicine influences actual practice is unclear within conventional medicine and even less understood within CAM. I will offer an introduction to the clinical area of homeopathy for attention deficit hyperactivity disorder in children while proposing this as a useful example of the tensions between research evidence and clinical practice, as well as the treatment choices made by the general public.

These overviews are not intended to be exhaustive systematic reviews of each area, but seek to highlight relevant issues that are reflected in the later chapters. References and sources were identified using broad searches of the main medical databases (MEDLINE, EMBASE, AMED, PsycINFO and others), and consultation with colleagues in the area of evidence based medicine.

1.1 Evidence-Based Medicine

1.1.1 Origin and definition

The rise of the evidence based medicine (EBM) movement is inextricably linked with the formation and development of the Cochrane Collaboration. The Cochrane group was founded by the Scottish doctor and epidemiologist Archie Cochrane (1909-88). Archie Cochrane spent four years as a prisoner of war in German camps caring for fellow prisoners as a medic. In part based on these experiences, he wrote a slim book entitled "Effectiveness and Efficiency: Random reflections on health services" which was published in 1972 (Cochrane, 1972). This

text critically analysed the UK health system, proposed ideas for reform and notably praised the introduction of the randomised controlled trial (RCT) which had so far been used infrequently. Cochrane stated that research into the effectiveness of medicines “was in an unfortunate state until the early 1950’s” and it was not until 1952 that there was a significant turning point. He associated this change with the publication of a well known paper which pooled three trials of chemotherapy (Daniels and Hill, 1952). The Cochrane Collaboration itself was not established until 1993, but since then has expanded at an exponential rate.

Evidence based medicine as an approach is generally associated with McMaster University and the mid-1980’s when a volume entitled Clinical Epidemiology introduced the idea of applying epidemiology to individual patient care (Lambert, 2006). EBM did not appear as an indexing term in medical databases such as MEDLINE until 1992 (Kristiansen and Mooney, 2004). The concepts of EBM and evidence-based practice have begun to spread into most areas of medicine and healthcare, and more recently into education, crime, justice and social welfare (e.g. the Campbell Collaboration), though this has not been without controversy. Although EBM is strictly concerned with synthesising research evidence, clinical expertise and patient values, several commentators have highlighted the overwhelming focus on research synthesis. EBM handbooks tend to focus on the location and synthesising of evidence, rather than clinical decision-making or elicitation of patient preferences, for example see Sackett, Straus, Richardson, Rosenberg and Haynes (2000). Studies have demonstrated that clinicians and health professionals tend, as do lay people, to make decisions on the basis of heuristics and partial information rather than consistent use of information (Elstein and Schwarz, 2002). There is therefore a tension between the evidence produced by clinical trials and the actual implementation of the results. The slow pace of research influencing actual clinical practice is an area of ongoing research (Hanbury, Thompson, Wilson, Farley, Chambers, Warren, Bibby, Mannion, Watt and Gilbody, 2010).

Sackett et al. provide us with one of the most commonly quoted definitions of evidence based medicine:

Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external evidence from systematic research. By individual clinical expertise we mean the proficiency and judgement that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients

predicaments, rights and preferences in making clinical decisions about their care (Sackett, Rosenberg, Gray, Haynes and Richardson, 1996, pp 71).

Given such a detailed statement, the question is: what constitutes evidence? This issue has been discussed in detail in numerous papers (for example Rycroft Malone, Seers, Titchen, Harvey, Kitson and McCormack 2004). It has been characterised as a conflict between those who argue that “evidence” should be a restricted term used only for research findings, and those who suggest a broader definition that recognises the use of observational, experiential information in decision-making. Researchers from the traditions of anthropology and ethnography have highlighted the narrow definition of what is usually accepted as evidence within EBM - quantitative and usually epidemiological (Lambert, 2006), a definition which by its nature appears to exclude patient voices and narratives. These non-statistical research findings have not as yet been formally incorporated into the EBM framework, although systematic reviews have begun to take account of both quantitative and qualitative studies. For example, Kate Flemming and her work on palliative care and pain relief (Flemming, 2010), and the work of the EPPI Centre in London.

Some proponents of EBM have tended to promote the RCT as the definitive research method, and placed it below only the systematic review/meta-analysis in the hierarchy of evidence.

As has been succinctly put by Kristiansen and Mooney, both observational studies and RCTs are vulnerable to various biases (Kristiansen and Mooney, 2004). The RCT, while controlling selection bias, is not always able to cope with measurement bias via blinding; generally participants are aware they are in a trial and strategic behaviours cannot be ruled out. The RCT as a design has been criticised for lack of generalisability to real-life populations (Van Spall, Toren, Kiss and Fowler, 2007; Rothwell, 2005). As a research tool it may not always be the most appropriate where real world applications are of interest, or broader questions are being addressed. Observational studies may be more likely to avoid this kind of problem, but both designs largely fail to address issues of external validity which are often taken for granted. It is worth while reminding ourselves that one of the strongest advocates of the RCT also reminds us that:

I did not want to give the impression that it [the RCT] is the only technique of value in medical research (Cochrane, 1972.pp25)

Given that both types of design are potentially subject to bias, it is difficult to establish which is “least” biased in the empirical sense because we have no “gold standard”. While researchers may believe that the RCT is superior in some or many instances, this is not entirely based on evidence per se. At least one meta-analysis has demonstrated that non-randomised controlled studies in a surgical area were as accurate as RCTs (Abraham, Bryne and Young, 2010).

1.1.2 Benefits, challenges and implementation

The volume of research evidence available to practitioners continues to grow exponentially. Looking only at RCTs, the Medline Trend database records over 25,000 RCTs as published in 2007, and according to the Centre for Reviews and Dissemination over 2,500 systematic reviews are published each year. Researchers have identified the challenges inherent in attempting to stay abreast of current research, and suggest this contributes to delays in recommending effective treatments (Antman, Lau, Kupelnick, Mosteller and Chalmers, 1992).

Evidence based medicine and systematic reviews have influenced medical practice by providing reliable summaries of the research evidence. In the field of cancer and chemotherapy for example, a major individual patient data review and meta-analysis for non-small cell lung cancer was initiated in 1992 and completed in 1995 with further updates in 2007 (NSCLC-Collaborative-Group, 2000, 1995). The results suggested newer chemotherapies were more beneficial for patients, while older regimens were harmful. This review helped to encourage new targeted research and has informed many major cancer guidelines in the UK and beyond.

A systematic review was commissioned by the Department of Health (UK) to inform NICE guidance (TA168) on the effectiveness of influenza treatments in 1999 (NICE, 2009). The review clearly influenced the guidelines and advice given to both members of the public and health care practitioners (Burch, Corbett, Stock, Nicholson, Elliot, Duffy, Westwood, Palmer and Stewart, 2009). This included recommending that drugs used to treat seasonal influenza should not be given routinely unless the patients were considered to be at risk of complications.

These brief examples illustrate that good quality research can be effectively synthesised and inform health policy and guidelines. Services may start or stop being offered based on the available evidence, and recommendations can be made regarding healthcare practitioner's daily decisions.

Studies examining the impact of published, evidence-based guidelines on clinical practice have offered conflicting results as to how successful these are in changing daily practice. Where evaluations have been carried out, e.g. within surgery for tonsillectomy or the use of ultrasound machines for central venous catheterisation, there is evidence that guideline adoption may be patchy at best at least within the UK health services (e.g Sheldon, Cullum, Dawson, Lank-shear et al. 2004; National Prospective Tonsillectomy Audit 2008; Wigmore, Smythe, Hacking, Raobaikady et al. 2007). There are clear suggestions that the uptake of such guidance has much to do with the presentation of the information, underlying complexity of the area, funding and support (Moulding, Silagy and Weller, 1999; Grimshaw, Thomas and MacLennan, 2004).

Evaluations have suggested that successful implementation can produce significantly improved health outcomes (Wigmore, Smythe, Hacking, Raobaikady et al., 2007). However the gap between the research findings and implementation in clinical practice continues to adversely affect patients health.

The example of infant sleeping position recommendations highlights the potential adverse consequences when a body of evidence is ignored. Despite clinical trials identifying the front sleeping position as being a significant factor in increasing the risk of Sudden Infant Death Syndrome in the 1970's, and the first review being published in 1988, a public health campaign was not launched until 1991 (Gilbert, Salanti, Harden and See, 2005). It has been estimated that between 1974 and 1991 there were nearly 12 additional baby deaths per week due to sleeping position. On a more positive note, an interrupted time-series study has shown that after the introduction of the "Back to Sleep" campaign, deaths fell by 50-70% (Gilbert, 1994). This intervention (putting the baby to sleep on their back) was simple, required no additional equipment and was easy to communicate (Pollack and Frohna, 2002).

McGregor et al. have pointed out that guidelines which require a change of practice are reliant on practical constraints. Access to training and availability of equipment even when practitioners are motivated to take the new information on board may interfere with implementation (McGregor, Rashid, Sable and Kurian, 2006).

Qualitative studies have explored the attitudinal reasons why guidelines and other manifestations of EBM may not always be swiftly and comprehensively implemented. For example Armstrong looked at depression in primary care and the impact of EBM on primary care physicians (Armstrong, 2002). He described a disconnection between formalised EBM and individual clinical decisions where doctors rationalised the continued use of individual judgement and contextual decision making by referring to uniqueness and patient centeredness. It has been proposed that resistance to EBM evolved in order to protect the individual practitioner's choices (Broom and Tovey, 2007), and that:

practicing physicians engage in forms of resistance in order to retain the perceived integrity of their medical work (Broom, Adams and Tovey 2009.pp3)

Some researchers have suggested that EBM can in fact have negative effects on healthcare professionals as they are pointed towards evidence based guidelines or summaries, reducing their critical appraisal skills and separating them from the actual evidence itself. Pope has looked at EBM within urological/gynaecological and pelvic surgical practice using a social movements framework (Pope, 2003). Pope's work explored the resistance to formalised training and established procedures which seemed to be linked to surgeons following an experientially learned practice that focused on the 'how' rather than 'what' procedure to use.

1.1.3 Summary

EBM has been loosely conceptualised as a multi-faceted movement that aims to take account of professional knowledge/expertise, and integrate this with the best research evidence on treatment effectiveness and patient experience. Where guidelines and new interventions have been successfully implemented, patients have generally benefited and treatments based on good quality evidence are often more successful. There are issues around the management of large amounts of evidence, synthesis, dissemination of the findings, and the practical resources needed to implement change. There remains however a degree of resistance to EBM and an ongoing challenge in the translation of research findings into clinical practice. There are issues of power relationships surrounding EBM and what it might mean for all healthcare professionals which are broader than the remit of this thesis.

1.2 Complementary/Alternative Medicine

1.2.1 Defining complementary/alternative medicine

Definitions and descriptions of complementary/alternative medicine (CAM) have varied over the years largely dependent on the viewpoint of the individual writers. Holism is a quality of good care that can be present or absent from any healthcare system/therapy or practice. Likewise the treatment of root cause rather than mere symptoms can be facilitated by a GP, all be it in a shorter consultation than with a medical herbalist for example. Some contrasting definitions are given in Table 1.1 on the facing page as exemplars.

Complementary and/or Alternative Medicine can be briefly conceptualised as referring to systems or individual therapies which are largely provided out with conventional medical systems and may use alternative explanatory frameworks to that of biomedicine. This broad description is deliberately inclusive and non-specific since the definition of CAM is an area of ongoing debate and can be seen as both culturally and socially constructed in nature (Sharma, 1995). It is important to remember that these definitions are culturally situated. Thus that what in a particular Western country might regard as being “alternative” may be the traditional medicine of choice elsewhere. For example, osteopathy in the UK is still largely considered to be part of CAM, particularly cranial osteopathy, while in the USA osteopaths chose to become part of the orthodox medical profession (unlike chiropractors) in the 1950’s and 1960’s (Meyer and Price, 1993).

Table 1.1: Definitions of CAM

Source	Definition
www.skeptics.org.uk: a UK based organisation	Conventional medicine consists of medicines and treatments which have been tested in clinical trials and have been proven to work. Alternative medicine is defined as treatments that have not been verified through peer-reviewed, controlled studies, or which have failed to pass such studies. As such, they are not recognized by the medical community.
National Centre for Complementary and Alternative Medicine (NCCAM) USA	Complementary and alternative medicine, as defined by NCCAM, is a group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine.
The Cochrane Collaboration	A broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health systems of a particular society or culture in a given historical period.
World Health Organisation (WHO)	Traditional medicine refers to health practices, approaches, knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises, applied singularly or in combination to treat, diagnose and prevent illnesses or maintain well-being. In industrialized countries, adaptations of traditional medicine are termed “Complementary” or “Alternative” (CAM).

1.2.2 Prevalence of CAM use in general

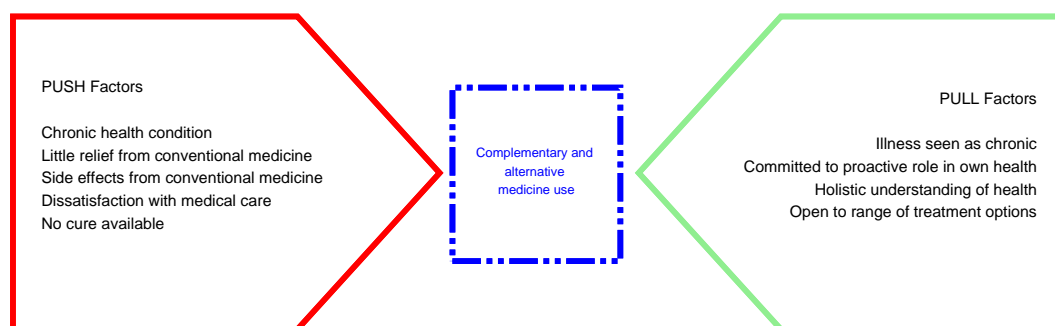
A number of population based surveys over the past two decades have reported significant and increasing numbers of people choosing to use such therapies (Eisenberg, Kessler, Foster, Norlock, Calkins and Delbanco, 1993; Eisenberg, Davis, Ettner, Appel, Wilkey, Van Rompay and Kessler, 1998; Ernst and White, 2000; Thomas, Nicholl and Coleman, 2001; Emslie, Campbell and Walker, 2002; Featherstone, Godden, Selvaraj, Emslie and Took-Zozaya, 2003; Lie and Boker, 2004). Although some treatments are now covered by medical insurance in the UK and USA, most therapies are not, meaning that patients pay largely out of their own pockets (Ernst and White, 2000). Interestingly in an era increasingly dominated by the call for evidence based medicine and practice, patients continue to seek out CAM which is comparatively under-researched (Furnham, 2002b).

Studies have been conducted in America, the UK, Australia and Japan with varying results. A variety of research techniques have been used, including telephone interviews with random population samples (Eisenberg, Davis, Ettner, Appel et al., 1998), face to face interviews as part of a larger survey (MacLennan, Wilson and Taylor, 1996; Thomas and Coleman, 2004)), convenience telephone sampling (Ernst and White, 2000) and postal questionnaires (Thomas, Carr, Westlake and Williams, 1991; Emslie, Campbell and Walker, 2002).

The majority of studies have provided a definition of CAM although it is clear that this varies across countries and cultures, with definitions that are by no means interchangeable. One study (Ernst and White, 2000) chose to ask open ended questions about CAM use, the majority of others such as Eisenberg (1993, 1998) base their inquiries on a pre-set list of therapies in common use (Eisenberg, Kessler, Foster, Norlock et al., 1993; Eisenberg, Davis, Ettner, Appel et al., 1998). In examples such as that of the study by Yamashita et al. specific practices that may in the UK or USA be considered as CAM were excluded from the estimates (Yamashita, Tsukayama and Sugishita, 2002). In this cultural setting herbal teas are an everyday part of life and 'ethical kampo' refers to herbs commonly prescribed by orthodox western doctors. Without a common definition of what the term CAM refers to, it is difficult to directly compare results.

The most recent data for the US comes from a national health interview survey, and for the UK from an additional 8 questions within the 2001 Omnibus survey which used a large nationally representative sample (Barnes, Powell-Griner, McFann and Nahin, 2004; Thomas and Coleman, 2004). There have been numerous more recent surveys of CAM use but these have largely focused on specific disease-populations (especially in cancer) rather than the general public. Thomas and Coleman's data suggest that within the UK men and women use CAM in equal proportions (although most surveys report more use by females). Attending a CAM practitioner was significantly associated with higher income, social class and full-time education

Figure 1.1: Push:Pull model of CAM use



after the age of 18yrs – however adults in all social and income groups reported some CAM use. In total, 10% of the sample had visited a CAM practitioner in last 12 months, and 6.5% had used one of the ‘big five’ therapies (herbal medicine, acupuncture, chiropractic, osteopathy and homeopathy).

1.2.3 Reasons for using CAMs

The topic of why people choose to use CAM as a form of healthcare, particularly when this means paying out of pocket for the treatment, continues to be the subject of ongoing research. This section offers a brief over-view and is intended to highlight that CAM users are most often seeking additional symptom relief, may be dissatisfied with conventional care or avoiding some aspects, but that they are unlikely to be “in flight from science” as has sometimes been claimed (Bishop, Yardley and Lewith, 2007). Decisions about using CAM’s can be at least partially explained by push factors (pragmatic reasons such as not receiving sufficient relief from symptoms, unhappy about side-effects etc.) and pull factors (the attraction of the CAM approach, desire to use natural products) and that the level of influence exerted by these variables will vary between individuals, see Figure 1.1. The research thus far has suggested that the push elements are responsible for the largest group of people who choose to use CAM.

Luff and Thomas used qualitative methods to explore reasons for using CAM within the NHS in England where the patients are not paying for treatment (Luff and Thomas, 2000). They reported that common themes were inefficacy of conventional treatment for this problem and the perceived positive benefits of CAM therapy rather than an existing preference for CAM treatment (Luff and Thomas 2000). The Thomas and Coleman data reported that of those using CAMs, 62% reported using CAM to treat an illness for which conventional treatment had previously been sought, 17% where conventional advice was not sought and 34% to maintain or improve health.

1.2.4 EBM and CAM

Complementary and alternative medicine (CAM) has engaged with the development of evidence-based practice in a number of different ways and for various reasons. In general, CAM practitioners operate out-with the conventional medical systems regardless of country, and patients often fund the costs of such treatments from their own pocket rather than being covered by the national health system/insurance schemes. CAM is a heterogeneous group of therapies and systems and it may not always be helpful to think of them as a block.

Some CAM professions have actively moved towards professionalisation, for example medical herbalists, acupuncturists, chiropractors and osteopaths. The reasons behind such a move may relate to the apparent imbalance in power between the accepted and fringe medicines, lack of access to patients and desire to provide integrated healthcare. By claiming an EBM basis for a therapy or treatment system practitioners have a clearer case for arguing in favour of insurance coverage or health service provision. As Christine Barry writes

increasing integration requires alternative therapists to start to play the “evidence” game” (Barry, 2006, pp 47).

This has implications in terms of adopting the EBM approach and subscribing to the underlying values. There have been clear calls for research to be conducted into complementary therapies coming from both researchers, sceptics and governments.

Evans, Schultz and Sadler (2008) have written about the changing knowledge base in Western Herbal Medicine and note that the main Australian professional organisation (National Herbalists Association of Australia, NHAA) has been lobbying for increased professionalism and recognition alongside using the discourse of science to explain herbal medicine effects. In a similar vein, Kelner et al's 2006 paper describes how part of the professionalisation of homeopathy in Canada has taken place in terms of a changing curriculum that now includes basic medical sciences, but research is not seen as particularly relevant to the profession (Kelner, Wellman, Welsh and Boon, 2006). This has not been a move greeted with universal approval, writers have described the emerging division between herbalists who embrace scientism versus those who prefer a more traditional approach that incorporates vitalism and holism (Jagtenberg, Evans, Grant, Howden, Lewis and Singer, 2006). A similar process has been documented within the chiropractic profession in the USA as the distance between those practitioners espousing the philosophy of vitalism, and those advocating the specific techniques of adjustment has increased. As a result three quite different practice-guidelines have been developed and the internal debates continue to develop (Villanueva-Russell, 2005).

Adams has examined the attitudes and perspectives of GP's who used both complementary and conventional medicine within their NHS practices. These doctors described their style of practice as a mixture of scientifically based principles combined with the intuitive application of knowledge to individual patient situations - much as most conventional doctors might identify with. Of the practitioners interviewed in this study, a small number stressed that EBM was a useful approach when combined with their clinical expertise, but the majority felt EBM was both restrictive and a threat to their style of practice. Their desire for clinical freedom included the ability to practice CAM which was seen as a clear example of individualised treatment (Adams, 2000).

The evidence-based approach offers valuable opportunities for CAM practitioners both in terms of evaluating and refining their treatments, and potentially allowing access to NHS patients. The RCT is sometimes seen as a difficult design to apply to CAM interventions, although with care some of these problems can be overcome through pragmatic comparative designs. The acupuncture literature in particular points to an increased understanding that some CAM modalities comprise complex packages of care. These care packages come with specific and non-specific effects, however trials currently tend to evaluate only single components of these packages, or structured versions of a component that is unlike normal practice (Paterson and Britten, 2003; Paterson, Ewings, Brazier and Britten, 2003; MacPherson, Mercer, Scullion and Thomas, 2003; McFerran and Phillips, 2007; Long, Mercer and Hughes, 2000; Price, Long, Godfrey and Thomas, 2011; Wayne, Hammerschlag, Langevin, Napadow et al., 2009).

1.2.5 Summary

CAMs continue to be utilised by a significant proportion of the population in most countries, with the available evidence suggesting this is usually in response to needs not met by conventional healthcare. Alongside the EBM movement we have seen a rise in pragmatic and/or comparative trials in health services research, and CAM more generally. CAM practitioners have engaged with EBM for a number of reasons but these seem to relate to power issues, provision and access of therapy and to patients leading to greater professionalisation rather than a push from practitioners who want to adopt an EBM approach to their own practice. Understanding the gaps and dissonance between an evidence base and actual practice is essential for ensuring that research is relevant to practitioners, policy-makers and patients.

1.3 Homeopathy

Homeopathy is an interesting example of CAM and continues to provoke strong feelings within the orthodox medical profession as evidenced by the ongoing debate about placebo effects and mechanisms of action (Shang, Huwiler-Muntener, Nartey, Juni, Dorig, Sterne, Pewsner and Egger, 2005; Shang, Juni, Sterne, Huwiler-Muntener and Egger, 2005; Rutten and Stolper, 2008; Ludtke and Rutten, 2008). There are three homeopathic hospitals within the NHS in the UK (correct at December 2011) although the majority of homeopathic consultations take place outside of the NHS and are paid for by the patients directly. There are around 400 homeopathically qualified GPs practicing in the NHS, and some small outpatient clinics, in contrast to over 2,000 non-medically qualified (NMQ) homeopaths.

1.3.1 Definitions and descriptions

This therapeutic system originated 200 years ago with the German physician and pharmacologist Samuel Hahnemann (1755-1843). As systematised by him, it has numerous features to distinguish it from botanical and conventional approaches to diagnosis and treatment (Hahnemann, 1913 [1810]). The fundamental principle is the treatment of 'like with like': any natural or man-made substance capable of causing specific disease states and symptoms in healthy individuals may be used to treat the same symptoms when they occur as part of sickness. The material medica of homeopathy is based on provings (notes and observations of healthy individuals symptoms in response to being given a remedy), clinical observations and toxicology reports, thus in some senses homeopathy at least in terms of the remedies used is evidence-based. Whether or not this can claim to be "evidence" is controversial and highlights the varying definitions of this contested term.

During homeopathic diagnosis, the symptoms of each patient are considered primarily as an expression of a unique personal illness, as well as evidence that the patient can be assigned to a conventional disease category. Qualitative aspects of the patient's experience of illness (for instance, emotions such as 'feeling forsaken' or symptom modalities such as 'restlessness increased after 1800 hours') are of particular relevance in determining treatment. Concomitant symptoms and co-morbid conditions are also included in the analysis as part of a 'symptom complex'.

In homeopathic treatment according to Hahnemanian principles therefore, there are no uniform medicines to be given for particular conditions. The medicine for each patient is chosen based on their symptom picture and unique characteristics which are then matched with a suitable medicine. Homeopathic pharmacy involves a unique process in which the source material

is serially diluted, with violent succussion or shaking at each stage. Called dynamization or potentization, the process may be repeated many times until no molecules of the starting substance theoretically remain. During treatment, medicines, dilution, dosage and repetition may be changed in response to changes in the patient's condition.

Different homeopathic approaches have been tested in clinical trials, and categorized as classical, clinical, complex and isopathic subtypes (Linde, Clausius, Ramirez, Melchart et al., 1997). Classical homeopathy is the complex intervention described above, involving an in-depth consultation and individualized analysis regardless of the condition being treated (Chapman, Weintraub, Milburn, Pirozzi et al., 1999). Clinical homeopathy provides a standardized prescription for a predefined condition, based either on traditional recommendations, or new analysis of symptoms (Clark and Percivall, 2000). Complex homeopathy combines several clinical medicines into a single formula (Weiser, Strosser and Klein, 1998). Isopathic medicines are prepared from known or presumed aetiological agents (Taylor, Reilly, Llewellyn-Jones, McSharry et al., 2000). Classical homeopathy can potentially include the other modalities, as part of an individualized course of treatment.

1.3.2 The practice of homeopathy

Homeopathy was introduced to the UK from Germany by Dr Frederick Quin who founded the British Homeopathic Society in 1844, and the London Homeopathic Hospital in 1849 (Hughes, 1994 [1902]). Initially this system of medicine was practiced by conventional medical doctors. This was met with strong opposition from the mainstream medical groups, despite the British Homeopathic Society's (later named the British Homeopathic Association) moves to medicalise homeopathy and integrate existing allopathic ideas. Partly in response to the perceived dilution of homeopathy with allopathic medicine, lay practitioners who claimed to follow traditional Hahnemanian principles began to increase in number under an alternative organisation; the English Homeopathy Association (now the Society of Homeopaths) (Nicholls, 1984, 1992). This division between medical and the non-medical or professional homeopaths continues to the present day both in terms of professional organisations and training.

Homeopathy met similar resistance when introduced to America (by Hans Gram). Initially homeopathy prospered, and before the First World War there were 22 colleges and 56 purely homeopathic hospitals (Campbell, 1984). However the vigorous opposition from the American Medical Association (founded to oppose the American Institute of Homeopathy) was successful in almost wiping out the practice of homeopathy. American homeopaths such as JT Kent and other Swedenborgians were responsible for shaping the development of homeopathy and introduced more metaphysical ideas, the use of ultra-high potencies and characterisation of remedy

pictures (Campbell, 1984; Dean, 2004). It is difficult to define homeopathy as such, but worth noting that when the term classical homeopathy is used in the literature, this usually refers to the Kentian tradition.

Homeopaths are not statutorily regulated in the UK at present and there are no minimum training requirements, although they have been encouraged to explore voluntary regulation by the House of Lords report and various initiatives by the Foundation for Integrated Health (FIH) (Select Committee on Science and Technology, 2000). A promising collaborative initiative between organisations representing professional homeopaths was set up under the name CORH (Council of Organisations Registering Homeopaths), however this process stalled and was disbanded in 2007. Several organisations are now pressing ahead with their own plans for voluntary regulation including the largest registering body, the Society of Homeopaths.

Homeopathy courses for non-medical practitioners are provided by private colleges (some of which were affiliating to universities between 2004-2010) and universities such as Westminster resulting in diplomas, certificates or degrees. The situation when this thesis was completed was rather more constrained, this is dealt with in more depth in Section 7.1. Training usually lasts around 3 years on part-time or full-time basis and is likely to include supervised practice before and after qualification (Alliance of Registered Homeopaths, 2004). The Faculty of Homeopathy provides recognised training courses for qualified healthcare professionals; doctors, nurses, dentists, pharmacists and veterinary surgeons. These are postgraduate modular courses which take between 2-3 years to complete.

Several global systematic reviews and meta-analyses have examined trials of homeopathy meeting specific criteria with mixed results. Regardless of the positive or negative outcome, most have concluded that the homeopathy used in trials is unlikely to reflect usual practice (Kleijnen, Knipschild and Ter Riet, 1991; Linde, Clausius, Ramirez, Melchart et al., 1997; Cucherat, Haugh, Gooch and Boissel, 2000; Linde and Jobst, 2000; Ernst, 2002; Dean, 2004).

1.3.3 Prevalence and reasons for homeopathy use

Within the UK general population, CAM use is estimated at around 10% when considering practitioner-based therapies (Thomas and Coleman, 2004). Homeopathy accounts for 1.9% of this total; in comparison with 1.9% for osteopathy, 1.6% for chiropractic and 1.6% for acupuncture. Internationally the use of homeopathy varies between countries; in the USA, for example, 3.6 % of the population have used homeopathy in their lifetime and 1.7% in past 12 months (Barnes, Powell-Griner, McFann and Nahin, 2004). However, homeopathy does appear more popular in some parts of northern Europe, for example, in Germany between 10-20% of adults

have used homeopathy and data from Norway suggests around 37% of the population use some form of homeopathy (Hartel and Volger, 2004; Steinsbekk and Fonnebo, 2003).

The available survey data suggests that a sizeable proportion of children and young people are being treated with homeopathy both in the UK and internationally. A cross-sectional survey based in the south-west of England has reported that 17.9% of children under 16 years had used some form of CAM and 61% of these children had experienced homeopathy or used a homeopathic remedy (Simpson and Roman, 2001). Children under the age of 10 years make up a quarter of the patients seen by Norwegian homeopaths and homeopathic treatments accounted for 14.1% of paediatric CAM practitioner visits in 1996 in the USA (Steinsbekk and Fonnebo, 2003; Yussman, Ryan, Auinger and Weitzman, 2004).

Given the lack of consensus about the effectiveness of homeopathy, a number of studies over the years have examined the reasons why people continue to seek it out. Furnham and others have asserted on the basis of a considerable body of research that patients seek out alternative treatments in part due to dissatisfaction with orthodox medicine rather than a strong belief in the theory of a particular therapy such as homeopathy, although many rate the importance of the whole person approach highly (Furnham and Smith, 1988; Furnham and Bhagrath, 1993; Furnham, 1993; Furnham and Forey, 1994; Furnham and Beard, 1995; Furnham, Vincent and Wood, 1995; Furnham and Vincent, 1995; Furnham and Kirkcaldy, 1996; Furnham, Yardley, Fahmy and Jamie, 1999; Furnham, 2000; Furnham and Lovett, 2001; Furnham, 2002a).

Overall, the more therapies a person has heard of or used, the more positive they tend be about CAMs in general and homeopathy in particular (Furnham, 2000). Homeopathy patients appear, from the available research, to be consulting for chronic long-term conditions for which orthodox treatment has proved ineffective or has unacceptable side-effects/risks. These conclusions largely agree with the findings of a systematic review of beliefs around using CAM in general (Bishop, Yardley and Lewith, 2007). None the less, they should be considered with caution as the studies conducted so far have used adult homeopathy patients from NHS clinics and funded hospitals, while the majority of people using homeopathy are likely to consult lay practitioners in private practice.

There have, as yet, been no population-based studies looking at reasons for using CAM with children in any detail (Tsao and Zeltzer, 2005), although it is clear from the data presented in the preceding paragraph that children are increasingly being taken to alternative practitioners or given remedies. Although research tentatively suggests that CAM is used more for acute conditions in children, given the concerns in adult users about side-effects, it seems reasonable to hypothesise that a proportion of parents are using CAM for their children for similar reasons, particularly in chronic conditions. Indeed a review paper looking at the use of CAM in developmental disability concluded that it

“demonstrates the ongoing search for effective and balanced treatment of these lifelong conditions.” (Brown and Patel, 2005)

Homeopathy is widely promoted as a safe treatment with minimal side effects for children and young people by practitioner organisations. For example the Society of Homeopaths states on its website (correct at 2009) that

“Homeopathy is ideal for babies and children as it is a gentle yet highly effective system of medicine. The highly diluted natural substances that form homeopathic remedies mean that they are safe to use in the very young, including newborn babies.” Society of Homeopaths website (2009)

1.3.4 Summary

Homeopathy is a controversial system of treatment which originated over 200 years ago. Based on using highly dilute solutions of substances which are reported to cause similar symptoms in health individuals, homeopathy has yet to offer a scientifically accepted method of action. Given the complex and varied nature of homeopathic practice, characterising and describing the intervention itself is one of the many challenges within homeopathic research. Despite the uncertainty around how homeopathy might work, significant numbers of people choose to consult homeopaths most commonly for chronic conditions. The combination of increasing numbers of children and young people being treated with homeopathy, and the continued promotion of this therapy as a relatively risk-free beneficial treatment, presents a pressing argument for further research in paediatric homeopathy.

1.4 Attention Deficit/Hyperactivity Disorder

1.4.1 Diagnosis

Attention-deficit/hyperactivity disorder (ADHD) has existed as a diagnostic category since 1980, with the publication of the Diagnostic and Statistical Manual (DSM) Version III (Barkley, Fischer, Edelbrock and Smallish, 1990). Hyperactivity syndrome began to be distinguished from brain damage syndromes in the 1960's and since the 1970s hyperactivity syndrome has been closely associated with attention deficits. This has led to wide acceptance in some circles that ADHD is a complex disorder with both developmental and biological underpinnings. Brain imaging and

genetic research are current areas of interest, but observation of behaviour remains the basis of diagnosis in the absence of reliable tests for biological markers.

DSM-IV diagnostic criteria for ADHD include the three core signs of inattention, hyperactivity and impulsiveness. It also recognises three subgroups of ADHD: i) predominantly hyperactive-impulsive type (not showing significant inattention); ii) predominantly inattentive type (not showing significant hyperactive-impulsive behaviour); and iii) combined type (displaying inattentive and hyperactive-impulsive symptoms) (APA, 2000). Hyperkinetic disorder (HKD) is the term used in ICD-10 used more commonly in Europe, and refers to a more seriously affected subgroup similar to patients diagnosed as having DSM-IV combined type ADHD (WHO, 1992).

Diagnosis is usually determined by child/adolescent psychiatrists or paediatricians according to either the DSM-IV or the ICD-10. Both sets of diagnostic criteria state that for a diagnosis of ADHD/HKD symptoms must have been present for at least six months, causing distress and in conflict with the child's developmental level, and impairment should present and be apparent in two or more settings. The symptoms should have been present before the age of 7 years, and should not be better explained by an alternative diagnosis. Diagnosis is only given by secondary care specialists within the UK, therefore treatment may be initiated before diagnosis has been confirmed.

A world-wide pooled population prevalence of 5.3% in children under the age of 16 years has been postulated by Polanczyk and others using the most up to date data (Polanczyk, de Lima, Horta, Biederman et al., 2007). Using ICD-10 criteria, prevalence had been estimated at around 1% of school-aged children in the UK, increasing to 5% if DSM-IV criteria were applied to the population in 2000, which translated to around 366,000 children in England and Wales (Lord and Paisley, 2000). The most recent data within the UK suggests that current prevalence stands at 5% of school-aged children (National Institute for Clinical Excellence, 2008). A US population-based birth cohort study of 5,781 children estimated a prevalence of 7.5% at age 19 years using DSM-IV criteria in 2004 (Barbarese, Katusic, Colligan, Weaver et al., 2004). Lower UK prevalence may be due to the use of the narrower ICD-10 criteria, and to diagnosing the condition only after referral to secondary care, among other factors. ADHD can affect both males (more commonly) and females, of any ethnicity. The affected population has generally been defined as children and adolescents to age 18 years. After this point the patient is usually referred to adult services although in some areas this occurs at age 16 (ADDISS, 2003). However, increasingly ADHD has been postulated as a long-term condition which continues into adulthood for a substantial number of sufferers - up to 65% (Jadad, Boyle, Cunningham, Kim et al., 1999). with relatively few effective treatment options (Asherson, Adamou, Bolea, Muller et al., 2010; Moncrieff and Timimi, 2010; Koesters, Becker, Kilian, Fegert et al., 2009; Manuzza, Klein and Moulton, 2003).

There is an ongoing debate around the social construction of ADHD as a disease category and there is as yet no clear consensus on the underlying aetiology (Cooper and Shea, 1999; Brady, 2004; Rafalovich, 2004). It is important to note that while the previous paragraphs outline the ideal approach to ADHD diagnosis, the reality is that ADHD remains a contested condition without biomarkers or proxy indicators which can be easily measured. ADHD prevalence rates are affected by cultural perceptions/expectations and the willingness of physicians to attach the ADHD label (Neufeld and Foy, 2006). Some paediatric specialists have spoken out extensively against the idea that ADHD is a medical condition at all, or that such children should be treated with stimulant medication (Malacrida, 2004). Educational psychologists may use terms such as Attentional Difficulties which includes children with diagnosed ADHD, as well as children with less severe symptoms, or those who have not been formally assessed to more accurately describe the children they deal with on a daily basis. ADHD remains a nebulous concept that overlaps with other, similarly contested conditions such as Oppositional Defiant Disorder or Conduct Disorder (Biederman, Newcorn and Sprich, 1991). This cluster of conditions have been attacked by writers such as Slee who suggest that emphasising the cause as within the child or biological is to ignore the true, social causes of these problems (Slee, 1995; Conrad, 1975, 2004). This tendency to polarise the debate as nature versus nurture, biological versus social causative factors has been recognised as unhelpful, but undoubtedly continues to influence both the research community as well as support and advocacy groups (Cooper and Ideus, 1995).

1.4.2 Living with ADHD

The inattention, hyperactivity and impulsivity that characterises ADHD has been shown to result in poor academic performance and difficulties in social and behavioural functioning in and out of the home (Greene, Biederman, Faraone, Ouellette et al., 1996; Stein, Szumowski, BlonDIS and Roizen, 1995). ADHD symptom profiles tend to shift towards inattention in later years, however persistence of the condition has been associated with other psychopathology, school failure, poor self-esteem and emotional problems (Biederman, Faraone, Spencer, Wilens et al., 1993; Biederman, Faraone, Taylor, Sienna et al., 1998; Wilens, Biederman and Spencer, 2002; Biederman, Faraone, Milberger, Guite et al., 1996; Barkley, Fischer, Edelbrock and Smallish, 1990). ADHD diagnosis in children is associated with an increased risk of accidents, including injuries inflicted on others and on themselves, and collisions when walking or cycling (DiScala, Lescohier, Barthel and Li, 1998). Children diagnosed with ADHD generally do less well academically and experience poorer mental and emotional health compared to those without this diagnosis (Taylor, Chadwick, Hepinstall and Danckaerts, 1996; Hechtman, Abikoff, Klein, Weiss et al., 2004). Parents and guardians of children with ADHD are also negatively impacted

in terms of financial burden, quality of life, inter-personal relationships and work status (Noe and Hankin, 2001; Brown and Pacinin, 1989; Barkley, Fischer, Edelbrock and Smallish, 1990).

The effects of ADHD have been shown to reach into adolescence and adulthood. Children previously diagnosed with ADHD are at increased risk of cigarette smoking and substance abuse (Pomerleau, Downey, Stelson and Pomerleau, 1995; Milberger, Biederman, Faraone, Wilens and Chu, 1997). One study reported that participants with ADHD were significantly more likely to make the transition from an alcohol-use disorder to a substance-use disorder, and were also significantly more likely to experience dependence on substances (Biederman, Wilens, Mick, Faraone and Spencer, 1998). A relatively small study by Rosler has pointed towards significantly higher levels of psychiatric morbidity in the young adult prison population compared with controls, including considerable presence of ADHD (Rosler, Retz, Retz-Junginger, Henges, Schneider, Supprian, Schwitzgebel, Pinhard, Dovi-Akue, Wender and Thome, 2004).

Although it is beyond the scope of this thesis to present the full details, there has been a steady research tradition of using qualitative methods, particularly ethnography, to explore the experience of children living with a diagnosis of ADHD since the early 1990's. Many of the studies have emphasised that data collected from the children themselves points towards ADHD as a bio-psychosocial condition with wide-ranging effects on their daily life - something which is not always recognised by parents, teachers and health professionals who may be approaching the symptoms from only one angle (Brady, 2004; Hughes, 2003; Roache, 2003; Friio, 1999). The children involved in the research to date have been clinically diagnosed with ADHD, and many have been taking medication. Studies which have directly explored the experience of taking drugs such as Ritalin reveal a complex picture containing both positive and negative effects. Diagnosis and medication seemed intertwined, and marked the child out as different from peers. The medication may have had beneficial effects, but the taking of it was seen as stigmatising (Owen, 2000; Santoro, 2003). One thesis drew out the idea that, while for some children taking medication was felt to be empowering, there was an associated anxiety about how they would cope without it (Clarke, 1998).

The research focusing on the experiences and challenges faced by parents of children with ADHD has largely been mother-oriented. These studies have explored the discourses around parenting, the impact on mothers in terms of self-esteem, self-worth and control, and power relations between mothers and health professionals (Pearson, 1999; Bennett, 2004).

The research thus far has not been connected to trials of treatments. Although most of the studies focus on children who have been offered or are taking medication, there does not appear to be a similar literature around psychosocial and behavioural treatments.

1.4.3 Treatments for ADHD

Currently available treatments for ADHD include behavioural training for teachers and parents, and parenting skills classes as well as medication. Drug therapy began in the 1930s, (Bradley, 1937). and started to attract attention in the 1950s (Laufer, Denhoff and Solomons, 1957). Since the 1970s, stimulant medications such as dexamfetamine, and methylphenidate have increasingly been used as the treatment of choice, but remain controversial (Coghill, 2004; Timini, 2003). More recently, the first licensed drug treatment claimed by the manufacturer to be a non-stimulant was atomoxetine, followed by alpha2 agonists such as reboxetine, guanfacine and clonidine although not all of these treatments are available in the UK (Antshel, Hargrave, Simonescu, Kaul, Hendricks and Faraone, 2011).

Within the UK, methylphenidate, atomoxetine and dexamfetamine are recommended, within their licensed indications, as options for the management of ADHD (National Institute for Clinical Excellence, 2008). Parent and teacher training programmes are often used as a first level of treatment in both the UK and USA, while the Multi-Treatment Approach studies from the USA have provided reasonable evidence that behavioural therapy can be as effective as stimulant treatment for some children (MTA Cooperative Group, 1999a).

The most recent guidelines within the UK for treating ADHD in children, young people and adults have been produced by the National Institute for Clinical Effectiveness (NICE). They recommend that parents/carers should be offered a referral to training/education programme as a first stage regardless of diagnosis of the child, school age children with severe ADHD should be offered pharmacological treatment through a secondary care provider and the parents/carers offered a group-based training and education programme (National Institute for Clinical Excellence, 2008). Drug treatment is recommended as part of a comprehensive, multi-component intervention, although regional variations in the levels of service available may mean this is not possible. A technology assessment review carried out for NICE concluded that while there are a number of trials demonstrating effectiveness of pharmacological treatments, in general these studies are short-term and use physician or parent-rated outcome scales with no reference to the patients being treated (King, Griffin, Hodges, Weatherly, Asseburg, Richardson, Golder, Taylor, Drummond and Riemsma, 2006). Further trials incorporating child/young person centred outcomes measures and using long term follow-up were strongly recommended.

A number of papers have raised issues both about the appropriateness of prescribing stimulants on a long-term basis to developing children without information on side effects and issues of non-compliance, including an estimate that up to 30% of children are unable to tolerate drug treatment or are unresponsive (e.g. Garland, 1998; Daley, 2004; Marcovitch, 2004). Research

has continued to highlight the potential side-effects of stimulant medication including growth deficits, tics, appetite changes, headache, insomnia, anxiety, irritability and stomach ache (King, Griffin, Hodges, Weatherly et al., 2006; Swanson, Elliott, Greenhill, Wigal et al., 2007) and concerns have grown that such medication may be inappropriately prescribed (Goldman, Genel, Bezman, Slanetz and for the Council on Scientific Affairs, 1998; Bjornstad and Montgomery, 2005). A systematic review from 2011 addressed the effectiveness and safety of long term medication for ADHD and concluded that there was limited and inconclusive evidence to support long-term benefits after 2 years of treatment (van de Loo-Neus, Rommelse and Buitelaar, 2011).

1.4.4 Summary

ADHD is a controversial diagnosis which requires severe behavioural disturbance to be present for at least 6 months, and is characterised by inattention and hyperactivity. The exact causes are still under investigation, and the contribution of social versus biological factors continues to be debated. Quantitative and qualitative studies demonstrate that regardless of the veracity of the label, children diagnosed with ADHD are likely to experience more accidents, are more vulnerable to later drug-use and do less well academically among other negative outcomes. Children labelled with ADHD experience the world differently and may struggle to adapt to medication routines. Living with an ADHD diagnosed child also has numerous adverse effects on the parents and guardians. The effective conventional treatment options include psychosocial and behavioural interventions, and pharmacological treatments with a range of delayed release formulations. The long-term efficacy and adverse effects of these treatments are still under investigation.

1.5 Complementary medicine and ADHD

1.5.1 Reasons for CAM use

Perhaps understandably some parents and carers have chosen to use non-standard/alternative treatments either in place of or alongside stimulant medication, despite the lack of evidence available (Brue and Oakland, 2002). Survey research in Australia has reported that from a list of 12 possible factors in choosing to use CAM: minimizing symptoms (88.9%), adding benefit to the doctors treatment (69.7%) and avoiding side-effects of prescribed medications (67.4%) were the most commonly endorsed. Importantly, 50% of the families who had tried some form of

CAM said that they did so in the hope that the non-standard treatment could replace prescribed medication/treatment (Sinha and Efron, 2005).

Although there is a reasonable amount of research looking at attitudes and attributions around use of CAM generally and for specific conditions within the adult population, as mentioned there is little with respect to children and even less within the ADHD sub-group. Questionnaires have been used to ascertain attitudes towards treatment and beliefs about ADHD from parents of boys aged 5-13yrs diagnosed with ADHD in British Columbia, Canada with interesting results (Johnston, Seipp, Hommersen, Hoza et al., 2005). 73 families completed the questionnaires, 81% of which were currently using medication. The majority of the families used medication and behaviour management rating these as above average in effectiveness, however half of the families also reported using non-standard treatments. Those families responded to behaviour scenarios about ADHD indicating that they believed the behaviour was significantly more internal to the child, and significantly more global/stable than families who did not use these treatments. Unfortunately families were not asked about their reasons for seeking these treatments.

1.5.2 Prevalence and range of treatments used

A wide variety of non-standard treatments and interventions have been proposed for use with ADHD diagnosed children including, but not restricted those listed in Table 1.2 on the facing page (Brue and Oakland, 2002; Rojas and Chan, 2005).

A survey from Western Australia in 1993 of children diagnosed with ADHD asked about a variety of non-standard treatments used by these children including dietary manipulation, coloured glasses and visiting a chiropractor (Stubberfield and Parry, 1999). Nearly 70% of their sample were currently taking stimulant medication, and of these 66% had tried at least one non-standard treatment. Of the children not taking stimulant medication, 62% had also tried a non-standard therapy.

Data from Australia indicates that the proportion of diagnosed ADHD paediatric patients has risen slightly to 67.6% use with modified diet and vitamin or mineral use again being the most common. Around 6% reported having tried homeopathic treatment with around half saying it had been effective (Sinha and Efron, 2005).

One American survey of children referred for evaluation of ADHD, not necessarily diagnosed, found a similarly high level of CAM use of 54% in the past year (Chan, Rappaport and Kemper, 2003). A similar type of survey has been carried out in a school district in a Florida where parents/carers of children diagnosed with ADHD, where it was suspected, or teachers had

Table 1.2: Alternative treatments used for ADHD

Alternative Treatments used for ADHD
Dietary modification
Essential fatty acid
Vitamin A
Grapine and L-glutamine supplementation
Oligoantigenic diet
Homeopathy (e.g. stramonium cina, hyoscyamus niger)
Electroencephalogram (EEG) biofeedback, also known as neurotherapy
Yoga
Massage therapy
Utilization of school-based environmental green outdoor settings.
Chiropractic
Herbal medications (e.g. <i>Ginko biloba</i> , <i>Melissa officinalis</i>)

serious concerns about emotions or behaviour were recruited. Parents were asked if their child had used chiropractic, homeopathy, massage, acupuncture or faith healing and a summary of the results from 822 children presented in Table 1.3 (Bussing, Zima, Gary and Garvan, 2002).

Table 1.3: CAM use and ADHD diagnosis

Modality used	Diagnosed (n=146)	Suspected (n=222)	General concerns (n=454)
CAM	12%	7%	3%
Faith healing	5%	5%	4%

Children with a diagnosis of ADHD and therefore with more severe symptoms were significantly more likely to use one of the four named CAMs. Parents of these children were also more knowledgeable about ADHD. Unfortunately the authors do not present the therapy specific usage data by category but as a proportion of the whole sample. Looking at the 822 children together gives a CAM usage of only 5%, of which homeopathy accounted for 3%; however it

is unclear if homeopathy use was equally distributed across severity categories. The low rate of CAM use in this study is likely to be the result of not including dietary, mineral or vitamin interventions, and the inclusion of both diagnosed, suspected and designated at risk children, most previous studies have used children with diagnoses or severe symptoms only.

Gross-Tsur et al interviewed a sample of patients diagnosed with ADHD and attending a clinic as part of a comparison study with epileptic children in Israel (Gross-Tsur, Lahad and Shalev, 2003). They found a low rate of CAM use for ADHD (7.5%) however 1/3 of the children had used CAM at some point in their lives. All of those children using CAM were also receiving stimulant medications. This study also interviewed a sample of children from the emergency room as controls, and no significant difference was found between the groups on CAM use. It is unclear from the paper if the interviewer asked about vitamin/mineral use; since this has been reported previously as widely used this may account in part for the lower figures.

1.5.3 Summary

To summarise the limited data available, between 7% and 69% of ADHD diagnosed children may be using some form of non-standard or alternative treatment for relief of symptoms. Use of homeopathy by children at risk of or diagnosed with ADHD is reported at 3% in Florida, but as high as 6% of diagnosed children in Australia while there is little reliable data on the use of CAMs or homeopathy for ADHD in the UK. Where reported, reasons for using CAM centred around the hope to reduce medication and seek additional relief from symptoms not currently well controlled by conventional treatments.

1.6 Research Aims and Objectives

This thesis is focused on the interplay between research evidence and clinical practice within homeopathic treatment of ADHD in children and young people. The preceding sections have summarised both the disease (ADHD) and intervention (homeopathy) of interest, and argue that in view of the increasing numbers of children diagnosed with ADHD receiving non-standard treatments, this is a valuable research topic. CAM is not unique in struggling to marry research results and clinical practice, but may sometimes face increased difficulties given the complex and individualised nature of the interventions.

The prevalence of homeopathy use and its advertising justifies examining the area in more detail. Concerns have been voiced by both the media and scientific voices about the available

treatment options for ADHD including the reliance on medication. Despite a lack of strong evidence in favour of homeopathy generally, people continue to use it for a variety of reasons. There is a challenge within homeopathic perspectives when limiting by condition as many homeopaths claim not to use such labels. Considering an intervention and disease pairing makes sense in terms of evaluating an evidence base where outcome measures are likely to be disease specific. While homeopaths may be less interested in the diagnosis presumably they are interested in improving the symptoms, so given that the NHS runs under the biomedical model of health and disease the groupings made sense for this research.

The research aims for this project were divided between establishing the current evidence base in terms of RCTs, and exploring everyday clinical practice of homeopaths working with ADHD in the UK.

Homeopathy and ADHD: the research evidence

1. Describe the homeopathic treatment for ADHD as tested in clinical trials
2. Assess the efficacy and effectiveness of homeopathy as a treatment for ADHD/HKD
3. Evaluate the safety of homeopathy as a treatment for ADHD/HKD

Homeopathy for ADHD: clinical practice

1. How do homeopaths in the UK understand and treat ADHD in children/young people (CYPs)?
2. How do homeopaths assess the impact of their treatments on CYP's?
3. To what extent does the homeopathy practised in controlled trials of homeopathy for ADHD reflect usual practice for UK homeopaths?
4. Would UK homeopaths be willing to practice as per the controlled trials, i.e. would they change their practice?

Summary

The focus of this thesis is to explore the dissonance and overlap between the research base and clinical practice in the treatment of Attention Deficit Hyperactivity Disorder (ADHD) by homeopaths. A summary of the development and sometimes thorny implementation of evidence

based medicine has been presented. A discussion of what complementary/alternative medicine might mean, and its interaction with the evidence-based healthcare movement has been outlined. Homeopathy and ADHD have been both defined and problematised, and the available information on use of complementary/alternative medicine for children and young people with ADHD summarised. This chapter has concluded with the main research aims. The next chapter outlines the theoretical positions adopted during the research, and the methods chosen to address the questions given above.

Chapter 2

Methodology Overview

This chapter outlines the choice of a mixed-methods approach to exploring the homeopathic treatment of children with ADHD. The basics of subtle realism as an epistemological stance are outlined, and the essential components of Grounded Theory as adopted for this project are described. The interwoven data collection process is diagrammed and each appropriate technique discussed in general terms. The following chapters discuss the implementation of the data collection strategies, results and subsequent analyses.

2.1 Epistemology

Research methods are sometimes written about assuming that there is a definite and fixed correspondence between method and underlying epistemology. This usually takes the form of claiming that quantitative methods are intrinsically positivist and can only be used in such a manner, while qualitative research is fundamentally interpretive or constructionist, which has the overall result of casting doubt on the value of combining research strategies. A number of writers have cast doubts on these hard and fast distinctions suggesting that the link between the natural sciences and inferential statistics (for example) is less firm than expected e.g. Brannen (1992); Bryman (2004). In fact, it has been argued that research techniques can be used interchangeably across epistemological positions, chosen more for practical and technical reasons than based on underlying theory. Mixed methods research acknowledges that there is more than one way to explore an issue.

The underlying epistemological position adopted throughout this thesis is one of subtle realism as described by Hammersley (1992b). This position stands between naïve realism and relativism. Realism suggests that research can uncover the underlying realities that exist beyond the researcher, and good research will correspond to this reality. Relativism highlights the social

constructivism of experiences, accounts and phenomena where multiple social realities exist with no one account being prioritised over any other, “*one version of the world amongst others*” (Hammersley, 1992c, pp48). Hammersley has outlined how neither of these approaches are compatible with ethnographic research (and by comparison, qualitative research more generally) and suggests subtle realism as an alternative which offers escape from arguments dominated by circularity. The key principles of subtle realism are summarised below and are to be found in a number of texts on qualitative research, particularly in Health Services Research (Murphy, Dingwall, Greatbatch, Parker et al., 1998; Spencer, Ritchie, Lewis and Dillon, 2003; Pope and Mays, 2006).

- Knowledge is defined as a set of beliefs that we are reasonably confident about, rather than beliefs which are known to be valid with certainty
- Phenomena exist independently of our claims or research on them. Our claims may represent the phenomena more or less accurately but should attempt to approach better representations
- Social research represents reality from particular points of view, rather than reproducing it per se. This can result in multiple descriptions and explanations of the same phenomena.

Subtle realism embraces the opportunities offered by mixed methods research, and avoids dichotomising the qualitative and quantitative divide.

2.2 Grounded Theory

A grounded theory approach was adopted throughout this project from design, through data collection, to analysis. While grounded theory is traditionally invoked within purely qualitative research traditions, it was originally conceived of as an approach to data collection and analysis that emphasised working from the original data and remaining open to emerging concepts, without limiting the methods themselves.

Grounded theory as a distinctive methodological approach was first developed by Barney Glaser and Anselm Strauss in the 1960's, two sociologists working on projects around death and dying. Grounded theory was intended to offer an empirical method for collecting and analysing data which stayed grounded in the original material, generating original dense theory (Glaser and Strauss, 1967). At the time of grounded theory's development, sociology was increasingly dominated by quantitative techniques and the use of large over-arching theories.

Grounded theory began to reverse this trend combining interactionist perspectives with systematic conceptual comparison and development primarily within qualitative research. Glaser and Strauss continued to use and refine the analytic principles of grounded theory, publishing their own particular versions of the methodology (Glaser, 1992, 1999; Strauss and Corbin, 1990, 1998).

As noted by other writers, grounded theory has been used widely, particularly within nursing and health services research areas. Perhaps because texts such as “Basics of Qualitative Research” have made it a relatively accessible methodology, it has been a popular analysis style (Strauss and Corbin, 1990, 1998). Criticisms have been made around the quality of grounded theory in general alluding to this popularity and a tendency to use the grounded theory label as a gloss over the methodology of individual projects. Clarke described this problem as “analysis lite”, where the processes of grounded theory are not fully developed and there is a failure to develop deeper analytical categories (Clarke, 2007). This thesis explicitly details the elements of grounded theory analysis that have been adopted, and attempts to show through rigorous and transparent documentation that these elements have been used to their fullest extent. Additionally, the advice of Charmaz and Clarke (2005; 2007) has been taken with the result that only modest claims are offered within the analysis, avoiding over-generalisation and maintaining an awareness of constructivist viewpoint - the resultant theory is therefore presented as a “*located and limited story*” pp 360 Daly (1997).

2.2.1 Grounded theory and mixed methods research

The grounded theory approach was originally adopted for two reasons; firstly, this research project was exploring new areas of research which have not been well documented and grounded theory was specifically developed for such a task (Glaser and Strauss, 1967). Secondly, grounded theory contains a number of detailed steps which have been well-described in the literature facilitating their use by a novice qualitative researcher (Glaser, 1992; Cresswell, 1998; Strauss and Corbin, 1998; Charmaz, 2006). Additionally, although grounded theory is most often associated with qualitative research, it was never intended to be used solely in this way according to the founders of the method. The adaptation of this approach to mixed-method and quantitative data was seen as an opportunity to push the boundaries of the traditional qualitative versus quantitative divide.

when we speak about combining methods we want to make the point that to build dense, well developed, integrated and comprehensive theory, a researcher should make use of any and every method at his or her disposal, keeping in mind that a true interplay of methods is necessary.” (Strauss and Corbin, 1998, pp 33)

Glaser in particular has published on the use of grounded theory in guiding the analysis of quantitative data, Glaser (2008, 1994), although Strauss and Corbin have also advocated a pluralistic approach to method choices. Despite these early encouragements, the idea does not appear to have been taken up to any great extent in the research community.

One of the few published papers located on the use of grounded theory in this way looked at the use of a particular kind of auction system (e-reverse auctions) and the impact on buyer-seller relations (sample size = 143). The paper describes in some detail how the theoretical background to the area was used to guide the exploratory analysis of survey data and in particular in facilitating the explanation of various correlations and relationships between concepts Losch (2006). The study itself was based on a small pilot study and a critical literature review, which contradicts some of the more traditional interpretations of grounded theory (not conducting a literature review prior to data collection) but does mirror the pragmatic approach taken in this thesis.

A further article by Martínez (2007), looked at decisions on which gas station to buy petrol from. This study used grounded theory throughout the interviews, focus groups, questionnaire analysis and cluster analysis stages to guide the analysis and interpret the results. From an initial starting point of conventional open and axial coding applied to focus group discussion transcripts, a provisional model was proposed. The questionnaire was designed to explore this model and collect a larger quantity of data. Cluster analysis among other methods was used to test the proposed model, and the results informed further development of the underlying core concepts. While neither of these papers tackle areas specifically relevant to my research, they provide proof of concept to the extent that grounded theory is shown to be a useful addition to exploratory research which includes quantitative data. Both papers used the form of grounded theory coding and analysis as described by Strauss and Corbin, rather than the coding families suggested by Glaser.

The following key elements of grounded theory were adopted in this piece of research: theoretical sensitivity; purposive and theoretical sampling; constant comparison; memo writing. These are outlined below and discussed in more detail in Chapter 5 of this thesis. Strauss and Corbin's writings were used along with Charmaz's practical guide to grounded theory when learning and applying the coding stages (incident, open and axial). Throughout the project attention was paid to the roots of grounded theory while bearing in mind the more recent awareness of constructivism introduced by Charmaz among others, and the ongoing development of the methodology itself (Charmaz, 2005, 2006; Clarke, 2007; Bryant, 2010) .

2.2.2 Reflexivity and theoretical sensitivity

This research sits firmly under the umbrella of Health Services research, which is often associated with positivist research methods and attitudes. The grounded theory and mixed-methods approach adopted here has encouraged appreciation of the reflexivity and awareness of the position of the research more usually found within the qualitative tradition. This thesis has been deliberately written to clearly identify the writer as the researcher, as such use of the third person has not been scrupulously adhered to.

Theoretical sensitivity refers to the researcher remaining open and aware of the nuances of a participant's words/actions, the researcher's ability to reconstruct meaning from generated data and identify the important and crucial parts. It also includes a researcher's insight into the phenomenon being investigated.

the attribute of having insight, the ability to give meaning to data, the capacity to understand, and capability to separate the pertinent from that which isn't. All this is done in conceptual terms rather than concrete terms (Strauss and Corbin, 1990, pp 42)

Glaser (1978) suggests reading widely in the literature of a chosen field to increase researcher sensitivity to different perspectives on particular phenomena. Strauss and Corbin detail specific techniques to increase sensitivity such as far out comparison and questioning (1990; 1998). Both of these techniques were used at varying stages, in particular during discussion with two research mentors. These mentors were identified early on during the doctoral research through a supportive research network (the Alternative and Complementary Health Research Network) and provided guidance on data collection and analysis based on their own experiences of qualitative and quantitative research within CAM and health sciences more generally (Dr Joanne Reeve and Dr John Hughes). One mentor worked as a GP and specialised in mental health with an interest in population health, her questions helped to place the data in a very different light and pinpoint where I had perhaps not considered assumptions being made by myself or my participants.

It is important for the researcher to maintain theoretical sensitivity by focusing on the data itself, immersing in the data and trying to generate categories from the data rather than one's existing ideas and preconceptions. Bracketing is one of the ways in which a researcher may increase awareness of their own preconceptions, and thus seek to exclude these from the analysis process. Researcher beliefs are written down in detail prior to beginning data collection, and where possible these are challenged during the data collection and analysis phases, while

remaining open to the possibility that these may in fact be useful concepts if they emerge from the data analysis - each included concept in a sense must win its way into a piece of grounded theory (Strauss and Corbin, 1998). While it seems unlikely that writing beliefs down can remove them from the awareness of the researcher, the method was used as a starting point for discussions with research supervisors. Examples of some of my pre-identified beliefs in relation to homeopathy are given in Table 2.1 on the facing page with an indication of how these were challenged or changed during the research.

Table 2.1: Bracketing example (homeopathy)

<i>Potential challenges in the form of prior beliefs</i>	<i>Source of belief and adaptations needed to avoid biasing data collection/analysis</i>
<p>There are many different kinds of homeopathy but 'classical' single remedy homeopathy is the 'original' form</p>	<p>I had to be careful not to make assumptions about the meaning of terms such as classical homeopathy during interviews and observations. While this may be the accepted view in academic and historical writing about homeopathy, there was far from a consensus among practitioners I collected data from.</p>
<p>Homeopaths will talk to the children more than parents, seeing the child as being the most important person in the consultation, they will demonstrate very child-centred practice.</p>	<p>This particular prior belief was founded in my experiences working at the Glasgow Homeopathic Hospital (GHH) which provided integrated care services. Although this was true some of the time, it was not universal and two of the Key Informants specifically did not use the child as the main source of information. It was important I did not assume this practice was less valid or less effective and probed the responses of these practitioners to better understand their reasons. I became aware that my experiences at the GHH had exposed me to one particular way of practicing, which I had interpreted as best practice. The idea of 'child-centered' practice was more context specific than I first thought, and homeopaths did not approach this in the same way as health services researchers or social scientists.</p>
<p>Homeopaths will be relatively dis-interested in the research evidence, or see it as irrelevant to their practice</p>	<p>This view was based on my previous contact with practitioners of various CAMs and my work to promote research awareness within massage therapy. Contrary to my initial thoughts, homeopaths were interested in research, however the way in which they approached and understood research was different to what I had expected and deserved further exploration.</p>
<p>Homeopaths will agree on how to treat particular conditions or groups of patients</p>	<p>This belief was partially borne out of my previous experience working within Glasgow Homeopathic Hospital as well as reading the limited published articles in the area, but was shown to be overly simplistic during data collection. Some of my initial interview questions were framed from the assumption that there would be a standard interviewing approach or family of remedies to choose from. The answers quickly disabused me of this notion and reminded me to stay open to a wide range of responses.</p>

Beliefs about homeopathy Akin to all researchers, I entered this field with a range of personal and professional experiences and beliefs based at least in part on my prior experiences. The topic was already determined by the funding award, however I had some previous experience with homeopathy having worked as a research assistant for Glasgow Homeopathic Hospital between 2001-2001. As a *self-employed remedial massage therapist* I worked alongside professional homeopaths in various clinics and would sometimes receive referrals from them. I am not a homeopath, nor have I used homeopathy for myself, however some of my canine companions have been treated by a vet using both homeopathy and acupuncture.

As I made clear during my interview for the doctoral position, I have no particularly strong feelings regarding the efficacy of homeopathy. I remain intrigued by the sometimes hard to explain effects observed in some trials, and curious about the potential impact of the long and involved consultation process. While working at the Glasgow Homeopathic Hospital I had the opportunity to observe integrated conventional and complementary treatments being delivered to patients with serious chronic diseases, many of whom appeared to benefit. Whether the improvements were the result of any particular treatment or simple a gentler approach within a peaceful setting was never easy to determine. Without specific training in homeopathy but a deeper understanding than most lay people, I appreciate that homeopathy is a controversial topic evoking strongly held attitudes. Throughout my work as a massage therapist and latterly as a researcher, I have remained open minded about the potential benefits of homeopathy while being sceptical about the proposed mechanisms of action.

Beliefs about ADHD Prior to the beginning of this project I had little direct experience of working with children with ADHD although I had studied the topic within my Psychology degree. I was initially sceptical as to the provenance of the diagnosis, and have always been cautious about the apparent trend towards medicalising socially unacceptable behaviour. It seemed reasonable to assume that for some parents and children, there might be advantages to being labelled as suffering from ADHD, although contact with some of my colleagues' clients (when working as a massage therapist) had exposed me to children who seemed to have a genuine attention deficit. As a consequence of reading the qualitative research around ADHD, and conducting two interviews with children diagnosed with the condition, I was more convinced that there is a group of children and adults who have a measurable and significant challenge.

Beliefs about research Between 2000 and 2004 I was active within Scotland in promoting research in complementary medicine, and presented at several practitioner conferences to encourage therapists to become more involved with auditing and reporting on their own practices. I had been surprised and enthused when studying for my first massage therapy qualification in

1999 to find a range of literature including trials on the effectiveness of bodywork for various conditions, and continued to subscribe to publications such as the *Journal of Bodywork and Movement Therapy* while I was a practitioner. I also wrote brief critical appraisals of research papers for two massage therapy magazines for several years. The ideas of evidence-based practice seemed both sensible and achievable to me as a student of psychology, and I remain a firm supporter of the concept within healthcare and more generally. The implementation of evidence-based practice remains an interest of mine, as does the area of communicating research findings to practitioners in a manner that is practically useful to them.

2.2.3 Sampling

Theoretical sampling refers to the way in which emergent themes and categories from the collected data guide the subsequent sampling and data collection and is most commonly associated with grounded theory research. Purposive or selective sampling occurs when participants are sought out on the basis of their presumed knowledge and experience and is often used in the initial stages of qualitative research to help define a topic of interest. When sampling theoretically, further research participants are selected to develop the emerging themes and categories, and the data collection tools may also be altered (Glaser and Strauss, 1967; Strauss and Corbin, 1998).

The actual process by which this is achieved has been relatively under-developed. Work by Draucker and others have offered a theoretical sampling guide to help implementation of the concept (Draucker, Martsof, Ross and Rusk, 2007). This suggests that methods such as criterion and snowball chain sampling are more likely to be used initially when the topic area is relatively unfamiliar, with open coding beginning as soon as possible. Theoretical sampling then takes place alongside and in contribution to axial coding to avoid the risk of prematurely closing down the analysis (Charmaz, 2000).

Grounded theory usually requires that theoretical sampling should continue until theoretical saturation has been reached with further data collection yielding no new data. In the truest sense of the term, saturation is unlikely to occur, however data could be collected until no new substantial contribution is being made to the emerging theory. The latter approach was adopted for this research, and both purposive and theoretical sampling were used with further details given in Chapter 5.

2.2.4 Constant comparison

The constant comparative technique refers to the process when a new piece of data is coded, it is compared with all/some of the previously coded data within that specific category. Questions are asked such as - does it fit, how does it add to the category, has it suggested any new dimensions? This leads to the development of theoretical properties and assists the researcher to think in terms of the dimensions of each category (Strauss and Corbin, 1998; Charmaz, 2006). Constant comparison was used throughout the coding and analysis stages. Constant comparison also encourages the simultaneous engagement in developing research questions, data collection and data analysis rather than following a stepwise order. This technique was utilised by re-reading transcripts and recoding as an exercise in consistency, reassessing each group of codes periodically and again when exploring axial coding with other sources of data for the mixed-methods synthesis.

2.2.5 Memo writing and keeping a research journal

Memo writing has been emphasised by various writers on grounded theory and other qualitative methods and is one way of creating a clear paper trail from data to emergent theory and categories. Briefly it refers to the researcher writing notes on their thoughts/perceptions of codes and categories, and any subsequent questions and ideas about data collection. Memo writing is said to be crucial in moving from description towards more theoretical coding (Glaser 1992b) and can benefit from the use of direct quotations (Charmaz 2006) to ensure the voices and meaning of participants are represented. Throughout this project a research diary has been kept, initially as a way to record thoughts and ideas around the systematic review. This diary was then expanded and used more frequently during the mixed-methods component providing retrospective insight into choices made at the time and reflections on the research process in action.

2.3 Choosing the research strategies

2.3.1 Constraints and influences

Initially a pragmatic pilot RCT of homeopathy for ADHD had been planned to be carried out in North Yorkshire with the aim of trialling recruitment procedures, outcome measures and exploring the CYPs experience of homeopathic treatment. This project was part of a funding initiative by the Research Capacity Development programme sponsored by the Department of

Health. As part of the preparation for this trial, a systematic review of the existing evidence was carried out. At this point two key facts emerged; firstly due to external circumstances it would be extremely difficult to continue with the planned pilot RCT, and secondly the contrasting pictures emerging from the published research versus homeopaths involved in the trial preparations cast real doubts on the validity of the proposed trial.

An overview of the history of this project is provided in Table 2.2 on page 39 which outlines the development of my doctoral research and the influencing factors. Multiple approaches were made to relevant ethics committees as the research developed, and these are also indicated in Table 2.2 on page 39. Although it was initially intended to include interviews with child/parent dyads this was not possible due to lack of interested participants and the necessary change in project focus.

Table 2.2: History of the project

Significant Dates	Stage	Project Activity	Ethics Applications
Summer 2004	One	National Coordinating Centre for Research Development Capacity ring-fenced funding awarded to the Department of Health Sciences, University of York to support a post-doctoral and a doctoral research fellow to study homeopathy for the treatment of ADHD in children	
August 2004		Interviews held for the doctoral research position and award made to myself.	
October 2004 - July 2006		Essential research training modules undertaken and protocol for the Cochrane review prepared. Initial contact made with sources of participants for a planned RCT of homeopathy for ADHD and protocol prepared. Doctoral research expected to focus on evaluation of the outcome measures used in the trial using a mixed methods approach. Systematic review begun.	NHS ethics prepared but not submitted Departmental ethics prepared and submitted
August 2006		Due to concerns about the treatment protocol and lack of contact between the lead post-doctoral funded researcher and the Child Adolescent Mental Health Services personnel in York, the RCT was no longer feasible.	

Table 2.2: History of the project

Significant Dates	Stage	Project Activity	Ethics Applications
October 2006	Two	A second incarnation of the research project was developed intending to follow-up children diagnosed with ADHD and attentional difficulties who were receiving treatment from homeopaths or Educational Psychologists, and explore the suitability of existing outcome measures for monitoring change in these two settings. Interviews with the professionals, CYP participants and their families (dyads) were planned. Recruitment of homeopaths (two specialist practitioners agreed to participate) and educational psychologists (two large teams in the north of England) began.	Further ethical submission made and approved by departmental ethics committee
December 2006		Preliminary findings of the systematic review presented at an international CAM conference. Initial interviews with key homeopath informants highlighted discrepancies between their practice and that seen in the published trials which influenced thinking on the research topic generally.	
January - March 2007		Made aware of a homeopathy conference focusing on the treatment of children through key informants. Ideal data collection opportunity. Survey developed and piloted. Interviews with homeopathic practitioners begun. Referrals from educational psychologists arriving.	Ethics submission prepared and approved by departmental ethics committee
April 2007		Society of Homeopaths conference "Children and Homeopathy" used to distribute survey.	

Table 2.2: History of the project

Significant Dates	Stage	Project Activity	Ethics Applications
May 2007	Three	No child/parent dyads identified or recruited at this stage via the participating homeopaths, the Educational Psychology teams were being reorganised and no longer able to contribute. Two local paediatric specialist homeopaths identified in the initial stages of the research had both, for personal and health reasons, temporarily closed their clinics and were unable to assist with recruitment as originally planned. Additional recruitment of homeopaths from a wider geographical area attempted but largely unsuccessful. Project focus moved to concentrate on homeopaths in practice. Not pursuing interviewing child/parent dyads and focusing only on homeopaths.	Amendment to project approved by departmental ethics committee including participant observation data collection
June 2007 onwards		Participant observation data collection at workshops/seminars. Events were identified through advertising from the Society of Homeopaths and suggestions from practitioners. Interviews ongoing including opportunistic contact made with a visiting expert from France, IPD collated and analysed.	
December 2007		Data collection completed, analysis ongoing and new research position started in March 2008 with Centre for Reviews and Dissemination, University of York.	

The project went through three distinct stages of development: Stage One - the intended evaluation of outcome measures in the setting of an RCT; Stage Two - the intended exploration of homeopathy in practice and evaluation of outcome measures relating to homeopaths and educational psychologists, including interviews with CYPs; Stage Three - final project focus concentrating on the homeopathic treatment of ADHD from the perspective of practitioners, trialists and experts in the area and incorporating work from the previous stages where possible.

The condition of ADHD itself was relatively narrow and considered to be unlikely to form a speciality for many homeopathic practitioners, therefore data collection strategies were required that would facilitate access to relevant sources and practitioners. Methods were chosen based

on the specific question of interest, the available resources and the data collection opportunities available. This allowed access to different perspectives on the same issues via a wider range of data and expanding the area of enquiry (O’Cathain and Thomas, 2006) beyond mono-methods. These decisions mirror Crabtree and Miller’s exhortation to:

“...reject the tyranny of methodology and use whatever method best answers the question at hand and to report honestly what is done.” (Crabtree and Miller, 1999, pp88)

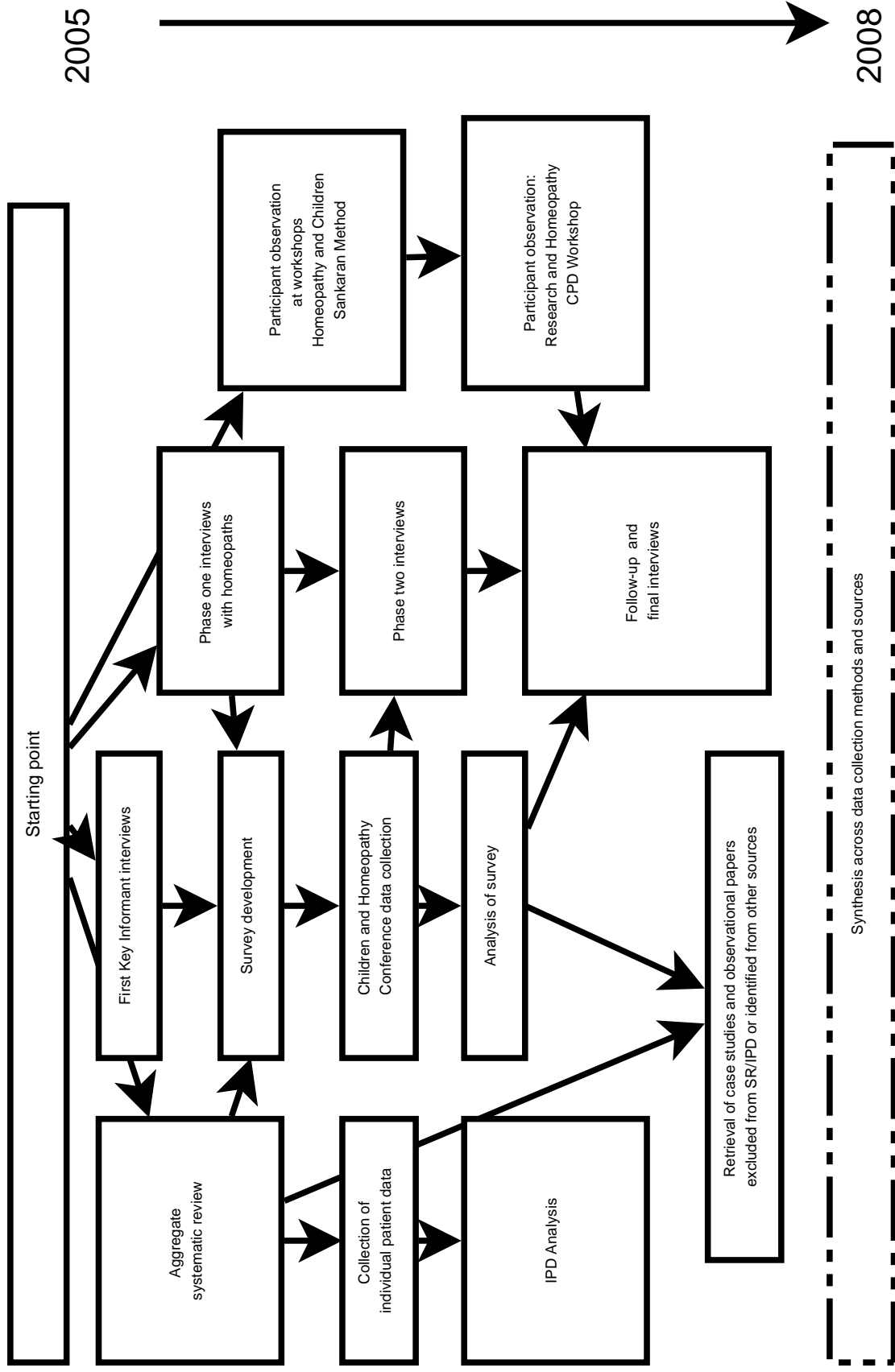
For example questions such as “how do homeopaths understand and treat ADHD” for example are suited to more in-depth qualitative methods. However to compare current UK practice with the homeopathy practiced in trials ideally requires a larger sample such as might be obtained using survey methods and collecting primarily quantitative data. The following chapters provide detailed information on each of the data collection and analysis methods chosen.

Figure 2.1 on the next page illustrates the evolving process of research design, data collection and synthesis. The arrows in the figure represent the flow of ideas from one method and stage through to the next - only the most important links are shown to avoid over cluttering the diagram. The boxes for each stage in the process are illustrative rather than a representation of the amount of time spent on each. The eventual concurrent design was hoped for, but not planned a priori to the data collection commencing.

As shown in Table 2.2 on the preceding page, the original project idea included a systematic review to inform a pragmatic RCT. With the decision to halt development of the RCT in August 2006, a second focus was developed intending to use parent/child dyad interviews alongside practitioner interviews to explore outcome measurement within homeopathy and educational psychology. This project also met significant barriers relating to recruitment and it was not possible to continue (May 2007). The third and final incarnation of the research programme retained the systematic review and added IPD analysis. The practitioner interviews with homeopaths were also retained including planned follow-up interviews. Survey questionnaire and participant-observation data collection were added in to supplement these data, taking advantage of particular opportunities that arose during the time-scale of the project (see Table 2.2 on the previous page, row ‘June 2007 onwards’).

The programme of research therefore took quite a different approach to the topic of homeopathy for ADHD to that originally planned. The discussion chapter reflects on the results of choosing to progress using a mixed-methods exploration of the topic rather than a discrete trial plus qualitative component, and proposes how future research may benefit from these fortuitous events. The methods selected are outlined below indicating why they were deemed appropriate

Figure 2.1: Data collection schematic



The arrows in the figure represent the flow of ideas from one method and stage through to the next - only the most important links are shown to avoid over cluttering the diagram. The boxes for each stage in the process are illustrative rather than a representation of the amount of time spent on each.

for this piece of research, and fuller details of how they have been used are contained in the relevant methods chapters.

2.3.2 Systematic Review

The original instruction in grounded theory was to avoid reviewing the literature before collecting data - for two reasons; 1. maintain the tabula rasa and/or 2. since research questions emerge from the data collection and analysis it would be difficult to conduct a literature review in advance of this. The most that could be expected might be a survey of the research in a particular area of interest.

Strauss and Corbin(1998, pp48-52) offer a useful summary of how the literature may be used during a grounded theory study, which I have paraphrased below:

1. literature may provide useful concepts for the analysis
2. while familiarity with the literature may block creativity, it can also enhance sensitivity
3. where the researcher is entering the field with a particular approach in mind it makes sense to study the existing theory
4. literature itself may form a secondary source of data
5. the literature may provide “stepping off point” questions
6. where the literature and the emerging findings differ, useful angles for analysis may be apparent
7. theoretical sampling may be enhanced by the literature
8. literature may be used to confirm the findings or illustrate where a concept has only been partially developed

In this thesis, reviewing the literature was used to address all of these points. A systematic review of the research on homeopathy as a treatment for ADHD in CYPs was the most appropriate method to transparently identify, retrieve and synthesise the evidence base. Traditionally large areas of literature and research have been summarised in what are now termed “narrative” reviews. These reviews tended to provide few details on their methods of locating papers, reasons for inclusion/exclusion or evaluate the quality of the studies whose results they reported (Egger, Smith and Altman, 2001; Lipsey and Wilson, 2001). Different authors reviewing the same topic might therefore come to very different conclusions, which in the case of healthcare decision making could dramatically affect patient care.

Systematic reviews differ from narrative reviews in the following ways; clear establishment of an a priori protocol and objectives, transparent searches of the literature with stated inclusion/exclusion criteria, quality assessment of relevant papers, and more objective conclusions.

They are now a common feature of many journals and are placed at the top of the commonly accepted evidence hierarchy (see Figure 2.2 adapted from SUNY Downstate Medical Center (2004)), demonstrating comprehensive coverage of the research evidence, inclusion of the highest quality information with least likelihood of bias, methodical exploration of this data and where appropriate synthesis such as meta-analysis.

Figure 2.2: Evidence Pyramid



Meta-analysis is the statistical pooling of results from more than one study where appropriate. This is a particularly useful technique in areas where several small studies may have been carried out with relatively low power (chance of detecting a real effect) but combining the trials through meta-analysis facilitates a more accurate estimate of a treatment's effect or impact.

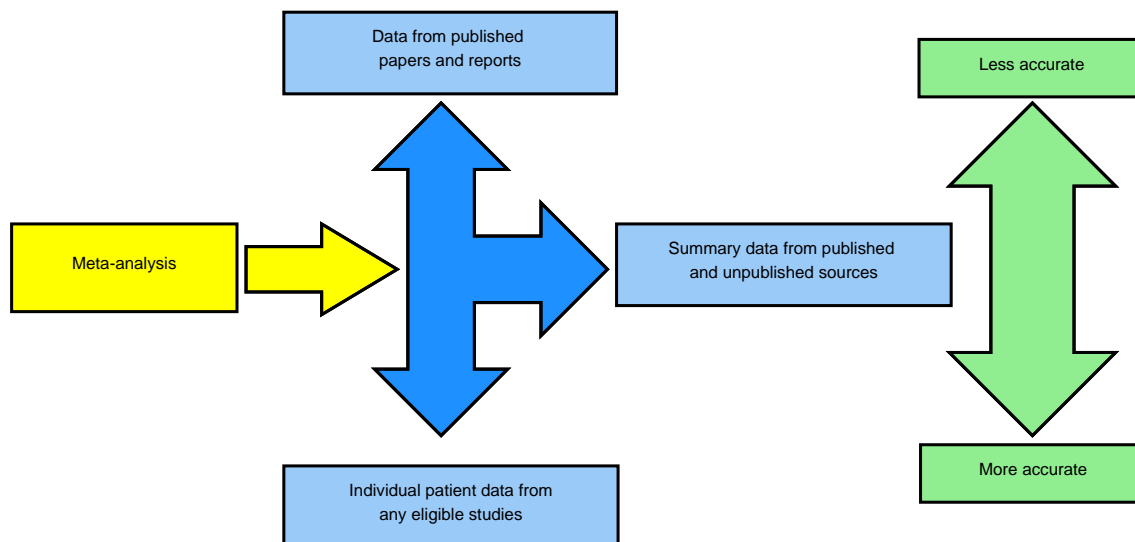
Standard methods have been developed for carrying out systematic reviews of effectiveness by the Centre for Reviews and Dissemination and by the Cochrane Collaboration, and these were followed throughout (CRD, 2009; Higgins JPT, 2008). This review was carried out under the auspices of the Cochrane Developmental, Psychosocial and Learning Problems Group (CDPLPG).

2.3.3 Individual Patient Data (IPD) analysis

IPD analysis involves obtaining the raw data on all randomised participants from eligible trials. This data is then screened, checked and verified with the original authors, and re-analysed to produce summary statistics. The finalised summaries are combined to produce an overall estimate of treatment effect. Although IPD usually follows from a systematic review, this is not

always the case. There are several kinds of meta-analysis which may be seen in the literature - see Figure 2.3 for a summary.

Figure 2.3: Types of meta-analysis



IPD analyses are considered gold standard because they can address the reporting biases inherent in reliance on published studies and allow separation of within and across trial variation minimising the potential for ecological biases when exploring heterogeneity (Stewart and Clarke, 1995; Stewart and Tierney, 2002; Stewart, Tierney, Clarke and on behalf of the Cochrane Individual Patient Data Meta-analysis Methods Group, 2009). Discrepancies between IPD and aggregate analysis may arise as a result of missing trials, excluded patients, choice of endpoint, method of analysis, and decisions about the timing of publication reporting trial results (Stewart and Parmar, 1993).

Relying solely on data from published papers and reports can result in misleading and biased treatment estimates. The aggregate review described previously, following Cochrane procedures, can be seen as taking up the intermediate position according to this diagram. A summary of the potential benefits from IPD reviews can be seen in Table 2.3 on the following page adapted from Stewart and Clarke (1995).

Table 2.3: IPD Benefits

Benefits of IPD meta-analyses
Undertake subgroup analyses
Carry out detailed data checking
Ensure analysis is appropriate
Update follow-up information
More complete identification of relevant trials
Better compliance with providing missing data
More balanced interpretation of results
Wider endorsement and dissemination of results
Clarification of further research
Collaboration on further research

IPD methods are based around collaboration between the analyst and the original authors to facilitate checking the procedure and statistically examining the randomisation across treatment arms. Where information is missing or of poor quality the IPD approach of close contact with trialists is likely to increase the amount of usable data, and identification of unpublished trials. Analysis by intention-to-treat principles is considered vital for good quality meta-analyses, and this is more likely to be possible under IPD conditions. Trials may report analyses based on a proportion of the included patients and it can be unclear how many were excluded and why. IPD encourages re-instatement of excluded patients where appropriate and gives a fuller understanding of exclusions in each trial. More sensitive analyses may be possible dependent on the data obtained, and alternative or more appropriate methods of analysis can be explored. Subgroup analyses are dependent on trials recruiting sufficient numbers of participants, and reporting detailed results. IPD analysis offered the opportunity to provide further insight into the design and conduct of the available trials, and explore the impact of factors such as age and gender which have previously been shown to affect ADHD related outcomes.

2.3.4 Mixed-methods

Most important, because our approach to theory building is one of emergence, we believe that ... the design, like the concepts, must be allowed to emerge during the research process. Remember the idea behind varying methods is to carry out the most parsimonious and advantageous means for arriving at theory. (Strauss and Corbin, 1998, pp33)

For the purposes of this thesis the term mixed methods is used to refer to a combination of qualitative and quantitative techniques being used to explore a common issue or area. Taking a brief over-view of the area, mixed methods have been seen as being potentially useful in three general senses: triangulation, facilitation or complementarity.

Using mixed methods to achieve triangulation (use of different strategies to measure one concept) has been identified as developing from the work by Campbell and Fiske (1959) on multimethod-multitrait matrices (Hammersley, 1992c). Historically a qualitative component would be used to enhance the validity of the findings of a quantitative study, although as a concept this is controversial. More recently triangulation has been used to describe the use of multiple methods to explore a single research question.

Facilitation refers to research designs where one component aids in the development and implementation of a second. For example a traditional combination would be using a series of qualitative interviews to develop and explore items for a questionnaire. Some research has used surveys to identify suitable participants for later qualitative interview, when their survey responses may also form the basis for a discussion.

Complementarity tends not to privilege one source of information over another, and is seen when techniques are chosen to explore difference aspects of the same concept/problem. Bryman also describes this as "*filling in the gaps*" where one method would not provide all of the necessary data (Bryman, 2004, pp458).

A more recent categorisation of mixed-methods studies has been provided giving six key arguments for combining qualitative and quantitative methods (O'Cathain, Murphy and Nicholl, 2007a):

- Comprehensiveness
- Increased validity through agreement of findings
- Development or facilitation

- Emancipation
- Satisficing (not possible to do a single method study)
- Salvaging where one method saves another

This research project has used mixed methods to achieve comprehensiveness and development/facilitation. The area of research (homeopathy for children with ADHD) is both controversial and poorly understood indicating a need to explore and chart details of the homeopathic treatment of children. As a result of scarce previous work in this area it was unclear if one method could provide the necessary picture therefore several were considered. Each individual method was used to develop and refine the other methods.

Key informants: Key informants played an important role in the development of this research and informed the survey, participant observation and interview contents. They comprised experienced homeopaths within usual practice and academia who provided specialist knowledge, balanced views across different styles of homeopathy and contributed to various stages of the project.

Survey of practitioners: The Society of Homeopaths' 2007 annual conference and AGM was entitled "Vital Childhood". One of the challenges to data collection in this project identified fairly early on was that homeopaths are usually generalists. This conference however presented an opportunity to collect data from practitioners who were presumably actively interested in treating children. Additionally, the keynote speakers were the Reichenberg-Ullman's who are well known in the homeopathic world for their books on treating behavioural disorders and their specialist homeopathic clinic in the USA. Survey methodology was adopted as being the most appropriate way to access and collect data from the large number of delegates anticipated (around 200). One of the aims with this phase of the research was to gather information on homeopathic practice and views on trial treatments from a larger sample to provide a context within which the qualitative data could be situated.

Documentary analysis: Information on how homeopaths treat children is relatively scarce, and tends to be found in specialist booklets, occasional textbooks and in case reports. It was considered important to explore what information was available to practitioners and researchers. The documentary evidence was gathered from the systematic review search results (producing case reports and seminar descriptions), suggested references mentioned by the key informants and further sources/references given by the survey respondents.

Practitioner interviews: As mentioned, the initial interviews informed the development of the survey, but the survey itself also influenced the interview schedule for subsequent interviews. The vignettes constructed for the survey were incorporated into the interview and broadly similar questions were asked. Further interviews were carried out using this revised schedule and format.

Participant observation: A continuing professional development (CPD) workshop being conducted by one of the original key informants was identified as being a potential source of data on how homeopaths are learning to work with children. The workshop was a one-day session on using homeopathy with children and young people led by a professional homeopath who runs a specialist children's clinic in West Yorkshire. Further participant observation was carried out at a CPD workshop on Research for Homeopaths in response to emerging themes and issues within the analysis, with this data informing the follow-up interviews with selected practitioners. Finally the Society of Homeopath's conference on Children and Homeopathy provided a further informal data collection opportunity.

2.4 Summary

This chapter has outlined the epistemological and theoretical positions adopted throughout the research, and introduced Grounded Theory as the structure which blends the different techniques for data collection within a mixed-methods approach. The constraints around the development of the research have been summarised, and each of the key data collection/analysis techniques signposted.

The following chapters set out the methods for data collection and analysis in more detail, followed by respective results chapters. For ease of reading these have been divided into: systematic review/IPD methods and results sections, followed by a mixed-methods methods section, and a mixed-methods synthesis section.

Chapter 3

Systematic Review: Aggregate Data

3.1 Research Aims

A systematic review of the evidence around homeopathy as a treatment for ADHD was carried out to answer the research questions listed below. The previous chapter gave an overview of what constitutes a systematic review, while this chapter sets out in greater detail the procedures established a priori for collecting and analysing the evidence base.

1. To describe the homeopathic treatments for ADHD as tested in clinical trials
2. To assess the efficacy and effectiveness of homeopathy as a treatment for ADHD/HKD
3. To evaluate the safety of homeopathy as a treatment for ADHD/HKD

3.2 Protocol development and registration

The following databases were searched prior to beginning the review to check for existing or ongoing reviews in the same area: MEDLINE, AMED, The Cochrane Library and the Database of Abstracts of Reviews of Effectiveness (DARE), with none being identified. The PRISMA reporting guidelines were followed throughout (Moher, Liberati, Tetzlaff, Altman and Group, 2009). Both the protocol and final review were published with the Cochrane Library (Heirs and Dean, 2007). Registration, and peer review in the case of a Cochrane review, serves as a useful guard against selective outcome reporting in the final report and unreasonable amendments to inclusion criteria which may influence the final conclusions (Kirkham, Altman and Williamson, 2010). The protocol was not registered with PROSPERO (the international prospective register of systematic reviews) as this resource was not yet available when the review was being conducted (Booth A, 2011). A copy of the original protocol is included in Appendix 1 (pg 343).

3.3 Criteria for considering studies for inclusion

Published and unpublished studies in any language which met the following criteria were considered for inclusion.

3.3.1 Study design

This part of a review restricts the included studies according to their design and allocation of participants. It is generally accepted within health services research that randomised trials are the most efficient and least open to bias of the available research designs. When implemented correctly, randomisation ensures that all participants have the same chance of being allocated to either the intervention or control group, reducing external influences such as physician preference for particular patients or treatment arms. Non-randomised studies may have important differences between the comparator groups that impact on treatment effectiveness estimates.

Therefore when assessing efficacy and effectiveness, studies were considered where they had used random or quasi-random allocation (e.g. by day of the week, alternate numbers, case number or alphabetical order), and compared homeopathy with no treatment, placebo, medication, behavioural or educational interventions, or other usual care.

Randomised controlled trials and quasi-randomised trials were included in the review to evaluate effectiveness. Quasi-randomised trials were included in meta-analyses only as part of a sensitivity analyses due to their vulnerability to bias.

Any design including non-randomised controlled studies, cohort studies, case-controlled-studies, and consecutive case series were considered for the safety component.

3.3.2 Population

The following criteria were applied to both safety and effectiveness components of the review:

Diagnosis Participants diagnosed with ADHD or HKD according to recognised criteria from the DSM-IV or ICD-10 were eligible for this review (APA, 2000; WHO, 1992). Although the review was focused on CYPs and the main interest was in those under the age of 18 years, trials which included adults were still eligible for inclusion provided the CYP data was reported separately.

Co-morbidity Classical homeopathy treats 'whole patients', in addition to their conventional disease labels, therefore co-morbidity was not used as criteria for exclusion. Sub-grouping was intended to be used take account of participant groups with additional diagnoses.

3.3.3 Interventions

The following criteria were applied to both safety and effectiveness components of the review:

Eligible interventions were homeopathic medicines prepared according to national pharmacopoeias, or other explicit protocols. Eligible comparisons for this review were compiled by consulting the relevant literature (MTA Cooperative Group, 1999b,a; King, Griffin, Hodges, Weatherly et al., 2006).

These included but were not limited to the following:

- Wait-list or no treatment
- Pharmacological treatment (e.g. methylphenidate etc.)
- Usual care (if patient has not been referred to a secondary centre for assessment; this covered any intervention being offered by the GP, primary mental health worker or educational psychologist if involved)
- Multidisciplinary packages (secondary care: school-based interventions, behavioural training, parenting skills)
- Placebo (usually this consists of the patient participating in a normal homeopathic consultation but receiving placebo medication instead of the medicine).

Studies attempting to estimate the added value of homeopathy (in, for example, trials of medication plus homeopathic treatment versus medication alone) were also considered.

3.3.4 Outcome measures

Previous controlled trials of conventional and alternative therapies for Attention-Deficit Hyperactivity Disorder have relied on narrowly defined, symptom specific assessments without taking into account a broader perspective of expected change (Bjornstad and Montgomery, 2005; Coulter, Dean and Gilbody, 2006; King, Griffin, Hodges, Weatherly et al., 2006). Treatment

which relieves ADHD severity is logically predicted to influence symptoms as well as peer relationships, emotional health and general well-being. Reviews of outcome research in ADHD have called for a wider assessment of outcomes beyond mere diagnostic criteria (Schachar, Jadad, Gauld, Boyle, Booker, Snider, Kim and Cunningham, 2002; Jadad, Boyle, Cunningham, Kim and Schachar, 1999; King, Griffin, Hodges, Weatherly, Asseburg, Richardson, Golder, Taylor, Drummond and Riemsma, 2006). In the majority of trials in this area the outcomes have been assessed by a proxy such as a parent or teacher rather than directly by the child/young person (King, Griffin, Hodges, Weatherly et al., 2006). Although some symptom specific self-completion measures have been developed (such as the Conners Adolescent Self Report or the Brown Scales) these versions are not commonly used in research, and self-completed quality of life measures have not been used to date in clinical trials.

Research with children and young people has shown that they are capable of reporting on their own health status from as young as 4 years, and their accounts may differ significantly from those of proxies in important aspects such as mood and social functioning (Eiser, Mohay and Morse, 2000; Riley, 2004; Verrips, Vogels, den Ouden, Paneth et al., 2000; Verrips, Stuijbergen, den Ouden, Bonsel et al., 2001; Eiser and Morse, 2001a). The literature around choosing outcome measures for trials involving children and young people strongly recommends that where possible multiple informants should be accessed including both the child/young person and main caregiver(s) or parent(s) (Eiser, 2004; Eiser and Morse, 2001b). Given the lack of child-centred outcome measure use in ADHD, it is unclear to what extent the available generic or specific scales, most of which are based on proxy reporting, reflect the areas of principal concerns to the children themselves.

Trials reporting at least one of the following outcomes were included in both the safety and effectiveness components of the review. Outcomes should preferably have been measured using validated and published scales such as those reviewed by Collett and colleagues (Collett, Ohan and Myers, 2003).

Primary outcome

- Overall severity of the problem behaviours measured using a rating scale completed by parent, clinician or child such as the Browns Outcome Scales or the Conners ADHD Scales

Secondary outcomes

- Severity of the core symptoms (e.g. hyperactivity, inattention and impulsivity)
- School/academic performance measured via grades or teacher reports
- Depression/anxiety-related outcomes using a rating scale completed by parent, clinician or child
- Conduct/oppositional disorder outcomes using a rating scale completed by parent, clinician or child
- Adverse effects, preferably measured with a validated scale (based on parent or child responses) such as the Barkley Stimulant Drugs Side Effects Rating Scale (Barkley, 1990)
- Quality of Life as assessed by parent, child or clinician using a validated outcome measure such as the Child Health Questionnaire or PedsQL (Landgraf, Maunsell, Speechley, Bullinger et al., 1998; Matza, Rentz, Secnik, Swensen et al., 2004; Varni, Seid and Kurtin, 2001), or proxied by a measure such as the Clinical Global Impression score changes (National Institute of Mental Health, 1985)

3.4 Searching the literature and retrieving the studies

3.4.1 Search strategies and limits

The search strategy was devised by the original review team (Mike Emmans Dean and Morag Heirs) with input from the Cochrane Developmental, Psychosocial and Learning Problems Group librarians.

Databases were searched without language restrictions for any paper mentioning homeopathy and its synonyms (homeop\$ OR homoeop\$ OR homöop\$ OR omeop\$). It was important to search across languages because numerous studies have demonstrated that reports published in English are more likely to report positive results, and homeopathy is widely practised in both Germany and Latin America (Moher, Fortin, Jadad, Juni et al., 1996; Egger, Zellweger-Zahner, Schneider, Junker et al., 1997). This search strategy was adopted to maximise sensitivity and aimed to identify all records containing homeopathic terms.

The records from each search were compiled into a single EndNote library and de-duplicated. The library was then searched, using the following disease-specific terms:

1. Attention Deficit Disorder with Hyperactivity/
2. adhd
3. add
4. addh
5. adhs
6. hyperactiv\$
7. hyperkin\$
8. attention deficit\$
9. brain dysfunction
10. or/1-9

An RCT filter was not used as a broad range of study designs were evaluated (see Types of Studies above). The results were then searched for population-specific terms to divide studies into those dealing with children or young people and those concerned with adult patients.

1. Child/
2. Adolescent/
3. (child\$ or boy\$ or girl\$ or schoolchild\$ or adolescen\$ or teen\$ or young pe\$ or youth\$)
4. or/1-3

3.4.2 Databases and resources searched

Databases were selected to cover the widest range of electronic resources where relevant papers might be located including conventional medical databases such as MEDLINE, CAM specific databases like AMED and homeopathy specific resources such as the library held at the Glasgow Homeopathic Hospital. Comprehensive searches are a key feature of systematic reviews and help to ensure transparency. Review papers have shown that unpublished research is more likely to have negative findings, which are of equal importance to the positive in a systematic review, and inclusion of unpublished work may influence the findings, therefore efforts were made to locate relevant unpublished research through searching conference proceedings and other grey literatures (Dickersin, 1997, 1990). The databases shown below were searched from inception to October 2011 unless otherwise noted.

Medical and Social Science databases: Cochrane Library; MEDLINE (including pre-Medline); BIOSIS; CINAHL; EMBASE; ERIC; LILACS (Latin American database); PsycINFO; Science Citation Index

CAM or homeopathy specific databases AMED; Centre for Complementary Medicine Research (University of Munich, Germany) Database; CISCOP (Research Council for Complementary Medicine); HomInform (Glasgow Homeopathic Hospital Library) [this database was searched using disease terms only as all references are homeopathic in focus];

Trial registers searched: Cochrane Central Register of Controlled Trials (CENTRAL); Clinical Trials (USA); Current Controlled Trials (UK); National Research Register (UK)

Conference proceedings and other sources: ISI Proceedings; GIRI - International congress on ultra-low doses; Liga Medicorum Homeopathica Internationalis; SIGLE (Grey Literature in Europe); Dissertation Abstracts International

The European Committee for Homeopathy thesis database which contains PDFs was hand searched [<http://www.homeopathyeurope.org/>].

Notes: CISCOP and SIGLE were searched only until December 2005 as they have not been updated since then.

Contacting authors and experts: Alongside extensive searching as described above, information on unpublished trials was requested from authors of published studies, and experts and information groups in the areas of ADHD and homeopathy. Full lists of those contacted are given in Appendix 2 (pg 353).

3.5 Selection of studies

Two reviewers independently screened the titles, abstracts and keywords of all records using disease- and population-specific terms, and noted their decisions on potential study acceptability. Relevant articles were obtained and screened by two reviewers independently with no disagreement on inclusion/exclusion decisions. The reference lists of retrieved articles were scanned to identify further trials.

Study selection was carried out by Morag Heirs and Mike Emmans Dean initially, with updated search results being screened by Morag Heirs and Su Golder (Research Fellow, Centre for Reviews and Dissemination, University of York).

3.6 Data management and extraction

A data extraction form was developed and tested on the most complex of the included studies before being refined. A copy of the final tool is provided in Appendix 3 (pg357). Data on settings, populations, method of diagnosis, interventions, outcomes, and analysis were extracted by one reviewer and independently checked for accuracy by the second reviewer.

Attempts were made to contact authors for missing data, and all such correspondence was logged with some additional data being retrieved.

Homeopathic treatments were categorized as:

1. Individualised ('classical', 'constitutional')
2. Formula (single constituent 'clinical' or multi-constituent 'complex')
3. Isopathy

This taxonomy was based on published guidelines for reporting homeopathic treatments and clarified to ensure that each category was mutually exclusive (Dean, Coulter, Fisher, Jobst et al., 2007). Each trial was independently assigned to one of these groups by both reviewers with no disagreements arising.

3.7 Assessing risk of bias

Two reviewers independently assessed the risk of bias in the individual trials according to the following areas (as specified in the revised Cochrane Handbook (Higgins JPT, 2008)). This approach was chosen rather than a check-list or scale as being both more transparent and informative (Wood, Egger, Gluud, Schulz et al., 2008; Moher, Jadad, Nichol, Penman et al., 1995; Singh, Murphy and Bhandari, 2010). Further, the items considered below have all been shown empirically to influence trial results, while many of the items included in other scales have little evidence to support their use and may reflect quality of reporting which does not always relate to the risk of bias in a trial (Soares, Daniels, Kumar, Clarke et al., 2004; Katrak, Bialocerkowski, Massy-Westropp, Kumar et al., 2004).

Each of the following items were judged to have been: met (low risk of bias), not met (high risk of bias) or unclear (uncertain risk of bias). Making judgements on the level of risk of bias incurred by a study for this item is dependent on both the quantity of missing data and the reasons given by authors for missing/incomplete data and how these were dealt with. See Appendix 4 for details of criteria requirements (pg 365).

Sequence generation

Sequence generation is the process by which participants are allocated to a treatment group e.g. verum homeopathy or identical placebo. Ideally this should be based on chance and unpredictable (e.g. randomisation), and lists are most often generated by a computer program. If participants are allocated alternately, by birthdate or similar, this is quasi-randomisation which is more amenable to subversion. True randomisation should ensure that the intervention groups are balanced across baseline allowing clearer comparisons and treatment effect estimates (Jadad, 1998).

Concealment of allocation of treatment group

Allocation concealment is important because once the allocation sequence has been generated it is vulnerable to subversion. It is important to ensure that each participant is given their assignment with the administrator having no fore knowledge of the subsequent allocation. For example, a child is accepted for enrolment into a placebo-controlled trial of homeopathy. The researcher might then telephone an allocation service for the treatment group assignment. The researcher should not know what the next assignment would be to reduce the chance of intentional subversion by holding the patient back. A key methodological paper has shown that inadequate concealment of allocation can substantially affect the results of a trial exaggerating the benefits of an intervention (Schulz, Chalmers, Hayes and Altman, 1995).

Blinding

Blinding is the term used when a participant/physician/researcher/statistician is unaware of what treatment the participant has been allocated to receive. Blinding is an important tool in reducing the risk of ascertainment bias (where results are systematically distorted by knowledge of the intervention received by each participants) occurring after randomisation although it is not always possible to implement fully. Unblinded or open label studies are more likely to report favourable results and larger effect sizes (Schulz, Chalmers, Hayes and Altman, 1995; Jadad,

1998). Where it is not possible to conduct a fully blinded study, as a minimum the outcome assessors should be blinded to allocation.

Incomplete outcome data

Incomplete outcome data can increase the risk of bias in the effect estimates for an intervention either as a result of data having been excluded, or where some data was not available due to attrition. Attrition occurs when data on some participants is missing because they have withdrawn, not replied to questionnaires, data is lost and so on. Excluded data includes situations where incomplete data is excluded from analysis, participants are later judged ineligible or are only included if they received the full treatment programme (Higgins JPT, 2008).

3.8 Data synthesis

Where sufficient data were available and statistical combination was appropriate based on the population and intervention details, a meta-analysis was undertaken, using RevMan 4.2 software (Collaboration, 2003).

Dichotomous outcomes were not reported in any of the included studies.

3.8.1 Estimates of treatment effect

Continuous outcome data were extracted as means and standard deviations where available or calculated from the published data. Where continuous outcomes were measured with similar, but not identical, instruments across studies, standardised mean differences were calculated. Where some scales increased to show benefit and others decreased one set of values was multiplied by -1 to ensure that, for this review, a decrease in mean value represents an improvement in symptoms. Confidence intervals of 95% were calculated for treatment effect estimates.

Mean differences and standardised mean differences from each trial were combined using both random and fixed effect models to explore the effect, if any, of using more or less conservative models. Fixed-effect models weight the contribution of each study proportional to the amount of information observed in the study. This considers only variability in results within studies and no allowance is made for variation between studies. Random-effect models allow for between-study variability in results by weighting studies using a combination of their own variance and the between-study variance (Borenstein, Hedges, Higgins and Rothstein, 2009).

Generic inverse variance analysis was used when only an overall effect estimate and measure of variance was available, and in order to pool cross-over with parallel trial data. The generic inverse variance method is a widely used and easy to implement method of combining study results. It is very flexible and can be used to combine any type of effect measure provided that an effect estimate and its standard error is available from each study.

Studies were grouped according to the comparator used and analyses carried out for the primary outcome (global symptom assessment), core symptoms (e.g. hyperactivity, inattention, impulsivity), overall behaviour and by assessor (parent, teacher, self or clinician).

3.8.2 Sensitivity analyses

These were carried out to explore the impact of pooling different types of homeopathy (individualised, formula or isopathy), and the inclusion or exclusion of quasi-randomised studies.

3.8.3 Heterogeneity

Heterogeneity refers to the variation between studies and their effect estimates which occurs other than by chance. It can be the result of clinical diversity amongst the included study populations, or as result of methodological differences such as combining randomised and non-randomised data. Considerable heterogeneity suggests that the studies are not amenable to being combined, and any pooled estimate may not be reliable.

Heterogeneity between the included studies was explored narratively by considering differences in (a) the study population, (b) intervention, (c) outcome measures, and (d) study quality. Forest plots were visually examined and the degree of overlap of the confidence intervals assessed.

In addition, where pooling was appropriate, heterogeneity was quantified using the Chi-square test and I^2 which describes the variation of effects that may be due to heterogeneity rather than sampling error (Higgins and Thompson, 2002). Conventionally it has been suggested that I^2 values of up to 40% might be unimportant, 30% to 60% might be moderate, 50 to 90% may be substantial and 75% to 100% considerable. Bearing in mind that such tests are relatively insensitive, produce wide confidence intervals, and are unreliable with small numbers of studies - these results are shown in this review for completeness rather than as proof of heterogeneity being present or absent.

3.8.4 Publication bias

Publication bias was largely addressed by making strenuous efforts to identify published and unpublished trials in any language without date limits. Although many systematic reviews attempt to test for publication bias by using funnel plots, such graphical representations of data are inappropriate and misleading with small numbers of included studies (Egger, Davey Smith, Schneider and Minder, 1997). Further, as has been reiterated in a recent paper, asymmetry in funnel plots can be the result of many factors rather than simply publication bias (Sterne, Sutton, Ioannidis, Terrin et al., 2011).

3.9 Search results

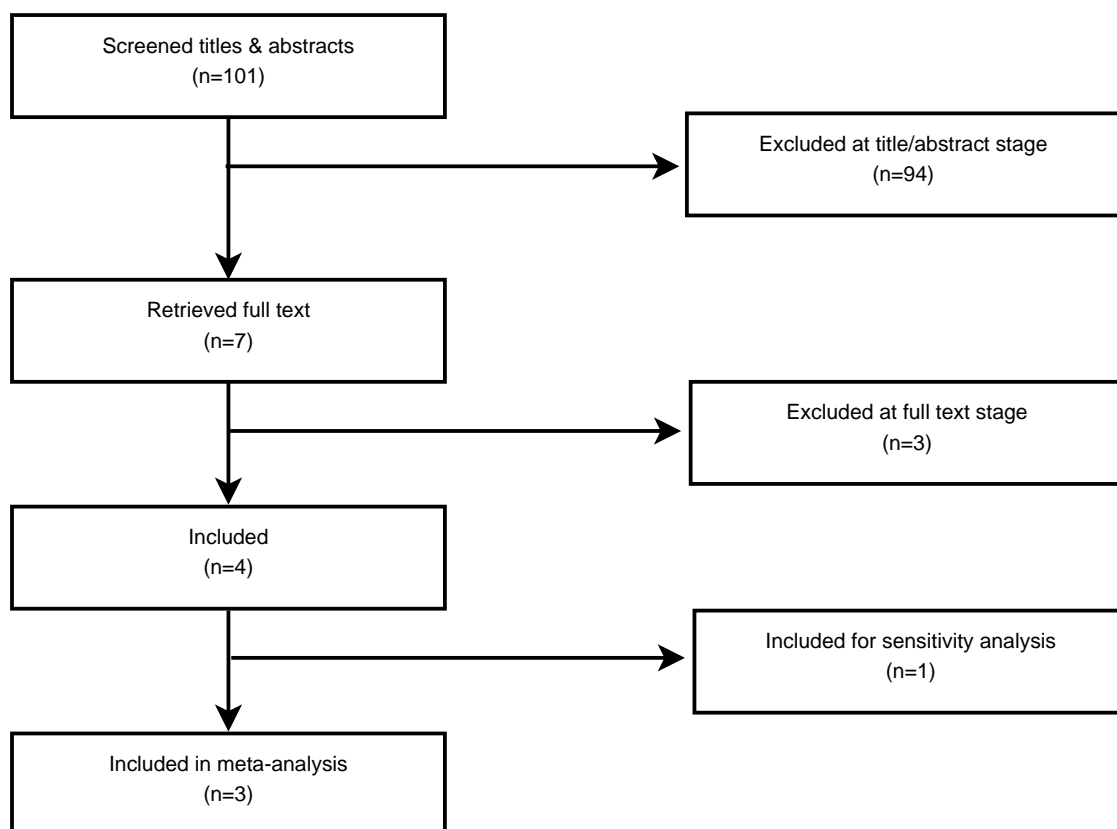
Searches were carried out from inception of the databases to March 2006 where possible by MKH, MED and the CDPLPG librarian. Updated searches were run in March 2010 and again in October 2011. Results from these searches were compiled in Endnote and de-duplicated automatically. This produced a library of 9,732 citations. Searching with disease-specific terms identified a total of 100 potential papers after de-duplication by hand.

3.9.1 Effectiveness

Titles and abstracts were assessed and 95 papers excluded from the review. See Figure 3.1 on the next page for the flowchart. The seven remaining studies were retrieved, of which four met the eligibility criteria. One of these exclusions was an observational uncontrolled open-label study (Frei and Thurneysen, 2001), the second was a duplicate publication containing no additional information (Lamont, 1998), and the third was a poorly reported study of a complex homeopathic medicine which did not appear to have been randomised or quasi-randomised (Hultsch, 2007). All studies were carried out by different research teams between 1997-2005 and are published articles.

One ongoing study based in Canada has been recorded, however contact with the authors has confirmed that no data is yet available. Analysis was expected to take place in early 2012 and this trial will be included in any further updates to the review.

Figure 3.1: Flow chart for efficacy/effectiveness papers



3.9.2 Safety

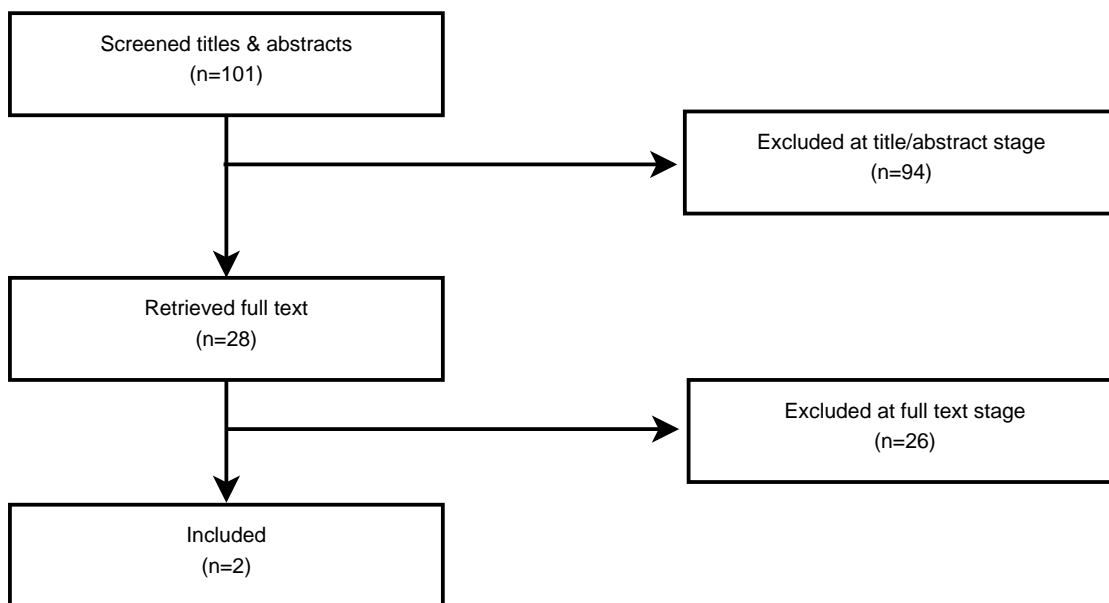
Titles and abstracts were assessed and 73 papers excluded from the review. See Figure 3.2 on the following page for the flowchart. 28 potential studies were retrieved in full for assessment, or fuller details obtained via the Hom-Inform database service. All authors of eligible papers from the efficacy section were contacted to ascertain if they held any unpublished safety data from current or previous research. Two papers were included for this section, a published journal article that was also included in the efficacy review, and a study comparing a complex remedy with Ritalin which may have been a comparative cohort design (Jacobs, Williams, Girard, Njike et al., 2005; Hultzsch, 2007).

3.10 Summary of included studies

Setting

Two of the four studies included in this review were carried out in the USA - Jacobs et al. (2005) delivered the homeopathy in a private clinic based in Seattle, while Lamont (1997) conducted

Figure 3.2: Flow chart for safety papers



the consultation following psychological testing in the child's foster home or facility. The third study was located in South Africa (Strauss, 2000) with the final study conducted in Switzerland using a private homeopathic practitioner's office (Frei, Everts, von Ammon, Kaufmann et al., 2005).

None of the papers reported the time of year of the study - so it is unclear if participants were in school or on holiday/vacation during the trials.

Participants

All of the participants in these studies were children, with ages ranging between 7-15 years. All four papers reported that they used children with an existing diagnosis of ADHD. In two of the studies this diagnosis was re-confirmed either by a psychiatrist or with a battery of diagnostic questionnaires before entry into the trial (Jacobs, Williams, Girard, Njike et al., 2005; Frei, Everts, von Ammon, Kaufmann et al., 2005).

Interventions

All four studies compared active homeopathy with identical placebo homeopathy (a matching sugar pill or solution); three papers used individualised homeopathy (Jacobs, Williams, Girard, Njike et al., 2005; Frei, Everts, von Ammon, Kaufmann et al., 2005; Lamont, 1997) and one used a standardised formula containing various potencies of two medicines (Strauss, 2000).

The individualised homeopathy was distinctly different in each of the three studies and is detailed in the summaries below.

The homeopaths prescribing in these studies had varying degrees of post-qualification experience ranging from 20 years (Jacobs et al. 2005) to 4 years (Lamont 1997).

Outcome measures

All studies reported data on at least one of the core aspects of ADHD/HKD as evaluated by the parent or primary carer. Three of the trials used a well-known validated outcome scale designed for assessing ADHD symptoms - the Conners' Ratings Scales. Strauss used an older version (1973) while Jacobs and Frei both used the revised forms CRS-R (2001) (Conners, 1973, 2001). Frei used the full parent-rating scale in assessment and unblinded follow-up, with the primary outcome measure being the Conners' Global Index-Parent form (CGI-P) which is a ten item summary scale. Jacobs used both the CGI-P and the CRS-R parent forms throughout their study yielding more detailed outcome data.

Lamont used an unpublished 5-point rating scale of change in hyperactivity (Lamont, 1997). A study reviewing the impact of using unpublished rating scales to assess outcomes in schizophrenia concluded that use of these measures significantly increases the likelihood of treatment superiority, suggesting that as reviewers we should be cautious about the results (Marshall, Lockwood, Bradley, Adams et al., 2000).

Three trials reported using child-performance tests to assess attention and impulsivity. Jacobs used the Conners' Continuous Performance test, Strauss used a checking task [the Children's Checking Task, CCT] that assessed sustained attention, and Frei used the Test battery for Attention Performance (TAP) to measure attention and impulsivity (Conners, 1995a; Lezak, 1983; Zimmerman and Fimm, 1992).

Design

Of the three papers which described their studies as randomised, Jacobs, Williams, Girard, Njike et al. (2005) and Frei, Everts, von Ammon, Kaufmann et al. (2005) gave details of the randomisation procedure while Strauss (2007) included no description of randomisation in the published paper but details were later obtained clarifying that simple randomisation had been used. The fourth study, Lamont (1997), allocated participants by alternation (quasi-randomisation) which is a less reliable method for minimising variation than true randomisation (Kunz and Oxman, 1998).

All of the trials apart from the Frei et al. (2005) study used parallel group comparison designs with pre-post measurement. Frei et al. used an initial screening period followed by a placebo controlled cross-over design. Follow-up periods ranged from 2 to 4.5 months across the trials.

3.11 Detailed study characteristics

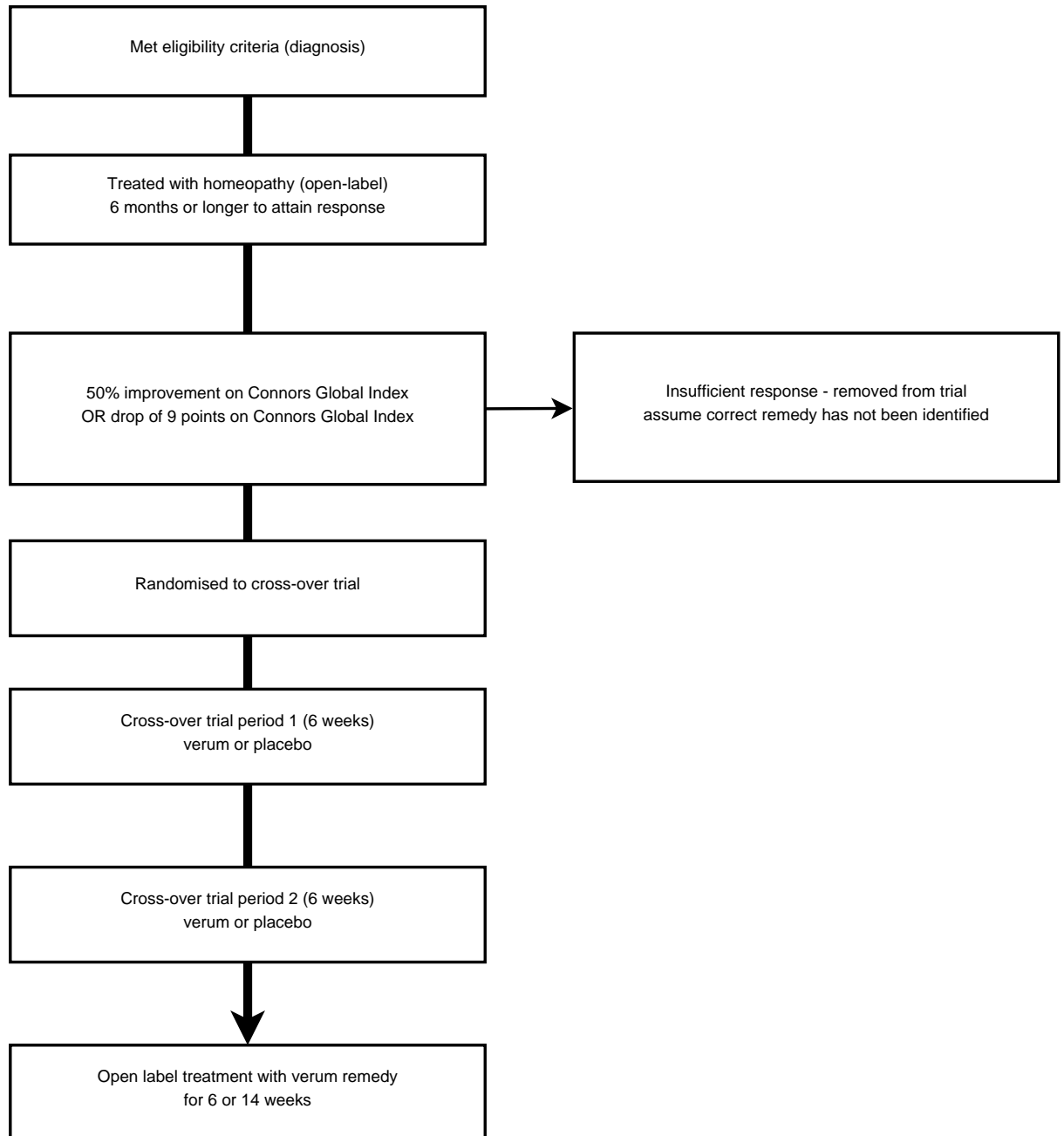
Homeopathic treatment of children with ADHD: A randomised double blind placebo controlled crossover trial (Frei, Everts, von Ammon, Kaufmann et al., 2005)

This Swiss study included children aged 6-16 years diagnosed with DSM-IV ADHD (mean age of 10 years) recruited from surgeries and support groups. The diagnosis was re-confirmed for entry. This trial aimed to identify children who successfully responded to homeopathy by demonstrating at least a 50% reduction in their ADHD symptoms. From previous research it was assumed that this gain would only be maintained while the child continued to take the remedy allowing a placebo-controlled comparison where the outcome of interest was deterioration in symptoms under placebo compared to maintenance of improvement under verum or real homeopathy.

The initial consultation took place with parent(s) and child but the four-weekly follow-ups were carried out with the parents only to minimise psychological support to the children. An initial screening period was used to identify a subset of children who responded to homeopathy. An indefinite number of follow-ups were allowed at this stage and medicines could be prescribed or changed until a successful response was obtained. Participants who successfully responded to homeopathy (50% amelioration of symptoms on Conners' Global Index) were then entered into the randomised cross-over trial. Allocation was based on stratified computer generated randomisation tables. Participants received either: their normal homeopathic medication or a placebo for six weeks in each phase with no further consultations. 83 participants took part in the screening phase and 62 in the trial itself with 31 in each group. The medicines were given in LM liquid potencies as daily drops and prescribing was based on work done previously by the research team including methods from Bönninghausen and a specially developed questionnaire (Frei, von Ammon and Thurneysen, 2006). The primary outcome measure was the Conners' Global Index - Parent form at entry to the trial, end of cross-over period 1, end of period 2 and after 14 weeks. An extensive battery of neuropsychiatric tests was also carried out at baseline and following an open-label follow-up period.

A summary of this rather complex and unconventional trial design is given in Figure 3.3 on the next page.

Figure 3.3: Frei et al (2005) participant flow



The use of a cross-over design for this trial presents some additional complications as the results may have been influenced by or even concealed by regression to the mean in the first phase, or a carry-over effect in either cross-over phase (Bland, 1994; Elbourne, Altman, Higgins, Curtin et al., 2002).

Homeopathic treatment of ADHD: a controlled study (Lamont, 1997)

This was a quasi-randomised, controlled single-site trial comparing individualised homeopathic medicines with placebo medicine pills in children diagnosed with DSM-IV ADHD in California, USA. All participants were recruited when children were referred for psychological testing. All of the children were either in care, foster homes or under the supervision of a social worker. There was a high level of ethnic diversity (35% Black, 47% Hispanic and 18% Caucasian). Following diagnosis by the researcher, a homeopathic consultation was carried out to identify an appropriate individual medicine using classical homeopathic prescribing and the RADAR repertory software (no further details reported). Children were then alternately assigned to verum (n=23) or placebo (n=20) conditions and received their medication by post. Medicines were given as 6x200c pills taken daily in both placebo and verum homeopathy arms for up to 5 days. During the trial up to three medicine changes were possible in the verum arm. A partial cross-over design was used where those children initially assigned to placebo were later given verum medicines. The author reports that none of the participants were aware of the use of placebos during the trial as there had been significant problems with compliance in an unpublished pilot study. Follow-up lasted approximately 2 months with 43 children of an average age of 10 years taking part. Symptoms of hyperactivity were measured by an unpublished five-point scale of change in hyperactivity. This scale was administered by telephone 10 days after each homeopathic prescription.

The efficacy of a homeopathic preparation in the management of ADHD (Strauss, 2000)

This South African study compared the effects of a commercially available combination homeopathic medicine with identical placebo in children aged 7-10 years reported as having ADHD. Children were classified as medicated (n=10) or not medicated (n=10) on entry to the trial. Participants were recruited via posters at support groups and in doctor's surgeries. All the children were aged between 7 and 10 years and had previously received a diagnosis of ADHD from a registered psychiatrist according to legislation in South Africa. The narrow age group included was justified as being the time frame problems were most likely to be presenting to health professionals. There was no clinical consultation as a standard medicine was used, and children were randomly allocated to four groups of five as follows:

Arm A (n=5) verum homeopathy + Ritalin

Arm B (n=5) placebo homeopathy + Ritalin

Arm C (n=5) verum homeopathy + no Ritalin

Arm D (n=5) placebo homeopathy + no Ritalin.

The study was described only as randomised, personal communication with the author reported that a fellow researcher carried out the randomisation using a computer and then made up the medication (Strauss, 2007). The formula containing various potencies of two medicines was taken as daily drops in both placebo and verum conditions for two months. Outcomes were measured at baseline, 30 days and 60 days: an earlier version of the Conners' Rating Scales was used to assess improvements as rated by the parents and a cancellation task was used to evaluate sustained attention during the study (Conners, 1973; Lezak, 1983). Participants took the homeopathic medicine throughout the 60 day trial period and were followed up to termination of the medication.

Homeopathy for ADHD: a pilot randomised controlled trial (Jacobs, Williams, Girard, Njike et al., 2005)

This study was a randomised placebo controlled trial of individualised homeopathy for children diagnosed with ADHD using the DSM-IV. Participants were recruited through advertising and direct mailings to healthcare professionals and psychologists. The computerized Diagnostic Interview Schedule for Children was used to ensure children met the DSM-IV criteria for ADHD. An in-depth homeopathic consultation was carried out by one of two privately practicing homeopaths based in Boston, USA, for each child followed by the prescription of a homeopathic medicine. At the point where the prescription was sent to the pharmacy each participant was randomised to receive verum or placebo homeopathy according to a computer generated blocked, stratified number generation algorithm. The prescribing method used in this study is one of the newer approaches and termed the Bombay or Sankaran method (Jacobs, 2006). The medicines were prescribed without restrictions and with the freedom to vary the potency and frequency at the follow-up visits on 6 and 12 weeks. The placebo homeopathy followed the same structure and neither homeopath nor patient was aware of the treatment allocation. 43 children with a mean age of 9 years took part in the study, 21 in the verum group and 22 in the placebo group. ADHD symptoms at 18 weeks were measured by validated rating scales completed by parents and teachers and computer tasks that assessed attention and impulsivity (Conners, 2001, 1995a).

3.12 Assessing the risk of bias in the included studies

Methodological quality was assessed independently by two reviewers using criteria outlined on page 58 within the data extraction form. Results from the quality assessment are summarised below with full details available in Appendix 5 (pg 367).

It is important to distinguish between reporting quality, and the methodological quality of the studies. Research has shown that methodologically sound trials may be reported badly leading to erroneous conclusions about the research itself (Huwiler-Muntener, Juni, Junker and Egger, 2002). To avoid this confusion, where information was missing or unclear the authors were contacted meaning that this review attempted to assess the risk of bias in the actual research rather than relying only on quality of reporting. Successful contact was made with the authors of three out of the four eligible studies (Hsu-Schmitz, 2006; Frei, 2006a,b; Strauss, 2006a,b, 2007). Attempts to contact the author of the fourth study (Lamont, 1997) have been unsuccessful to date; these included hard copy letters to the given address on his two published articles (no reply), telephoning the relevant number for this address (not in use), contacting the editors of journals publishing his articles (no further information) and telephoning the American Psychological Association (no longer a registered member).

3.12.1 Sequence generation and allocation concealment

Of the four studies included in this review, two of the randomised controlled trials reported details of both the sequence generation (computer generated stratified randomisation) and concealment of randomisation in sufficient depth in the published papers to merit a positive judgement for these categories (Jacobs, Williams, Girard, Njike et al., 2005; Frei, Everts, von Ammon, Kaufmann et al., 2005). This substantially reduces the likelihood of bias or subversion in these trials. The third randomised controlled trial Strauss (2000) merely described the allocation process as random with no further details in the published paper but following correspondence was judged to be sufficient because the computerised random allocation was performed by a colleague Strauss (2007). The final study was quasi-randomised, alternation being performed by the clinician who was also the researcher and performed the analysis, making the study potentially more susceptible to bias (Lamont, 1997).

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3.12.2 Blinding

Jacobs et al. (2005) and Frei et al. (2005) both reported blinding of patients, care providers and outcome assessors and described procedures for ensuring this was maintained throughout the trial. Frei did not assess if the blinding was successful or not and Jacobs checked with the prescribing homeopaths but not the parents or children in their study. Strauss (2000) reported the study as double-blind but did not provide any further information in the published paper. Based on correspondence, it seems likely that the participants and author (also the assessor and researcher) were blinded to allocation although there were no checks of blinding success. Lamont (1997) chose not to reveal to the carers/parents or children that they were taking part in a placebo controlled trial meaning both were blind to allocation. Lamont was not blind to allocation and was the outcome assessor for the study.

3.12.3 Outcomes data

Reporting of the analysis and results was variable between the four studies. Jacobs et al. (2005) reported point estimates and variability in a variety of forms, performed an intention to treat (ITT) analysis and reported loss to follow-up (one in placebo group) and missing values due to drop-outs (two in intervention, three in placebo). They did not report what procedures they used to deal with missing data.

Frei et al. (2005) reported medians and ranges in their published paper although the data were not skewed and means/SD's were later obtained and not all variables were presented with measures of variability (Hsu-Schmitz, 2006; Frei, 2006a). Withdrawals after the first cross-over period were assumed to be missing at random by the authors. There were no losses or drop-outs but four patients were withdrawn due to medical conditions. An ITT analysis was used and reported.

Strauss (2000) presented only mean scores and percentages in the published paper with no measures of variability given or possible to be calculated. Contact with the author and fortuitous

receipt of the original thesis revealed that only mean values or percentages were reported (Strauss, 2006a). 22 patients were originally randomised to the study with one being withdrawn due to lack of compliance and a second being advised by their general practitioner to drop-out (Strauss, 2007). No data have been presented on these two patients, and they were excluded from all analyses.

Lamont (1997) presented mean scores but it was possible to estimate the standard deviations based on the t-values reported using methods from the Cochrane Handbook (Higgins JPT, 2008). Three children were withdrawn from the active intervention arm after changes to their stimulant medication and these were not included in the final analysis.

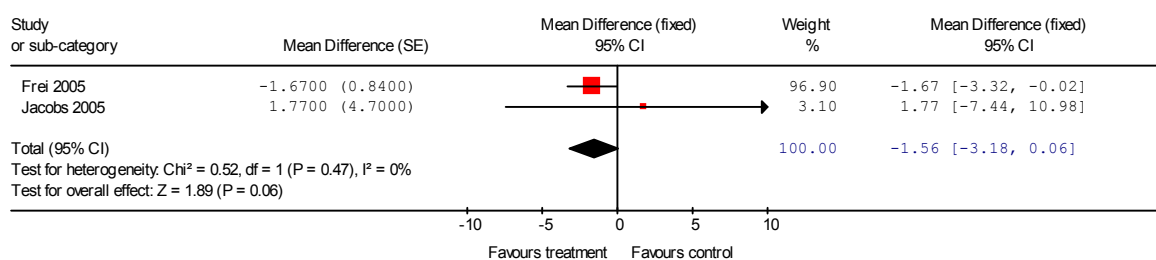
3.13 Effectiveness results

This section reports the results for each of the outcomes of interest identified in the Methods section; grouped by rater (coded as parent 01, teacher 02, child 03) under the following headings; global ratings, core symptoms, related outcomes. All studies used homeopathy versus placebo therefore no grouping by comparator intervention was necessary. Summary estimates are presented for each primary study, and where possible a pooled treatment effect estimate. Most of the pooling possible was between Strauss (formula approach) and Jacobs et al. (individualised homeopathy). While I acknowledge the substantial differences in treatment approach (as detailed in the description of included studies section) it was felt that pooling was still appropriate since overall all of the included studies could be interpreted as addressing the ongoing controversy of whether homeopathic dilutions have any efficacy over a placebo dose.

Effect sizes and 95% confidence intervals have been calculated where possible and unless otherwise noted a minus sign favours the active homeopathic intervention rather than the placebo control. Final post-intervention values were used in preference to change scores as advised by the CDPLP Group. Fixed and random effects models were both checked but fixed effects models were sufficient for most analyses given the lack of heterogeneity. Effect sizes were calculated as standardised mean differences (SMD) since not all trials had used the same outcome measure or version of a particular ratings scale. SMD's allow for comparisons across different outcome measures within the same variable of interest.

Figure 3.4: Pooled analysis of global ADHD scores (2 studies)

Review: Homeopathy for attention deficit/hyperactivity disorder or hyperkinetic disorder
 Comparison: 01 Homeopathy versus Placebo (Parent Ratings)
 Outcome: 01 Conners Global Index Scores (Parent) CGI-P



3.13.1 Parent Rated Outcomes

Primary outcome: global symptom score

Two studies (Frei et al. 2005; Jacobs et al. 2005) measured overall symptoms using the Conners' Global Index rated by parents (CGI-P). Higher scores on this ten item scale indicate poorer functioning and more severe symptom load. Strauss (2000) used an older version of the Conners' Rating Scales (CRS) which included a domain termed the Hyperactivity Index but has been renamed the Global Index in later revisions to better reflect the item content (Strauss, 2000; Conners, 2001).

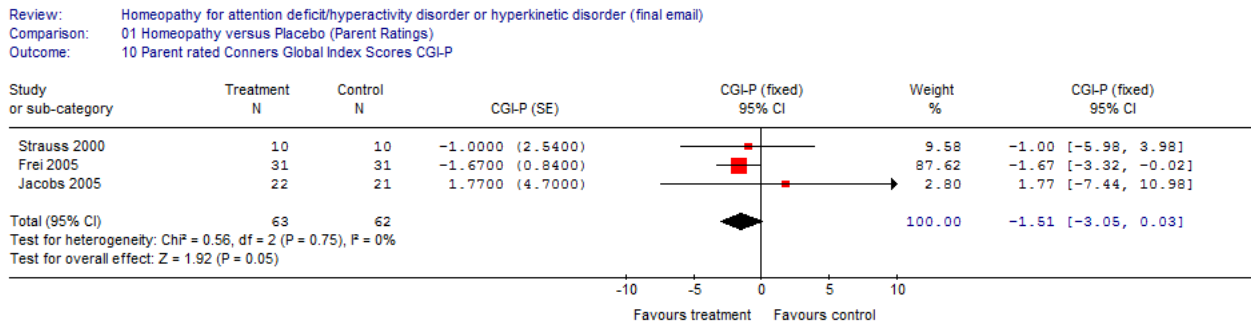
The effect size for Frei et al. (2005) was calculated as advised by the statistician with the CDPLP Group: a mean difference in final scores and 95% CI was provided by the authors and the standard error calculated from this. This gave a treatment effect suitable to be pooled in a generic inverse variance weighted average treatment effect. A statistically significant benefit of verum homeopathy over placebo in the cross-over phases of the Frei et al. (2005) study was noted [-1.67 (CI -3.32, -0.02)].

A generic inverse-variance analysis was carried out to pool the results from the two trials of individualised homeopathy versus placebo. Both studies used the same outcome measure - parent rated Conners' Global Index scores - providing data from a total of 105 participants. In the analysis Frei et al. (2005) was given substantially more weighting than Jacobs et al. (2005) as a result of having a larger sample and less variance around the estimate. The combined data showed non-statistically significant evidence of the effectiveness of homeopathy over placebo in improving CGI scores for children with ADHD [average treatment effect -1.56 (CI -3.18, 0.06)], with no statistical heterogeneity. Please see Figure 3.4.

Conducting an additional analysis by pooling all three studies (two individualised and one formula) used data from 125 participants and produced a very similar result, see Figure 3.5. The addition of Strauss shifted the mean difference very slightly in favour of homeopathy but not

to the level of statistical significance and did not result in significant statistical heterogeneity [average treatment effect -1.51 (CI -3.05, 0.03)].

Figure 3.5: Pooled analysis of global ADHD scores (3 studies)



Secondary outcome: Core symptoms

ADHD index Only Jacobs et al. (2005) measured overall ADHD symptoms using the ADHD Index sub scale of the Conners’ Parents Rating Scales - Revised (CPRS-R) brief form and found no evidence for effectiveness of verum homeopathy over placebo homeopathy [SMD 0.17 (CI -0.43, 0.77)].

Hyperactivity Jacobs et al. (2005) reported data on the Hyperactivity subscale from CPRS-R scored by the parents which showed no evidence of effectiveness of homeopathy on hyperactivity symptoms [SMD 0.21 (CI -0.39, 0.81)].

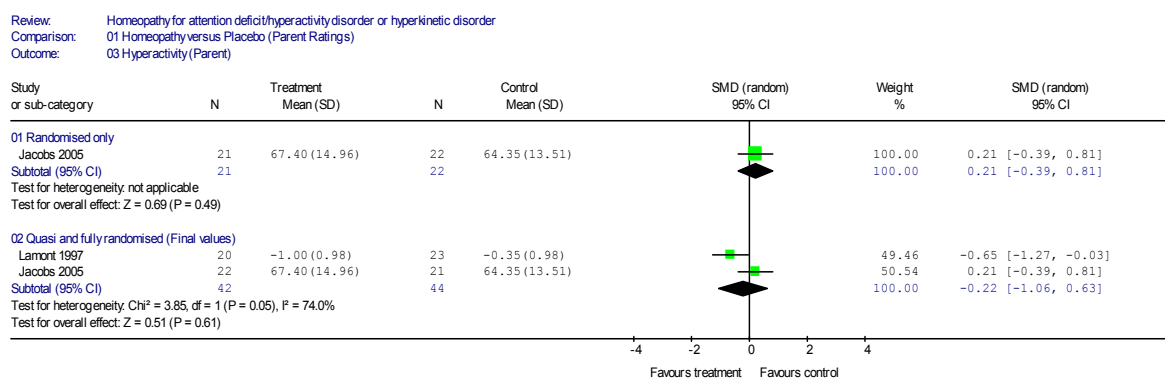
Lamont (1997) used a five point rating scale completed by parents or carers that evaluated any observed change in hyperactivity in the past 10 days. This produces a change score without a reference baseline. This scale is reported to have been used in a previous pilot study but no information was available on its development or validation. Lamont’s study reported results from the first medicine prescription and using these data evidence of effectiveness was found [SMD -0.65 (CI -1.27, -0.03)].

The study design also involved varying the medicine if the original prescription was judged to be ineffective in the verum group. These results were reported as follows: "when more than one homeopathic medicine was given, the improvement score from the best one only was used" (Lamont, 1997). Full change scores were not presented for all prescriptions therefore it was unclear which medicine administration the verum improvement scores referred to, therefore these data were not considered for this review.

A final set of results were also reported based on the partial cross-over design; where those participants receiving placebo were then given verum homeopathy and a within-subject analysis carried out. Again it was unclear which medicine administration the verum improvement scores referred to, therefore these data were not considered for this review.

A sensitivity analysis pooling Jacobs et al. (2005) and Lamont (1997) using final values and first prescription data only found no evidence of the effectiveness of homeopathy in improving hyperactivity in children with ADHD [SMD -0.22 (CI -1.06, 0.23)]. See Figure 3.6. Significant heterogeneity was present in this analysis and the results should be considered with caution.

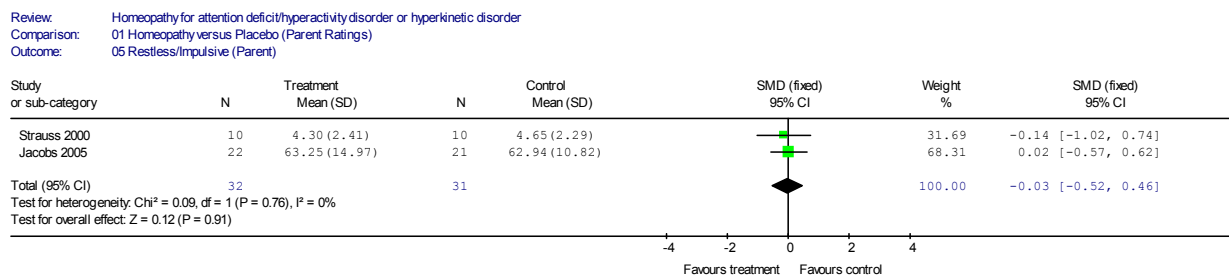
Figure 3.6: Pooled analysis of hyperactivity scores (2 studies)



Inattention Only one study reported data on inattention, Jacobs et al. (2005) used the CPRS-R domain of inattention but no evidence of effectiveness was found [SMD 0.39 (CI -0.21, 1.00)].

Restless/Impulsivity Two studies reported restlessness/impulsivity outcome data, Jacobs et al. (individualised homeopathy) reported scores from the CPRS-R (2005). Strauss (formula homeopathy) reported similar data from the older CRS (2000). These two studies provided data from a total of 63 participants (32 verum homeopathy and 31 placebo homeopathy) and indicated no evidence of the effectiveness of homeopathy in improving restlessness/impulsivity in children with ADHD [SMD -0.03 (CI -0.52, 0.46)]. See Figure 3.7.

Figure 3.7: Pooled analysis of restless-impulsive scores (2 studies)

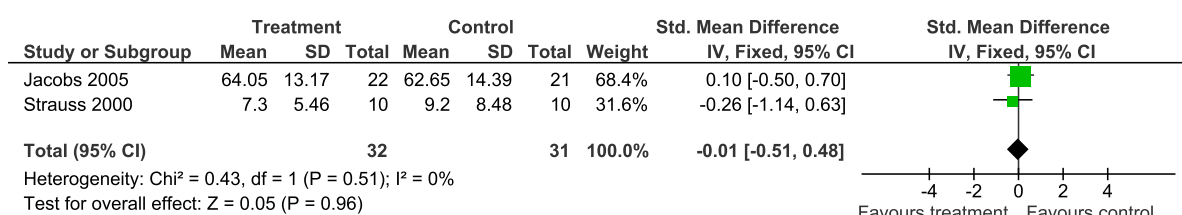


Secondary Outcomes: Related outcomes

Anxiety One study reported Anxiety as an outcome based on a domain within the older CRS (Strauss, 2000). Strauss' data showed a non-significant difference in levels of anxiety [SMD -0.55 (CI -1.45, 0.34)].

Conduct/Oppositional Related behaviour issues were measured using the relevant domain of the CPRS and CRS by Jacobs et al. (individualised) and Strauss (formula) respectively (2000; 2005).

Figure 3.8: Pooled analysis of oppositional scores (2 studies)



These two studies provided data from a total of 63 participants (32 verum homeopathy and 31 placebo homeopathy) and pooling indicated no evidence of the effectiveness of homeopathy in improving conduct problems/oppositional behaviours in children with ADHD [SMD -0.01 (CI -0.51, 0.48)]. See Figure 3.8.

Emotional Lability This is a domain only included in the newer revised Conners' scales, only Jacobs et al. reported these data and found no evidence of effectiveness [SMD 0.21 (CI -0.39, 0.81)] (2005).

3.13.2 Teacher Rated Outcomes

Jacobs et al. (2005) was the only study to use teacher based ratings of symptoms and behaviour. All data were collected using the Conners' Global Index-Teacher form (CGI-T) which provides a global total [MD 0.41 (CI -0.20, 1.01)] and two further sub-domains covering Core Symptoms and Related Outcomes respectively. Restless/Impulsive [MD 0.39 (CI -0.21, 1.00)] and Emotional Lability [MD 0.41 (CI -0.19, 1.02)]. No significant differences were recorded in any of these three teacher-rated variables.

3.13.3 Child Completed Outcomes

Inattention

Frei et al. (2005) assessed inattention using the Test battery for Attention Performance (TAP) but did not provide sufficient data to allow the calculation of an effect size for the included cross-over phases of the trial (Zimmerman and Fimm, 1992).

Jacobs et al. (2005) and Strauss (2000) both used child-completed tasks to assess levels of attention in the participants. Jacobs et al. used the Conners' Continuous Performance Test (Conners CPT) (Conners, 1995b). The CPT is a computer program that flashes up successive letter stimuli, respondents are required to press the space bar or click the mouse whenever any letter except the letter 'X' appears on the computer screen. The number of omission errors (missed targets) were then taken as a measure of inattention.

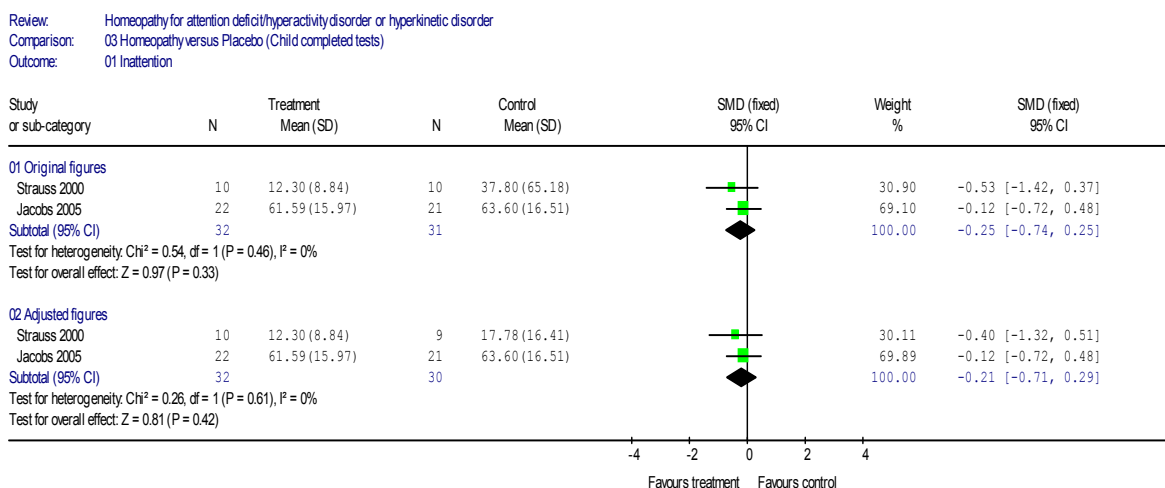
Strauss used a pencil and paper task described as the Children's' Checking Task (CCT) (Lezak, 1983). In the CCT, the child is presented with a block of characters (letters/symbols/numbers) and asked to score through a target whenever it appears in the block. The original paper presented the results as percentage correctly identified. Using data provided by the author, MKH converted the percentages into raw scores and then multiplied these by -1 to provide a measure of inattention rather than successful attention.

Jacobs et al. (2005) and Strauss (2000) measured inattention through child completed tasks that were either computer based or pencil-and-paper. Data were pooled to give results from a total of 63 participants (32 verum homeopathy and 31 placebo homeopathy). Pooling indicated no evidence of the effectiveness of homeopathy in improving attention in children with ADHD [SMD -0.25 (CI -0.74, 0.25)]. See Figure 3.9 on the next page.

Impulsivity

Based on the Continuous Performance Test described above and used by Jacobs et al. (2005), the number of commission errors (false alarms) can be used to reflect levels of impulsivity. No evidence of effectiveness was found [MD -0.07 (CI -0.67, 0.53)]. Frei et al. (2005) assessed impulsivity using the Test battery for Attention Performance (TAP) but did not provide sufficient data to allow the calculation of an effect size.

Figure 3.9: Pooled analysis of inattention scores (Jacobs & Strauss)



3.14 Safety results

Despite extensive searching and contact with authors in the area only two sources of safety data were located. Jacobs et al. (2005) used a Stimulant Side-Effects Checklist during their randomised controlled trial and reported that no adverse events were recorded in either group.

A further study was located during searches for documentary evidence (described in the following chapter). This two-group study was published in 2007 in a paediatrician magazine in German (Hultzsich, 2007). Funded and co-ordinated by a homeopathic remedy manufacturer, it compared a complex homeopathic drug named Zappelin with Ritalin in the treatment of ADHD. Very few details on the study procedure were reported and additional information was not forthcoming from the manufacturers. A total of 75 centres allocated 408 children to either Ritalin or Zappelin. The population was reported to comprise 74% diagnosed with ADHD and 25% with Hyperkinetic disorder. It was entirely unclear if any kind of randomisation was attempted, therefore this study was not included further within the effectiveness analyses. No formal statistical analysis was carried out in the publication.

The study of Zappelin reported safety data as numbers of adverse events although no further definition was provided (Hultzsich, 2007). A total of 19 non-severe adverse events were reported, five events in five patients receiving Zappelin and seven events in five patients receiving Ritalin were felt to be related to the treatment.

It was not possible to calculate any summary statistics for this outcome.

3.15 Discussion

Twenty-four reports of single or multiple case studies, one uncontrolled observational study, one controlled comparative study, and four controlled trials of homeopathy for ADHD were located. Three randomised controlled trials and one quasi-randomised study were included in the assessment of efficacy and effectiveness in this review, reporting research conducted over a ten-year period. Frei et al. and Jacobs et al. were the most methodologically sound trials in this review (2005; 2005). Due to the nature of the data gathered and reported, it was only possible to pool them on one outcome (Conners' Global Index score). Here the analysis showed a beneficial effect of homeopathy but it was not statistically significant.

This raises important questions around the power of such trials. Frei et al. (2005) was based on *a priori* power calculations and recruited to their target. Jacobs et al. (2005) was a pilot trial and they addressed the power issue in their paper, noting that the direction of effect in their study generally favoured placebo rather than verum, making it less likely that it was lack of power producing the results. Power or lack of may have been more of an issue for Frei et al. as this trial was interested in maintenance versus deterioration after successful treatment, and as the authors mention, patients did not display the expected degree of returning symptoms under placebo. The power calculation also appears to have been based on reduction from pre-treatment values rather than the expected difference between trial arms.

Three of the included studies (Jacobs et al., 2005; Strauss, 2000; Lamont, 1997) looked at the overall change in symptoms during homeopathic treatment while the fourth (Frei et al., 2005) examined the maintenance or deterioration of previously achieved improvement. While varying forms of homeopathy were used in each trial, results were pooled where possible to address the common question about what effects, if any, can be observed as a result of using ultra-low dosages as has been done in other reviews (Linde, Clausius, Ramirez, Melchart et al., 1997). Three studies used individualised homeopathy as the treatment model although they drew on different prescribing strategies and sources while one used a standard formula prescription.

Focusing on the three trials included in the meta-analysis, it is clear that significant heterogeneity exists between these trials in terms of how the homeopathic treatment was operationalised and implemented, as well as the effects. Strauss (2000) used a formula of medicines given without individualisation to patients over a relatively short period of time, and the results did not indicate a beneficial effect over placebo. Jacobs et al. (2005) used a form of individualised homeopathy (based on the Bombay method) similar to how classical homeopathy is used in practice with freedom to vary the medicines as well as potency (strength) and frequency. Critics have suggested that the treatment period of 18 weeks was too short to show benefit from homeopathy, hence the negative findings (Frei, Thurneysen, von Ammon and Jacobs, 2006). Frei

et al. (2005) used a treatment protocol including questionnaires and a particular approach to remedy identification based on an observational study (Frei and Thurneysen, 2001). This more rigorous randomised cross-over trial (Frei, Everts, von Ammon, Kaufmann et al., 2005) showed a small but statistically significant benefit from homeopathic treatment when core symptoms were rated by parents. Interestingly this study differed from Jacobs et al. in that children were only seen once by the homeopath and all follow-ups carried out with the parents by telephone. The authors' stated intention was to reduce the non-specific effects of homeopathy and test the impact of the medicine itself as far as possible.

In summary this review found no evidence that homeopathy has a statistically significant impact on the overall severity, core symptoms or related outcomes of children diagnosed with Attention Deficit Hyperactivity Disorder. It was not possible to comment on the safety of homeopathic treatment due to the paucity of data available.

Chapter 4

Systematic Review: Individual Patient Data

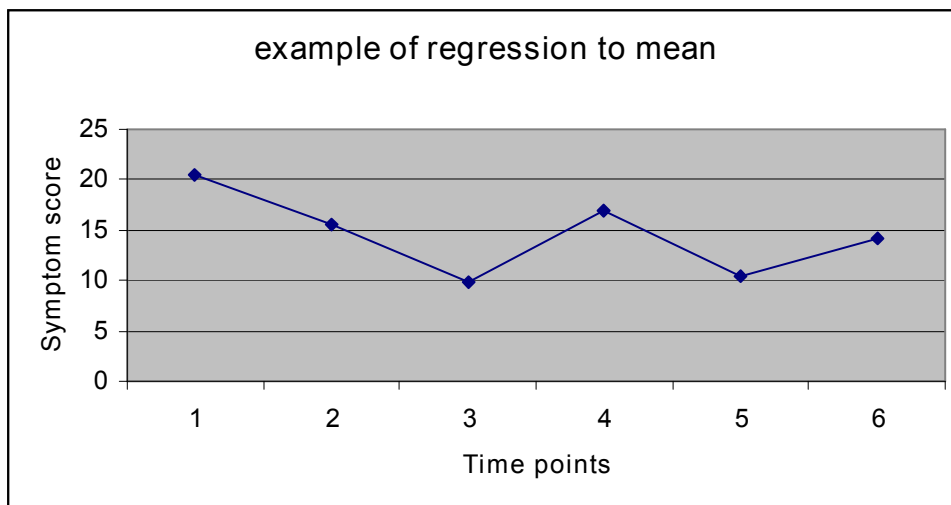
4.1 Research Aims

The systematic review presented in the previous chapter was based on trial level data collected from published and unpublished studies. It found no evidence to suggest that homeopathy has a beneficial effect on ADHD symptoms across the four included studies.

The cross-over design used by Frei et al. allowed for individualisation of treatment without restricting the initial treatment period (Frei, Everts, von Ammon, Kaufmann et al., 2005). However the design itself may have been particularly vulnerable to artefacts such as regression to the mean, or carry-over. Regression to the mean is a common statistical artefact occurring in most if not all trials (Bland, 1994). Generally people are likely to enrol themselves or their child in a trial when the condition is particularly bad. Statistically therefore these participants have fairly extreme scores, over time these would be expected to return to around the mean value regardless of an intervention. There may be some repetitions of this pattern before the symptom scores settle down, see Figure 4.1. By choosing participants who had recently responded to homeopathic treatment for randomisation into a cross-over trial, Frei et al. have potentially increased the difficulty of demonstrating a statistically significant treatment effect.

Cross-over designs are recommended for use with chronic, stable conditions and particularly where treatments are not predicted to have lasting effects (Senn, 2004; Elbourne, Altman, Higgins, Curtin et al., 2002). Frei and Thurneysens's observational study anecdotally reported a recurrence of symptoms when homeopathy was stopped, but did not directly measure this using an outcome measure such as the CGI (Frei and Thurneysen, 2001). Therefore the potential duration of any carry-over, and the extent to which symptoms would achieve starting levels of severity remains uncertain.

Figure 4.1: Example of regression to the mean



The most directly comparable trials (Jacobs et al. and Frei et al.) had not reported the same level of detail for the primary outcome measure meaning that only limited pooling was possible in the aggregate review (Jacobs, Williams, Girard, Njike et al., 2005; Frei, Everts, von Ammon, Kaufmann et al., 2005). Retrieval of more detailed data on the Conners outcome scales could facilitate further analysis.

The inclusion of one trial in the aggregate review necessitated requesting additional data from the author as the published figures were not amenable to the meta-analysis (Strauss, 2000). Strauss generously provided an electronic copy of the original thesis from which the paper was written including raw data tables. Calculation of the summary estimates for the aggregate review highlighted some potential inconsistencies within the data set which could be further explored by adopting an individual patient data (IPD) approach.

The largest study published to date comparing behavioural therapy, pharmacological therapy and treatment as usual has shown that co-variables such as age, gender, severity of symptoms among others have the potential to influence treatment effects (MTA Cooperative Group, 1999b).

Individual patient data (IPD) analysis has the potential to address all of the above issues, explore important covariates and provide updated, reliable treatment effect estimates for each trial. The research aims were specified as follows:

1. Re-estimate the effect of homeopathic treatment on global severity, core symptoms and associated symptoms of ADHD by pooling the most accurate and complete treatment estimates from each trial
2. Explore the impact of selected baseline variables on treatment outcomes

3. Explore the Frei et al. (2005) cross-over trial data for evidence of period effect, carry-over or regression to the mean

4.2 Protocol development

A protocol was prepared shortly after completing the aggregate review when it became clear that there were still areas in the data worth exploring further. The protocol was developed with input from Prof Lesley Stewart (Director for the Centre for Reviews and Dissemination, University of York) and a thesis Research Advisory Group member, Dr Susan O'Meara (member of the Cochrane Wounds Group and the Cochrane IPD Methods Group). The protocol was then forwarded to the authors of all four eligible trials asking for their comments and cooperation. A copy of the protocol can be found in Appendix 6 (pg 373).

4.3 Inclusion criteria

The inclusion criteria were based on those developed for the aggregate review reported in the previous chapter and are summarised below. See the previous chapter for more details. Inclusion was also dependent on making contact with the authors and receiving at least some of the requested data

Population Children and young people (up to age 18 years) diagnosed with ADHD or HKD according to recognised criteria from the DSM-IV or ICD-10 were eligible for this review (APA, 2000; WHO, 1992). Trials which also included adults were still eligible for inclusion provided the CYP data could be separated out.

Intervention Eligible interventions were homeopathic medicines prepared according to national pharmacopoeias, or other explicit protocols.

Control Eligible comparisons included but were not limited to the following: wait-list or no treatment; pharmacological treatment (e.g. methylphenidate); usual care; multidisciplinary packages (secondary care: school-based interventions, behavioural training, parenting skills); placebo homeopathy.

Outcomes Trials were required to report on at least one of the following outcomes: global ADHD symptoms; core symptoms (e.g. hyperactivity, inattention and impulsivity); school/academic performance; depression/anxiety-related outcomes; conduct/oppositional disorder outcomes; adverse effects; quality of life.

Study design Randomised and quasi-randomised controlled trials were considered for inclusion.

4.4 Data requested

IPD were requested from the eligible trials by email. Trialists were requested to provide: participant ID, age, date of birth, gender, date of randomisation, treatment allocation, baseline and follow-up outcome scores. Data could be provided electronically or in hard copy.

4.4.1 Baseline variables

Baseline variables of interest to this IPD meta-analysis were selected based on findings from the MTA trial, one of the largest studies comparing medication, behavioural therapy, combined care or standard treatment on ADHD which attempted to explore longer term follow-up and a more pragmatic setting for treatments (MTA Cooperative Group, 1999b,a; Boyle and Jadad, 1999).

Age Since the trials eligible for inclusion in this review had used a fairly wide age range, this was included as a potentially important baseline variable.

Gender Gender differences in the prevalence of ADHD across cultures have been noted with substantially higher levels in males, but there has been little exploration of sex-related responses to treatment to date (Gaub and Carlson, 1997).

Severity Trials identified for this review have used varying inclusion criteria and it is possible that initial disease severity may be a factor in treatment response (MTA Cooperative Group, 1999b).

Psycho-stimulant use The MTA study authors suggested that previous psycho-stimulant use may be associated with less favourable outcomes in future treatment, earlier treatment failure may identify children who may not respond quickly to treatment (MTA Cooperative Group, 1999b). Frei et al have reported that children previously treated with medication for ADHD took longer to respond to homeopathy, although this may also be explained with reference to homeopathic theory where allopathic medicine is believed to suppress the symptoms and result in a more difficult treatment process (Frei, Everts, von Ammon, Kaufmann et al., 2007).

Co-morbidity Specifically oppositional-defiant disorder and conduct disorder, diagnoses common to both the ICD-10 and DSM (APA, 2000). Oppositional-defiant disorder is characterised by an ongoing pattern of hostility and aggression towards authority figures beyond normal age-appropriate behaviour. Conduct disorder is exemplified by repetitive behaviour patterns that repeatedly violate social norms and/or the rights of other people, and is a risk factor for delinquency and other psychiatric conditions. These conditions have been shown to have particular impact on the prognosis of treatment for ADHD, possibly via the impact of disruptive behaviours on peer and family relationships (Jensen, Martin and Cantwell, 1997).

4.4.2 Outcome variables

Outcome variables of interest were drawn from those examined in the aggregate review. The primary outcome of interest in this meta-analysis was global assessment of ADHD symptoms as assessed by parents. Core symptoms (hyperactivity, inattention and impulsivity), depression/anxiety, conduct/oppositional disorder and adverse events were included as secondary outcomes of interest as assessed by parent, teacher or child. Treatment acceptance and compliance was the secondary outcome of most interest - maintaining involvement has been suggested to be important for active treatments such as medication management or behavioural treatment in previous ADHD research, therefore we planned to explore this where data was available on acceptance and attendance at the scheduled sessions (Charach, Ickowicz and Schachar, 2004).

4.5 Data Management

Authors were requested to provide the variables detailed above in whatever format their data were available in. MRC guidelines recommend using a standard request form to facilitate data provision, reduce missing data and ease the process for trialists and researchers (Stewart

and Clarke, 1995). In this review however, a standard format was not requested due to the small numbers of trials and participants involved in an attempt to reduce the work for individual trialists.

Received data sets were saved in the format supplied. Each data set was then formatted where necessary (using Excel) and imported into SPSS before being saved in separate files for each trial. Variable names were clarified at this stage where necessary and any recoding/formatting carried out. Hard copy data were double-entered by Morag for accuracy.

All trial data were held securely and used only for the purposes of this meta-analysis.

4.6 Checking and cleaning procedures

Stewart et al gives details of a standard data checking procedure developed by the Cochrane Group and the MRC Clinical Trials Unit which have been followed as far as possible for this meta-analysis (Stewart and Clarke, 1995). Data are checked, not to discover fraud, but to improve accuracy and follow-up, ensure intention-to-treat analyses, facilitate the inclusion of all randomised patients, assess the quality of trials and assess the integrity of the randomisation procedure. In this manner, the checking procedure within an IPD is analogous to the assessment of risk of bias in an aggregate review. All checks were carried out trial by trial before any pooling was considered.

4.6.1 Preliminary checks

These are carried out by comparing the provided information with the variables of interest to ensure all requested variables are present and codes are interpretable. Where necessary clarification was sought and missing variables requested.

The following sections detail the main checking procedures carried out for each trial data set. Each check, the output, queries to trialist and responses were recorded.

4.6.2 Detection of duplicates

Patient identifier was used to sort the data (ascending) and the SPSS command “identify duplicate cases” used. Data had been sorted and entered into SPSS such that no multiple patient identifiers were expected. Any duplicates were queried with the trialist. Any apparent missing values were also queried where the identifiers appeared to follow a sequence.

4.6.3 Date consistency checks

Date variables for each patient were checked for consistency according to the available data. Dates supplied were ordered in ascending sequence and checked for any infeasible values – where found these were verified with the trialists. Some dates were expected to occur subsequent to one another e.g. date of randomisation should fall before date of follow-up, where there was more than one treatment period these should follow chronologically. In both cases the earlier date was subtracted from the later date to give time elapsed, this variable was then ordered and checked as before. Any discrepancies were checked against the protocol, if available, and clarified with the trialists.

4.6.4 Verifying integrity of randomisation

Fully randomised trials ought to have similar numbers allocated per arm according to the randomisation ratio, and randomisation to arm should be approximately evenly spread out across days of the week that allocation was possible. If patient identifiers follow a chronological sequence they ought to be parallel with dates of randomisation, and randomisation should approximately evenly allocate patients to each arm over time. These factors were checked in the following ways where data were available:

Numbers allocated per treatment arm: Taking the randomisation ratio into account, a table of number of participants per group was produced as well as a pie chart to check if numbers were as expected. Chi-squared test was used assess the statistical significance of any observed between-group differences

Days of the week randomised by arm: Where date of randomisation was provided (or a suitable proxy) these data were converted to day of the week using the relevant SPSS function. A table of participants allocated to each arm by day of week was produced along with a bar chart. This output was assessed to determine if differential allocation had occurred, thus indicating quasi-randomisation.

Sequence of patient identifiers: If patient identifiers were chronological, they were ordered by date of randomisation (or suitable proxy) and the sequence examined for any discrepancies.

Sequence of dates of randomisation by arm: A cumulative frequency plot was used to graph cumulative numbers of patients randomised by trial arm according to randomisation date. These plots should show similar allocation patterns with the potential for some crossing over. Other patterns (e.g. divergence, constant or no crossing) were noted for discussion.

Check of dichotomous baseline variables by arm: A frequency table was produced, checked for unexpected codes and Chi-square test used to check for any statistically significant differences.

Check of continuous variables by arm: A table of summary statistics was produced showing mean, median, standard deviation, minimum, maximum values. These were checked for any unlikely values. The data were checked for normality using graphs (stem and leaf plots, box plots) and statistical tests (Kolmogorov-Smirnoff). Normally distributed data were tested for any baseline differences using an independent samples t-test, non-normal data were tested using a Mann Whitney U test.

Patient age: Where trials provided age, date of birth and date of randomisation an additional accuracy check was carried out. The reviewer calculated patient age by subtracting date of birth from date of randomisation, and checked this against the original age variable.

4.6.5 Assessment of follow-up

Follow-up should be consistent across treatment groups and correspond to the stated duration of the trial (as per published paper/protocol). Duration of follow-up was calculated by subtracting date of randomisation from date of last follow-up where available. Data were then ordered by duration of follow-up and patient identifier for each treatment group. This allowed checking of the expected versus actual duration, and if follow-up was similar across treatment arms.

4.6.6 Summary of primary and secondary outcomes

Continuous primary and secondary outcomes: summary tables containing mean, median, standard deviation, maximum and minimum were produced for baseline and final follow-up by arm of trial (placebo or verum).

4.6.7 Check for excluded patients

Missing patient identifiers were compared with the known number of exclusions (based on published papers and contact with trialists). Where the numbers matched, this was verified with the authors, any discrepancies were forwarded for discussion. Reasons for exclusion by patient identifier were then requested and coded. Patients randomised for treatment who did not then receive the allocated intervention were also checked for.

4.6.8 Check against main publication

The results of the data checking were verified against the relevant publication and any apparent discrepancies noted for discussion with the trialists.

4.6.9 Verification of data

A summary of the data checks, summarised baseline characteristics and a list of queries were supplied to each trialist with an explanatory letter. Trialists were asked to respond to the data checking queries and examine the supplied documents and report any inaccuracies. Updated and/or missing data were also requested at this point.

4.7 Analysis plan

4.7.1 Re-analysing and confirming trial data

Each study was re-analysed appropriately to explore statistical issues such as carry-over where relevant, and generate effect estimates. These analyses were also provided to the original trialists to verify the results and discuss any discrepancies.

4.7.2 Frei - carry-over and period effects

Statistical checks for period effects and carry-over were carried out as recommended by Altman (1990).

Period effect: or does it matter whether patients received the treatment in phase 2 or phase 3. This was tested using a two sample t-test looking at the mean difference between phase 2 and 3 for each arm. If there was no period effect these mean differences should be similar.

Treatment-period interaction: does it matter what order the patient receives the treatment in, usually a test for carry-over. If there is no interaction the patient's average response should be roughly the same regardless of order of treatment. Carry-over in this trial might be seen if the patients successfully treated with homeopathy did not worsen when moved onto placebo in the cross-over trial. This was tested by comparing the average treatment response for each arm ([phase 2 mean + phase 3 mean] divided by 2) with a two-sample unrelated t-test.

4.7.3 IPD Meta-analysis

A data set was created containing all cleaned, checked and verified data from all three included studies. Baseline and outcome variables were entered using identical coding. Both two-stage and single-stage meta-analyses were planned for exploratory purposes. Analyses for the IPD approach were carried out using the R software environment using the *glm* package. The original R implementation of *glm* was written by Simon Davies working for Ross Ihaka at the University of Auckland, but has since been extensively re-written by members of the R Core team (The R Foundation (core group), 2011). Data were imported to the R environment from the cleaned and checked Excel spreadsheets.

Details of the Two-Stage Analysis

In this kind of meta-analysis, each trial level effect is derived from IPD, and the trial level effects are combined as the original analysis. Subgroup analyses based on individual parameters can be derived for each trial and tested for interactions as an alternative to meta-regression allowing the researcher to explore the impact of covariates on trial results and overall summary effects.

The effect sizes were calculated by subgroup within trial (age, gender) to give an overall estimate for males (stratified by trial) and then pooled to compare males versus females within homeopathy as a treatment for ADHD. Multiple regressions by trial were then performed separately to explore which variables influenced prediction of the final CGI score. Akaike's information criterion (AIC) was used to assess the goodness of fit for each potential model within a given set of trial results. AIC values test competing models when explaining a particular data set and attempt to trade-off accuracy of prediction and complexity in terms of the number of variables required.

Details of the One-Stage Analysis

In a single-stage meta-analysis all trial data are analysed simultaneously, however data is still stratified by trial to preserve randomisation and trial effects. The impact of variables such as baseline score, age and gender is included by incorporating co-variables and “treatment x covariate” interaction terms in the analysis model.

Meta-analysis of randomized controlled trials based on aggregated data is vulnerable to ecological bias if trial results are pooled over covariates that influence the outcome variable, even when the covariate does not modify the treatment effect, or is not associated with the treatment. Single stage IPD analysis models are one way of trying mitigate the possible impact of ecological bias (Govan, Ades, Weir, Welton and Langhorne, 2010).

4.7.4 Heterogeneity

As previously discussed in the aggregate review, heterogeneity has been considered under the headings of intervention/clinical differences, trial design and statistical differences. The process of obtaining full IPD resulted in more detailed information being made available about both the treatments and the data collection techniques and tools used.

Statistical heterogeneity was explored by looking for outliers and Cook’s Distance when carrying out regression analysis. Cook’s Distance values indicate data points that may be outliers, where there may be missing data, and the impact of deleting some observations.

4.8 Included studies

Four trials were eligible for inclusion in this patient level review as in the aggregate review. No further studies were identified through contact with the authors or from the updated searches carried out in 2011. Authors were sent a copy of the protocol for the planned IPD analysis and data were requested.

Studies were coded using the first author’s name and date of publication for ease of reference, and this format has been used in the following text and tables.

Patient level data were retrieved for three out of the four eligible trials, see Table 4.1 on the following page. Despite multiple attempts to contact Lamont by phone, email, letter and via journal editors no response was forthcoming, therefore this trial could not be included. Inclusion

Table 4.1: Included studies for IPD analysis

Trial	Interventions	Design	Number of patients (%)
Frei 2005	Individualised single remedies based on refined methodology, given as daily LM drops	Placebo controlled cross-over randomised trial	62 (50%)
Jacobs 2006	Individualised single remedies based on Sankaran style prescribing, various potencies	Placebo controlled parallel group RCT	43 (34%)
Strauss 2000	Standardised compound of remedies given daily	Placebo controlled parallel group RCT	20 (16%)
Total			n = 125 (199%)

of Lamont would have added a further 43 participants to the analysis although these children were from a distinctly different background - all were either in care, foster homes or under the supervision of a social worker.

4.9 Data received

Tables 4.2 and 4.3 summarise the baseline and outcome data which was received from each of the participating trialists.

4.9.1 Frei 2005:

IPD was received from the Frei trialists in the form of an Excel spreadsheet. Variable labels were in German and were translated by a colleague. Data were provided for the following aspects of the trial for both open label run-in, crossover phases 1 and 2, and open label follow-up periods: ID, date of birth, gender, age diagnosed, date and age at trial entry, Conners' Global Index scores, computerised attention test results. Unfortunately the date of randomisation had not been recorded and was therefore unavailable. Additional data were provided via email giving

Table 4.2: IPD baseline data provision

Baseline variable	Frei 2005	Jacobs 2005	Strauss 2000
Age	Yes	Yes	Data destroyed
Gender	Yes	Yes	Data destroyed
Disease severity	Yes	Yes	Yes
Medication use	summary per arm only	summary per arm only	Data destroyed
Co-morbidities	Not collected	Excluded from trial	Data destroyed

dates of all examinations during the trial and the excel spreadsheet used for analysis along with SAS code was also received.

4.9.2 Jacobs 2005:

The data from this trial was supplied as an Access database and additional information was provided as a copy of the preliminary report (Word format). The following information was provided: ID, date of birth, gender, date and age of entry into trial, date of randomisation (clarified by email), Conners' Global Index scores also broken down by domain, Conners' Parent Rating Scales overall and by domain, Conners' Performance Test (CPT) domain scores. Unfortunately despite several attempts to locate the data, IPD on stimulant medication use was not able to be retrieved and therefore not available for use in the analyses.

4.9.3 Strauss 2000:

IPD was received electronically as word documents and tables with some additional information provided by email. Patient ID, Parent Symptom Questionnaire domain scores and Children's Checking Task scores were available. The CCT scores were transformed as described earlier to give mean errors per task for each participant. Data were not available on participant age, gender, medication status, co-morbidity or treatment compliance. The original patient enrolment forms had been shredded some years previously during a move between two clinics.

Table 4.3: IPD outcome data provision

Outcome Variables	Data provided by:		
	Frei 2005	Jacobs 2005	Strauss 2000
Global symptoms measured by the CGI-P	Yes	Yes	Yes
ADHD Index	No	Yes	No
Hyperactivity	No	Yes	Yes
Restless/Impulsivity	No	Yes	No
Inattention	No	Yes	No
Depression/anxiety	No	Yes	No
Conduct disorder/oppositional behaviour	No	Yes	No
Impulsivity child completed task	Yes*	Yes*	No
Inattention child completed task	Yes*	Yes*	Yes*
Restless/Impulsive	No	Yes	No
CGI-Index	No	Yes	No
Adverse events	No	Yes	No
Academic achievement	No	No	No
Treatment acceptance/compliance	Yes	Yes	No

CGI = Conners Global Index (P = parent form, T = teacher form): CPRS = Conners Parent Rating Scale :PSQ = Parent Symptom Questionnaire (old version of Conners) : CPT = continuous performance test (computerised test of attention) : CCT = Children's Checking Task, paper based test of attention : TAP = Test Attention Battery, German computerised test of attention

*No further analysis or comparison of these data were possible due to lack of comparable data and difficulties in extraction.

4.10 Results of the data checking processes

Each trial's data were checked with preliminary queries being sent to the authors, followed by any issues arising from the main checking. Once checking and cleaning was complete the data sets were merged for IPD meta-analysis.

Preliminary checks and queries: these consisted most commonly of requests for missing variables, clarification of variable labels and confirmation of the coding used. In some cases the data were no longer available or accessible due to staff movements or loss of data.

Full details of the checks and results for each trial are reported in Appendix 7, Frei et al. is reported on page 383, Jacobs et al. on page 397, and Strauss on page 411.

4.10.1 Detection of duplicate cases

Only one trial was found to have a possible duplicate participant (Jacobs 2005) where outcome data for one patient appeared to have been duplicated in week 6. This was confirmed and removed from the final data set.

4.10.2 Verification of randomisation

A number of checks were carried out to verify the randomisation and check if quasi rather than true randomisation methods had been used. These checks were: numbers allocated per arm, day of the week of randomisation, sequence of dates of randomisation and checking the balance of available baseline variables.

All three trials reported using randomisation with one using medication status as a stratifying variable (Jacobs 2005), and a second stratifying based on age and initial disease severity (Frei 2005). Two trials used computer-generated randomisation lists and one used a randomisation list applied by a colleague (Strauss 2000).

No significant imbalances in the number of patients per treatment arm were observed when graphical, tabular and statistical checks were carried out. The relevant tables, pie charts and results from the Chi-squared tests are presented in Appendix 7 (pg 383).

Day of randomisation could only be checked for two trials, data on this was not available for the third trial (Strauss 2000). For one trial the date of randomisation (DoR) was not available but was reported in an email as being "some days before the date of the first examination", therefore

date of first examination was used as a proxy for DoR (Frei 2005). Neither of the two checked trials showed signs of randomisation being influenced by day of the week and any unusual days (e.g. Sunday) were confirmed with the trialists as being expected. Appendix 7.1 shows the distribution of patient allocation by day of the week for each trial.

For the two trials where DoR and sequential patient identifiers were available (Jacobs 2005, Frei 2005) these values were assessed in relation to one another. No anomalies were noted in Frei 2005, but four patient identifiers appeared out of sequence in Jacobs 2005. It is unclear why this was the case and the trialists were unable to find a reason.

Cumulative plots of randomisation by treatment arm were examined for the same two trials and followed expected patterns. The graph for Jacobs 2005 deviated slightly from that anticipated, but not sufficiently to cause concern – this trial was also relatively small therefore variation could simply be an artefact of the sample size. These graphs are presented in Appendix 7.2.

Baseline variables including age, gender and initial disease severity were checked both graphically and statistically using Chi-square tests for dichotomous data and t-tests for continuous data. While no significant imbalance in any of the baseline variables reported was identified, these checks did highlight a potential data entry error for one participant's age in the Frei 2005 trial who appeared to be 17 years old at recruitment – eligibility criteria were ages 6 to 16 years. Trialists confirmed this was an error in the file provided, the patient was aged 15 years and 3 months on entry to the study.

Overall it was concluded that randomisation procedures appeared to be satisfactory for two trials (Jacobs 2005, Frei 2005) and likely to be satisfactory for the third trial for which less data were available (Strauss 2000).

4.10.3 Summary of primary outcome

For each trial a summary of the primary outcome measures were prepared, all data were continuous so these were given as mean, standard deviation (SD), median, maximum and minimum for baseline and final assessment time points. Mean differences were also calculated. These were checked against the published data and provided to study authors for verification.

All data were also checked for unexpected results, based on the known minimum and maximum values. Discrepancies were noted in the data from the CGI-P from Frei 2005. As described previously the CGI-P is a ten item scale where each item is scored between 0-3, however the data file included scores such as 9.5. The authors confirmed that these results were not produced

by averaging two care-givers scores, but because the parent often set a cross between two values (Frei, 2006d). This has implications for the validity of the collected data and comparability with Jacobs et al who used the same scale but following published guidance on scoring. It also suggests that the original decision to pool Jacobs 2005 and Strauss 2000 should be considered more cautiously.

4.10.4 Secondary outcome: Treatment compliance

This variable was proxied by attendance at assessment/treatment sessions where possible. No data were available from Strauss 2000, for the other two trials visual checks were carried out to ensure that data were present for all of the relevant time points. Frei 2005: no data were available for the open-label phase, during the crossover phases two patients missed one assessment each, and one patient missed two assessments. Jacobs 2005: no significant differences between treatment arms were noted in terms of attendance (tables and tests shown in Appendix 7, pg 383).

4.10.5 Date consistency checks

Trials varied in the dates provided, Table 4.4 summarises the available data from Frei 2005 and Jacobs 2005.

Table 4.4: IPD Date Consistency

Trial	DoB	DoRand	Recruitment date	Assessment dates
Frei 2005	Yes	No	Yes	Yes: Primary outcomes at end of screening, end of crossover 1, end of crossover 2, open label follow-up: all at 6 weekly intervals
Jacobs 2005	Yes	No	Yes	Yes: Assessments at 0, 6, 12, 18 weeks CGI-P assessed weekly
Strauss 2000	Yes	No	No	No

Strauss 2000: the author was not able to provide any data therefore no checks were possible.

Frei 2000: examination dates should have been approximately 6 weeks apart for all treatment phases. Discrepancies for duration of the randomised cross-over phases were observed for four participants and queried with the authors. All but one discrepancy were due to data entry errors, one participant appears to have been treated for three weeks rather than six weeks in one phase.

Jacobs 2005: Only one discrepancy for Jacobs 2005 was identified where a data entry error had duplicated a date entry instead of a week 18 date entry. For the four assessment dates, the later was subtracted from the earlier, and in all cases gave the expected value of 6 weeks.

4.10.6 Check for excluded patients

Strauss 2000: Two patients were excluded from the Strauss trial (information provided by the author), these patients were initially enrolled but advised to withdraw by their primary healthcare provider and no further data were collected. They could not therefore be re-instated.

Jacobs 2005: Assessment of the patient identifiers raised questions if some patients had withdrawn and/or been excluded in the Jacobs trial. The authors confirmed that six participants were assessed and randomised but then withdrew - no further follow-up data were available. Eleven patient IDs appeared to be missing - these represented patients assessed who were then deemed ineligible for the trial. Overall there was no additional patient data that could be re-instated.

Frei 2005: Frei reported four patients withdrew during the trial but an ITT analysis was performed for the primary outcome measure. Clarification was sought as to the IDs of these patients, and if the five missing IDs were excluded patients. Where possible data were re-inserted from a more complete data file for two patients, outcome scores were not available for two patients in the cross-over trial.

4.10.7 Additional checks for Frei 2005

Given the complexity of this particular trial, additional checks were carried out to verify the data set was accurate and complete. As described earlier this was a four phase study including an initial assessment, open-label treatment phase, two randomised placebo controlled cross-over arms, followed by an open-label treatment phase. Strict criteria were placed on both the

initial inclusion to open-label treatment phase, and the level of improvement required before randomisation to the cross-over trial. All participants were required to demonstrate a decrease in CGI scores of 50% or 9 points. A small number of patients did not appear to have conformed to this criteria, all but one were resolved as being the result of data entry errors. One participant does not appear to have demonstrated the required drop in severity but was still included in the trial (values confirmed with authors).

Period effect test: Comparison between Arm 1 (verum - placebo) mean difference of 0.65 (SD 6.82) and Arm 2 (verum – placebo) mean difference of -3.75 (SD 6.04) was carried out using a two-sample unrelated t-test. This found a significant mean difference of 4.40 (SE 2.64) $t = 2.58$ (58), $p = 0.01$ suggesting that regardless of which treatment patients were receiving, everyone did significantly worse in the first crossover period, and significantly better in the second crossover period.

Carry-over test: A two-sample unrelated t-test comparing the average treatment response found a mean difference of 1.23 (SE 0.98) which was non-significant, $t = 1.26$ (58), $p = 0.213$. Therefore there was no statistical indication of a carry-over effect within the cross-over trial. This test is known to have relatively low statistical power, therefore the existence of carry-over was also checked graphically, see Figure 4.2 on the next page. The scatter plot should, in the absence of an interaction, have shown no horizontal difference between groups and data should lie symmetrically either side of the line $y=0$. The different coloured circles represent the two trial arms.

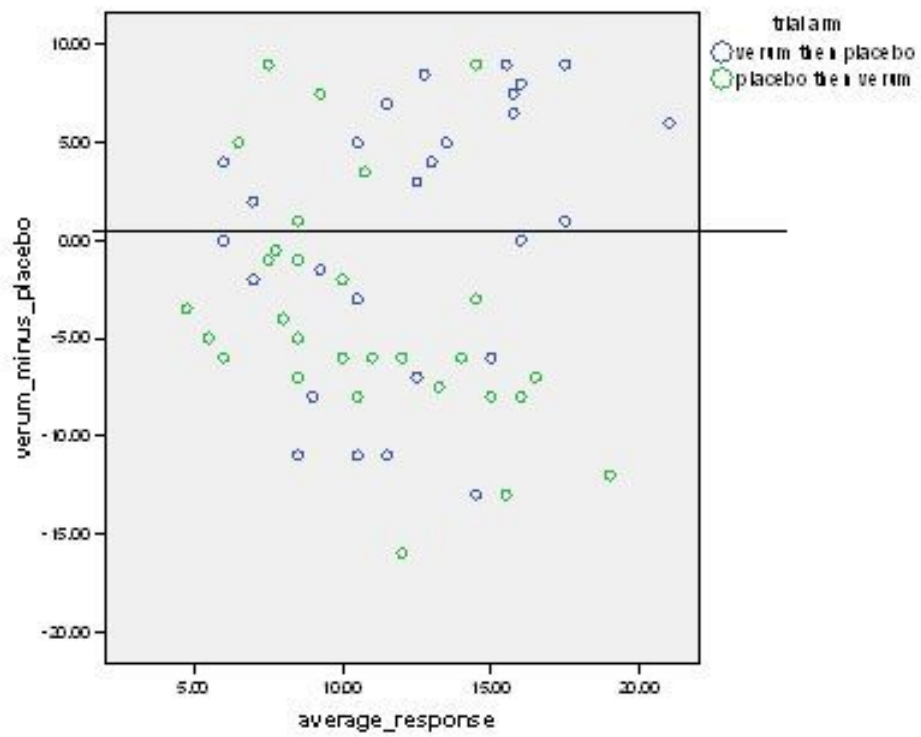
The graph demonstrates that there may well have been a carry-over effect which has implications for further sensitivity analyses.

4.11 IPD Results (two stage model)

4.11.1 Stage One

Part one of the two-stage model focused on predicting what the final value/outcome would be based on the available variables (e.g. gender, treatment scores and age) using linear model regression. This started to unpack what else might be influencing the patient's outcome beyond treatment allocation. This process was carried out for each trial data set independently. Diagnostic plots (described on page 90) were prepared for each data set and the results are

Figure 4.2: Scatter plot carry-over test



summarised in the following sections, Standard Error values have been converted into confidence intervals for ease of interpretation. Plots can be provided on request. The second part of the two-stage model takes the adjusted treatment estimates produced in stage one, and combines them using standard meta-analytical approaches as per the aggregate analysis.

Strauss 2000 (Trial 1)

There were no apparent departures from normality based on the diagnostic plots, although a couple of possible outliers were found in the Cooks Distance plot this may well be a chance result in a small dataset, all values have been verified with the author.

As can be seen from Table 4.5 the initial model shows an adjusted treatment effect in favour of homeopathic treatment when baseline risk, medication and pre-treatment severity are accounted for. The treatment estimate is statistically significant in favour of placebo however the confidence interval is quite wide, adjusted treatment estimate 4.97 (95% CI: 1.78 to 8.16). The r-squared values suggest that these variables explain between 67-72% of the variation.

Table 4.5: Strauss 2000 initial model

Variable	Estimate	95% CI	SE	t value	Pr(> t)
(Intercept)	-9.29		5.87	-1.58	0.13
Medication	0.95	(-2.82, 4.72)	1.92	0.49	0.63
Treatment arm	4.97	(1.78, 8.16)	1.62	3.05	0.01
Pre-treatment score	0.99	(0.61, 1.38)	0.19	5.08	0.00

Multiple R-squared: 0.7227, Adjusted R-squared: 0.6707

This small data set allows for adjustment based on one or two factors (medication, pre-treatment score), AIC and STEP analysis was used to explore these data to find the most parsimonious model with fewest covariates. The model started by including all possible covariates and interaction terms

[post-treatment score ~ Medication + treatment arm + pre-treatment score + Medication:treatment arm + Medication:pre-treatment score + treatment arm:pre-treatment score]

The most parsimonious model was made up of pre-treatment score plus treatment arm without including medication, but the differences in treatment effect were similar to that of the full model and there was an overall significant difference in favour of placebo, adjusted treatment estimate

= 4.71 (95% CI: 1.75 to 7.67), see Table 4.6. The r-squared values were broadly similar to that of the full model. There was no evidence of significant interactions between terms, nor does medication status have an impact. This was not surprising since medication use was deliberately balanced between groups at randomisation.

Table 4.6: Strauss 2000 AIC model

Variable	Estimate	95% CI	SE	t value	p value
(intercept)	-6.73	-	2.68	-2.509	0.02
treatment arm	4.71	(1.75, 7.67)	1.51	3.128	0.001
pre-treatment score	0.93	(0.27, 1.20)	0.14	6.55	0.0001

Multiple R-squared: 0.7185, Adjusted R-squared: 0.6854
Starting AIC=55.57 Final AIC=48.26

Notably this differs from the aggregate treatment estimate (which was unadjusted and showed no significant difference between active and placebo treatment groups) and shows a significant effect in favour of placebo over active treatment.

Jacobs 2005 (Trial 2)

Diagnostic plots based on the fitted model: seem to be broadly acceptable again given the small data set. Possible outliers for this model were IDs 2,4 and 28 although this data has been double checked with the authors.

A basic model querying if the post-treatment scores could be predicted by treatment allocation alone found no significant effect of trial arm, -0.26 (95% CI: -5.80 to 2.28), p=0.928.

Using a model containing the key reported variables (treatment arm; gender; age; pre-treatment score), treatment arm appears to be having the largest effect on the final raw scores, but only baseline severity is coming out as a statistically significant predictor for the chosen outcome measure, see Table 4.7 on the next page.

This may be due to the larger variance associated with the treatment arm variable. The r-squared value suggests relatively little of the variance in post-treatment scores is being explained by the included variables. Note that raw pre and post treatment Conners Scores were used rather than the standardised T-scores since the data provided included age and gender variables.

Table 4.7: Jacobs 2005 initial model

Variable	Estimate	95% CI	SE	t value	p value
(intercept)	3.66	-	7.52	0.49	0.63
gender	0.09	-1.16, 1.34	0.64	0.14	0.89
age	-0.01	-1.39, 1.36	0.70	-0.02	0.99
treatment arm	-1.80	-7.17, 3.57	2.74	-0.66	0.52
pre-treatment score	0.63	0.20, 1.06	0.22	2.85	0.001

Multiple R-squared: 0.375, Adjusted R-squared: 0.2614

Using the STEP function resulted in a model containing the following variables to accurately predict post treatment scores: age, gender, age x gender and baseline severity. Treatment allocation did not feature in this model which according to AIC scores was the best fit for the data. R-squared results continue to suggest that even this model explains less than 50% of the variation in post-treatment scores, see Table 4.8.

Table 4.8: Jacobs 2005 AIC model

Variable	Estimate	95% CI	SE	t value	p value
(intercept)	-0.47	-	6.96	-0.07	0.95
gender	5.01	-2.10, 12.12	3.63	1.38	0.18
age	0.25	-1.08, 1.58	0.68	0.37	0.71
pre-treatment score	0.63	0.22, 1.04	0.21	2.96	0.01
gender:age interaction	-0.05	-0.13, 0.03	0.04	-1.40	0.18

Multiple R-squared: 0.4148, Adjusted R-squared: 0.3084
Starting AIC=113.96 Final AIC=106.59

This reinforces the results from the original analysis where no significant benefit from treatment was found, and further suggests there may be confounding due to age/gender despite these variables being balanced during randomisation.

Frei 2005 (Trial 3)

The Frei 2005 study, as explained earlier, was unusual in both design and conduct. It used a run-in period to identify an individual remedy for each patient who showed the requisite reduction in symptoms, then entered these patients into a randomised cross-over trial comparing the individualised remedy versus placebo. The results showed an unexpected worsening of symptoms during cross-over period 1 across both treatment arms, and then the predicted results in cross-over period 2 (placebo - increase in symptoms, remedy - reduction in symptoms).

By looking at the trial results both with and without the second cross-over period data, we are exploring what extra information the data can provide us with. It is not uncommon for reviewers to use only first period data from cross-over trials to facilitate pooling with parallel RCTs although this approach can be criticised for not using all of the available data. In this particular trial it appears that something unusual occurred in the first cross-over period, thus ignoring the second period data may give an erroneous picture of the results. Time and treatment are difficult to disentangle in this analysis. If we had a larger dataset it might have been possible to de-trend the time element and look for correlations without time as a factor, but this was not possible here.

Models were explored as follows and the most parsimonious model from each set of analyses is reported below:

- First cross-over period data alone: basic model with treatment arm only; full model with selected variables and interaction
- Second cross-over period data alone: basic model with treatment arm only; full model with selected variables and interactions
- Second cross-over period data: basic model with selected variables including period 1 results; full model with selected variables and interactions including period 1 results

As before, each model was created within R, and normality checked for each model rather than the raw data itself. Outliers were identified and checked, and sensitivity analyses where potential outliers were deleted were run to evaluate robustness of the results.

Cross-over period 1 A basic model querying if the end of cross-over period 1 scores could be predicted by treatment allocation alone found no significant effect of trial arm, 0.629 (95% CI: -2.22 to 3.47), $p=0.667$.

The full model included pre-treatment score, age and gender, plus interactions between these variables, to predict post-treatment score, see Table 4.9. Step analysis returned an AIC value of 224.83. The final model suggested by this analysis returned an AIC value of 214.35 which suggests the model was better when built around patient age, baseline severity and an interaction between age and severity, but the r-squared values highlight that the model still explains very little of the data. Treatment arm or the effect of the intervention was lost within three iterations of the model. Trial participants were intentionally randomised to account for age, gender and baseline severity when entered into the cross-over trial, but age and severity are still explaining the majority of the results according to this analysis.

Table 4.9: Frei 2005: Cross-over period 1

variable	estimate	95% CI	SE	t value	p value
(intercept)	31.74	-	12.21	2.599	0.0118
age	-2.36	-4.77, 0.05	1.23	-1.92	0.0595
pre-randomisation score	-1.97	-4.46, 0.52	1.27	-1.55	0.1257
age:pre-randomisation score interaction	0.25	-0.01, 0.50	0.13	1.93	0.0589

Multiple R-squared: 0.1215, Adjusted R-squared: 0.07603

Cross-over period 2 A basic model querying if the end of cross-over period 2 scores could be predicted by treatment allocation alone produced a significant treatment estimate of -2.78 (95% CI: -4.84 to -0.73), $p=0.01$. The r-squared values (Multiple R-squared: 0.1083, Adjusted R-squared: 0.09295) suggest that this model left large amounts of variation unexplained.

The full model contained the key variables (pre-randomisation score, age and gender, and interactions between these) to predict post-treatment score in the second cross-over period, without including period 1 data. Essentially the second period data has been analysed here as though it came from a parallel controlled trial.

Using the STEP function for the full model started with $AIC=168.64$, and only reduced this to $AIC=166$ with the following variables included, see Table 4.10 on the following page. Treatment arm remained as a significant predictor, as did the interaction between age and gender, and gender and pre-randomisation score. The adjusted treatment estimate from this model was -11.93 (95% CI: -22.81 to -1.05), $p=0.036$. As before the r-squared values remain very low.

These results suggest that taking the period 2 data alone there was a significant treatment effect, however stepwise regression demonstrated that the variance was better explained by a combination of factors as shown below, where treatment arm was no longer significant.

Table 4.10: Frei 2005: cross-over period 2

variable	estimate	95% CI	SE	t value	p value
(intercept)	36.57	-	13.45	2.72	0.009
gender	-18.13	-38.83, 2.57	10.56	-1.72	0.092
age	-1.80	-4.25, 0.65	1.25	-1.44	0.155
treatment arm	-11.93	-22.81, -1.05	5.55	-2.15	0.036
pre-randomisation score	0.14	-0.17, 0.45	0.16	0.90	0.371
gender:age	1.87	0.07, 3.67	0.92	2.05	0.045
gender:treatment arm	-6.97	-16.38, 2.44	4.80	-1.45	0.153
gender: pre-randomisation score	1.50	0.28, 2.72	0.62	2.39	0.020
age: treatment arm	0.82	-0.20, 1.84	0.52	1.57	0.122

Multiple R-squared: 0.3409, Adjusted R-squared: 0.2375

Cross-over period 2 (model includes period 1 data) A basic model using cross-over period 1 results and treatment allocation to predict period 2 results produced a significant treatment estimate of -2.82(95% CI: -4.86 to -0.78) , the results from period 1 were not a significant variable.

This model included all previous terms, with the addition of cross-over period 1 results, and an interaction between period 1 and period 2 results. The most parsimonious model retained gender, pre-randomisation scores, period 1 results as well as interactions between gender and pre-randomisation, and period 1 and period 2, see Table 4.11 on the next page. Treatment arm was removed as a predictor in the second to last iteration of the model. The r-squared values indicate that this model, unlike any of the previous, successfully predicts a large proportion of the variance.

Table 4.11: Frei 2005: full cross-over results

variable	estimate	95% CI	SE	t value	p value
(intercept)	11.50	-	0.81	14.17	0.0001
gender	-3.89	-7.56, -0.22	1.87	-2.08	0.04
pre-randomisation score	-0.02	-1.18, 0.14	0.08	-0.21	0.84
period 1 results	-0.87	-1.01, -0.73	0.07	-12.34	0.0001
gender:pre-randomisation score	0.33	-0.04, 0.70	0.19	1.70	0.09
phase 2: phase 1	0.08	0.07, 0.09	0.004	16.46	0.0001

Multiple R-squared: 0.8471, Adjusted R-squared: 0.8329
Start: AIC=83.29 Final AIC=72.34

4.11.2 Stage Two

The previous sections have outlined the process of re-analysing the cleaned and checked patient data trial by trial using regression. An adjusted treatment effect has been calculated for each trial based on a simplistic regression where only treatment allocation was used as the predictor variable. A fuller model containing age, gender, pre-treatment severity and medication (where available) and interaction terms was specified, and stepwise regression based on AIC values used to devise the most parsimonious model to predict post-treatment scores on the Conners Global Index (the primary outcome measure from all three trials). As the Frei cross-over trial was both a more complex design, and presented some unexpected trends in the results, further exploratory regression analyses were conducted to explore the impact of using only period 1 or period 2 data, and the effect of using both data sets.

The simple regression provided an unadjusted treatment effect estimate, while the stepwise regression provided an adjusted treatment estimate. For the Jacobs trial (trial 2) the treatment effect was excluded from the final model as retaining it would have created an over-fitted model including variables that explain little or none of the variance. This was also true for some of the exploratory analyses for Frei (trial 3). To take account of this while also extracting the treatment estimates required for the meta-analysis,

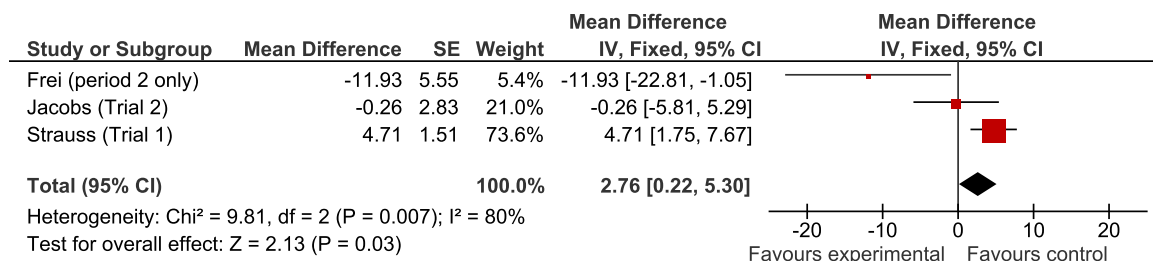
The following treatment estimates from Table 4.12 on the following page were used for the generic inverse variance meta-analysis (used to allow pooling of parallel and cross-over trial data).

Table 4.12: Estimates used for stage 2 meta-analysis

Trial	Treatment estimate	SE	95% CI	Source
Strauss 2000 (1)	4.71	1.51	1.75, 7.67	AIC model
Jacobs 2005 (2)	-0.26	2.83	-5.80, 5.28	Initial model
Frei 2005 (3) period 1 only	0.629	1.45	-2.22, 3.47	Initial model
Frei 2005 (3) period 2 only	-11.93	5.55	-22.81, -1.05	AIC model
Frei 2005 (3) period 2 results adjusting for period 1	-2.82	1.04	-4.86, -0.78	Initial model

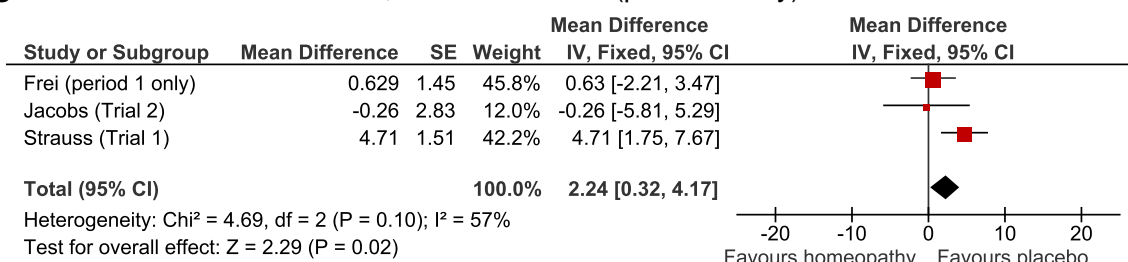
The primary analysis pooled data from Strauss 2000, Jacobs 2005 and Frei 2005 (period 2 only) in an effort to explore the impact of using only one period of data given the uncertainties around this cross-over trial. These analyses were conducted as an exploration of the data rather than as a definitive proposition. The main analysis pooling Strauss 2000, Jacobs 2005 and Frei 2005 (period 2 only) found a significant difference in favour of placebo, 2.76 (95% CI: 0.22 to 5.30), with significant heterogeneity present. See Figure 4.3.

Figure 4.3: Pooled IPD: Strauss, Jacobs and Frei (period 2 only)



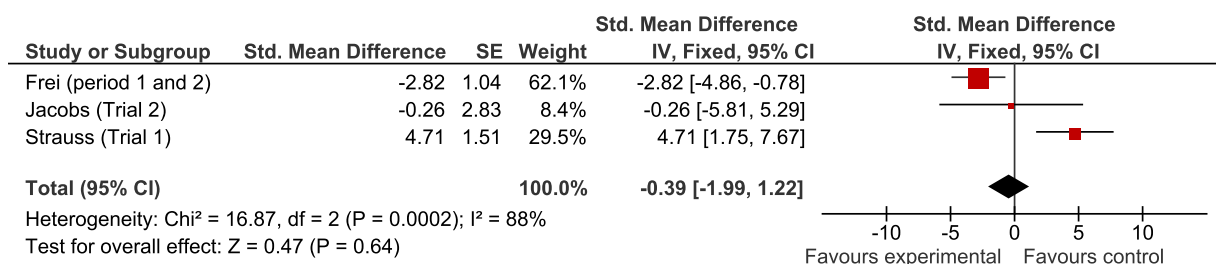
Sensitivity analyses explored the impact of including only period 1 data from Frei 2005 as is more common in health services research meta-analyses. This found a significant difference in favour of placebo, 2.24 (95% CI: 0.32 to 4.17), with significant heterogeneity present. See Figure 4.4 on the facing page.

Figure 4.4: Pooled IPD: Strauss, Jacobs and Frei (period 1 only)



Finally an analysis using Strauss 2000, Jacobs 2005 and both period data from Frei 2005 was conducted to clearly compare these results with those from the original aggregate analyses. This found a non-significant difference in favour of homeopathy, -0.39 (95% CI:-1.99 to 1.22), with significant heterogeneity present. See Figure 4.5.

Figure 4.5: Pooled IPD: Strauss, Jacobs and Frei (period 1 and 2)



4.12 IPD Results (one stage model)

A single stage model using patient ID, trial ID, gender, age, treatment arm, baseline severity to predict post-treatment scores was implemented using R. Only period 2 data was used from the Frei 2005 trial since this was an exploratory model and it appears that something unexpected occurred during the first crossover phase.

Applying a regression model produced only baseline severity as a significant predictor of post-treatment scores, 0.37 (95% CI: 0.14 to 0.60). Neither age, gender nor treatment allocation significantly affected the results. The r-squared values were relatively low (r² 0.28, adjusted r² 0.25) suggesting there may have been other factors influencing the data.

No further single stage analysis was conducted. The methods themselves are statistically complex and not likely to prove informative given the poor data set available. This single stage model did not account for the complexity of the data or lack of comparability between the outcome measures, but was an initial attempt to model the data while reducing ecological bias.

4.13 Discussion

Three randomised controlled trials were included in the assessment of efficacy and effectiveness in this review, reporting research conducted over a ten-year period. In summary this review found no evidence that homeopathy has a statistically significant impact on the overall severity, core symptoms or related outcomes of children diagnosed with Attention Deficit Hyperactivity Disorder whether analysed in an aggregate or IPD fashion. Although two-stage IPD models mimic the analytical approach used in conventional aggregate meta-analysis, the checking and cleaning process allows more rigorous scrutiny of the data. Several published examples demonstrate where this has resulted in different results. Although the final effect estimates have not differed in this review, closer examination of the data has revealed some potential discrepancies and errors in the way the data were collected and used. Further it is now unclear to what extent the attention tasks are broadly equivalent, meaning the aggregate analysis result itself should be approached with caution.

The IPD analysis process and examination of the original data revealed significantly more about the research processes used in each of the three trials considered. During the aggregate review it became necessary to re-analyse the results presented by Strauss. The IPD analysis more fully de-constructed these data and found that re-analysis substantially changed the results from a significant benefit to no benefit from homeopathy. It also demonstrated the importance of taking baseline values into account and considering these in both design and analysis stages.

IPD is of course reliant on the data provided by trialists, and even though the trials were not particularly old, obtaining the relevant details from the Jacobs et al. study was surprisingly difficult. Two different departments plus a homeopathic pharmacy had held the records, but after various staff movements retrieving these was in some cases impossible. As a result we were unable to satisfactorily explain some of the differences between the published results and the summaries produced during data checking.

Exploration of the raw data provided by Frei et al led to the discovery that although a validated outcome measure had been used (Conners Global Index) it does not appear to have been administered in the correct fashion. The scores provided by parents rating their children's behaviour included partial values such as 3.5, when the scale is designed to be rated using whole numbers only. While this may appear to be a minor point, it is indubitably true that small changes can alter the reliability and validity of psychometric scales, and make it more difficult to justify using weighted rather than standardised mean differences when pooling results. The CGI is supplied in a standard template to prevent changes being made, and to facilitate the production of standardised scores. These T-scores are adjusted for age and gender, with the

resulting values being more relevant and easier to compare across groups of children. The Jacobs trial used adjusted T-scores while Frei did not. The IPD conducted for this research used unadjusted raw scores as reported in the files provided from both trials to better explore the impact of possible co-variates.

One of the key aspects of IPD is encouraging transparency within research and via the checking process increasing confidence in the findings - this could be particularly useful in such a contested research area as homeopathy, however it was our experience that some researchers were uncomfortable with the re-analysis of their data and protective of their results. This may be in part because trials which initially appear to be of relatively good quality are less reliable when examined in detail.

4.14 Conclusions from Aggregate and IPD analyses

The systematic review was carried out according to best practice guidelines and has been published as a Cochrane review, with relatively few limitations. The additional searches carried out for documentary evidence retrieved one additional study not found by any other means, however due to apparent design flaws this was not included in the analysis. The IPD process however was carried out partially as a result of fortuitous circumstances when one author provided data beyond that which had been requested. While the IPD analysis process has been both educational and informative, the less formal nature may have resulted in less complete data provision, and in an ideal world the more usual stages would be followed as recommended by Stewart and others (Stewart and Clarke, 1995; Stewart and Tierney, 2002; Stewart, Tierney, Clarke and on behalf of the Cochrane Individual Patient Data Meta-analysis Methods Group, 2009).

An editorial has suggested that there is in fact no need for further reviews of homeopathic research and attention should be focused on carrying out good quality primary research (Ludtke, 2007). The author claims that reviews are unlikely to contribute to the knowledge pool and instead "*give known answers to known questions*" (pp155).

I would agree in situations where a review has not been carried out in sufficient detail, see for example Altunc, Pittler and Ernst (2007). Altunc *et al* carried out a systematic review of paediatric and adolescent homeopathy which produced little in the way of conclusions, failed to critically appraise the included studies in detail, and made a general statement about the paucity of good quality research.

In contrast, this review has explored relevant studies in detail revealing and discussing essential aspects of trial design and the homeopathic intervention. A good systematic review casts a

fresh light on the primary data such as demonstrating that one trial (Strauss) had mistakenly concluded a beneficial effect due to inappropriate analysis methods. Without this review, further studies in the treatment of ADHD with homeopathy are unlikely to benefit from the existing work. The editorial piece by Ludtke asks:

Do we really gain anything from doing more and more reviews and meta-analyses?
Can we really expect to generate new evidence on the effectiveness of homeopathy
by continuing on this path? (Ludtke, 2007)

While we may not generate new evidence on effectiveness, good quality, detailed systematic reviews can bring the available evidence together, critique it and provide concrete recommendations on how further research should proceed (Heirs, 2009). The suggested direction for such research is dealt with later on in this thesis.

Overall therefore, a trial of formula homeopathy found no difference between placebo and verum homeopathy (Strauss, 2000), a trial of classical individualised homeopathy that attempted to replicate usual practice found no significant difference between verum and placebo (Jacobs, Williams, Girard, Njike et al., 2005), and a trial of individualised homeopathy with minimised non-specific effects found a statistically significant benefit from homeopathy (Frei, Everts, von Ammon, Kaufmann et al., 2005). No significant benefit from homeopathy was seen in either aggregate, one-stage IPD or two-stage IPD, however the IPD results clearly suggest that the key factor in patient improvement was the baseline severity scores, rather than treatment per se. There is insufficient evidence to draw robust conclusions about the effectiveness of any particular form of homeopathy for ADHD at present, and the available evidence should be considered with caution.

Exploring homeopathy in clinical practice

Chapters Three and Four have focused on identifying, evaluating and exploring the evidence base around homeopathy as a treatment for ADHD. The systematic review and IPD analysis methods are almost synonymous with the EBM approach and if the results were taken at face value seem to suggest that homeopathy may not be a useful treatment option for ADHD. The more in-depth exploration of the trial data during the IPD analysis, which goes beyond a normal aggregate review, has cast further doubts on the reliability of the published trial data including the statistically significant result obtained by (Frei, Everts, von Ammon, Kaufmann et al., 2005).

The question remains however, to what extent does the homeopathy tested in these trials represent usual clinical practice within the UK or further afield. This is an important point: if we

have a relatively unreliable evidence base that finds little to support homeopathy for ADHD, but does not reflect clinical practice, then the implications are quite different than if the evidence is representative of usual practice. The following chapters will outline a truly mixed-methods exploration of how homeopaths think about and treat ADHD in CYPs and contrast the clinical practice with that described in trials, case studies and textbooks.

Chapter 5

Mixed Methods: data collection and analysis

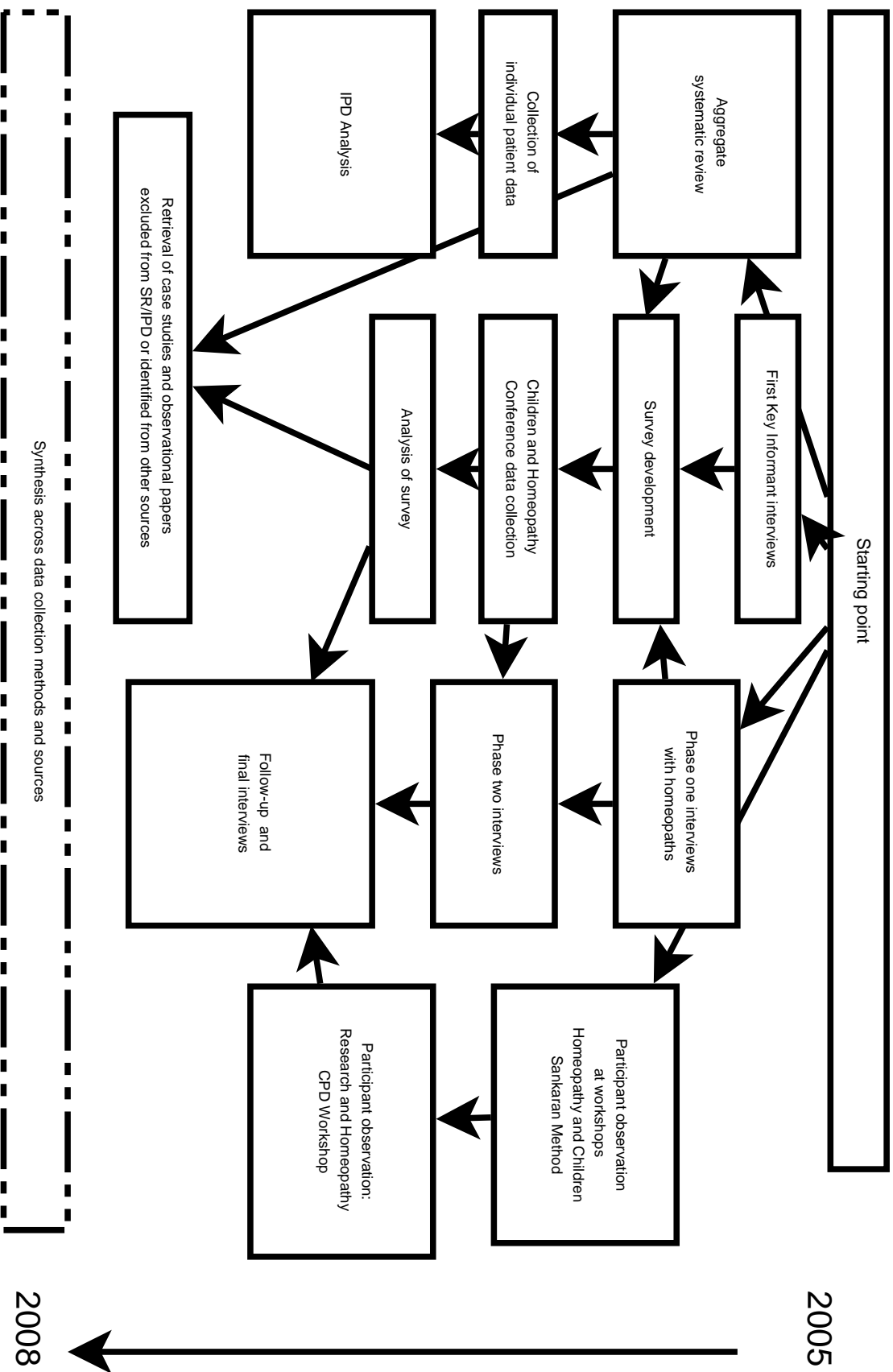
5.1 Background & Research Aims

This section introduces the specific design, analysis and data collection methods adopted to further explore the topic of homeopathy for the treatment of ADHD. The concepts of subtle realism and grounded theory were introduced in Chapter 2 and continue to inform this work. Figure 5.1 on the following page is a useful reminder of the structure of the project as a whole, where the mixed-methods components took place over three years.

Looking at the trials carried out in homeopathy for ADHD, it was unclear to what extent these interventions represented usual homeopathic practice in terms of contact with the children, making remedy choices and prescription details. Exploring the actual clinical practice of homeopaths offered the potential to facilitate a more detailed understanding of the eclectic practice of homeopathy, and improve trial design. As with other forms of CAM, there would appear to be a significant gap between the anecdotal reports of success and the results of RCTs. One potential explanation is simply that the trials are not testing what practitioners actually do (Fonnebo and Launso, 2005).

Initial questions emerging from the systematic review and IPD analyses included: how are children with ADHD currently being treated in terms of both homeopathic models and consultation content, and how is homeopathic treatment for ADHD evaluated in practice? Classical or constitutional homeopathy is the most commonly practiced form of homeopathy in the UK and does not work with diagnostic labels but prefers to “treat the whole person”. Remedies are chosen based on the entire symptom picture for each individual including their more idiosyncratic preferences or dislikes. Homeopathic practitioners are likely to carry out a similar consultation

Figure 5.1: Schematic of research process



for any child regardless of diagnosis, although presumably adapting to the age of the patient. Therefore, the chapters that follow will deal both with the treatment of children by homeopathy in general, as well as specifically for ADHD.

An initial attempt to answer these questions from the literature revealed that relatively little has been written about treating children with homeopathy in comparison with adults. Homeopaths working with children are dealing with either acute type cases (such as fever), or chronic conditions that may include behavioural problems and are described by some homeopaths as “difficult children”. These two areas of treatment (acute versus chronic) may lend themselves to quite different treatment approaches as is often the case in adults (Vithoukias, 1980).

The available texts on paediatric homeopathy tend to detail particular systems and approaches to identifying remedies and types of children; such as the “cycles and segments” model or the “sociability-activity-destructibility” axis (Jain, 2004; Herscu, 1996, 1991). Much of these writings focus on interpreting the materia medica for use with children (Herscu, 1991; Borland, unknown), although some do offer suggestions for case-taking such as relying primarily on observation or examining drawing or handwriting (Bonath, 2004; Jain, 2004).

Evaluating the impact of treatment is a relatively new area for academic research in homeopathy but is a vital part of homeopathic practice. Classic texts recommend, for example, that practitioner should enquire about general health, energy levels, the chief complaint and so on in follow-up consultations, suggesting a wide assessment of the patient (Vithoukias, 1980). Less guidance on how to proceed with the child or young person has been published (Herscu, 1991), leaving open the question of how much the homeopath works directly with the child/young person or through the parent as a proxy. Given the lack of information in the literature, it was relevant to explore how homeopathy is used with children and how the impact is assessed in clinical practice.

Research questions:

1. How do homeopaths in the UK understand and treat ADHD in children/young people (CYPs)?
2. How do homeopaths assess the impact of their treatments on CYP's?
3. To what extent does the homeopathy practised in controlled trials of homeopathy for ADHD reflect usual practice for UK homeopaths?
4. Would UK homeopaths be willing to practice as per the controlled trials, i.e. would they change their practice?

Table 5.1: Ethics applications

Significant Dates	Project Stage	Relevant Ethics Applications Made
March 2006	Initial contact made with sources of participants for a planned RCT of homeopathy for ADHD and protocol prepared. Doctoral research expected to focus on evaluation of the outcome measures used in the trial using a mixed methods approach.	Departmental ethics for RCT and outcome measure evaluation prepared and submitted
October 2006	A second incarnation of the research project was developed intending to follow-up children diagnosed with ADHD and attentional difficulties who were receiving treatment from homeopaths or Educational Psychologists, and explore the suitability of existing outcome measures for monitoring change in these two settings.	Further ethical submission made and approved by departmental ethics committee relating to interviews with practitioners and children.
January 2007	Made aware of a homeopathy conference focusing on the treatment of children through key informants. Ideal data collection opportunity. Survey developed.	Ethics submission for survey prepared and approved by departmental ethics committee
May 2007	Project focus moved to concentrate on homeopaths in practice. Participant observation data collection opportunities were identified through advertising from the Society of Homeopaths and suggestions from practitioners.	Amendment to project approved by departmental ethics committee including participant observation data collection

5.2 Ethics and consent

Ethical permission for this research project and all of the relevant data collection methods was granted by the Department of Health Sciences Research Governance Committee. This process included formal review of the research protocol and consent forms/processes (examples shown in Appendices 9, 10 and 12). Multiple approaches were made as required by the organic development of the research process. These are indicated in Table 5.1.

Survey It was clearly stated on the survey materials that returning the questionnaire acted as implied consent to participate. Respondents had the option to include their name and contact

details if they were interested in being further involved with the project, but this was not compulsory and all data was analysed anonymously.

Interviews Potential participants were contacted using publicly available details from practitioner registers and sent an introductory letter inviting them to consider being interviewed. A more detailed information sheet was enclosed with a consent form and stamped addressed envelope. Interested participants were asked to return the consent form if they were interested in taking part. A follow-up phone call gave potential participants the chance to ask further questions and the option to withdraw. During the interview it was clearly explained that they had the right to stop the interview at any point, or choose to not answer any particular question(s). The questions were focused around professional topics rather than personal issues and it was not anticipated that the interview itself would cause any distress. All data were given alternative identifications and considered anonymously as was explained in the interview. Given the specialised nature of the topic potentially identifying information was removed where possible when choosing quotations for the final synthesis.

Participant observation For all of the settings where active participant observation was carried out, an information sheet was produced (example in Appendix 12 pg 449) and distributed at the beginning of the workshop/event. I was introduced by the organiser and explained that I was primarily there to learn and participate, although I was also interested in the kind of questions that practitioners might be asking and discussing. I explained that I would be taking notes to aid my memory during the event, but that no one would ever be identified in either the notes or any subsequent analysis. No recording devices were used, and formal individual consent forms were not utilised. The guidance from the British Sociological Association was used when planning and conducting this part of the research (British Sociological Association, 2002).

5.3 Data Collection: Key Informants

5.3.1 Overview

Key informants (KI) and key informant interviewing are terms and techniques borrowed from ethnography. Typically key informants are individuals who possess specific knowledge or skills, are willing to share these and are involved in a relationship with the researcher over time.

key informants are key to the researcher's understanding of that culture. They differ from other informants by the nature of their position in a culture, their information rich connection to the research topic, and by their relationship to the researcher. (Gilchrist and Williams 1999 pp 73)

Key informants can provide information in a variety of ways to the researcher including; through formal interviews, informal conversations, manuscripts, pictures, their interpretation of events or information, non-verbals such as dress code and speech (Bogdewic, 1999). Key informants were used in this project for the following reasons:

1. efficient gathering of information - it is unlikely that a researcher can interview everyone in a situation or observe everything, key informants can provide a short-cut to some of this information and by building a relationship with a few individuals much richer data may be collected as a result.
2. gaining access to otherwise hidden or inaccessible information - this is most easily seen through the provision of sponsorship when the key informant will ease access for the researcher, or when the key informant can provide information not available elsewhere

According to the literature, a key informant should be active within the culture of interest as well as being culturally sensitive and reflective. These qualities, as well as a willingness to engage with research, may also mark the key informant as being atypical. The relationship between researcher and key informant is expected to vary in intensity and demands according to the project development with the key informant playing differing roles throughout stages of data collection and analysis (Lofland and Lofland, 1984).

As Gilchrist and Williams (1999) outline, the literature in anthropology focuses on the relationship between researcher and key informant, successful and otherwise, with much less to say on the topic of actually choosing a key informant. Johnson (1990) suggests that key informants can be chosen based on data or theory driven processes initially, although the final criteria is more focused on personality - is the person able and willing to work with the researcher, is there potential compatibility for this relationship.

a key informant for me may not be a key informant for you (Gilchrist and Williams 1999 pp 77)

It is also acknowledged in the literature that serendipity may have a part to play, in which case only the personality and compatibility criteria need be considered. While chance acquaintance

may provide useful informants the researcher is advised to be wary of such a key informant being so similar to the researcher as to be unable to provide the alternative perspective required. The process of recruiting key informants to this project and the details of these relationships is reported more fully below. Thick description has been provided as advocated by Crabtree and Miller (1999); Guba and Lincoln (1994). This summarised in Table 5.2 on page 123.

Having worked as a research assistant within a homeopathic hospital alongside medical homeopaths I was not unfamiliar with the language and concepts of homeopathy. However key informants were a crucial part of this project because I am not a homeopath myself and had no direct experience of the professional homeopathic community.

5.3.2 Sampling

The key informants for this piece of research were sampled purposively and theoretically. The first key informant for this project was also an advisor/supervisor of the thesis and involved with the project from the outset. The second key informant was chosen based on theory, according to Johnson's model (1990) and identified early on in the research process as a potential counter-balance to key informant 1. The researcher and key informant 2 co-taught on a module introducing homeopathy to 1st and 2nd year medical students in 2006, and had discussed various issues around research in homeopathy.

The third key informant was a professional homeopath specialising in the treatment of ADHD and other behavioural disorders who contacted Morag soon after seeing the abstract of the systematic review presentation. The key informant suggested meeting up to discuss the research area. This was a classic example of a serendipitous encounter which has proved to be very valuable for the development of the research. The decision was made to include this key informant partly based on her extensive knowledge of the area. Additionally key informant 3 had travelled to study with French and American homeopaths to learn about homeopathy for behavioural problems and was clearly interested in conveying this experience. She was chosen on the basis of data since she is a specialist in treating children with homeopathy for all sorts of conditions, particularly behavioural problems.

5.3.3 Key Informant One

A qualified homeopath with an occasional practice, this key informant had undergone an apprenticeship rather than formal classroom training in homeopathy and was particularly interested in research. Key informant 1's practice style and opinions seemed to be very much informed

by an academic grounding in Health Services Research, and the researcher was aware that these might be particularly atypical of the homeopathic community in general.

This key informant provided valuable orientation within the field of homeopathy through discussion of general issues, expressing opinions on the trials of homeopathy for ADHD, providing reading lists and texts, and commenting on the development of the research project. He also contributed to the development of the survey and took part in a think-a-loud interview. See Table 5.2 on the next page

5.3.4 Key Informant Two

Key Informant 2 was a research active practitioner who also taught at the main college of homeopathy in the region, demonstrating deep integration within the community of practitioners. She had experience in treating children with homeopathy, but also treated the full range of ages and conditions.

The relationship has moved between more formal face-to-face and telephone interviews, and less formal chats by email and phone. As with Key Informant 3, there was an element of reciprocity whereby I would locate useful electronic journal articles as a favour to the key informant. Teaching together on sessions about research and practice allowed a fairly frank and open exchange of opinions, and this continued throughout the project. As a practitioner who has delivered individualised homeopathy in a trial setting, Key Informant 2 provided invaluable insight particularly later on when some of the emerging categories began to concentrate on the interface between practitioners and research.

5.3.5 Key Informant Three

A professional homeopath specialising in the treatment of ADHD and other behavioural disorders who had travelled to study with French and American homeopaths to learn about homeopathy for behavioural problems. The relationship with Key Informant 3 has been relatively informal throughout the research project with an emphasis from the key informant on reciprocity. For example, all of the meetings took place at the Key Informant's home and included discussion over lunch. On one occasion the key informant asked me if I could recommend any research articles on homeopathy for autism as Key Informant 3 was working on a section for a forthcoming guide published by a parent support group.

I then encountered Key Informant 3 at the Society of Homeopath's conference when publicising the survey, and she encouraged her colleagues to complete and return their questionnaires.

Table 5.2: Summary of Key Informant Details

Key Aspects	Key Informant 1	Key Informant 2	Key Informant 3	Key Informant 4
Identification	Research Advisory Group member involved with the planned pilot RCT	Introduced to KI 2 by KI 1, then made the decision to formally involve KI 2	KI 3 contacted Morag after presentation of the systematic review at Exeter (Coulter, 2007b)	Initially involved in the pilot RCT as a potential practitioner, contacted to discuss treatment protocols
Background	Research active, experienced occasional practitioner of homeopathy	Research active as a practitioner within trials, experienced homeopath also teaching in homeopathic training college	Non-research active experienced practitioner specialising in the treatment of children. Travelled extensively and studied with other homeopaths who specialise in behavioural conditions.	Some audit and action research activity, specialist in homeopathic treatment for children
Primary role	information	Rich information	Sponsorship and information	Information
Initial relationship	Supervision for the PhD thesis	Co-teaching on a module about homeopathy for 1 st and 2 nd year medical students, informal discussions about the systematic review	Brief telephone and email contact to exchange details, followed by a longer face-to-face discussion at KI 3's home	Telephone contact as provider of practitioner perspective on ADHD/homeopathy trials
Contribution and changes in the relationship	Originally PhD supervisor, line manager and co-reviewer on the Cochrane systematic review. Part way through the project withdrew from research, little contact possible following this	More detailed discussions about the research project, followed by two recorded interviews, ongoing relationship delivering modules	Introductions to other homeopaths by email and in person, second less formal face-to-face contact, arranging interview and translation with a French paediatric homeopath	Two telephone conversations rather than a deep relationship

Key Informant 3 provided names and introductions to potential participants, particularly in arranging an interview with a French paediatric homeopath. Key Informant 3 translated during this interview, and the interview itself was published in the Homeopathic Links journal (Heirs and Hall, 2009).

5.3.6 Key Informant Four

The final key informant was initially in contact with the co-ordinator of the planned pragmatic RCT as an advisor on the homeopathic protocol. The fourth key informant was much less heavily involved in the project than the other three - her participation was limited in part by health problems. Key Informant 4 was primarily interested in a comparative trial and when this was no longer taking place was less interested in the project. She provided valuable information on the kind of protocol that might be acceptable to homeopaths which informed some of the questions arising from the systematic review.

5.3.7 Summary

Overall four key informants were involved with this project. Sampling was initially purposive where the informants were contacted or serendipitous opportunities followed up on the basis of presumed knowledge, with later informants selected based on the collected data. The informants contributed through informal telephone and email conversations, formal interviews and one directly assisted in contacting and recruiting participants. Their contributions assisted in my understanding of the homeopathic community, helped with access for data collection and in some cases were involved in the later discussions about the analysis of the interviews and observations, providing a much appreciated practitioner perspective.

5.4 Data Collection: Survey

5.4.1 Background

The preliminary findings of the systematic review on homeopathy for ADHD were presented at an international CAM conference in December 2007 (Coulter, 2007b). The results and related issues were discussed at that conference with research active representatives from one of the major professional homeopathic organisations. A professional homeopath specialising in the treatment of ADHD and other behavioural disorders contacted me soon after seeing the abstract of the presentation and suggested meeting up to discuss the research area.

These conversations with professional homeopaths highlighted a potential discrepancy between the type of homeopathy used in the clinical trials, and that used in practice - at least when looking at the UK. These particular homeopaths also seemed to take a very child-centred approach in their practices, which was markedly different from at least two of the studies identified in the systematic review.

Questions were arising at this point around how homeopaths actually treated ADHD in practice – and it was clear that it might well be more fruitful to ask how homeopaths treated children/young people (CYPs) since the actual diagnostic label is said to be less important to a homeopath. These ideas were incorporated into an interview schedule to be used with practitioners. Three interviews were carried out, at this stage the interviews were fairly structured and quite formal. The interviewing schedules are discussed in more detail later in this chapter.

Surveys are a

system for collecting information from or about people to describe, compare or explain their knowledge, attitudes and behaviour (Fink, 2003) pp1.

They can take the form of self-administered questionnaires (mail, internet or in-person) or face-to-face methods such as structured interviews, or be carried out by telephone. Surveys generally can collect qualitative and/or quantitative data although they are most commonly associated with the latter (De Vaus, 2002). Typically this kind of research attempts to describe a set of particular characteristics/cases or people, and then compares them to draw conclusions about association and causation. A survey was used to collect data on the homeopathic treatment of children from a larger number of participants than would be possible through interviewing alone. A conference focusing on homeopathy for children created a convenient data collection context.

The systematic review of homeopathic treatment for ADHD in children found that each of the controlled trials adopted different prescribing methods, and used a variety of potencies and formats for remedy delivery. The level of interaction with the children and their parents in the trials varied considerably. It was unclear to what extent these trials reflected actual clinical practice in terms of the homeopathic treatment, but also the relative importance placed on therapeutic relationship and contact with the children. Further questions were raised when discussing the homeopathic methods with two key informants (Key Informant 1 and Key Informant 2).

An initial scoping search of the homeopathic literature produced relatively little information on the treatment of children with homeopathy, particularly in the specific case of ADHD, suggesting that there may not be specific models or accepted conventions followed by practitioners.

Homeopathy is an intrinsically eclectic profession and even when practitioners describe themselves as being within one school of homeopathy, they may use several different approaches in their clinical practice.

In terms of judging the external validity of the trials and designing future studies, it is vital to have a clear picture of the homeopathic interventions themselves. Pragmatic trials require that the intervention should mirror actual practice where possible - this requires an understanding of usual practice before such trials are possible. Therefore there was an identified gap in knowledge - how do homeopaths work with and treat children, in particular children with ADHD. Since homeopathic prescribing is based on assessing whether a particular remedy has affected the symptom picture, or if a different remedy/potency is required, it was felt to be of interest to explore how homeopaths themselves assess change in their patients.

A related question centred on whether or not homeopaths would be willing to practice as in the trials, were they to take part in a clinical trial. This information could inform the design of any subsequent trials, both in the area of ADHD and potentially in homeopathy more generally.

5.4.2 Research questions specific to the survey

1. What kind of homeopathy is used with children including any particular approaches?
2. Do both parent(s) and child attend first and follow-up consultations or are these carried out by telephone?
3. How do homeopaths monitor change in their child patients?
4. Is there anything in particular that homeopaths feel is important to think about when treating children with behavioural disorders?
5. How similar is the intervention used in trials of homeopathy for ADHD to that practiced by the respondents?
6. Would the respondents be willing to practice as per the trials for a further clinical trial?

5.4.3 Survey Sample

The population of interest for this piece of research was homeopaths who treat children, and hopefully with experience of ADHD or similar conditions. As discussed elsewhere in this thesis homeopaths are usually generalist practitioners and so may see a few children, or they may see many. Professional registers do not give details of practitioner specialisations, and it was

felt that a national survey would be overly costly and time consuming for the potential number of participants. A national conference for the largest body registering homeopaths within the UK (Society of Homeopaths) presented a solution to the challenge of identifying and targeting the desired sample. This event was entitled “Vital Childhood” and focused on the treatment of children with homeopathy with around 200 practitioners expected to attend.

5.4.4 Rationale for choosing a survey (self-completion questionnaire)

The research questions that this piece of research aimed to answer were a product of a systematic review and discussion with two key informants (Key Informant 1 and Key Informant 2). While some of these issues were being simultaneously addressed within the qualitative interviewing, it was felt that additional less in-depth data from a larger sample of homeopaths would contribute to the developing analysis. A forthcoming practitioner conference was identified as a suitable data collection context. The aim was to gather information from a large number of respondents relatively quickly and a survey using a self-completion questionnaire was one of the more attractive options (Fink, 2003).

An alternative would have been to carry out a number of structured interviews during the conference itself (Fink, 2003; Sapsford, 2007). However this would have been time-consuming, have restricted the number of delegates data were collected from, required a dedicated interview space and required delegates to miss conference presentations or social events to participate. Only one researcher (myself) was available to undertake this survey which placed some limitations on the project design.

There are limitations of the self-completion questionnaire but these were outweighed by demands of the data collection context. Acknowledged limitations include: inability to prompt or probe, the necessity of including few open-ended questions, ability of respondents to read the whole questionnaire and answer in their own preferred order, need for the questionnaire to be relatively short, greater likelihood of missing data and potentially lower response rates (Sapsford, 2007; De Vaus, 2002; Bryman, 2004).

5.4.5 Questionnaire Development

There are a number of general issues highlighted by writers on survey research techniques which may influence the results and should be considered during the development of survey instruments. The following sections/paragraphs outline question order effects and response sets and describe how these were addressed:

Question Order: question order effects have been studied within the social sciences, but have produced little in the way of consistent evidence or guidelines (Bryman, 2004). It seems logical that the order questions are asked in may alter the responses due to the context provided by nearby items, however the effect may be in either direction. Generally researchers are encouraged to beware of varying question order across participants – although this was out of direct control with the self-completion questionnaire used here. The possible effect of earlier questions on later question was considered in ordering the sections and items while recognising that in a self-completion situation participants may answer in any order (De Vaus, 2002).

Response Sets: this term refers to those situations where respondents consistently reply positively or negatively to questions, either because of a tendency to agree or disagree or when a perception of the social desirability of the answers interferes with the expression of a participant's actual opinion (Bryman, 2004; Sapsford, 2007). Social desirability is unlikely to have influenced the answers to this questionnaire as many of the questions were about the respondent's clinical practice, with opinion related questions being about comparing actual practice with the homeopathy used in trials. Potentially respondents may have been unwilling to criticise the homeopathy used in trials, therefore items were phrased to elicit comparisons between own practice and trial methods rather than give opinions on the trial methods.

5.4.6 Constructing the items

Once the research questions have been articulated the process of creating suitable indicators and items began. The material gathered from discussions with Key Informant 1 and Key Informant 2 was used to draft items for inclusion in a survey, and was particularly useful for choosing appropriate terminology. Initially the instrument included mostly open-ended questions but while considering the advantages and disadvantages of design, format and question-type a more structured questionnaire was created.

Items in this survey were initially derived from the research questions and interviews with two key informants. The actual wording of the items was then finalised taking into account guidelines for writing survey questions (De Vaus, 2002; Bryman, 2004; Fink, 2003). These suggest ensuring that the response options are evenly balanced and symmetrical with the question, with the following to be avoided:

- ambiguous terms
- long questions

- questions that ask about more than one thing
- unnecessarily broad questions
- leading questions
- questions with negatives
- technical terms

A mixture of open and closed questions were used in this questionnaire. Open questions are items where a question is posed and a free-text box or similar is provided for the answer to be written into. They can be more difficult to use in self-completion questionnaires and, as a result, closed questions are more commonly used. The advantages of open type questions include: respondents can answer in own terms, they allow for unexpected responses, they do not suggest certain kinds of response, they can be useful for new areas or where researcher is unfamiliar with the topic. Against this, the disadvantages include: they are time consuming for respondent to answer and the answers must be coded by the researcher. Close type questions which offer a range of pre-specified responses to respondents are: easier to code and analyse if well structured, facilitate increased comparability of answers, the options may clarify the meaning of a question for respondents and are usually easier and quicker to complete for the respondents. Despite these advantages, structuring closed questions so that they do not unhelpfully restrict possible answers, to avoid irritating the respondents who may not see their preferred response and ensuring that the options are mutually exclusive can be a difficult challenge.

Both open and closed questions were used in this survey while remaining aware of the advantages and disadvantages summarised above. Additionally for most closed questions an 'other' option was provided with space for a free-text response to avoid overly constraining the responses.

A wide variety of questions can be asked in self-completion questionnaires covering factual information about self or others, attitudes and beliefs, personal values and standards or knowledge (Dillman, 2000). Bryman (2004) and De Vaus (2002) suggest it is useful to be aware of the type of question being asked as a way of clarifying the purpose of each item, and thus ensuring the response options given are appropriate.

Types of questions

Factual information This was requested about the respondent's qualifications, training and practice location. Factual information was also collected on the age range and complaints treated, and the sources used by the practitioner. The final section of this questionnaire asked about practitioner's opinions of the homeopathy used in some clinical trials.

Comparisons between trials and personal practice Questionnaires utilising rating-scale questions around vignettes (descriptions of situations or events) are a classic method of eliciting opinions and comments (Finch, 1987; Hughes, 1998). Usually vignettes are constructed around fictional situations to manipulate presentation of the variables of interest. In this piece of research vignettes were written to summarise the homeopathy used in each of the three trials of individualised homeopathy for ADHD included in the systematic review. The vignettes were developed through discussion with the two key informants to ensure their clarity to homeopathic practitioners. A Likert type response scale was used to elicit opinions from the respondents in terms of how similar the homeopathy in the vignette was compared with the respondent's own practice (key areas were: sources and repertories; potency of remedy; frequency of remedy; duration of follow-up).

5.4.7 Design and presentation

Researchers experienced in the design and use of self-completion questionnaires have found attractively laid-out designs are more likely to be completed, as are designs that try to make the instrument look shorter (Bourque and Fielder, 2003). A balance needs to be struck between compressing items together which risks some questions being missed out, versus the instrument taking up numerous pages. The optimal length of any instrument depends on the sample and the topic being studied - research has suggested that when dealing with a more specialised audience a longer questionnaire can be used, indeed a brief one may be seen as too superficial (Dillman, 2000).

Dillman (1978; 2000) has made numerous recommendations for the design of surveys, but overall the focus is on creating a clear attractive presentation with items that flow logically into one another, and where the response options both make sense, and are easy to reply to. Instructions for each item need to be clear, and should always indicate if single or multiple responses are acceptable.

The final instrument is shown in Appendix 8 (pg 423). The survey was printed in colour, using good quality paper, as an A4 booklet. The total length was eight pages, of which five contained items for

completion, and each section was clearly marked to help breakdown the task into manageable chunks.

5.4.8 Maximising response rates

Self-completion surveys are known to be more vulnerable to low response rates than structured interview surveys (Hox and de Leeuw, 1994). Response rates are important as they have implications for the representativeness of the sample who actually respond. Where the sample has been chosen based on probability sampling, low response rates may indicate that the respondents are different in some way from those that do not respond (Sapsford, 2007). This particular piece of research used a focused convenience sample (delegates attending a particular event) so while a high response rate was desirable, as Bryman (2004) points out, where samples are unlikely to be representative of the population (homeopaths in general) response rates may be less important.

Survey methodologies are most effective when targeted to particular respondents (Dillman, 1978, 2000; Jackson and Furnham, 2000), in this instance taking advantage of a national event focusing on homeopathy and children was planned to help ensure a good response rate and increase the volume of relevant data as recommended by De Vaus (2002) and other writers.

The following recommendations on increasing response rates were incorporated into the instrument (Bryman, 2004; Sapsford, 2007; De Vaus, 2002):

- Clear covering letter that explained the aims of the research, academic affiliation and a guarantee of anonymity
- Pre-paid return envelope included, the return address was also printed on the back of the survey, and a large collection box was available during the conference
- Reminders - guidance on carrying out this kind of research usually suggests sending out at least one reminder mailing and up to three. Reminders usually include additional copies of the questionnaire. It was not possible to contact delegates at this conference directly or obtain mailing addresses, however the professional society agreed to send out a single reminder email to the membership including an electronic copy of the survey.
- Response rates may be improved by attractive questionnaires that focus on salient areas. This survey should have been relevant to delegates since it focused on the homeopathic treatment of children, which was also the theme of the conference.

- Most questions were closed as the advice is overwhelmingly to offer as few open-ended questions as possible. It was clear that in the context of a busy conference delegates might have little patience with open-ended questions requiring extended writing.

5.4.9 Piloting

Two think-a-loud interviews were conducted with volunteer homeopaths to finalise the survey design and adjust the questions where needed. Participants at this stage included one research active homeopath and a non-research active practitioner.

The main changes made at this point were to reduce the number of open questions - participants' suggestions were used to devise the closed-response options - and revise the layout of the Likert scales in Section Three of the questionnaire. The survey took around 15 minutes to complete (based on piloting).

5.4.10 Final Instrument

Section One: Items in this section asked about practitioner age, time in practice, training and clinical specialisation. A mixture of open and closed questions were asked here, with relatively short response boxes. This section served to orient practitioners to the focus of the questions - about their practice - and provided some basic background information on each respondent.

Section Two: These items gathered data on the age-range and complaints seen by the practitioner, models of homeopathy used, initial and follow-up consultations, evaluation of treatment and any particular foci when dealing with "difficult" children (children with behavioural difficulties - a descriptive term drawn from interviews with practitioners). A mixture of fixed-response questions and open questions were used including free text boxes to expand where appropriate.

Section Three: Three vignettes were presented summarising the homeopathy used in trials of individualised homeopathy for ADHD included in the systematic review. These were developed through discussion with qualified homeopaths to ensure their clarity.

Each vignette was followed by questions asking the homeopath to rate the similarity of their practice to the trial model using a 5-point Likert scale, and a free text box for comments/explanations.

The areas included in these questions were based on recommendations from the key informants. It is important to bear in mind that for homeopathic practice, each of the five areas below can be considered independently. For example a homeopath may use alternative sources/repertories in choosing remedies, but use similar potencies which are given less frequently.

The following areas were probed:

1. Sources and repertories (this affects the remedies practitioners can choose from and the way in which they analyse the case)
2. Potencies (the 'strength' of the homeopathic remedy or remedies given e.g. 30C, 200c, 1M or LM)
3. Frequency of remedies (how often a remedy is given e.g. daily, weekly or less often)
4. Duration of follow-up (how long after a remedy was given did the homeopath have the chance to evaluate the impact of treatment e.g. 10 days, 4 weeks, 6 weeks)
5. Evaluation at follow-up (how was treatment impact monitored)

A further question asked the homeopath to use a 5-point Likert scale to rate how willing they would be to use the model described in the vignette if they themselves were participating as a practitioner in a trial. Reasons for this answer were requested in a space below.

Finally the participants were thanked for taking the time to complete the survey. The final page asked them to give their name and contact details if they would be interested in being contacted for any further discussion, or clarification of their responses.

5.4.11 Negotiating access and distribution

I was aware of the upcoming conference through my non-practitioner membership of the Society of Homeopaths (SoH). Using my lay membership as an initial starting point, I contacted the SoH offices by telephone to discuss the possibility of carrying out a survey. The SoH has a small Research Group (comprised of three active practitioner-researcher homeopaths) and one of these representatives was nominated as my contact, I also knew this homeopath from previous conferences on CAM where they had attended and discussed presentations on homeopathy which eased the initial access discussions.

A draft survey along with a summary of the research aims and objectives was provided by email to the Research Group. After some further discussion it was agreed that the survey would be

made available at the conference in the standard conference packs. A fee was paid to cover the insertion of the surveys by SoH staff. The process of negotiating access took approximately 4 weeks in total.

The survey was included in the conference packs issued to delegates at the two-day Vital Childhood Conference, University of Leicester in April 2007. A covering letter informed potential participants of the purpose of the survey and invited them to complete it over the next two days. I arranged for several reminder announcements to be made during the conference. Survey completion/return was also encouraged by the placement of multiple posters including the survey logo around the event and I wore a large badge including the survey logo throughout the conference.

A box was placed on the conference research desk for completed surveys and I was present during the conference to answer any questions. Each survey was accompanied by a stamped addressed envelope to encourage questionnaire return if participants did not have sufficient time at the conference.

A reminder email was sent out by the Society of Homeopaths to the membership list two weeks following the conference, encouraging any delegates with questionnaires to complete and return them. An electronic copy of the questionnaire was included with this email.

5.4.12 Summary

This targeted self-completion survey was developed in accordance with best practice and piloted before distribution to people attending the Society of Homeopaths annual conference in 2007. The questions included a mixture of structured and semi-structured items and covered demographic information, details on the respondents' training and current practice, practical considerations around working with CYPs, and opinions of the homeopathy evaluated in trials around ADHD.

5.5 Data Collection: Qualitative Interviews

5.5.1 Overview

Interviewing has many forms including the structured interview (which produces more quantitative data and is tightly defined in its scope) and semi-structured to depth interviews where there may be only a few initial questions with the rest of the conversation being devoted to

probing and exploring the participant's responses. Qualitative interviews were used within this project to a) encourage the exploration of a respondent's experiences and understanding (Rubin and Rubin, 2005), and b) attempt to describe the actual daily practice of homeopathy with children rather than the best practice that might be described in teaching seminars (Denzin, 1970). Qualitative interviews are also able to accommodate the potential change in direction of questioning that may be needed in a novel area of research (Rubin and Rubin, 2005).

This form of data collection was felt to be culturally appropriate for studying homeopaths because practitioners spend much of their time interviewing and listening to patients. Depth interviews typically use open, direct, verbal questions that elicit stories and case-oriented narratives which was judged to be both familiar to and appropriate for homeopaths (Miller and Crabtree, 1999).

Advantages

The benefits of qualitative interviews (as opposed to structured or quantitative interviews) can be summarised in three categories as per *Murphy, Dingwall, Greatbatch, Parker et al. (1998)*. Each has direct relevance to the choice of interviews as a method of data collection in this project.

1. Interviews are seen to provide the opportunity to explore a respondent's experience, interpretation and understanding of events or concepts rather than imposing the researcher's preconceived ideas and categories (Miller and Crabtree, 1999; Rubin and Rubin, 2005). This carries with it the assumption that any differences between the respondent's account and the researcher's understanding are seen to be "legitimate, cultural differences" rather than one version being given priority in terms of truth. Homeopathy is a controversial area of practice and research with individual practitioners holding a variety of views and opinions. It was important to maintain and respect this diversity within the data collection.
2. Some researchers have suggested that qualitative interviews can facilitate respondent's talking about their private accounts rather than the approved public story which may be more optimistic, or less critical of services (Denzin, 1970). Silverman (2001) among others has disputed the degree to which this is possible by highlighting the fundamentally artificial nature of the interview with its associated conventions, rules and expectations. None the less, interviews do offer a better opportunity to access these private accounts than a structured encounter, or a closed-response survey.

3. Finally, one of the key strengths of the qualitative, or semi/unstructured interview is its inherent flexibility. Standard methodological texts advise constructing a topic guide but not sticking too rigidly to the format when interesting or unexpected angles arise (Rubin and Rubin, 2005). In many research situations the interview is used where there has been little previous work and this is very much the case for this research into the homeopathic treatment of children with ADHD, therefore the possible directions of data collection may be largely unanticipated - qualitative interviews offer the flexibility to accommodate this.

Challenges

Depth interviews have been described by Miller and Crabtree as:

a special type of partnership and communicative performance...a conversational research journey (Miller and Crabtree, 1999) pp 91

This quotation draws attention to both the shared making of meanings and the rules which commonly guide such encounters. Sociolinguistic studies reveal that various expectations are in operation within many interviews: hierarchical interviewer-respondent roles, responsibility for introducing new topics belongs to the researcher, the respondent talks most, turn allocation and rapport are controlled by the researcher. It is worth bearing these known rules in mind when conducting an interview, particularly where the researcher wishes to encourage more of a partnership to develop during the conversation.

It is also important to remember that, as the critique of interviews as data collection methods have highlighted, interviews are unlikely to produce veridical accurate accounts of behaviour, feelings and opinions. Interviews take place between two individuals and are likely to involve a certain amount of "impression management" (Goffman, 1959). However the information produced is not necessarily unusable, but should be analysed carefully with awareness of the context it was produced within (Hammersley and Aitkinson, 1995).

Summary Interviews as a data collection tool are considered appropriate when they match with the communication routine of the respondent, and are a culturally appropriate communication form for the topic. In both cases this is relevant for the study of homeopathy when collecting data from practitioners who spend most of their time listening to and interviewing patients. The treatment is decided on after examination of the practitioner's notes, and sometimes discussion with a supervisor or other practitioner, while the education of homeopaths often consists of lectures and case study presentations followed by extensive discussion of suitable remedies.

Depth interviews therefore typically use interaction styles which would be both familiar to and appropriate for homeopaths.

5.5.2 Format

In-depth interviews are often associated with face to face data collection although this is not an essential link. Telephone interviews meanwhile have been recommended primarily for structured data collection where the conversation is more akin to a survey being read aloud with little room to adapt questions or follow-up on interesting statements.

Work by Annie Irvine and colleagues has recently attempted to quantitatively explore the differences between face-to-face and telephone interviews using conversation analysis (Irvine, Drew and Sainsbury, 2010). The focus was on possible interactional differences rather than the substantive content of the interviews. The transcriptions were taken from a larger project where identical interview schedules had been used by the same pair of researchers for both face to face and telephone interviews.

Overall the tentative conclusions were that telephone interview participants were somewhat more reticent than those taking part in face-to-face interviews and that they felt less confident that they were 'getting it right' for the researcher. This may have been influenced by the researcher's less frequent use of response tokens during the telephone interviews.

Face-to-face interviews were the preferred data collection format for the initial interviews as this was a format I had more experience with from my previous research assistant work, and I felt it would be easier to establish a communicative relationship. In the later stages of the project when theoretical sampling required interviewing practitioners who lived considerable distances away, telephone interviews were conducted rather than lose the opportunity for data collection. Unfortunately the work by Irvine was not yet published during the conduct of my interviews, but there could be useful further research comparing the interactions between the two formats.

5.5.3 Interview schedule

The interview schedules are shown in Appendix 10 (pg 437). There were three main phases of interview schedule used in this project; the initial exploratory schedule which was used with the first three participants; a revised interview schedule which was used with the remainder; and a follow-up schedule that was used with those participants who were interviewed more than once.

The key topics covered were:

- practitioner background and style of homeopathy
- experience with children and ADHD
- first and follow-up appointments for CYP patients
- homeopathy as practiced in the published trials
- research and homeopathy

Copies of the vignettes describing the homeopathy as practiced in published trials for ADHD were taken to each interview and used as prompts and discussion foci, see Appendix 11 (pg 445). Full text of the published trials were available for any interviewee who wished a copy. For the telephone interviews a summary of the interview schedule and a copy of the vignettes was sent out before the interview took place in an attempt to provide coherence and focus.

The main differences between the initial and revised interview schedule was the removal of the questions about particular outcome measures. Initially the intention was to present copies of outcome measures that are commonly used to assess ADHD and a quality of life measure and discuss areas that might be affected by homeopathy but were missing from these measures. The early interviews strongly suggested that this was a difficult task that was relatively unsuccessful in generating data.

The follow-up interviews were partially tailored to explore issues and themes raised by the first interview, but also to probe areas that were emerging from the ongoing analysis. Questions were added to explore how respondents might feel about changing their own practice in line with some piece of research, and whether they felt research was relevant to them personally.

5.5.4 Sampling and recruitment

Homeopaths within the Yorkshire area were identified initially by consulting publicly available practitioner registers held by the two largest professional bodies: the Society of Homeopaths and the Alliance of Registered Homeopaths. A geographical limit was chosen as a starting point to facilitate face-to-face interviewing at time/place convenient to the practitioners. A letter inviting the homeopath to take part in the project, along with a consent form and SAE was sent out to all practitioners listed in the Yorkshire regions (see Appendix 9, pg 433). A £40 thank you payment was offered as an incentive to all participants who were interviewed.

This first stage of interviewing was intended to capture as wide a range of practitioners as possible. Convenience sampling was used in the sense that the first few practitioners to return

their consent forms were interviewed. These initial interviews helped to solidify the interview schedule, but also provided the basis for further theoretical sampling. At this stage a pool of local homeopaths had returned consent forms and indicated their interest in the project. These participants were contacted by telephone to explain the project further and establish background information (style of homeopathy, experience with children and ADHD) to help with further theoretical sampling.

Recruitment was also boosted by attending homeopathic Continuing Professional Development (CPD) events as a participant-observer where information leaflets and consent forms were distributed to interested practitioners. During the interviews if participants mentioned particular lecturers or well-known homeopaths who specialised in the treatment of children these were noted and later contacted where appropriate.

Grounded theory usually requires that sampling should continue until theoretical saturation has been reached with further data collection yielding no new data. In the truest sense of the term, saturation is unlikely to occur, however data could be collected until no new substantial contribution is being made to the emerging theory. This approach was adopted during the interview segment, the collected data being analysed concurrently with recruitment and interviewing.

5.6 Data Collection: Field Notes

Field notes are a record of events (from the researcher's perspective) and also a data collection tool in and of themselves. Field notes have been kept and collected throughout this research project as recommended by Lofland and Lofland (1995). Notes were recorded in more detail for the participant-observation phases, but also when discussing issues with key informants, and conducting interviews. Memo'ing, as described earlier, has been used to keep track of analytical processes and has been referred to as appropriate in the following chapters.

Lofland and Lofland (1995) suggest the following guidance when making full field notes:

- write promptly to avoid forgetting important information
- when taking notes try to be concrete where possible and keep a running description, stay at the lowest possible level of inference and report judgements according to the person who states/indicated them rather than as the researcher's own
- distinguish between verbatim accounts and those based on recall or paraphrase

They suggest including the researcher's own emotions and impressions – these are notes for the use of the researcher and unlikely to be seen by anyone else, and should be used as such. This can serve several functions

- by being honest about one's own feelings (in private) you may find others privately felt the same way, and this may lead to interesting analytical insights
- even if unshared, your emotional experience can still lead to insight, or may serve to highlight the distance between cultures/world views which should be appreciated

Detailed field notes are still likely to be incomplete, but the researcher's notes may provide starting questions to be followed up in later interviews or observations. Field notes were kept throughout this research project as part of a research diary and referred back to during the analysis and write-up phases.

5.7 Data Collection: Memos

Memo writing is said to be crucial in moving from description towards more theoretical coding (Glaser, 1992) and can benefit from the use of direct quotations (Charmaz, 2006) to ensure the voices and meaning of participants are represented.

In this project memos were used extensively as part of a research diary, they were useful for recording the development of ideas and categories. Memos were also used to explore different ideas when going through the axial coding process, and assisted with developing a reflective style of writing. An extract from a memo written about half way through the analysis process is given on the facing page, this writing was based around the temporary code "defining treatment by a homeopath" but as can be seen this led into questioning the function of consultations.

Memo: Defining treatment by a homeopath

One homeopath/researcher feels it is sufficient to look at "treatment by a homeopath" within a comparative trial.

But surely it can't all work? Not all methods will be equally useful? Why am I uncomfortable with this? Do we need to define what homeopathy is in order to be able to test it, and suggest that the NHS should provide it. While homeopathic training may cover similar areas (i.e. if all accredited by a particular body such as the SoH) practitioners then develop in very different ways.....as for all healthcare practitioners? CAM and conventional?

Is there a need to have some fundamental principles (minimum dose? totality?) BUT practitioners are guided by practical experience and results so will adapt their practice if someone else is getting good results - so are there any key features, unchanging principles?

I always believed that homeopathy consisted of the therapeutic relationship (being listened to, understand your own body as a whole) plus the dilute remedy. Is one part more important than the other?

->if homeopathy requires a person's own perspective, seeing it from their side, then how could a trial like Frei's possibly work when there seems to be so little relationship building? And yet is Frei suggesting there are other ways to gather the necessary info rather than always relying on an in-depth consultation?

Perhaps our homeopaths focus on the consultation because it is easier to talk up than the remedies? Undeniably a good thing? Because they are stuck with it?

(*French homeopath*) is pretty dismissive of the very in-depth approach (e.g. Sankaran) and feels able to do the same 'job' in far less time using known standard remedies. What if the consultation isn't really required in the same level of detail? Can imagine that the response would be "well it wasn't needed for those homeopaths, but its all just different ways of getting to the remedy".

What are the functions of the consultation?

- To explain how homeopathy works (new concepts of body and health)
- collect information; therapeutic relationship (potentially different to other CAMs as seen less often but may be very intense)
- start to encourage change via this new understanding of health and illness
- explain taking the remedy
- explain remedy effects

Why is there a need to "get to the heart of the case"? To ID the correct remedy/potency/dose

Lots of possible methods, not just 'classical' homeopathy and the method may be fitted to the patient so very few absolutes, tolerance of ambiguity, constant learning process. Is classical homeopathy the easiest to explain to 'outsiders'? Thinking about C Barry's thesis where the professional homeopaths seems so much more consistent and clearly grouped than in my experiences. Homeopathic diagnosis consisting of > finding the imbalance (may use miasms or more explicit classifications) > identify the symptoms relating to this and interpret them > match to remedy. Symptoms lead to ID of imbalance, but also are a way to confirm if the imbalance or remedy choice is correct.

5.8 Data Collection: Participant observation

5.8.1 Overview

Participant observation is a type of qualitative research which may involve several different data collection opportunities. It was developed as a method within anthropological studies of non-Western cultures, and values the involvement of the researcher in the culture or situation of interest (Flick, 2006). The researcher enters various selected research sites and observes/participates in the activities, sometimes interviewing individuals, seeking out key informants, sourcing documents and others. Denzin described the underlying assumption of participant observation being that the researcher will

share as intimately as possible in the life and activities of those he is studying.
(Denzin, 1970) pp187

This thesis did not utilise participant observation in its fullest sense, however the method was adopted where opportunities presented themselves to collect additional data through participant observation and the following conditions were met:

- it was considered an intrusion to have a complete stranger present and recording the situation of interest
- the situation of interest was hidden from the public
- the inhabitants were likely to have significantly different views than outsiders

(Bogdewic, 1999)

5.8.2 Role of the observer

The actual role of the observer has been classified into four potential options, although it is understood that a researcher may well move between some of these roles depending on the situation (Schatzman and Strauss, 1973). The roles open to the researcher include; complete participant, participant as observer, observer as participant and complete observer (Gold, 1958). Complete participation implies covert observation, while complete observer requires that the investigator refrains from any participant or interaction with those being observed. For this project I moved between participant as observer and observer as participant with the observed being aware of my academic identity. These two roles balance the degree of involvement and

intimacy with those being observed, the latter is usually associated with a more formal method of observation and briefer contact. This typology is more detailed than Gans' (1999) observer/researcher participant/participant three strand model and allows a fuller description of the adopted role.

The extent to which an observer impacts on the situation (reactivity) has been discussed widely in the literature (Murphy, Dingwall, Greatbatch, Parker et al., 1998). Initially the focus was very much on minimising the effect of the researcher by being inconspicuous and refraining from overt participation. Writers from the 1980's onwards have instead suggested that the key is to remain aware of such effects, monitor them and include this in the analysis (Hammersley and Aitkinson, 1995; Finlay and Gough, 2003; Flick, 2006).

5.8.3 Sampling/choice of observation settings

The observation carried out for this project consisted of recording both the information per se and the reactions and discussions of the attending homeopaths in the following settings: a workshop on homeopathy for CYPs run by a leading practitioner, a CPD style workshop on a particular method of prescribing, a seminar on evidence and research in homeopathy, and at a conference devoted to homeopathy for CYPs.

The paragraphs below summarise the setting for each observation opportunity, and how access was gained to each in turn. For the duration of this project I was a lay member of the Society of Homeopaths (SoH) and the Alliance of Registered Homeopaths (ARH), and engaged in various activities within the homeopathic community. For example I contributed to the development of the RedHot reporting guidelines for controlled trials in homeopathy alongside other homeopathic researchers (Dean, Coulter, Fisher, Jobst et al., 2006), and wrote a book review for the ARH journal (Coulter, 2007a). These activities and memberships ensured that I was kept up to date on events, seminars and CPD workshops taking place across the UK for lay homeopaths.

The CPD workshop on prescribing styles was chosen as a useful place to extend my own knowledge of homeopathic prescribing, particularly the newer Sankaran style which I was unfamiliar with but had been used in one of the clinical trials. As the workshop was held in York this provided an excellent opportunity to introduce myself and my research into the homeopathic community. Attendance at this event was relatively easily negotiated with the co-ordinator of the event via email.

The CPD workshop on working with CYPs was presented by a homeopath whom I had recently interviewed, and who was one of the key figures in homeopathy for children and adolescents

within the UK. Theoretically the workshop was hoped to provide important data, and the attendees might also be useful interviewees. Attendance was agreed with the presenting homeopath who introduced me at the beginning and was both welcoming and helpful throughout.

The practitioner conference on homeopathy for children has already been mentioned in the context of developing and distributing the survey. It was considered to be a key location where both experts and generalist homeopathic practitioners would be presenting and discussing relevant issues.

The final setting was a CPD seminar on research in homeopathy. This took place at an ideal point in terms of the emerging themes within the analysis, and provided an excellent opportunity to gather detailed data on a key topic. The process of negotiating access to this event was considerably more difficult than for previous settings, and is discussed and reflected upon in the Discussion Chapter.

The data collected from these observations further informed the topics and content of the ongoing interviews.

5.9 Data Collection: Secondary Sources

Secondary data sources comprising published research (randomised and non-randomised controlled trials, observational studies, case studies), book chapters/theses that presented original data or explored the homeopathic treatment and understanding of ADHD were considered here. It was judged to be important to avoid jumping directly from the published formal research papers to primary data collection with practitioners, which would have risked ignoring the wealth of less formally published material, particularly since this section of the project intended to reflect current clinical knowledge and practice in all its forms.

This thesis has not explored documentary sources in their fullest depth as might be done within a piece of sociological research as this was beyond the scope of the project. Paul Drew has outlined the different approaches which may be adopted when examining the contents of documents (2006):

- contents are deemed to be objective and factual as in a traditional positivist attitude (MacDonald, 2001)
- contents are seen as interpretative and reflecting the meanings that people attribute to their experiences and social realities (Jupp and Norris, 1993)

- documents are seen as interactional resources by readers and play significant roles in interactions where they may be drawn on as sources of fact and used as justifications (Drew, 2006)

The homeopaths who participated in this project appeared to largely use texts and articles as factual and objective, and there was little if any discussion of the reliability or construction of key documents such as Hahnemann's original writings on homeopathy. Within this piece of work I have used, for example, trial reports as being largely factual accounts of a process while paying attention to the information that may be omitted which might indicate lack of attributed importance. Homeopathic textbooks have not been taken as definitive answers or sources of information, but as representing significant influences within homeopathic education and understanding.

Homeopathic textbooks were consulted for comparison of terms and definitions which varied across the collected data. Standard texts as recommended by homeopathic training courses, and those suggested by the key informants, were accessed for additional information on topics such as the homeopathic understanding of health.

Based on the original searches carried out for the initial systematic review in 2008, additional publications not eligible for the SR were ordered for full text assessment. Where these papers were published in foreign languages a colleague from the Centre for Reviews and Dissemination kindly provided a translation to facilitate inclusion decisions.

Published and unpublished papers, theses, books and articles which discussed the treatment of ADHD with homeopathy were considered as contributing sources for this analysis providing at least one of the following criteria were met:

- the text presented an overview of homeopathic treatment for ADHD
- the text presented original single or multiple case studies where ADHD was treated with homeopathy
- the text explored the homeopathic understanding of ADHD

Unpublished information was searched for by browsing relevant resource lists from well known homeopathic websites, discussions with Key Informants, author searches based on survey responses and fortuitous contacts made while active in the homeopathic research community.

Information was gathered from the research papers and synthesised with the primary data collected as discussed above where possible. This included details of the practitioner's background, style of homeopathy, content of the consultation and methods of follow-up. The previous chapters have dealt with the statistical synthesis and analysis of those studies amenable to meta-analysis and IPD analysis. The same research studies have been drawn on in a more general sense to contribute to the model synthesis which follows in Chapter 6, with open label, observational and case studies have been considered alongside the RCTs.

5.10 Data management

5.10.1 Survey

Survey data were entered into an SPSS database by Morag and double-checked for accuracy and errors. Categorical and numerical responses were entered accordingly. Where free text answers had been given, these were typed verbatim into the relevant cells as string variables and then further analysed as described in Section 5.1.1.

Geographical location of practice was coded by categorising participant responses as Scotland, Wales, other or England. English regions were coded according to the Government Offices for the English Region's website (<http://www.gos.gov.uk/national/>). Listings of the colleges and their abbreviations were used by the researcher when entering participant's training college data to avoid any misunderstandings as there are a number of colleges with similar names.

Responses regarding which complaints CYP's attend homeopaths with were coded using the International Classification for Primary Care coding scheme for symptoms and complaints as has been used in surveys of acupuncture practice Lamberts and Wood (1987); MacPherson, Sinclair-Lian and Thomas (2006). Where appropriate a breakdown of the conditions covered by each code has been provided in the results section.

5.10.2 Interviews

All interviews were recorded whether face to face or by telephone and transcribed in full by an experienced research secretary within the Department of Health Sciences. The transcriptions included hesitations and vocalisations but did not make use of a full conversation analysis notation as this was deemed both too time consuming and beyond the scope of this project. As has been discussed by Poland among others, verbatim transcription itself is a term that is more complex than might be first assumed (Poland, 1995). Much of the emotional context

is poorly captured, and researchers are reliant on field notes to record head movements or facial expressions - the transcript then is not a faithful record of the interview but a partial representation which may in itself restrict the analyses.

During the transcribing period, it was important to review each transcript as it was returned for errors and omissions. The transcriber had some difficulty with the homeopathic terminology initially, and tended to omit names of people to preserve anonymity. It was important to catch this at an early stage since the names mentioned were never of patients, but frequently of key authors and practitioners whom I would wish to follow-up on and possibly interview. As has been acknowledged by other researchers, while it is undoubtedly time-saving to have someone else do the transcribing, research assistants and secretaries have a tendency to tidy-up the discussions which may significantly alter the meaning of the discourse (Poland, 1995; Patton, 1990). Even accidental changes to the punctuation of a statement (exchanging a comma for a full stop) can change the meaning.

Unfortunately the recording equipment failed on one occasion (field notes were used where possible) and resulted in a poor quality of file on one further occasion. While this did not make up a large proportion of the collected data it did influence the quality of the data collected from those participants. I re-read the transcript while listening to the original audio file to facilitate catching any errors and to interpret the homeopathic language. All interviews were anonymised using alternative names selected randomly from those appearing in the film, *It's a Wonderful Life*.

Each transcription was anonymised and uploaded into an NVivo project. This piece of software allows easy access to multiple documents and other file types while coding. It also facilitates initial model building and display.

5.10.3 Participant observation notes, memos and research diary entries

The notes taken during participant observation sessions, memos to self and large sections of the research diary were transcribed by the same experienced research secretary as dealt with the interview transcripts. These documents were included in the NVivo files for analysis and coding as explained in Section 5.11. Each type of data was clearly labelled as such within the NVivo environment. This made it simple, for example, to view all participant observation notes as a group.

5.10.4 Secondary sources

Standardised matrices were used to extract and record information from each source. For example, for each case study the following information was extracted, see Table 5.3

Table 5.3: Example of secondary source data extraction

<i>Category</i>	<i>Example information</i>
Source ID	Authors and year of publication
Type	Single case study, case series, uncontrolled study, opinion piece
n and diagnosis	# of participants, diagnosis if given
History taking notes	Any information reported on the method of case taking, techniques used, mention of questions directed toward parent or CYP
Prescription	Remedy incl. potency and dosage, reason for prescription, style of homeopathy used
Assessment	method of symptom assessment, duration of follow-up, involvement of parent/child

The matrices were printed off and stuck to the office walls for ease of reference. Where sources reported information on history taking, prescription or assessment these were added to the NVivo project file in text documents with source identifier attached.

Definitions and statements found in the key texts and homeopathic reference books relating to models of health and illness were typed into text documents and included in the NVivo project for coding as described in Section 5.11.

5.11 Analysis and synthesis

5.11.1 Overview

Analysis was ongoing during data collection as is usual within any grounded theory project, and crossed over between data types. For example, the initial interviews were analysed concurrently with some of the survey responses, while later interviews were analysed without specific

reference to the survey. Participant observation during the workshop on research for homeopaths generated ideas which informed both the conduct and analysis of the final few interviews. The model presented in Chapter 6 was initially generated from the interview data and information from the clinical trials. The categories established at this stage were then explicitly explored using data from observations, the survey and textbooks/published papers. These additional sources of information provided angles to interrogate and challenge the developing model.

Grounded theory advocates using both broad and focused coding styles simultaneously and/or cyclically. Throughout the coding process Strauss and Corbin's guidelines on open and axial coding proved to be the most fruitful alongside Charmaz's incident to incident coding. The multiple coding families outlined by Glaser (1978) were explored in relation to the evolving synthesis but were discarded as not usefully contributing to the analysis.

The following sections outline the specific coding strategies adopted, and elaborate on some of the material presented previously in Section 2.2. Where appropriate examples have been offered to demonstrate the practical application of coding principles, and considerations for each data type are detailed as necessary.

5.11.2 Matrices

Three possible techniques have been proposed to integrate data from mixed-methods projects: following a thread; triangulation; and using a mixed-methods matrix (O'Cathain, Murphy and Nicholl, 2010). This project has adopted the use of a matrices based approach during the axial and theoretical coding stages and this has been reflected in the synthesis chapter by displaying matrices for each component category around the core concept. Matrices were used to help guide the analysis and synthesis stages in part based on the work by Miles and Huberman (1994). The matrix format was a useful tool to collate free text responses from the survey, prompt further discussion with key informants as well as for presenting data extracted from the various secondary sources.

For example, the item: "what kind of homeopathy do you practise?" was asked as an open ended question. The raw responses were grouped as far as possible using terms and definitions derived from Watson (1991):

Classical/constitutional/single remedy where one of the distinguishing features is the attempt to identify a single remedy which encapsulates the entirety of the individual seeking treatment

Practical/polypharmacy prescribing more than one remedy either simultaneously or in alternation

Eclectic where respondents self-identified as eclectic/mixed methods practitioners and was, based on discussion with the key informants, likely to cover practitioners who used a variety of methods above and beyond strictly classical homeopathy.

The item asking about who attended the consultation was presented as a closed response question but with space for comments below in a free text box. Many of the responses were coded as other because respondents seem to find it difficult to answer the question. Most ticked more than one box and wrote that at various times any or some of the options might apply. A matrix approach was used to assist in the analysis of this section: for first consultation and follow-up consultation answers the data was laid out as in Table 5.4.

Table 5.4: Attending the consultation - example analysis matrix

<i>ID#</i>	<i>Option(s) ticked for 0-5 years</i>	<i>Option(s) ticked for 6-12 years</i>	<i>Option(s) ticked for 13-17 years</i>	<i>Free text comments/other responses</i>
12	Parents and CYP	parents and CYP	Parents first then CYP	Might not have CYP in for very long in younger age groups

Bearing in mind the frequency of replies (so for first consultation, 0-5 yrs, most participants said both parent and CYP would be present) the free text comments were read through for caveats on the main response for each age group, and indications of the other options that might be used. These were then summarised and are presented along with the numerical results. Where reasons were given to explain why parents and CYPs might be seen together, these were also included in the open and axial coding described below. A similar approach was also adopted for the survey responses to the vignettes of homeopathic treatment within each of the clinical trials.

The sheer volume of the data collected was more easily managed combining NVivo and matrices. Matrices were also constructed during the development of each element within the model. This facilitated exploring how different data sources contributed to each of the categories and themes, and ensured that none of the data types were given undue weight. For example the interviews contributed more data in terms of detailed transcripts than the participant-observation notes, however it was important to ensure that both sources were able to shape the categories appropriately.

5.11.3 Open coding

Initial or open coding can be carried out as line-by-line coding or by breaking down the transcripts into incidents and events. Descriptive labels are used as codes, these may be abstractions from the researchers own conceptual framework, taken from the known literature or in-vivo - actual words from participants that succinctly summarise an idea (Strauss and Corbin, 1998). These codes should be more than just description and aim to be at a higher conceptual level than the original text (Miller, 1995). These open codes may also be defined in terms of their properties - definition writing - which helps to advance the coding process, maintains transparency and is likely to reveal where items have been misclassified. More focused coding occurs when these codes are grouped into categories, subsumed by a larger concept or idea. The following extract in Table 5.5 illustrates the open coding carried out on an interview quite early on in the project:

Table 5.5: Open Coding

transcript extract	open codes
<p>... you need to find something in the consultation that the child is really interested in so in your sort of initial chat where the child comes in, you might ask them about, you know, what books they're reading or what films they see. You try to find something, whatever it is that that child has a passion for and then by asking them about that and watching their reactions and their gestures when they're talking and then picking up on those gestures you can actually get to the core of a case through something that they're really passionate about... KR1</p>	<p>need for information what is child interested in, engage initial chat: books/films ... interests what the child is passionate about ... observe gestures and reactions ... get to the core of a case passionate</p>

5.11.4 Focused and axial coding

Focused or axial coding refers to the more abstract coding that develops links between categories, illustrating dimensions and properties. Axial coding begins to reassemble the data which

was fragmented during open coding and should provide precise explanations of phenomena.

One of the key features of grounded theory when considering theory development is the questioning of each category to establish its key features, or axial coding. Strauss and Corbin described this as the six C's or the causes, consequences and conditions affecting each category. In this model of homeopathic practice these questions were particularly helpful when considering the large and somewhat unwieldy categories within The Homeopathic Consultation. By taking a category such as "building relationships" it was useful to examine the data for evidence of why this was considered to be important, the purpose it served, and the implications if these activities were unsuccessful.

Axial coding (according to Strauss and Corbin) involves:

1. detailing the properties of a category and its dimensions
2. identifying the conditions, interactions and consequences associated with a category
3. relating a category to its subcategories
4. looking for cues in the data that suggest how major categories might relate to one another

The large groups of open codes were collapsed to form more discrete and definable categories, although as expected this was not a linear process. Some open codes were more difficult to group than others and moved between categories until a sensible fit was achieved. The consultation category ended up being divided into three sections (building relationships, collecting information, balancing adult/child perspectives), this made sense theoretically but was also essential to deal with the over 45 codes it contained. An abbreviated example of the move from open to axial coding and therefore to category formation is shown in Table 5.6 on the facing page. This process was applied to all of the data collection methods/results, not just the interview transcripts.

Schematic diagramming was used as extensively part of the axial coding process and some of these diagrams have been retained within the final synthesis and are shown in Mixed-Methods Synthesis.

5.11.5 Incident to incident coding

As each of the key categories began to form, I moved from line-by-line and word-by-word coding towards comparing incidents. This was adopted as a pragmatic approach to handling a very large data set, where transcribing and open coding of every piece of secondary data was

Table 5.6: Axial coding and category building

Category	Sub-categories	Axial coding notes	Example open codes
Balancing child/adult perspectives	Age of child & level of interaction expected	Specific ages of CYPs that homeopaths will directly address or try to gather information from, less interaction than expected can be a prescribing point, it will always depend on the child	age isn't useful, avoid upsetting child, look for engagement, can't expect too much, child talking to stranger is unusual, older children no different to adults
	Who the questions are put to
	Talking to children on their own
	Proceeding with caution: disparity between viewpoints

simply not possible given the time and financial restrictions. This approximates the incident to incident coding described by Charmaz as being particularly useful when dealing with data that has already been translated into your own or someone else's words such as field notes or observations (Charmaz, 2006).

For example, having drawn a collection of codes together under models of health and disease, I then returned to the case studies, clinical trials, and textbooks. I sought to compare the consultations reported in these sources with the codes and categories developed from the interview and survey data. Again matrices were a useful way to summarise the codes and draw comparisons across data sources.

5.11.6 Deviant case analysis

Attention to negative cases is a well established technique also known as deviant case analysis used to increase confidence in research findings (Miles and Huberman, 1994; Silverman,

2005). Charmaz has warned that sampling negative cases may not always complement grounded theory, for example resulting in the importing of cases rather than the discovery of them within the collected data (2006). Where negative cases are identified through comparative analysis of the data, they help to point to where the emerging theory may need further development. In this project, participants were not sought specifically to contradict or dis-confirm the emerging analysis, but were chosen as a result of theoretical sampling to further develop the developing categories.

Examination of negative cases has been compared with the emphasis on on variation within categories by Strauss and Corbin (1990), and is intended to help deepen and delineate the boundaries. Within this project for example, explicit comparisons were drawn between the responses and codes generated from the homeopath who felt it was unhelpful to have the CYP present during a consultation with those generated from other participants who felt that CYP presence was a crucial component. This comparison helped to clarify where there were important differences of opinion, but also highlighted that there were still substantial similarities in approaches between homeopaths.

5.11.7 Summary

Grounded theory and its associated processes (outlined in Chapter 2.2) of: theoretical sensitivity; constant comparison; memo'ing to develop categories; open, and axial coding; schematic diagramming and attention to negative cases, have been used to provide a framework to handle a large volume of mixed data. The procedures of grounded theory coding provided a useful template to start working with the data, and helped to encourage a methodical exploration of the data rather than being distracted by interesting diversions. The data collection and analyses phases were interwoven both intentionally and fortuitously allowing theoretical sampling to develop the central concept and related categories.

5.12 Attending to quality and rigour

Quality is a thorny issue within both qualitative and quantitative research traditions. For a novice qualitative researcher, one of the key debates is whether or not the quantitative concepts of quality could be applied to qualitative research all be it with some modifications (Hammersley, 1992a; Mays and Pope, 2006), or if alternative standards are required (Guba and Lincoln, 1994), although some researchers continue to argue that such evaluations are alien to qualitative research altogether (Smith, 1984). Two major reports have summarised the issues around

evaluating qualitative research, concluding that in the main similar standards are applicable and have presented their suggestions for judging the quality of qualitative research (Murphy, Dingwall, Greatbatch, Parker et al., 1998; Spencer, 2003).

As a mixed methods project, this thesis rejects the anti-realist position which requires separate criteria of quality applicable only to qualitative research, and instead adopts subtle realism as the model of choice. Assuming that there is some underlying reality, attempts to represent this reality via qualitative or quantitative research can be assessed using similar criteria (Kirk and Miller, 1984; Hammersley, 1992a). Grounded theory with its roots in the post-positivist paradigm has been more concerned with the analytical procedures, and the original standards intended to ensure rigour fail to take account of the constructivist approaches (Hall and Callery, 2001).

The work reported in Spencer et al (2003) and summarised in Mays and Pope (2006) provides a comprehensive and transferable framework to explore the quality and rigour within a piece of qualitative research. It was developed on the basis of a systematic review of quality assessment approaches and tools, reviewing existing quality frameworks, in-depth interviews and workshops. It subsumes the criterion set out by Maxwell (2002) which was aimed at projects using subtle realism (descriptive validity, interpretative validity, theoretical validity, generalisability and evaluative validity). The framework can also be argued to include the criteria as laid out by Glaser (1978) (fit, work, relevance and modifiability) and later developed by Charmaz (2006; 2005) (credibility, originality, resonance and usefulness).

Spencer et al's framework has been used as a template for this project when reporting details of the methodology, analysis and results sections for survey, interview, observation and other data collection methods to increase transparency. The framework consists of 18 detailed questions which are grouped around four guiding principles. These principles, and how this piece of research has attempted to account for them, are discussed below in general terms. Section 6.10.3 presents a detailed response to each of the items indicating what extent this project has met these principles. These items largely cover the same ground as set out by O'Cathain and in-tend to demonstrate that the methods have been rigorously applied and transparently reported throughout (O'Cathain, Murphy and Nicholl, 2008).

Research should be defensible in design

The methods overview chapter and this chapter have set out both the aims of the research project, and why the chosen methods are able to provide useful answers. Each method of data collection and analysis has been justified with reference to the research aims and background,

while recognising inherent limitations and challenges. The samples chosen and data collected have been transparently described throughout the thesis, and the discussion chapter explores how well this reflects the populations and communities of interest.

Research should be rigorous in conduct

This principle has been addressed through transparent reporting of data collection methods, and analysis. Where possible the following chapter demonstrates the depth and richness of the collected data to avoid claims of shallow exploration. Attention to negative cases is a well established technique also known as deviant case analysis used to increase confidence in research findings (Miles and Huberman, 1994; Silverman, 2005). Cases or sections of data were actively sought that might contradict or dis-confirm the emerging analysis or theory. This developed the analysis and expanded it to include and account for the diversity present within the data. This was an integral part of the analysis process and further enhanced by the use of the constant comparison technique throughout. Reflexivity and awareness of the researcher's impact on the data collected and analysis processes is key to establishing rigour in qualitative research. Memo'ing, recording initial preconceptions and discussion with supervisors and mentors including some group coding were all used as methods of increasing the researcher's own reflexivity (2003). This is also discussed further in Reflexivity.

Research should be credible in claim (Charmaz: credibility and resonance)

Concepts such as credibility are familiar across many qualitative traditions and require that the research demonstrates establishing familiarity with the setting/topic, depth of the data, systematic comparisons across a range of observations, strong logical links and sufficient evidence to allow an independent reader to evaluate the claims. These are demonstrated by reporting the data collection procedures transparently (as in this chapter) and reporting the coding and analyses processes with enough supporting information to demonstrate the relevant categories within the collected data (as in the next chapter). These criteria are not easily judged to be present or absent in a tick box fashion, but like useful quality assessment tools for quantitative research require careful reading of the research report.

This piece of work has actively involved key members of the homeopathic community in design, data collection and analysis stages in order to promote resonance with the knowledge and experience of others. The use of a mixed-methods design helps to demonstrate consistency and boundaries of the findings and claims from the synthesis. These claims are discussed clearly with supporting evidence presented to help the reader evaluate the conclusions, while

being cautious not to overstep the bounds of how far the results can be generalised. The settings in which the data were collected, and the cultural/social attitudes, are discussed in sufficient detail to allow an independent reader to evaluate the applicability of the findings.

Research should be contributory in advancing wider knowledge or understanding (Char-maz: originality and usefulness)

This project was based around a systematic review of homeopathy for ADHD, thus ensuring that the existing evidence base was taken into account during the design phase. The results from this review and IPD analyses have informed the research questions and data collection for the mixed-methods component, and the synthesis aims to set out areas remaining to be investigated. The synthesis aimed to present a more comprehensive picture of homeopathic research than is usually covered by efficacy focused systematic reviews, and link this into how such research may be used or resisted by healthcare professionals and practicing homeopaths. The results were intended to be disseminated both within the CAM research community and homeopathic practitioners.

5.13 Summary of the mixed-methods approach

Following from a systematic review and IPD around homeopathy for children with ADHD, further research questions were developed. A mixed-methods design based on grounded theory was proposed to synthesise data collected from primary and secondary sources that were largely qualitative in nature, focusing on the homeopathic treatment of children and young people. Data were collected from multiple sources including in-depth interviews, self-completion surveys, key informant discussions, documentary sources including case studies and text books, and participant observation notes. Field notes, a research diary and memo'ing were used throughout data collection and analyses both as a way to record information, and also to progress the synthesis of these data. As far as possible principles of rigour have been adhered to including describing the sampling, data collection, analysis and ethical considerations appropriate to each method. Finally the mixed-methods component of the project has been discussed in terms of the four guiding principles set out by Murphy, Dingwall, Greatbatch, Parker et al. (1998); Spencer (2003) in an attempt to establish rigour and quality of both the processes and findings from the synthesis.

Chapter 6

Mixed-Methods Synthesis

6.1 Introduction

This programme of research has evolved over time with contributing data collection exercises taking place concurrently as discussed in Chapter 2. The initial statistical analysis of the clinical trial data took place after close reading of the published clinical trials and discussion with key informants. At this point the other data collection strategies were initiated: retrieval of published papers such as case studies; conducting a survey of practitioners, individual interviews and participant observations. A grounded theory approach was explicitly adopted from this point onwards as the shape of the project began to develop.

Each type of data was initially considered individually, a summary of the published material was written, the survey responses were collated and analysed, and the transcripts of the first 8 interviews and 2 observations were coded separately. This first stage of analysis where each component was explored individually allowed a voice to emerge that was based on the data collected in each setting, rather than imposing a framework, or allowing a richer data setting to conceal valuable data from a quieter source. The interview data was by its nature the richest in detail, and this was used as a starting point to develop a model in the second stage of analysis, and explanation of what was being observed. While working from open through to axial coding and utilising incident-by-incident coding, there were natural spaces where data from the other sources seemed to fit. By explicitly returning to the survey, published paper and observational data to challenge and develop the model, a more integrated explanation was developed.

Further interviews and observations were conducted to try and create a more rounded picture of the homeopathic treatment of children, with ADHD as an additional focus. The initial systematic review and discussions with key informants had raised questions about how homeopaths

thought about research and evidence, and this was further explored via interviews and a fortuitous opportunity to attend a research work shop as a participant observer. These activities both informed the model, and helped to clarify where additional categories could contribute, for example in the category of what shapes and changes practice. Near the end of the synthesis process, I returned to the initial individual analyses to ensure that none of this data had been omitted or lost during the process. This helped to balance the more comprehensive information collected during the interviews and maintained a more even approach.

6.1.1 Description of the secondary data sources

Based on the original searches carried out for the initial systematic review in 2008, a total of 26 additional publications not eligible for the systematic review were ordered for full text assessment. Where these papers were published in foreign languages a colleague kindly provided a translation to facilitate inclusion decisions. Seven publications could not be located via the British Library or the Glasgow Homeopathic Library, or when the authors were contacted and were therefore excluded. Three papers were not eligible (over view of CAM rather than homeopathy or only concerning conventional treatment options) and two papers were summaries of other studies without adding any further information. Four further publications were identified by browsing relevant resource lists from well known homeopathic websites, discussions with Key Informants, author searches based on survey responses and fortuitous contacts made while active in the homeopathic research community. A BSc dissertation was provided by a final year homeopathic student who had contacted Morag following publication of the Cochrane Review. Tables 6.1 on the next page and 6.2 on page 162 summarise the secondary sources drawn on in this project.

Clinical trials and evaluations The systematic review had identified four clinical trials as described in the previous chapter: (Frei, Everts, von Ammon, Kaufmann et al., 2005; Jacobs, Williams, Girard, Njike et al., 2005; Strauss, 2000; Lamont, 1997). Additional papers originating from the Frei et al research team which were not eligible for the systematic review included an open label observational study and a book chapter relating to the RCT and incorporating five-year open label follow-up data from the cross-over trial. One non-randomised controlled study comparing Ritalin with a complex homeopathic remedy was identified (Zappelin) and was then incorporated into the SR analyses as well as this section (Hultzsich, 2007), a commentary on this study was also located. Two observational studies carried out as part of community projects working with children with behavioural problems, but not formally published, were identified during in-depth interviews.

Table 6.1: Secondary data sources (trials and studies)

Type	N	Notes
RCTs	3 trials plus 1 related publication adding new data	<p>Strauss - one published paper (Strauss, 2000)</p> <p>Jacobs - one published paper (Jacobs, Williams, Girard, Njike et al., 2005)</p> <p>Frei - main published paper reporting trials results (Frei, Everts, von Ammon, Kaufmann et al., 2005) and book chapter adding further follow-up data (Frei, 2009a)</p>
Controlled studies	2 unique publications	<p>Lamont non-randomised study (Lamont, 1997)</p> <p>Zappelin controlled study (Hultzsich, 2007)</p>
Observational studies and audits	3 publications	<p>Frei and Thurneysen (2001) open label trial</p> <p>McLean and Garland (2005)'s observational study set within an English school working with primary-aged children at risk of exclusion</p> <p>Hughes, Bostock and Seymour (2004) an audit of a SureStart homeopathy project based in Calderdale (UK) which included some children with attentional difficulties and hyperactivity</p>
Case studies	9 papers	<p>All 9 papers presented at least one case study, some gave more than one but there was no indication of a formal case series. At least two papers repeat case studies published elsewhere making it difficult to estimate the number of unique patients described in these papers. (Reichenberg-Ullman, 1992, 1996; Reichenberg-Ullman and Ullman, 1992, 1993; Johnston, 1996; Ullman and Reichenberg-Ullman, 1993; Hoffman and Fessir, 2004; Cannell, 2000; Avedissian, 2005)</p>

Table 6.2: Secondary data sources (practitioner oriented literature)

Type	N	Notes
Theoretical articles	15	<p>These papers presented treatment strategies, remedy lists or case taking suggestions relating to working with children in particular and ADHD in most cases. 3/15 papers also presented brief case studies, however the main focus was on the treatment details and theory of ADHD according to homeopathy. Three articles discussed novel prescribing methods used in the Frei cross-over trial.</p> <p>(Frei, von Ammon and Thurneysen, 2006; Frei, Everts, von Ammon, Kaufmann et al., 2007; Frei, 2009b; Glass, 1994; Guess, 1995; Goodman-Herrick, 1997; Reichenberg-Ullman and Ullman, 2000a, 1999; Diamond, 1995; Ball, 1997; Reichenberg-Ullman and Ullman, 1993; Schulz, 2005; Reichenberg-Ullman and Ullman, 1990; Jordan, 2000)</p>
Theses	2	<p>Philippa Fibert's undergraduate dissertation - summarised trials and compiled remedy lists (Fibert, 2009)</p> <p>Nancy Kelly's undergraduate thesis - presented case summaries not all of which had been published elsewhere, discussed the homeopathic approach to ADHD (Kelly, 1995)</p>
General textbooks	10 books	<p>These sources comprised a mixture of classic texts as recommended by key informant 1 and those given as essential reading on homeopathy training courses between 2005-2007</p> <p>(Watson, 1991; Dudgeon, 1994[1854]; Hahnemann, 1913 [1810]; Kurz, 2005; Dhawale, 1985; Roberts, 2005; Campbell, 1984; Owen, 2007; Hughes, 1994 [1902]; Sankaran, 1999)</p>
Child/ADHD specific texts	9 booklets, texts and chapters	<p>Textbooks, booklets and chapters found through literature searches, suggested by survey responses and browsing homeopathic book stands at CPD events</p> <p>(Foubister, 1954[1994]; Herscu, 1991, 1996; Kaplan, 2002; Jain, 2004; Borland, 1929, unknown; Rousseau and Fortier-Bernoville, 1988[1976]; Reichenberg-Ullman and Ullman, 2000b)</p>

Ongoing work: Philippa Fibert's ongoing MSc "A Case series of 20 children diagnosed with ADHD, treated with homeopathy for a year each" which was due for completion in September 2012 (Fibert, 2012).

Case studies/case series/theoretical texts Nine papers were retrieved that clearly reported single or multiple case studies. None of the papers reported a case series, and it was difficult to establish which cases had been reported in more than one article. Contact with the most prolific authors (the Reichenberg-Ullmans) found they could not provide copies of the papers or identify unique references.

Fifteen articles were classified as presenting primarily theoretical information around the causes of ADHD from a homeopathic perspective, most effective treatment styles, suggested remedy groups and so on. Some of these used brief cases as examples but the cases were not the main focus of the article. Three of these papers were related to the Frei cross-over trial and discussed the process in developing the specific methodology used in selecting and prescribing remedies, and the procedures during the trial in comparison to usual practice.

Summary documents This category included two dissertations which summarised published trials and case studies, but also compiled information on commonly used remedies. Kelly (1995) also presented a selection of case studies from prominent USA homeopaths, although some of these could be identified as having been published elsewhere and were represented in the case study category.

Books Texts were selected for use as sources in this review initially according to the inclusion criteria as per the previous chapter to inform on homeopathy and ADHD. Based on information from the survey respondents, key informants and interviewees further texts on more general treatment of children with homeopathy, as well as classic texts setting out homeopathic principles were retrieved.

6.1.2 Description of the primary data sources

As previously outlined in Chapter 5, primary data were collected from three sources: practitioner interviews, completed surveys and participant observation at four events.

Demographic details

Survey 38 completed questionnaires were returned at the research desk or by post giving a response rate of 19% for the survey. Conference attendance overall was 200 delegates attended the event and of these approximately 10% were students, 90% were qualified practitioners (information supplied by the event organisers). Survey respondents were comprised of 8% students and 92% qualified practitioners. The majority of respondents were female (31 out of 38) and the mean age was 52 years (min = 38 yrs, max = 66 yrs, SD 6.51). Respondents had been in practice for between 0-25 years with a mean of 9.5 years (SD 7.14). Most of the survey respondents practiced in England (84%) covering 9 regions, with three respondents attending from Scotland.

Survey respondents were drawn from over 15 different training colleges covering a variety of styles, mainly classical but also including practical homeopathy. The most commonly mentioned were the Northern College of Homeopathy (n=4), London College of Classical Homeopathy (n=5) and the College of Homeopathy (London) (n=4). Three practitioners had studied with more than one college for their basic certificate and three gave only the duration of their course rather than the provider.

Interviews A total of 14 homeopaths were interviewed with 19 formal interviews being recorded and transcribed. Some homeopaths were interviewed more than once to clarify responses, follow-up issues that arose during research and to explore emergent themes during the analysis. Those participants who were also Key Informants (KIs) also contributed more informally during discussions and email correspondence with such data being incorporated into field notes and a research journal. The majority (79%) of the interviewees were female (n=11) and the mean age of the sample was 51 years (38 to 61 yrs, SD 6.24). Interviews were deliberately conducted over a range of experience levels as is reflected in the data on years in practice. Practitioners had been in practice for an average of 9.6 years at the time of interview (SD 7.9), and this ranged from 6 months to over 30 years across individuals.

As with respondents to the survey, the majority of those interviewed trained at a college which followed a classical approach at least in the early years. Five had studied with the Yorkshire School of Homeopathy, other colleges mentioned included the Lakeland College, Northern College, South Down School and the North West College. Two homeopaths were introduced to practical homeopathy in the early stages of their career, and a further two underwent more of an apprenticeship training - an approach which is now largely extinct.

The majority of the interviewees were based in the North of England although two trained and practiced in the south of England and one was a French paediatric homeopath. As explained

in the methods chapter, use was made of local contacts via KIs and initially face-to-face interviews were preferred. Where there was the opportunity to interview practitioners with specific experience or knowledge outside of the geographical area this was carried out via telephone.

Some participants chose to share their patient information leaflets during the interview, or provide copies of pieces they had written for professional journals. These were drawn on during the analysis and have been clearly marked as such in the following sections.

Participant observation Participant observation notes were taken at four events: a workshop on homeopathy for CYPs run by a leading practitioner, a CPD style workshop on a particular method of prescribing, a seminar on evidence and research in homeopathy, and at a conference devoted to homeopathy for CYPs. Summary details for each of these events are shown in Table 6.3 on the next page although relatively little data could be collected on the actual delegates due to the nature of the events.

Experience of treating children and young people

The majority of respondents within the survey (73%) did not specialise in any particular aspect of homeopathy. 13% reported that they specialised in the treatment of children (either generally or for behavioural problems) and the remaining 8% said they specialised in endocrine disorders, providing adoption support or the history of homeopathy.

Almost all respondents (92% to 97%) in the survey said they treated children and young people between 0 to 17 years, which is as expected since most homeopaths work as generalists and treat anyone who is seeking homeopathy. Participants who were interviewed responded in a similar manner with a case load of between 5 and 50% of patients falling into the CYP age range.

Homeopaths (from the survey) reported treating CYP's for the following conditions in order of frequency; psychological, skin, respiratory, general complaints, ear and digestive. The psychological category included behavioural problems, anxiety, fears, sleep problems and bed wetting.

Interview respondents again gave similar responses listing skin conditions, asthma and infections under physical complaints, and behaviour in general. The answers here reflect the kind of responses from the surveys, but also give a sense of how the presenting problems vary across the age ranges. It also suggests that these homeopaths end up working more like GPs than specialists.

Table 6.3: Participant observation settings

	<i>CYP & homeopathy workshop</i>	<i>CPD workshop on Sankaran prescribing style</i>	<i>CYP & Homeopathy practitioner conference</i>	<i>CPD event on research in homeopathy</i>
<i>Event details</i>	Part of a series of CPD workshops organised by the Society of Homeopaths. This workshop focused on the specifics of working with children and adolescents, techniques, ethical issues.	A regional workshop to explore and demonstrate Sankaran style homeopathy including case studies and group discussions.	The Society of Homeopaths annual event, topic was 'homeopathy for children' and included expert speakers on various aspects, conditions and approaches	Part of a series of CPD workshops organised by the Society of Homeopaths. This workshop was advertised as suitable for new and experienced practitioners who wished to be able to deal with those who questioned the research in homeopathy
<i>Location</i>	Held in London, UK	Held in the North-East of England	Held in Leicester, UK	Held in the North West of England
<i>Delegate details</i>	n=36 Most practitioners were relatively new to working with children and had come for advice and recommendations, larger proportion appeared to have qualified in the last 1-3 years, a couple were final year students. Participants from across England, Wales and Scotland	n=24 All delegates were practicing homeopaths with a variety of experience in the topic under discussion. Included newly qualified and experienced practitioners	n=200 across UK and some from Europe	n= 36 Attended by a mixture of delegates including final year students, the newly qualified and those who had been in practice for some time but felt the need for additional knowledge in this area.

George: The most common would be skin problems followed by asthma, hayfever and then a few with behavioural problems...things like ADHD, for example.

The conditions treated will come and go depending on awareness of a disease or diagnosis, and length of treatment was felt to depend on the condition:

Mary: So, I had molluscum last year and hay fever, so that was the trend at that time. I see a lot of children on a longer-term basis with things like asthma and eczema...I'll be seeing them for years maybe, very infrequently, but over a number of years.

Violet was unusual in having two practices, one was private and the second based within an adoption agency. The kind of conditions being treated varied considerably between these two settings both in terms of presenting issues and the potential for resolution.

Violet: most of the children that come to my private practice have no pre-existing conditions and are generally there because the parent are aware of the importance of diet and health and things like that, I suspect that why they respond so easily. The children who are coming to the adoption agency really it's like lion taming, I can't really think of another way of describing it. I have to be really using all my wits. Some people come specifically for behavioural difficulties particularly if they've got a diagnosis of autism or some form of attention deficit. Anxiety in different forms...

6.1.3 Summary

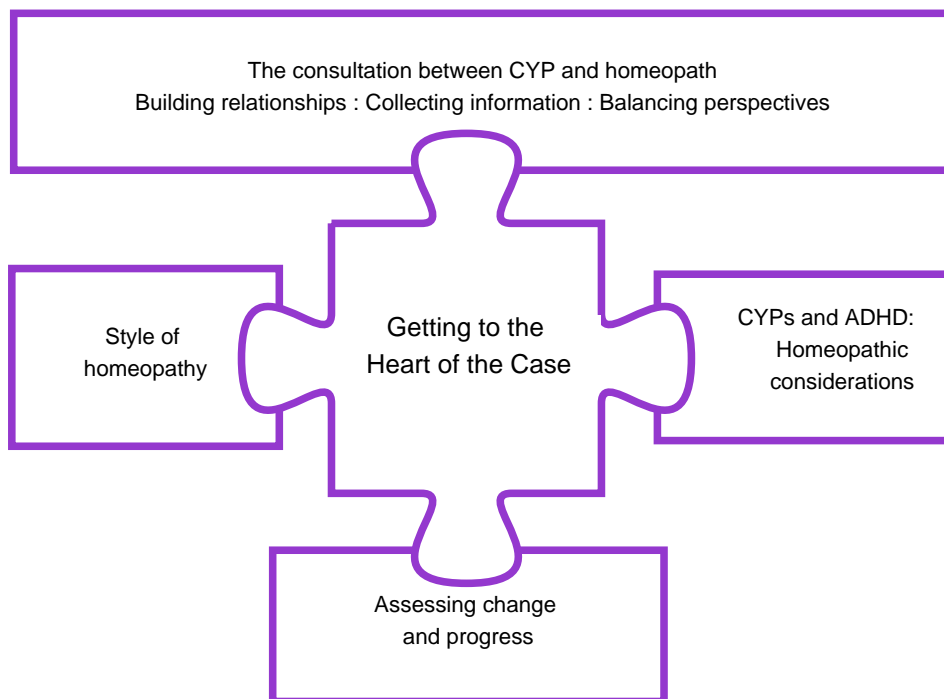
A total of 34 papers, articles, books and reports were used as secondary sources of data to contribute to the mixed-methods synthesis around homeopaths working with children who have ADHD.

As can be seen from the previous sections the primary data samples were closely related although this was not intentional. Those taking part in both the survey and the interviews broadly reflect the known demographics of professional homeopaths across the UK in terms of gender and age (Peter Morell <http://www.homeoint.org/morrell/british/index.htm>). As was intended a variety of experience levels were incorporated into the sample. There does not appear to be any particular reason to expect that the geographical distribution of respondents would have unduly influenced the data collected, and again the similarities between survey and interview participants is purely coincidental.

6.2 Getting to the Heart of the Case: the grounded theory

A synthesis of data collected from primary and secondary sources that were largely qualitative in nature was used to develop a comprehensive model that described homeopathy in practice. It focused on the homeopathic treatment of children and young people. The core concept was “getting to the heart of the case: how is homeopathy practiced”, see Figure 6.1 for the overview of the model. Appendix 16 demonstrates one of the previous versions of the model (pg 463).

Figure 6.1: Getting to the Heart of the Case (simple)



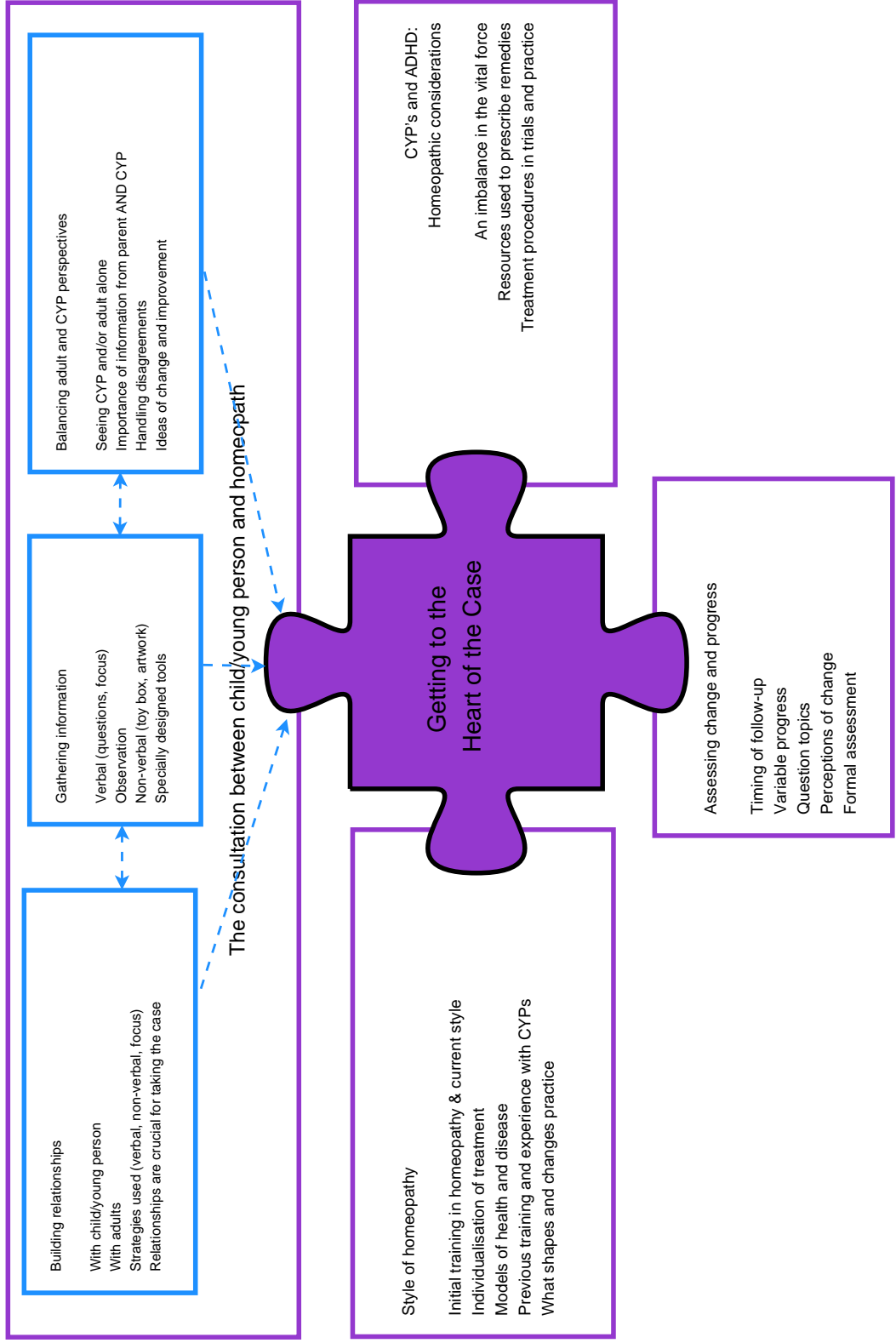
Associated categories which contributed to this concept were:

- personal or individual style of homeopathy
- children/young people and specific ADHD considerations
- the consultation process with children/young people [building relationships; collecting information; balancing perspectives]
- assessing change and progress

Figure 6.2 on the next page provides both a diagram of the synthesis results and a map with which to guide readers through the rest of this chapter.

Although some data sources are naturally more prominent in specific categories, the model as a whole was developed on the basis of initial individual analysis, followed by synthesis through

Figure 6.2: “Getting to the Heart of the Case” detailed schematic



the development and explanation of the model. All data sources have contributed to all areas of the model, even if this is only by a lack of available data. For example, the largest section of the model focuses on the consultation and associated processes and experiences. The case studies have added a little to this area, while the published trials are largely silent on this aspect. This has helped to highlight where there are failures of reporting, which makes it difficult to relate the research to everyday practice. In the descriptions of each category, a matrix has been used to illustrate the relative contributions from each data source, and a brief narrative indicates the importance of each source.

6.3 Style of homeopathy: *old music with a touch of jazz*

This category was initially developed while extracting data from the trials included in the systematic review, and was informed by the RedHot reporting guidelines for controlled trials of homeopathy. Data from the interviews and surveys helped to develop the category and details from the additional published papers were then incorporated. It was an umbrella term for what has shaped practitioners, how they express their individual methods and how these might change in the future. I was interested in how homeopaths practice because individual practice seemed to come from a larger culture of homeopathy and specific training methods. It was also shaped by the pre-existing beliefs that a practitioner has, and their previous experience with children as professionals, parents or family members. Table 6.4 on the facing page outlines how each of the data sources contributed to the development of this category.

6.3.1 Initial training, current style and individualisation

Initial training

The initial training was a key influence on a practitioner's current style of homeopathy, but it was important to remain curious about the meaning of the descriptive labels used by respondents. When asked about their training and style in interviews respondents tended to start off mentioning labels such as classical homeopathy. In the survey, the majority of practitioners described themselves as classical, constitutional or single remedy prescribers (74%), with a smaller number identifying themselves as practical (8%) or eclectic homeopaths (13%).

Understanding what classical homeopathy meant to these practitioners was somewhat challenging. The same term was used for a broad range of approaches in education and practice, not to mention that a classically trained practitioner who followed the doctrine of giving single remedies might still prescribe multiple remedies in some situations. Some practitioners seemed to

Table 6.4: Matrix of contributing data sources (Style of Homeopathy)

<i>Personal Style of Homeopathy</i>	<i>Published Papers</i>	<i>Survey</i>	<i>Interviews (includes KIs)</i>	<i>Observations</i>
<i>Initial training and current style</i>	Basic information on the training of most practitioners	basic information given	Detailed information given and some aspects explored	relatively little information collected
<i>Individualisation of treatment (consult style, remedy choice, potencies)</i>	Details provided by all papers in varying levels of detail	basic information on who is present, and opinions on trial procedures was collected	Plenty of information on the importance of this aspect and how it is implemented	Limited data collected
<i>Models of health and disease</i>	Most of the single and multiple case studies did not discuss this in detail. More information was provided in one of the Reichenberg-Ullman's articles and in Nancy Kelly's thesis	not covered	Explored throughout interviews	Limited data collected
<i>Previous knowledge and experience with CYPs</i>	Trials by Lamont and Frei explicitly related their methods to previous experience and knowledge, the Jacobs study is not explicit but used two well known homeopaths with extensive experience treating ADHD. Some of the case study articles outlined the practitioners experience	not covered	Detailed information collected on how this might shape practice	Limited data collected where possible
<i>What shapes and changes practice</i>	Not covered	not covered	Addressed in interviews and specifically in later follow-up interviews	Data collected at all events

differentiate between using a classical approach to take the case, and then perhaps prescribing more than one remedy, or using other than a classical approach to prescribing.

Anne: My case taking I suppose is still classical, relatively classical but my prescribing is not classical at all because I use more than one remedy and I might repeat it more than once a month and I will speak to people in between if they feel they need to speak to me I will speak to them, I just don't say, go away and let that remedy need to do what it needs to do and I'll see you in a month regardless of how ill or fine or whatever you are.

Two practitioners, one very newly qualified and the other in practice for around seven years, both drew analogies between learning to drive a car to pass a test as opposed to how you then drive in real life. The value of keeping an open mind to new ideas, and incorporating their own life experiences and accumulated knowledge were highlighted. This further develops the characteristics of "style of homeopathy" as a fairly fluid concept. Many practitioners seemed to shy away from definitive labels, and said they were open to adopting alternative practices as appropriate.

Donna: it's like when you're learning to drive a car, you're expected to drive in a certain way to pass your test, which I think is fine. I think you need perhaps a model to follow through and in a sense I suppose I'm still using that methodology but I think you've got to keep an open mind about it

This category indicates that asking practitioners about where they trained, or even the style of homeopathy that they practice may provide less immediately useful information than was first presumed. Terms such as classical homeopathy can have a variety of meanings which should not be taken for granted. This grounding gave homeopaths an initial framework for their history-taking and remedy prescribing although these might develop further (see category on what shapes and changes practice).

Repertories

The most commonly mentioned repertories in both interviews and survey responses were Murphy's and Synthesis. Murphy's Repertory is a large textbook which lists the various diseases and symptoms along with relevant remedies, based on Kent's Repertory this version presents the symptoms alphabetically and includes additional information. Synthesis on the other hand is an ongoing project which has taken the structure of Kent's repertory and incorporated new

information, provings, clinical indications and toxicity data in the existing hierarchical format. While the majority of the information in both repertories would be expected to be the same, the different layout and varying inclusion of more recent data could lead to differences in remedy choices. Repertories are often updated both to reflect new information but also to correct errors in the original documents, or clarify where an indication was unclear or frequently misunderstood. The exact criteria for the addition of novel information into each repertory varies according to the editorial team.

One of the experienced practitioners (Anne) commented that she did not use computer repertories because she felt they might have impeded her learning as a student, and the need to be proficient using rubrics and repertories when teaching. Crucially Anne also mentioned that her practice is more intuition based than previously, which again reflects this idea of personal homeopathy style/practice being fluid, transitional and unique for each practitioner.

Anne: I don't use the computer stuff, initially I felt I didn't want it to stop my learning because I think it makes you lazy. I also teach students in colleges and you need to be using your brain and remembering rubrics. Now I like to use my intuition as well, you get to know remedies and you know, as soon as someone's there you know pretty much what you want to give them, then there are some things that you really need to sit down with.

It was interesting to note that very few people used or recognised repertories such as Bönninghausen. Although this repertory seems to be considered as more archaic by these participants, it was one of the primary tools underpinning all of Heiner Frei's trials in Switzerland. As a researcher, this matters because we have relatively little information or data on the impact of using different repertories on the eventual remedy choices. Assuming choice of remedy affects the outcome, this can be seen as a crucial stage in homeopathic treatment. Psychological studies in general have indicated that humans are far less rational and consistent than we might believe, and at least one study suggests that agreement on remedy choices between homeopaths using the same repertory cannot be presumed (Kuklinski and Quirk, 2000; Lothaller, Endler, Balzersen, Hofmeister et al., 2009).

Potency and frequency

The topic of potency and frequency of remedy prescribing emerged during interviews both as a specific issue around ADHD (see other categories for more information) but also as part of the discussion around an individual's style of practice. There are several different forms that a

homeopathic remedy can be given in (liquid drops, tablets, powders), and the strength and delivery method may be chosen to fit the patient/carer's understanding and expected compliance with homeopathy. Practitioners talked about using and combining ideas on potency/frequency according to individual patients rather than adhering to strict treatment protocols. The published papers generally mentioned potency and frequency in passing without any explanation, the Frei group of papers discuss their choice of daily LMs but this was unusual.

This is another aspect of the individualisation of homeopathy, and illustrates the lack of perceived right versus wrong methods. For example, the French homeopath only uses C potencies due to legal restrictions and was very happy with the clinical results, while another homeopath wanted the option of using the full range and expressed frustration at the idea of any restrictions. The homeopaths in this project did not at any point indicate there were potencies that they absolutely would not consider using, though the starting points might differ, this was reflected in observations from the SoH Conference and survey responses.

One of the KIs in this project (Lilian) brought up the idea that even though homeopathy as a profession is very fluid she felt there does have to be some boundaries, some variants or methods which are not suitable, particularly in terms of remedy discovery and provings where there could be important impacts on the patients. For example when a remedy is relatively new, or has been explored through meditative provings, she would be unhappy about giving these to children.

Lilian: there can be a point where you have to say, no I'm sorry I can't cross the line. I mean an example of that is there are a number of people who are introduced or discover remedies by using dream provings which is much admired and much used. Now I think that's rather vague and potentially rather unreliable way of finding out about remedies. I don't feel, for example, personally very comfortable about using them on children because I ask the patient's permission if they're happy to try it but I can't ask a child that. So giving remedies, that kind of background doesn't sit well with me. Other people, you know, give them without a thought, so I suppose that's one of my lines that I draw.

Individualisation

Individualisation was a key thread running through this theme. For most homeopaths, when asked how did they practice, the most common answer was some variation of "in an individualised way". This had implications for every aspect of homeopathy in usual practice from the focus of the consultation and choosing the remedy, but also when choosing appropriate potencies

both for the condition and the patient to maximise the chance of compliance, and matching the remedy/potency to the knowledge/understanding and acceptance of the patient.

Individualisation of the homeopathic experience is also one of the ways in which practitioners express their own unique understanding and practice of homeopathy. There are so many variables no two homeopaths will practice in the same way even if they trained at the same school, had similar experiences and labelled themselves as classical homeopaths. As the practitioners interviewed and observed for this research said clearly, they chose from the tools they have available and practice in the way that feels right for them. Homeopathy places a great deal of emphasis on feelings and the subjective experience of symptoms, and it is therefore perhaps not surprising that the practitioner's subjective experience of doing homeopathy matters too. Actually defining homeopathic styles therefore is clearly a difficult task, and it may be worth questioning what value there can be in such descriptions.

Lilian: ...this thing are you are practical homeopath or a classical homeopath, you know, I think I'm a sort of old music with a touch of jazz and I'm sure some so called classical homeopaths would consider the way I work not classical at all and I'm probably not consistently classical either.

Individualisation, and the freedom to individualise consult style, model, remedy choices/potencies, seemed to lie at the heart of the treatment process. Where practitioners had developed a more restricted way of working, this was based on their clinical experience and came from an initial position of perceived freedom. Each practitioner therefore was holding to their fundamental beliefs and principles as described in Models of health and disease, fundamental principles, while fitting the process to each client in turn.

During the participant-observation of a CPD workshop on prescribing techniques, it was interesting to note how much variation there was in the delegates initial remedy suggestions. There then developed a process of working towards consensus which reminded me of discussions I have experienced when working on inclusion and exclusion for papers in systematic reviews. This linked strongly to the experience of Mary who when working within the confines of a trial with another homeopath found that the process of discussing cases and remedy choices facilitated more consistency in their decisions. As a profession where the majority of practitioners operate as sole traders or isolated from other homeopaths, this suggests that day to day clinical practice may vary considerably between individuals.

6.3.2 Models of health and disease, fundamental principles

The basic principles that underlie homeopathy stand alongside the oft mentioned necessity of individual treatment for each person. Originally stated by Hahnemann that disease is the result of an imbalance in the vital force, and that this is best treated using the shortest, most reliable and safest manner i.e. with potentised homeopathic remedies. Disease is clearly stated as something that must be considered within the totality of the patient, and can only be cured through application of the law of similars. The exact details have been interpreted variously by homeopathic writers and practitioners, and in some cases added to. These beliefs seem likely to influence treatment decisions both within trials and everyday practice. The following section summarises the definitions and important factors according to a range of homeopathic textbooks, before moving onto the data from interviews, surveys and other sources.

Secondary sources

As discussed in the Methods sections, although I had worked alongside homeopaths in a professional capacity as a massage therapist and later as a researcher within Glasgow Homeopathic Hospital, I had not studied the details of homeopathy. I chose not to read further on this topic during the initial data collection phases to try and stay as open minded as possible to the views and explanations of the various sources of data. During the later stages of analysis and final interviews I read a variety of homeopathy texts suggested by my Key Informants and listed as key references in homeopathy training courses. The table in Appendix 13 (pg 451) summarises what appeared to be the main messages from each text in particular dealing with the theory of health and disease. This was not intended to be a definitive reading of all homeopathic textbooks, but represented a broad reading around the topic which ceased when no new information was gleaned.

All of these different ideas and methods agreed on: like cures like/principle of similars, minimum dose and individualised treatment. A single dose or single remedy was less clearly part of the consensus, and attention to specific areas of symptoms was also variable. Hahnemann's own writing introduced contradictory ideas on single or multiple remedy prescribing, individualised versus epidemic focused and so on, and this was reflected in the texts. Ultimately, the use of homeopathic principles still leads the practitioner back to the materia medica, the collected information from clinical practice, provings, toxicology reports. These principles suggest ways to explore and analyse the remedies, but treatment is still reliant on accurate information having been compiled in the first place.

Primary sources

The key areas that were mentioned during interviews covered: a fundamental imbalance; blockage in the higher purpose of the individual; health as being in balance; maintaining causes; constitutional factors; and the direction of cure. The model of health which homeopaths work from influences how they perceive the presenting complaint, choose treatments and assess patient progress. Discussion of the homeopathy practices described in the trials with one of the KIs highlighted that not all of these ideas are universally followed by all practitioners e.g. Hering's law or the direction of cure is mentioned by Jacobs, Williams, Girard, Njike et al. (2005) in their trial paper, but strictly speaking was not outlined by Hahnemann.

Violet: The basic philosophical principles of homeopathy in terms of the Organon, the application of the lowest potency, the quickest, faster route to cure, one remedy at a time, Hering's Law and making sure that new prescription is following the standard observation and direction of cure, I think those are the basic things. I mean other things come around case management and things like that really

Health itself was frequently referred during interviews to as a state of being in balance, such that any disease, illness represented an imbalance or blockage in a person's higher purpose or vital force. Homeopathy is presented as an intervention that gently taps one side or the other of the scales or see-saw to encourage the body to rebalance itself, re-establish equilibrium and reduce extreme behaviours or emotions. The treatment also helps to build this balance and create strength in the body to resist future disruptions. KI Mary used the idea of scales both as a metaphor and has a set of old baking scales which she uses in her practice to illustrate the impact of weaknesses and illnesses on the health of a client. A similar image was painted in several of the published theoretical papers.

This process may take time depending on the duration of the illness. The homeopathic model of health and disease is clearly placed in contrast to the allopathic model where medicines are described as being given to suppress symptoms without alleviating the underlying imbalance. These categories seemed unlikely to differ much between adult and child patients, though obviously these statements were made in the context of an interview around homeopathy for children.

Associated ideas

In the process of this re-balancing the following aspects were mentioned: aggravations, the direction of cure and the presenting complaint being the last thing to improve.

Aggravation This refers to a symptom worsening following treatment, possibly prior to improving, and will be returned to in the category of assessing change and progress. This was frequently mentioned in the case studies published by the Reichenberg-Ullmans.

Direction of cure: The direction of cure and hierarchy of symptoms (the order in which symptoms are expected to improve or worsen) is another common concept within homeopathic treatments and was mentioned by participants both here and in the context of explaining the process to parents/carers. Some participants drew out the idea that the body has to recover from previous allopathic treatments which have suppressed other/earlier symptoms - these may need to recur before resolving. The simpler idea that the presenting complaint will often be the last thing to improve was mentioned frequently as a unique feature of homeopathy, and relates to the need for commitment and duration of treatment.

Violet: often with homeopathic treatment the presenting complaint is the last thing to improve. Sometimes you get improvements with other things, so for instance, sleep might be much better or peoples toilet habits might be greatly improved or and so those are all steps. So if you gave a remedy and the only thing that improved was the persons sleep but the presenting complaint was still there then that's still seen as an improvement.

Maintaining causes Maintaining causes and constitutional factors were described as constraining or additional aspects to consider as influencing an individuals state of health. Maintaining causes could include the environment, diet, family influences, cultural and social aspects. A person's constitution refers to the underlying state of health that an individual possesses and/or has inherited (hence importance of asking plenty of questions about history in the case taking). Within the workshop, Lilian outlined what she felt were the three main maintaining causes of illness/disturbance within children (listed below) and there appeared to be widespread acceptance and agreement within the delegates.

- lack of free space (physical and mental) [our anxiety about their safety, inside activities, control, lack of private and wild spaces]
- increasing exploitation of childhood sexualisation of toys/clothes. Tutor mentioned as an example "Bratz" dolls
- aspirational approach to education e.g. tests and exams, pressure to perform well, children who are "perfect"

An example of both the impact of maintaining causes and constitutional factors can be seen in the following quote from a practitioner who sees patients in two quite different settings and felt they respond quite differently in part because of the health and social backgrounds.

Jean: most of the children that come to my private practice have no pre-existing conditions and are generally because the parent are aware of the importance of diet and health and general sort of consistencies of routine and things like that, I suspect that's why they respond so easily. The children who are coming to the adoption agency really it's like lion taming, I can't really think of another way of describing it. I have to be really using all my wits. I have to have all my wits about me because none of them are the same.

6.3.3 Experience with, and training in, treating children

The CYP specific training and previous experience with children demonstrates the range of previous experiences represented in this sample of homeopaths. Some practitioners explicitly linked their prior training, employment and experiences with the way they now chose to work with children. In a more general sense it appeared that popular culture ideas about childhood (as in the previous section where sexualisation of children was mentioned as a problem) also influenced practitioners' approach to treating children. All interviewees provided data on this category, however this information was less easy to collect during the participatory observation sessions.

In terms of training across the homeopaths interviewed for this study, there was a wide spread in terms of some having received CYP specific lectures or simply one or two materia medica focused sessions pointing to useful remedies. There appeared to be a division between colleges/lecturers who taught that working with CYPs is the same as working with adults, versus those who taught working with children as a distinct topic and skill set. Of the practitioners who were interviewed, some had been teachers, health visitors, nurses or other professionals who dealt with children on a regular basis. One participant had a background in mental health although not specifically CYP. About half of the interviewees had no particular background with CYP before training in homeopathy.

Some interviewees who had been in practice for a number of years felt that relatively little emphasis had been placed on working with children as opposed to adults during their training. Where lectures were given around treating CYP these were more focused on particular remedies and sometimes on children and babies.

Beth (notes): treating kids seen as same as treating adults. Nothing about family dynamics/relationship with homeopath

Anne (interview): There were odd lectures, probably guest speakers that came who specialised in children.

For these homeopaths, they largely learned on the job once they went into practice and began to find what worked or did not work for them. Where published papers and secondary sources covered practitioner training or experience with children, a similar picture emerged.

In contrast some of the more recently qualified interviewees reported that guest lecturers provided specific lectures in working with CYPs including conditions like ADHD and how to deal with disclosures, which complemented blocks of teaching within the normal curriculum.

Donna (interview): She specialised in children and is now I believe sort of on the lecture circuit, lecturing on children. So we had her input and so she covered both dealing with children, well from all angles really from just children coming as patients across the board to disclosures, you know, of say abuse for example and learn how to deal with that.

Where more specialised teaching was available, this included remedy choices, practical aspects such as setting up a suitable consultation space and how to gain insight during the consultation itself. The more detailed education sessions also seemed to reflect a perception that treating children required slightly different skills.

Ruth (interview): there was some practical content, so it was how to sort of set up a space both sort of physically setting up a room and also sort of emotionally setting up a space where a child could feel safe to express themselves, so it was things like, you know, providing the benefit of providing art materials so that some spontaneous art work could be done within a consultation and it also brought up some discussion about the benefits and otherwise of having a parent in the consultation or seeing the child on their own and the sort of safety implications on that and getting consent from the parent, the confidentiality issues and then also about how to get an insight because certainly within the style of homeopathy that [name] practises you're really looking for some sort of central point of imbalance within the child.

Practitioners attending the workshop on working with children were mostly women. Many spoke about their own children, however a much smaller proportion reported having a CYP specific

background. The workshop leader later suggested that those practitioners with professional CYP related training may feel confident enough to work with children without the additional support of a specialised seminar.

The impact of pre-homeopathy experience with children on consultation styles and information gathering techniques has only been partially explored in this project. Violet in particular mentioned that her pre-homeopathy experiences of working with children were a strong influence on her homeopathy practice.

Violet: I chose to work in situations where children and young people come to me voluntarily and that's actually a key aspect of my philosophy in working with children and young people and adults.

Teaching methods have changed through the years, as have ways of communicating with children moving from strict rote learning to the idea of encouraging independent creative learners through a more child-centred focus. For example see Chung and Walsh (2000); Wood (2007); Hartley (2009). For example, Wood's review of policy, theory and practice related changes in child education concluded that:

Children are seen as competent social actors within a complex network of social and cultural influences. This places children and significant adults at the heart of contemporary educational processes. (Wood, 2007, pp 119)

This group of participants appears to reflect the broader population of professional homeopaths in terms of age and gender. A number of these practitioners were mothers in their own right - bringing their personal experiences, beliefs and ideas to the consultation.

6.3.4 Shaping and changing practice

This category was initially shaped by data from one of the key informants who described her experience of prescribing within a trial for patients with fibromyalgia. Although the discussion of prescriptions between qualified practitioners in a trial is rather distant from usual clinical practice, it demonstrated a shift from trial-and-error prescribing to explicitly building on previous experience. The key informant mentioned that when reviewing the notes and prescriptions it appeared that nosodes (a particular type of remedy) had been a turning point for many of the patients - for most homeopaths working as generalists means they may not see a run of the same kind of patients and presumably are less likely to be able to make these discoveries. It

was interesting to listen to a practitioner who felt that a more detailed, grounded analysis had led to more accurate prescribing - in some ways this more closely mirrors the Frei style of trial, and goes against the popular trend towards Sankaran and sensation prescribing.

Mary: It was interesting because there was two of us working, so it made us a lot more classical actually because we had to really justify our every prescription and decisions... It made us very much more conscientious and grounded and justified. Less off the cuff, gut feeling and more justified.

[Mary also commented she felt they had obtained better results in the trial than they might have in usual practice because of this rigour]

Later interviews specifically asked practitioners about what had actually changed their practice, would they ever consider changing their methods and what might result in a change in the future. There was a strong theme around learning and adapting from personal experience or from the experience of other practitioners. For example, another experienced homeopath (Lilian) when talking about what has shaped or changed her usual practice, it was her patients and their reactions to her style that had influenced her most, in particular the little boy who simply hid under the piano and appeared to be unwilling to engage with her. Here the conversation was less around prescribing and remedy choice, instead seemed to focus more on consultation style and how to relate with the children.

Lilian: What's changed it is the children, you know, children have kicked my practice around. There was a little boy who was very, very socially confident, but who hid under my piano and wouldn't talk to me, so he taught me, he actually said, I feel he said, look I don't know what you're doing but it's not working.

I think probably the other greatest influence in me has been with [name] because of her work on play therapy, and it's not so much that I use play therapy techniques. It's more the actual, it's the philosophy of it, it's where you sit in relation to the child that I've learnt most from.

One of the interviewees (fairly experienced) described her experiences of attending seminars in novel or unusual methods of prescribing, adapting the ideas by integrating them into her practice where appropriate and continuing to evaluate their usefulness. There was no suggestion of a sudden change, but a certain openness to taking new ideas on board.

One of my key informants (Beth) suggested that personal experience may be the thing most likely to influence or change a homeopath's practice, simply because of the nature of the profession

Beth: Homeopaths are very individual, like working on their own, they don't like being told what to do. There are lots of ways of doing homeopathy which work, it's really down to personal preference which you adopt.

When discussing the example of the Frei study with Beth (which used LMs and polarity analysis which Beth does not currently use in her practice), Beth made it clear that she felt that very little would change her practice. She uses her individual way of working, which is borne out by the results seen in her patients. Beth said that conversations with colleagues, case studies at conferences or in journals might encourage her to look at a particular remedy, but would not affect her "practice", because those results are particular to that practitioner and would not necessarily work that way for anyone else. Beth suggested that younger practitioners who are less settled in their practice might be more open to these changes.

The following excerpt from Beth's report following a study award illustrates the impact of personal experience and contact with experienced practitioners - note that although Beth is herself relatively experienced, she commented frequently on the speed that the French homeopaths worked at, around 20mins per consult, and the sheer number of patients.

Beth's report: My time in France challenged my prescribing habits as I could see that the lower doses of remedies had the desired effect, is this because one expects them too, or does the Vital Force grab what it can and make the most of it? Or do we have the issue of the remedy here having to get through more external maintaining causes? Or is it just how we are taught and so what we do? My main personal learning both in France and the USA has been to find that all ways homeopaths work are effective...lots of different ways are reported by their practitioners and clients to work, so keeping an open mind is vital.

In contrast to this, several practitioners categorically stated that they would consider changing their practice if offered "evidence" that their methods were not the most effective, or there might be quicker solution. During interviews most of the practitioners who were open to the idea of changing or adapting their practice referred to seeing persuasive case studies or attending workshops as being the triggers for change. There was emphasis placed on the patient's responses, if it could be shown that patients were improving then the homeopath claimed they would at least explore the treatment. This suggests an open-minded, empirical style of working. It could be argued that this pragmatic approach reflects the original development of homeopathy based on directly observable patient improvement rather than complex underlying theories.

Gloria: If there was a way of coming to a homeopathic remedy to treat eczema that made a big difference to eczema, to people suffering from eczema, I would change my practice and work that way. Certainly I would, because I would want the best for that patient. But to change my whole practice (to this new way of working), I would want to know that it worked well for everything and not just eczema.

Violet when talking about her understanding of homeopathy and research, brought up the ideas of differing reliability in terms of sources. Case studies and personal guidelines are often reported in the homeopathic literature and are then adopted by other practitioners. In contrast Violet adopted a careful attitude to these ideas, suggesting that you need lots of information to actually progress, and that rigid rules would not necessarily make practitioners more methodical. She appeared to be critical where “different principles were getting mixed up”.

There was some evidence of increased awareness of the evidence-based medicine movement generally and within the NHS in particular, though this was couched in terms of defending homeopathy and justifying its availability. There seemed to be little recognition that research itself could be a useful learning tool for practitioners. Respondents in the interviews talked about reading journals such as the Society of Homeopaths Journal and Homeopathic Links, both of which focus heavily on case studies and similar descriptive accounts of practice, rather than comparative studies as you might expect in conventional medical publications.

The purpose of research for practicing homeopaths appeared to fall under three main headings, these were initially articulated by one of the KIs but also expressed by many of the delegates at the SoH workshop on homeopathy research:

- for the public, “we know it works but we need to show them”
- “for quotes/back-up in our own writing/articles”
- for communicating with organisations like local Government/NHS

A published case study by the Reichenberg-Ullmans from 1999 briefly mentioned a piece of previous research (Lamont, 1997) corroborating their experience as practitioners with success in treating ADHD. The Lamont study was referred to as a supportive source without particular details or any critique of the research despite being fundamentally flawed (see Chapters 3 and 4).

Interview participants viewed the purpose of research being to back up practice and open up treatment opportunities, particularly within the NHS. Where there were negative studies, these were often dismissed as using inappropriate methods, or more fundamentally as irrelevant where practitioners knew treatment was effective based on their own experience.

Gloria: I think its very important for homeopaths, so they can say to people, there is this research out there, and it helps us when we're having to, as we often do, stand up for ourselves and say homeopathy isn't quackery, its useful science and it works well for a lot of people

Ruth: maybe the lab methods don't work for testing homeopathy? Fundamentally if my patients get better then we know it works.

The participants from the SoH research workshop (n=26) largely introduced themselves as looking for positive information about homeopathy research to allow them to respond to a critical public, scientific friends and answer questions from local healthcare practitioners. There were statements to the effect that they believed there was a scientific basis but these practitioners felt ignorant of the details. The idea of needing "evidence" when communicating with health professionals came through very strongly. A substantial proportion were new or final year graduates looking to start their practice or make connections in the local healthcare setting. The following quotes are a sample of the statements which were repeated throughout the introductions from both new and experienced practitioners:

Homeopath (Wales and Nigeria clinics): felt "quite knocked" by scientific community, difficult to find answers to friends who are scientific. Wanted answers.

New graduate: Gave talk to Womens Institute but a GP in the audience asked about research - thrown because had no answers. Want answers and to monitor own practice.

New graduate: I know it works, I've seen it working and I want to have the information to convince other people it works.

The day itself consisted of overview lectures on research methods in homeopathy, summaries of some systematic reviews and introductions to some of the apparent challenges for homeopathy research. My observations suggested there were several occasions during the day where the audience appeared to be confused, unable to grasp the point, or terms such as randomisation were not explained. There was a display and introduction to some of the typical CAM journals - it was apparent that most of the participants had never seen or read these. Many practitioners are not connected to a university so will have little access to these publications.

Overall there was a strong emphasis on the positive findings of trials and systematic reviews both at a basic mechanistic level and clinical level. Reflecting this attitude it was noted in December 2007 the SoH web page on research made the following strong claim which was followed by a list of positive trials and systematic reviews (without an accompanying quality

appraisal) and list of conditions where there was “sufficient evidence” to support homeopathic treatment, again without quality appraisal.

Although more research is needed, the balance of evidence already shows that treatment by a homeopath is clinically effective, cost-effective and safe. SoH web page on research December 2007

The page now reads as follows (last viewed June 2011)

Although more research is needed, the balance of evidence so far suggests that homeopathy can be a clinically effective and safe treatment option.

Research and clinical trials were never mentioned in any of the data sources as being a source of ideas for changing practice for these homeopaths. “Research” appeared to be conceptualised as something that was most often done *to* homeopathy with the purpose of proving or disproving efficacy.

6.3.5 Style of Homeopathy: Summary

The idea of health as based on the vital force, along with other basic principles such as like treats like were presented as integral to homeopathy as a system of healing. Descriptions of these models did not seem to vary much across practitioners regardless of their original school of training or current practice style. While not necessarily detailed, these seemed to be constant and fundamental. Models of health and principles also re-emerge later on when talking about how practitioners introduce homeopathy to patients and carers - the extent to which the family/individual buys into these models is felt to influence the relationship, treatment outcomes and remedy/potency choices.

Practitioner training and the exposure to different lecturers during the three or four years of their homeopathy course clearly influenced each practitioner’s style of practice. The thread of individualisation was the strongest and most consistent feature and can be seen as explaining the various ways in which homeopaths pick and choose between methods of prescribing, potency and remedy choices. Exploring what shapes and changes a homeopaths’ practice suggested that that their practice was often in a state of evolution (within a set of basic principles) such that personal style is both individualised and changing.

The benefit of research to homeopaths was expressed as being to back up their practice and answer difficult questions. Audit type data such as collected by the SoH was also seen in the

light of convincing a sceptical public, rather than for self-development within the profession. As expressed previously, this is not a unique attitude within healthcare professions whether complementary or conventional. It does however raise questions about the function of research *on homeopathy* if the practitioners do not have the necessary skills to interpret the findings, or the inclination to learn from or adjust their practice accordingly.

6.4 CYPs and ADHD: Homeopathic considerations

This category explores issues out-with the consultation process that are specific to working with a CYP population, and specifically the condition of ADHD, including practitioner perceptions of the ADHD label and causative factors. The subsequent section discusses the treatment protocols used in the clinical studies, and deals with the data gathered from homeopaths who were interviewed within this research project about how they had or would treat ADHD. Data were also collected within two of the observation scenarios where usual practice was discussed. Specific areas are outlined where daily practice may differ when treating CYPs with ADHD as opposed to another client group, although much of the data may be applicable to work with CYP's in general.

The category was built initially from data extracted during the systematic review. This tentative framework was both added to and challenged by the data collected during the survey and interview processes. Some sub-categories were almost entirely silent within the published papers both clinical trials and case studies suggesting that either information on the homeopathic understanding and specific treatment of ADHD was not considered appropriate for trials published in conventional medical journals, or perhaps that these things were well known and of little interest in a specialist publication. The interviews provided the most depth in this category and descriptions of usual practice often appear to contradict the homeopathy practised within trials.

Fuller details on the consultation and information gathering process are contained in the following categories: Building a Relationship; Collecting the Information; Balancing CYP and Adult Perspectives. Only details relating directly to working with the ADHD patient group are considered here. Table 6.5 on the next page shows the contributing sources.

Table 6.5: Matrix of contributing data sources (CYP and ADHD Factors)

<i>ADHD and CYP factors</i>	<i>Published papers</i>	<i>Survey</i>	<i>Interviews</i>	<i>Observations</i>
<i>What is ADHD to a homeopath</i>	Brief details given although most concentrated on conventional diagnosis	Not covered	Detailed information collected	Limited information collected
<i>Treating ADHD within a research setting</i>	Details of remedies given although not details of the consultation itself	Opinions of respondents on the trial protocols sought	Opinions of respondents on the trial protocols sought	Not covered - although two practitioners from one trial presented at a major conference no mention was made of their experience
<i>Treating ADHD in usual practice Resources Remedy/dosage Other interventions</i>	The single and multiple case study articles gave some insight into usual practice although the details were brief	Basic information collected	Detailed information collected	Data collected from workshop on treating CYPs and the SoH Conference

6.4.1 ADHD: *an imbalance in the vital force*

The ADHD Diagnosis

The trials identified in the systematic review tended to focus on the conventional diagnosis of ADHD, symptomatology and effects on future prospects. There is little discussion in the papers of the homeopathic understanding of ADHD, although the later papers from Frei's team outline their clinical approach in more detail. Strauss' thesis (as opposed to the published paper) deals with the contents of the combination remedy and postulates why it might be of use in the treatment of ADHD, although his writing seems to focus on deficiencies and material doses of minerals and vitamins rather than homeopathic medicine per se.

As has been discussed earlier, homeopathy as a system of medicine does not tend to use conventional medical diagnoses, and to some extent concerns itself only with diagnosis sufficient to identify the most useful remedy choices. Despite this, all of the homeopaths who were interviewed seemed conversant with the label and associated symptoms.

Beth: Well it's a title given to a set of symptoms I guess, it means that their behaviour and emotional reactions to situations are different to the majority of other children, so they're out of balance in lots of areas, mostly in relation to not being able to concentrate and do tasks and socialise and interact with children of their own age and adults in a more usual way if you like.

One homeopath (works in a private clinic and adoption support) brought up the idea that what is diagnosed as ADHD may in fact be another condition entirely such as vaccine reaction or attachment disorder.

Jean: Sometimes vaccine clear out is as useful as anything else because again it's not ADHD it's a response to being particularly sensitive to one of the vaccinations that they're had and we can give that vaccination in potency and the child's functioning improves.

The interviewed homeopaths descriptions of children with ADHD extended to the demeanour of the child and other attitudes/features. This expresses the idea of the vital force struggling to rebalance within the child, a search to re-establish balance. Practitioners made it clear this was no different from any other condition or disease.

Violet: I think like any other ailment or illness it's whether it's on a physical, mental or emotional level that it's manifesting, I think it is the person, the child's attempts to normalise and balance their situation.

ADHD was a recognised label that served as a kind of shorthand for when a parent wanted to make an appointment for their child, but was not then seen as particularly helpful. In discussion with key informant Beth, she commented that she would make a note of the diagnosis but then move on to take the case as usual. Although the label might point to a particular group of remedies it would not be a deciding factor. Several practitioners mentioned that the label could have adverse effects in the sense that their case-taking and observations may be unduly influenced causing them to focus too narrowly at the outset of a consultation.

Tilly: it's so easy to put a label on something and I'm not - our aim as a homeopath is to be as non-judgemental as possible, I don't mean in a critical way but to be detached - I think detached observing is what they call it - and for me as soon as some one has got attention deficit or I use the term behavioural issues, it's almost like already beginning that process of narrowing the perception of them, where once that's removed it's possible to see a much bigger picture.

Referring back to the idea already presented of individualisation (taking the entirety of the symptoms presented rather than focusing on what would considered to be the key conventional diagnostic symptoms) one of the practitioners most experienced in dealing with both CYPs and behavioural problems expressed the following sentiment in relation to ADHD:

Lilian: I think the most important thing here is with homeopathic prescribing is you're always trying to look for the unique individual and sometimes you've got things where very strong psychological things are going on, very bad behaviour, being violent or... Those maybe incredibly obvious and very, very dramatic and very, very striking about the child but they may not necessarily be homeopathically significant because they're common to most children who are in that behavioural pattern.

Here Lilian has clearly stated one of the key challenges for homeopaths when treating conditions such as ADHD. The most obvious symptoms may in fact be the least useful homeopathically. Similar sentiments have been expressed by the researcher/practitioner Heiner Frei, who has refined the extent to which he includes these in the diagnostic process (Frei, 2009b).

Although there has been an ongoing debate as to the existence of ADHD as a medical condition in the popular media, the homeopaths within this study rarely raised this as an issue. One

practitioner alluded to the fashionable status of the ADHD label, while in contrast another felt that society is overly accepting of ADHD-type behaviours.

Jean: I think there's a huge problem with the diagnosis of ADHD for several reasons. I think it's an easy label, parents have come to me using it because it's something that's in the media, and actually it's about expectations and sometimes the child is just energetic in class if a child becomes destructive it's really - there seems to be a pressure on the parent to go the route of Ritalin and medication that will suppress that instead of saying, maybe the child learns in a different way and would benefit from learning in a different sort of context.

Some practitioners did mention the challenges associated with treating children who have been given a diagnosis. They alluded to the idea that parents may be unwilling to give up help which has been fought for, or unable to recognise significant progress, "you've really got your tee shirt on". This again is an issue mentioned in other areas of disease beyond paediatrics and usually termed secondary gain. Some practitioners felt that this could impede the benefits of treatment.

Lilian: it can be very unhelpful when children get these labels put on them because then, you know, you're in the loop aren't you, you're getting the disability benefit and you're going to the ADHD support group and all that and you've really got your tee-shirt on and the child's individual story can get quite buried in all that.

Causes of ADHD

The clinical trials did not attempt to suggest a homeopathic explanation for ADHD, but instead presented a brief over-view of the conventional medical opinion. The published case histories also tended to be silent on this area. Nancy Kelly's thesis (1995) summarised ideas around vaccination and overload of environmental toxins playing a role in causing the imbalance in the vital force, while some of the other more theoretical papers raised the ideas of miasms (Ball, 1997), early trauma (Diamond, 1995), while the Reichenberg-Ullmans tend to steer clear of the causal argument.

Answers and opinions from the interviews included almost no answer (seemed an irrelevant question) or circular reasoning linked to their definitions of health and well being e.g. anything that causes an imbalance in the vital force as has been mentioned in the previous section. As given above, for these practitioners all disease represents an imbalance in the vital force, the cause of any condition therefore is anything that results in this instability.

Beth: not sure. Sometimes it's a "never been right since x", other times it just pops up. I don't know what causes attention deficit hyperactivity disorder. What I think causes the imbalance I don't know either. I don't know is the answer to that but it is something that's caused an out of balance – I don't know. I don't know what causes it ADHD, it's something that triggers an imbalance in the vital force.

Hahnemann's own writings were less clearly developed as regards the cause of disease, however miasmatic theory was one attempt to explain chronic conditions which did not respond as quickly to homeopathic treatment. ADHD was never described by these respondents as simply a medical condition, and where mention was made of heritability this was related to a predisposition or innate tendency to a particular kind of weakness (miasm). For some practitioners they had very specific ideas which seemed to be based on their training, personal experiences and their own personal beliefs which then impacted on decisions about treatment and remedies.

Those interviewed described specific reasons or causes of ADHD type behaviour or imbalances as birth trauma, vaccine reactions (a common theme within homeopathic understanding of many conditions), a reflection of society as a whole so about more than just the individual child, and multi factorial hypersensitivity to any stimuli. This latter point is not so far removed from the theories underlying more physical therapy type interventions with children diagnosed with ADHD.

Lilian: the whole thing about ADHD or anything, is whether there is any kind of inherited factor in it. I think it's multi-factorial, and that's why I think homeopathy can be effective because clearly you've got somebody who is very, very finely balanced, they may respond very strongly to all sorts of things .

In terms of actual causes I think with any behavioural thing one of the areas I'd always look at is to go back to the birth. Forceps, being born very quickly, the mother being very traumatised and frightened either before, during or after the birth, things that have gone on in the pregnancy, you know, it's almost like they've been in a state of alert inside the womb.

Some practitioners mentioned that they might see a pattern of behaviour in the whole family, in some cases this might be where one or both of the parents has ADHD themselves, or more simply that there is a strong family pattern towards these kind of behaviours, more of a learned response than a pathology. Parenting style was also mentioned as being a maintaining cause.

Violet: If you have inconsistent parenting, a homeopathic remedy given to a child, I don't believe in the long term is going to make that much difference to the habitual learned parenting skills of the parent or carer.

One of the most experienced practitioners in this area (Lilian) expressed a view held by many of the practitioners who were interviewed, that there is a reason for the imbalance or behaviour problems even if it is not immediately obvious to an adult observer:

|Lilian: And there always seems to be a reason, there always seems to be something that you think, you know, it's that thing where you think, well if I was only 4 and that had happened and I was worrying about that I think I might go a bit bonkers too

Summary

In summary, ADHD is seen as a fairly broad label applied to a variety of children. While these homeopaths were aware of the main criteria, they did not seem to find it a particularly useful starting point for case taking or observation. ADHD was conceptualised by these practitioners as just one more manifestation of an individual who is struggling to find balance in their life or whose vital force is disturbed, rather than a unique set of ailments. There was some reference to labels being unhelpful in terms of treatment progress, and towards the debate around ADHD's existence. Published trials to date have focused on conventional medical diagnosis and symptoms rather than detailing in what way homeopathy may have an unusual understanding of ADHD, one consequence of this is an absence of focus on the less concrete ways in which homeopathic treatment may support a child and/or their family.

6.4.2 Treatment procedures within clinical trials

Only one of the four clinical trials reported using a treatment procedure tailored for ADHD, the RCT and associated observational studies by Frei et al. Based on published experience in treating paediatric complaints with homeopathy Frei reported that classical homeopathy and the usual patient interview were unusually poor in improving the symptoms of ADHD (Frei, 2009a). This was ascribed to ADHD frequently presenting as a stereotypical uni-dimensional condition where the parents report mostly diagnostic symptoms and struggle to give the strange, rare and peculiar aspects that are crucial to the prescribing of an individualised remedy.

Many of the details of the methodology were not available when this thesis was initiated, and the evolution of the prescribing process has been published in the years following publication of the RCT results. It would seem fair to say that the methods described in these papers conform to a particular type of investigative scientific homeopathy which does not necessarily reflect the approach of all practitioners. This may reflect the divide between medically and professionally trained homeopaths. The authors pre-empt criticisms founded on their use of symptoms from

conventional medical diagnoses by suggesting that there has been a misunderstanding within homeopathy that such medical symptoms should be excluded from consideration.

A summary of the treatments used in studies by Frei et al. (2005), Lamont (1997) and Jacobs et al. (2005) were presented as anonymised vignettes within the survey of homeopaths. The vignettes provided alternative interpretations of individualised homeopathy (rather than the formula approach adopted by Strauss; 2000). Detailed tables in Appendix 14 on page 457 summarise the responses to questions about similarity between vignettes and own practice. Relevant details are discussed below along with free text comments made by respondents. A summary of the vignettes is given in Table 6.6 on the next page, followed by the summary of numbers who were willing to consider practicing in this way in Table 6.7. Responses and comments from the interviews are also woven into the sections which follow.

Table 6.7: Survey respondent willingness to practice as per trials

Study	Willing		Unwilling		Missing/No opinion	
	Freq	%	Freq	%	Freq	%
Study A (Frei)	10	26%	23	61%	5	13%
Study B (Lamont)	12	32%	19	50%	7	18%
Study C (Jacobs)	27	71%	7	18%	4	11%

Within the survey data, specific questions were asked about potency and frequency of remedy prescriptions in relation to the three main ADHD trials in the literature. One of the aims was to gain a clearer impression of how far these trials represented usual clinical practice within the UK, however the collected data also indicates where the homeopaths might draw their own personal lines.

Study A (Frei, Everts, von Ammon, Kaufmann et al., 2005)

The majority of survey respondents (68%) felt their practice was dissimilar to this trial in terms of sources and repertories. Responses from those who felt their practice was dissimilar suggested that they did not use Bönninghausen, or used other repertories, and would consider using a wider range of remedies for treating children with ADHD.

Table 6.6: Homeopathy for ADHD trial vignettes

Aspect of protocol being rated	Study A (Frei et al. 2005)	Study B (Lamont 1997)	Study C (Jacobs 2005)
Sources/repertories	Bönninghausen (Allen's Edition with 125 remedies) and polarity analysis	classical homeopathy, Herscu's remedy suggestions and RADAR repertory software	Drawing on Sankaran and Scholten
Potencies	Single remedies given as liquid LM potencies	Single remedies given as 200c pills	Freedom to vary potency: Single remedies in the 200 to 1M potency for those not on allopathic medicine; 30C for those taking stimulant medications
Frequency of remedy	Given daily	6x200c pills taken daily for up to 5 days	Freedom to vary frequency. Repeated at 6-8 weeks for those not on allopathic medicine; weekly for those taking stimulant medications
Follow-up duration	4-week intervals, no time limit	10 days after remedy prescription (2 month duration in total)	6 week intervals
Evaluation method	By telephone with parents, using a symptoms rating scale	By telephone with parents, using a symptoms rating scale	Face-to-face parent and child, usual practice plus symptom scale

37% of practitioners who said their practice was similar seemed to be basing this on the fact that they use LMs as the primary or main potency in such cases, but some clearly stated that they would also use centesimals where appropriate. Those who disagreed (45%) did so because they never or rarely used LMs, and in some cases would not use LMs with children or in cases of ADHD. A further proportion of those who said the trial differed from their practice stated that they would not ONLY use LMs and potency choice would depend on the individual case. Some respondents mentioned practical problems and poor compliance as reasons for not using LMs.

Opinion was equally divided between saying their practice was similar/dissimilar for frequency of remedy. Both respondents who said their use of remedy frequency was similar AND those who said it was dissimilar, generally reported that the actual frequency of their prescription would depend on the energy or progress of an individual case. Additional points were raised including the use of intercurrents to treat acutes, and a preference for split doses rather than daily drops.

Within the interviews none of the practitioners were aware of the nuances of the prescribing used in these trials (as mentioned previously the detailed explanatory papers had not yet been published and the book was available only in German). Largely practitioners felt it was a complex system they were unfamiliar with and therefore unlikely to use.

The reasons and comments from those who *were* willing to practice as per the Frei vignette (26%) fell under the following general headings:

- Personal practice reasons (taking more clients from distance, seeing more ADHD)
- Interest in research (want to be involved, feel need for more evaluation of homeopathy to encourage use, open to different homeopathic approaches)
- Similar to own practice (have treated in this or similar way with good results, not too far from classical homeopathy)

However some caveats were placed on their willingness such as wanting face-to-face contact and more freedom to vary remedy/potency and frequency or prescriptions.

The majority of respondents (61%) in this survey were unwilling to practice as per the Frei vignette, and their reasons/comments were grouped under the following themes:

- Lack of knowledge about the particular methods

- Lack of similarity to own practice (particularly where respondents have evolved their own 'best practice' and feel confident this works for them, feel a need to practice in way they believe is most effective)
- Not happy with telephone follow-ups (unable to assess true progress, want more feedback from child, worried about missing valuable information) and this was not how homeopathy should be practised
- Protocol too restrictive/need more individualisation and freedom in prescribing

Study B (Lamont, 1997)

The sources for this study included classical homeopathy, RADAR and Herscu - similar comments were made by those who did (53%) and did not (37%) feel this was similar to their own practice. The main areas identified by practitioners were the use or not of Herscu, and the use or not of RADAR, or computer software generally.

Survey responses were equally split at 45% for similar and dissimilar to own practice in terms of potency. Potency was standardised in this study to the use of 200c only. Some of those who felt this was similar to their practice qualified their agreement by adding that they might not give 200c on a daily basis to children, may start with 30c or that the potency would depend on the case. Presumably they still felt their practice was similar in that they used this particular potency scale. Respondents who disagreed did so because they felt potency should be variable and dependent on individual cases, or they specifically would not use a repeated 200c in this manner.

Frequency was set at 6x200c pills taken daily for up to 5 days. Those who agreed that this was similar to their practice (32%) commented that they might use single doses, or if giving remedy daily would use LMs. Others said they would give fewer doses or not repeat as often, sometimes one dose might be sufficient. One participant raised concerns about compliance with the instruction to stop giving the remedy when a change was noticed. More respondents felt this was dissimilar to their own practice (58%) because they would vary potency and frequency according to the specific case. Several said they would give a single or split dose and monitor for any change without the repetition of the remedy. Dailies would be given only in acute situations, and one questioned the need for 6 pills/day.

Respondents who were willing to practice like this in a clinical trial (32%) said that they felt it was worth studying this method of treatment, and one said it was similar to their own practice. Most respondents were not willing to practice in this way (50%), and a range of reasons and comments on the treatment protocol were given falling under the following broad themes:

- Not similar to my practice or not a method I use
- Study length too short and follow-up/remedy change too soon (longer term treatment needed, takes time to see change or find a good remedy)
- Not happy with telephone follow-up
- Protocol is too restrictive/problems with the standardisation
- Lack of focus on the child
- Concerns about the protocol (could provoke a proving or cause aggravation, suppression, only suitable for an acute condition)

Study C (Jacobs, Williams, Girard, Njike et al., 2005)

Most of the respondents said that this trial with its use of Sankaran and Scholten was similar to their practice (66%), although some added that they used more methods/wider selection of repertories, or might not use these methods exclusively. One agreed that they would use LMs if the patient was on a drug regime. Those respondents who said this was dissimilar to their practice (21%) commented that they were unfamiliar with Scholten and Sankaran or had only a basic knowledge of these methods. Some said they were interested in the methods but had not yet incorporated them into practice, while others would not use them exclusively. One commented the protocol was too prescriptive and another that they prescribed on “the perceived totality of symptoms as set out in the Kentian hierarchy”.

The majority of survey respondents (82%) felt that they used similar potencies in their own practice, additional comments indicated that they might use more 30c's and increase potency slowly, or use other potencies generally. The few who felt this was dissimilar (5%) commented that the approach was too rigid and that they used a wider range of potencies. The respondent who described all of these examples as rigid basically felt that any restriction on prescribing freedoms was inappropriate and all aspects should be individualised and left up to each practitioner.

Again the majority of respondents (77%) felt that the frequency of remedy was similar to their practice although a few added some additional comments – repetition would depend on progress and only when needed, which might be more or less often than in the protocol. Those who felt this was dissimilar (10%) to their practice felt the protocol was too rigid, said they might use more frequent remedies, or felt that with sensitive children practitioners should be cautious with repetition.

The majority of respondents were willing to practice as per the Jacobs vignette in a trial, 71% (more than for any other study description), and their reasons provided a comprehensive picture for this choice:

- the Jacobs vignette is closer to their own practice, fits with their training and feels right/likely to produce good results
- Would need to learn more about these methods but willing to do this especially after the conference presentations
- Study is flexible enough in important areas and responsive to child's needs
- Positive opinions of the trial protocol: good length of study, good source material, child and parent treated appropriately, confident and comfy with method, natural way to do a trial, good way to test if Bombay method is reliable
- Interested in learning about outcome measures
- Reflects how many homeopaths practice even if they do not use Sankaran and Scholten specifically.

Those who were unwilling to practice in this way (18%) gave the following reasons:

- Lack of experience or not using these methods
- Protocol too rigid and limiting
- Need to practice in a way that practitioner feels is effective

Summary

The most favourable comments and judgements were made about the pilot study which did not find a significant benefit of homeopathy. The trial which was received relatively negatively by respondents (Study A, Frei, Everts, von Ammon, Kaufmann et al. 2005) used a modified and refined prescribing method based on clinical experience - the reactions of these respondents suggest that such changes may need careful introduction to the homeopathic community including the rationale for a procedure that seems to vary from classical homeopathy or constrains the individual practitioner's professional choices.

6.4.3 Treatment procedures in clinical practice

There was a contrast between the responses which indicated there was nothing special about treating ADHD, and the detailed descriptions of specific approaches in both treatment and consultation. Although as noted earlier relatively few of the interviewed homeopaths had extensive experience in treating children with behavioural problems, those who had this experience did not seem more likely to have specific strategies for treating ADHD. ADHD was recognised as a complex presenting complaint which often occurred with co-morbidities by all respondents.

It should also be noted that several practitioners explicitly stated there was little that they might “do differently” when treating this group of clients. These practitioners tended to describe cases they had treated as examples of going deeper than the typical diagnostic symptoms.

The example below also illustrates the homeopath moving beyond the symptom (rage) and using the response to a particular family of remedies to make a clearer diagnosis of the underlying imbalance or disharmony.

Jean: So if one of the main prescribing problems is normally explosions of rage, if it's in little girls I've found that the Lac remedies, the ones based on the milk of mammals nurture the child at such a deep level that I guess the rage is fear and so they're sort of biting before they're bitten because it improved with the Lac remedy it actually means that there was something about the need for attachment and nurturing that that remedy saw.

Resources Used for CYP Homeopathy

Within both interviews and published texts, reference was made to the limited number of remedies which have been studied and written about in terms of children, this was seen as both a strength and a weakness. For example having relatively few well known remedies for children narrowed down the choices, however it also made it more difficult to choose a remedy when none clearly fitted the case, and there was an absence of evidence/experience in using other remedies.

George Vithoukas - foreword to “The Homeopathic Treatment of Children” Herscu (1991): “There is at present a great necessity for information on the homeopathic treatment of children. We do not actually have enough literature on the subject except from Borland's booklet which is quite good but not sufficient for the needs of our time.”

Lilian: (from workshop) Because children's homeopathic experience of course is hugely unrecorded, for example, we don't have any true links, we can't prove on children, it's unethical, so we have the same problem as we have with any medication. We have no "maps" because we have no provings, or information from the materia medica, provings, meaning we need to make a leap from the adult experience of a remedy to the child

This quote raises another interesting facet around the idea of validity of evidence and reliability of sources. There is a substantial amount of debate within the homeopathic community as to the construction of both materia medica and repertories - which provings are included, updated with what information, which remedies are included and how they are organised.

Survey respondents were given a list of possible CYP related resources by author name (based on literature searches and interviews with KIs) and invited to tick each that they used. An 'other' option with space to record details was also provided. Two respondents did not select any of the available options or detail any alternative sources used when treating CYP's.

The most frequently mentioned source was Paul Herscu, whose writings were mentioned in the background to this chapter, and who was mentioned by almost all respondents (82%). Catherine Coulter, Douglas Borland and the Reichenberg-Ullmans were also mentioned by between 45-50% of the homeopaths. Part of the purpose of this question was to collect information on more obscure/less well known writers on homeopathy for children. The 'other' category provided names such as Tricia Allen, Tinus Smitz, Farokh Masters and Miranda Castro.

Herscu is a popular homeopathic teacher and practitioner who has developed a particular method of prescribing suitable for children and adults, as well as publishing a short text on the application of eight remedies in the treatment of children (1991; 1996). This text focuses on describing remedy pictures relating based entirely on clinically verified symptoms. Herscu has held seminars on the treatment of ADHD and other behavioural problems although the delegate reports which could be located did not report many particular details (Gruber, 1995; Guess, 1995).

The Reichenberg-Ullmans have been mentioned elsewhere - they have largely produced collections of single case studies and books which are aimed more at the general public (Reichenberg-Ullman and Ullman, 2000b; Reichenberg-Ullman, Ullman and Luepker, 2007; Reichenberg-Ullman and Ullman, 2008, 1999). Their books focus on homeopathy as a system of health and medicine, and present multiple case studies as examples of how effective homeopathy can be. Catherine Coulter is a well known homeopathic writer who focuses on homeopathic personality types (more of a Kentian approach) and her book comprises 23 mini-portraits of

types in children. Douglas Borland's short text was originally published in the early 1900's and contains 29 remedies divided into 5 constitutional groups and associated remedy pictures (Borland, unknown).

Farokh Masters' text "Clinical observations of children's remedies" is a more recent volume focusing on the author's own clinical experience of using a select number of remedies - 75 in this case (Master, 2006). The book covers examinations of children, but focuses on the physical examination and relevant medical tests, the author also being a medical doctor.

Although Sankaran/Scholten was mentioned frequently in the 'other' category their works contain nothing that is specific to CYP homeopathy, while Miranda Castro's published works on children are all aimed at the parent rather than a professional homeopath.

Only one practitioner mentioned a text by Pravin Jain (suggested by a key informant) although this was in comparison to the other books listed the most comprehensive; covering child developmental stages and case taking questions specific to paediatrics (Jain, 2004). As appears to be common, this 80 pages of information is then followed by a detailed materia medica covering 80 remedies (based on repertories and clinical experience). Jain also offers a flow chart to assist with the analysis of the case utilising the child's interest in their surroundings and behavioural traits.

In the majority of these texts, either existing materia medica have been taken and adapted for use with children, or an individual's clinical experience has been used to create detailed prescribing notes for specific remedies. Catherine Coulter's writing is based on her personality type analyses of homeopathic remedies which is very much a Kentian approach. Interestingly this means that most of the available text books and writing on paediatric homeopathy are not strictly based on two of the usual cornerstones of homeopathic knowledge: provings and toxicology reports, instead they are focused on clinically observed symptoms.

Lilian: it's a huge unwritten book because we have Herscu who is wonderful but it's just 12 remedies - it's a very limited range, because he's a very good model of actually taking an adult picture and interpreting it because he's a paediatrician.

Some practitioners reported being less confident in the use of the newer remedies because they feel there is less evidence to support their use, and the information may be less reliable.

Lilian: I'm not very happy in using remedies that haven't been used much, or are relatively unproven and giving that to children because we don't know what the remedies do. You know, when I'm talking to members of the public one of the things

that I think is very powerful to say about homeopathy, particularly for children, if you have a child with blazing red cheeks, not much sweat, very high fever is you give them Belladonna, exactly the same as you're giving a child in 1807, that's 200 years of consistent practice.

Homeopathic focus when treating “difficult children” in clinical practice

Some of the survey questions asked respondents to indicate which, if any, of the listed options they would particularly consider when treating a child with behavioural type problems including ADHD. As Table 6.8 demonstrates, the options provided were relevant to most of the respondents, although nosodes seemed to be used less often for this patient group. Particularly interesting was the relatively high level of response to parental behaviour - what this survey cannot tell us is whether parental behaviour is itself a source of remedy indicators, or if this indicates the homeopath's sensitivity to family dynamics as a contributory factor to behavioural problems.

Table 6.8: Focus in the homeopathic treatment of “difficult” CYP's

Focus during the consultation	Frequency
root cause	21
Nosodes	14
child interaction with peers/parents	28
previous ailments	23
pre-birth experiences	20
parental behaviour	22
Other	23

Details from the “other” category provide a more detailed picture of what these homeopathic practitioners might look for in the treatment of “difficult” children, expanded in table 6.9 on the following page. All of these areas could potentially give the practitioner clues towards the correct remedy, and further reflect the broad homeopathic perspective on health and illness.

Table 6.9: Other factors considered when treating “difficult” CYPs with homeopathy

Other factors expanded
birth stories or history
characteristic strange/rare/peculiar symptoms
diet/food intolerances/allergies
drawings
dreams
energy of the case/child’s energy
family history
focus on child’s interests
observation of play/behaviour
presenting symptoms
previous grief/trauma/bullying/abuse
the child themselves
the sensation of the case
vaccination history and response to vaccinations/antibiotics/drugs

Remedy and Dosage Choices for CYPs and ADHD Treatment

The responses from interviewed practitioners and workshop observations suggested that there was often a need to get started somewhere, and try to stabilise the child before attempting to find a single constitutional remedy (where this was the preferred method). As mentioned previously, children who have been diagnosed with ADHD or are suspected to have ADHD tend to present with clear and stereotypical symptoms which are causing great distress to both the CYP and their family. These very obvious symptoms, from a homeopathic perspective, may sometimes be misleading as the practitioner is actually interested in the “strange, rare and peculiar” symptoms.

Jean: so it's knowing where to start and knowing what will sweep up the worst of the symptoms depending on what the parent feels the most distressed by.

In terms of remedy choices, several practitioners mentioned that they found nosodes to be a useful starting point. The basis for this varied from clinical experience to Hahnemann's later writings in *The Organon*. Nosodes are remedies made from disease products such as diseased tissues or secretions which are then diluted and succussed in the usual fashion. These practitioners felt nosodes could be useful for CYP's with ADHD because this group of remedies is felt to be effective in moving on from past trauma. This clearly links in to practitioner perceptions of ADHD causation.

Mary: It's usually nosodes that I'm looking for, because there is a lot of nosode prescribing with children I find

The idea of ADHD specific remedies did not fit with the approach for many of these interviewees, although one practitioner had a shortlist of remedies based on her experiences and meetings with other experienced homeopaths. Key informant Beth visited the Homeopathy Centre in Houston (USA) where the practitioners specialise in treating autism, ADHD and chronic conditions. The approach there is to use sequential prescribing along with detoxification, suggested to be the method recommended by Hahnemann in the last, unpublished, version of *The Organon*. Beth also visited with the Ullmans (mentioned previously) who specialise in treating children with ADHD and autism using sensation-based Sankaran methods of prescribing. In contrast most practitioners emphasised the importance of sticking with well known general remedies - called polycrests - rather than having ADHD specific remedies to start with:

Mary: Yeah and it's the experience at being clever with remedies and sort of thinking that it might be something weird and wonderful and obscure. After a few goes at that I come back to the general polycrest and that's usually the one that works and I'll go straight to the polycrest and only look for something weird and wonderful if that doesn't work.

The potency and frequency of prescriptions given in ADHD cases did come up as a specific area where there were considerations beyond the general factors in any consultation. The idea that children with ADHD are naturally of higher energy, and depending on the level of Vital Force, are expected to burn off remedies quickly was expressed. Daily remedies might be prescribed when the Vital Force was felt to be particularly weak e.g. where there were physical complaints as well (notes from discussions with key informant Beth). This was in contrast to

the usual homeopathic approach where a remedy would be given once or in a split dose (three times, night-morning-night) and then allowed to take effect over a number of weeks or months. The practitioners who commented in detail on this issues all had moderate or more experience in treating children diagnosed with ADHD. There was also the suggestion that the high energy children may respond differently to remedies and be more challenging to prescribe for.

Ruth: some children respond better to one off or daily remedies, it seems to depend on level of their health, strength of vitality/Vital Force and how quickly they burn off the remedy. They might need daily treatment but I should be able to fade this off.

Commitment to Treatment for ADHD

Homeopathy as a treatment modality is rarely associated with immediate results, and practitioners often specialise in chronic conditions while expecting the recovery process to take some time. Both within interviews and workshop/conference observations it was clear that practitioners felt that CYP's with ADHD required long term treatment to see stable results. For example, the Reichenberg-Ullmans described their treatment model (SoH Conference) which asks parents/guardians to commit to a year of treatment and follow-up.

The Individualisation of Treatment section illustrated how practitioners may have to adapt their preferred prescribing style according to the degree to which the patient/guardian accepts the model of homeopathic health and treatment. LMs for example are often given very sparingly, or until a change, improvement or worsening of symptoms occurs. As one respondent highlighted, this very much involves the patient in the process of treatment, and may only be suitable for enthusiastic patients. These kind of potencies require that the patient is willing and able to monitor their own progress accurately and adjust the remedy use appropriately since there is an anticipated negative consequence to continuing to take the remedy beyond what is needed.

Donna: I don't use them (LMs) as much perhaps as some of my peer group does. I think you've got to be sure with an LM that they are comfortable with the process of what homeopathy stands for and sort of going and then seeing what happens for some people is quite difficult.

This was emphasised when working with CYPs and ADHD where recurrence of the symptoms could damage the therapeutic relationship, and be unbearable from both the CYP and adult's perspectives. The disappearance of symptoms could also result in the CYP and adult ceasing to continue with treatment, homeopaths felt this was understandable but misguided, and ultimately prevented them from resolving the root imbalance.

Violet: I think the biggest thing really is to get the commitment to on-going homeopathy and that is my biggest difficulty because people will come once or twice until they're perceived that the symptoms that they are complaining about as a parent has disappeared or abated or if they feel that they've got worse sometimes that will frighten them off. So my biggest difficulty is building up the trust so that they will come back again and again and that isn't always the case [unclear] in situations.

Expectation of Recovery with ADHD Treatment

Most of the data from the interviews and observations suggested practitioners would be aiming to have the child use the remedies fairly regularly initially, and perhaps keep them for back-up, but not to be taking the remedy constantly. This contrasts with both the conventional approach to medication for ADHD, and the treatment strategy followed in the Frei et al studies where daily administration is advised to maintain benefits.

Beth (notes) Although I would expect to see a significant improvement by 6 months, its always a balancing act between 'good enough' or 'better enough' for the parent versus the hassle of attending and expense of appointments.

More than simply the reduction in ADHD type symptoms, practitioners also explicitly mentioned that they anticipated the child or young person would become more robust and able to deal with difficult situations, or foods that previously had caused hyperactivity.

Lilian: I think so often with these kids, you know, you fetch up creeping around trying to avoid situations or avoid foods or avoid this or avoid that and actually what you need to do is to try and build the child so that they are more robust, you know, they can eat things, they can deal with all situations and, you know, they may go a bit wobbly but it'll settle down again and that's what you're trying to work towards.

Interventions Additional to Homeopathy for ADHD

All of the homeopaths who were interviewed were explicitly asked if they used or recommended additional treatments/strategies alongside homeopathy. As some mentioned, CYPs had often been placed on supplements or a restricted diet by the parents prior to coming for homeopathy, however some homeopaths actively prescribed while others suggested additional alternatives. This practice appeared to be shaped by more than just their homeopathic training. Some individuals had attending training courses prior to studying homeopathy, while others actively sought out compatible techniques to add in.

Tilly: we might talk about alternatives to that [talking about dietary choices]

The interventions and treatments mentioned by homeopaths were as follows (based on interviews and observations)

- herbal tinctures
- flower essences (Bach and Australian Bush)
- Reiki
- relaxation techniques
- Neuro Linguistic Programming
- Herbs and or supplements
- Emotional Freedom Technique
- dietary changes

These various modalities were mentioned in the context of being generally supportive to the healing process or a form of energy medicine - so similar to homeopathy. Practitioners did occasionally acknowledge the problem of “muddying the response” by adding additional factors into the treatment, but this was felt to be a minor disadvantage when some of the treatments could result in a speedy result. The treatments were all mentioned as secondary treatments, or as woven into the consultation itself.

MA The personal development side of it [school of practical homeopathy] at that time was absolutely key, and the homeopathy went along with that and then obviously I went on and did NLP which is really its about communication with self and others, so it fits together very nicely because I use it such a lot I don't think I'm even aware of it now. I use flower essences and herbal tinctures, but you know, then again it's just the energy medicine same as homeopathy so they work really well together.

Two practitioners specifically stated that they focused on dietary advice within the consultation and incorporated this into the treatment plan.

Jean: Lots of dietary advice although a lot of parents have got their head around additives and stimulants but haven't come across the idea of the Feingold diet, so that if children do have sort of switches and moods things that are slow release sugar and avoiding sort of excessive reliance on carbohydrate work really nicely.

Beth emphasised she uses more dietary and behavioural interventions than some practitioners in an effort to encourage the child and family to take responsibility. Describing herself as a health counsellor, this information is provided during the consultation and via information sheets. This was described by Beth as a back-up in case the parents decide not to continue the homeopathy, and because sometimes homeopathy was not sufficient on its own.

6.4.4 Summary

The ADHD label itself appeared to be familiar to the homeopaths and the homeopathic community, although the diagnosis was not perceived as particularly valuable. Since the fundamental problem was perceived to be a disruption to the vital force of the child, the focus of the practitioner was on identifying the cause of and treatment for the imbalance. This might be relating to birth trauma, inherited predispositions or other factors. The existing clinical trials have focused on using the conventional ADHD label without touching on the homeopathic understanding, while published case studies tend to only briefly mention the possible causative factors.

Practitioners' views on the homeopathy as practiced in the clinical trials were fairly consistent in reporting that their practices were dissimilar to Frei, Everts, von Ammon, Kaufmann et al. (2005) and Lamont (1997) in most respects, with the most similarity to the homeopathy described in Jacobs, Williams, Girard, Njike et al. (2005). The lack of flexibility and opportunity to individualise the treatment in Frei, Everts, von Ammon, Kaufmann et al. (2005) and Lamont (1997)'s approaches were cited as reasons why the interviewed practitioners would not be happy to work in those ways.

Children or young people with ADHD were not generally viewed as a particularly special case that always required particular considerations for remedy, potency or frequency choices. None the less, practitioners did indicate that they might consider prescribing more frequently, suggesting additional complementary therapies or looking at family commitment to the treatment. These factors appeared to be based more on practitioner experience than textbooks or published guidelines. More generally relating to the treatment of children, practitioners highlighted the paucity of resources to guide remedy choices compared with adults.

6.5 The consultation with a child/young person

This category was originally conceived of in opposition to the almost complete absence of details reported in the clinical trials. The trials reported little details of the consultation process

which seemed to contradict the key informants insistence that this was a crucial part of homeopathic treatment. As mentioned earlier, the Frei trials in particular appeared to have deliberately kept child:practitioner interaction to a minimum. With this in mind, the survey tapped into the physical facts of who was present, and to whom questions were addressed, while the interview questions probed deeper by asking practitioners to describe typical consultations with children of varying ages. The initial outline based on key informants was added to and developed with the interview data, while the observational data from the CYP and Homeopathy workshop added a further layer of detail. The resources mentioned most commonly by survey respondents contained very little information relating to the consultation process itself, despite these being the key references for practicing homeopaths.

The consultation can be seen as a direct manifestation of how homeopathy is individualised in practice - the central concept. Although not all practitioners will use a face-to-face visit, this was by far the preferred method of gathering information and relationship building. Based on the collected data from interviews, the survey and participant observation, a framework of three main categories was devised which directly contribute to the form, style and content of a consultation. Data from the published papers did not really contribute to this section. The contributions are illustrated in Table 6.10 on page 212.

The function of the consultation appeared to be to build trust and engagement - partly as therapeutic in its own right, and partly to make the right treatment decisions. The intended outcome of a consultation was to prescribe the correct remedy in the correct potency and frequency. For some practitioners they also imparted additional health-related information so may expect a shift in health beliefs, information levels and awareness.

The consultation was also clearly shaped and affected by many of the other categories such as practitioner style and training. The consultation itself then influenced how change/progress was assessed at later visits. Practical considerations with the consultation were overall very similar i.e. most of the respondents were in private practice and saw patients from a rented room or a designated treatment room in their own house. The duration of the appointment was between 1-2 hours depending on the condition, age and attention span of the child.

The three contributing categories were:

- Building relationships
- Gathering information
- Balancing child and adult perspectives

These first two categories both describe the function of a consultation and the strategies employed, but also the importance of these elements in feeding into and informing later remedy choices. Many of the ideas within these categories refer to where practice is different or similar for younger patients than adults. The concept of the consultation being the same or different for children is almost hidden as it weaves in and out of the other categories – trying to extract it independently simply loses the relevant context.

The interaction between and relationship with both CYP and parent represents one of the ongoing tensions which the homeopath must be aware of and balance. It can shape the format and style of a consultation depending on the relationship dynamic, and includes areas where the practitioner may need to make difficult decisions about which piece of information to use both in continuing a line or questioning or prescribing a remedy.

6.6 Building relationships: *without a relationship there is no case*

This section deals specifically with the relationships which are formed during the process of homeopathic treatment. Since the primary indicators for choosing a homeopathic medicine are the symptoms, emotions and experiences of the patient, homeopathy is well known for its focus on the patient - practitioner relationship. When working with children however, there are more people involved in the whole procedure. The relationships between homeopath, patient and other attending adults are all prominent.

Patient-practitioner relationships have received increasing levels of attention within research on conventional healthcare, however in these settings the function of such relationships may be rather different. Within conventional healthcare interactions (psychotherapies excepted) the function of the relationship is usually considered to be improving the patient experience, facilitating disclosure of relevant information and increasing adherence. While all of these factors are undoubtedly relevant for a homeopath, these practitioners have a greater need for accurate data collection in the sense of exploring the more unusual or obscure details of the patient's experience. In some homeopathic methods, it may be the associations the patient draws between symptoms, thoughts and so on that are crucial when making a prescribing decision. Without these data, the homeopath is essentially prescribing blind, and given the literally thousands of potential remedies to choose from this could lead to a frustrating experience for all concerned.

6.6.1 Building a relationship with the child/young person

Within a homeopathic consultation where a CYP was the focus of attention, the primary relationship was reported as being between practitioner and CYP.

Table 6.10: Matrix of contributing data sources (The CYP Consultation)

CYP Consultation	Published Papers	Survey	Interviews	Observations
Building relationships	The trial papers mentioned very little on this topic, only two of the other papers mentioned this.	Focus of questions question	Contributed extensively to all aspects of the category and developed through follow-up interviews	Some data came from the SoH Conference but the majority was collected during the CYP and Homeopathy workshop
Gathering information	Strategies and the importance of information gathering were mentioned in relatively few of the papers	Not covered	as above	as above
Balancing child and adult perspectives	Only one paper directly touched on the topic of balancing perspectives	The questions around who was present during a consult, and to whom the questions were directed added to the development of this category.	as above	as above

Gloria: I do form a relationship more closely with the child

This was echoed by most practitioners where the important message they wanted to convey was the child was being listened to regardless of their method of communication.

Lilian: and if by walking round and round the room singing is your way of communicating with me, well that's the way you're going to communicate with me, that's fine and I'll still be able to, you know, understand something of what's going on. I'll hear you if you're singing, I'll hear you're not talking to me, I'll hear you if you never look me in the eye and ignore me the whole time, I'll still hear you. And that's really, really important because kids with behavioural problems don't get heard because they don't communicate very well. Their way of communicating frequently doesn't work

Attention was paid to the adults and in some cases this was mentioned as important in terms of encouraging adherence to the treatment plan, however the main focus was still on the CYP. Even in those cases where the practitioner did not actually meet the child (unusual in this sample), questions were directed to the adult on what they thought the child's responses would be.

The emphasis on building links with the CYP came through strongly from all practitioners. Some specifically mentioned the often unbalanced power relationships that exist between children and adults. Practitioners were genuinely curious about the perspective of the CYP and appreciated that without this it was difficult to establish rapport or to hear their unique story. Without this information it was felt to be difficult if not impossible to "reach the heart of a case" and therefore prescribe appropriately.

Jean's article: In order to truly engage children during the homeopathic interview, I believe that we have first to acknowledge and then redress the power-based, potentially adversarial norm of adult-child relationships. We need to set the stage instead with the dual message: "You are an important person, and the more I know about you, the better I can prescribe".

This was reflected in one of the published papers which emphasised the potential value of putting diagnostic labels to one side to allow a clearer case-taking without bias or opinions affecting the practitioner's views (Jordan, 2000). This non-judgemental attitude was also felt to assist in seeing the child's behaviours as being reasonable survival tactics, rather than irrational acts.

As alluded to in the previous paragraphs, the relationship was felt to be important for a number of reasons;

Data collection to facilitate accurate prescribing

Jean: all of the remedies depend on the individual's perception of some things, and obviously the parent just can't give you that information

The therapeutic experience of being in the spot light, being listened to and prioritised.

Lilian: I don't know if all homeopaths agree with me but I feel very, very strongly about this, I don't think I do anything. I don't think the remedies do anything. I think what happens is they support the patient to do it for themselves and I'm always saying that to children, you know, look you were really scared about your exams, you've overcome that. It isn't just a remedy because you're giving a remedy for self-esteem with a good rapport, that's a very powerful prescription. This can be one of the few places where that child will actually feel that somebody is kind of pulling on their side for them.

The depth of the relationship and level at which the practitioner was comfortable working did vary among respondents. The CPD workshop on children and homeopathy presented the idea of the child leading and the practitioner following. Although a relatively common concept in homeopathy for adults, as the lecturer says below, not all homeopaths may feel able to implement this in their practice with children. There was some heated discussion within the workshop around this idea suggesting it was indeed a controversial topic.

Lilian: I know its not something that all homeopaths would feel comfortable with, I think they do feel that, and particularly with a young child who can't even talk to you but it's still the case, and I've felt that's been very, very fruitful because that to me, it has made the relationship work better so the information has been easier to receive and to hear and to understand.

6.6.2 Strategies to build the relationship with children/young people

The following section details specific strategies that the practitioners mentioned using to build rapport and focus on the CYP attending for treatment, many of which are anchored around prioritising the CYP before and during the consultation.

Resisting stereotypes Several practitioners mentioned trying to avoid reinforcing existing stereotypes, particularly with children who were having behavioural difficulties. Rather than starting from a place of preconceptions, they explicitly talked about attempting to see the patient as a fresh individual. The intention was expressed that the consultation should be a different experience from these children's usual contacts with health and educational professionals.

Paperwork focused on CYP By creating an initial focus on the child via preliminary paperwork and possibly speaking with them on the phone, and then greeting the child first, or clearly seating them in the centre of the room, the homeopaths intended to anchor the consultation on the child. Prioritising the child appears to be carried out in several distinct ways. Firstly, via contact with the child before the appointment: some homeopaths talk to the child on the phone before they come in for treatment just to say hello, while some send an introductory letter that sets the scene and lets them know what to expect.

Ruth: if the child is over say 12ish I quite like to speak to them on the phone first and have some contact. Its not always possible or appropriate but I always write to the patient even a primary school age child or even a toddler. I send them a letter and say I'm looking forward to meeting them and I usually make it quite light-hearted and say I'm going to be asking you some questions that afterwards you're probably going to think why did she ask me that, maybe it's because I must be mad. But whatever they say it's important to me and it's valuable to me whether it's right or wrong.

Greetings By greeting the CYP first, asking questions to the child primarily or giving them the main seat in the consultation room. This is sometimes verbally explained to the accompanying adult which also cements the meaning for the gesture. Lilian described getting the child involved in making a new file for their own information - giving the CYP some of the control and emphasising the confidentiality in the session.

Violet: I always start with talking to the child even if it's a baby. That's the person that I'm trying to have the energetic relationship with.

Returning to the child's perspective When the focus drifts or parents begin to answer for them, the practitioner may explicitly shift back to the child and their opinions.

Ruth: it's most beneficial if the child has had time to answer and if, I try and say this very quietly, and if possible if the parent could not interpret or correct what the child is saying...so I do ask the parents to take a back seat really

During the consultation the parent may be asked not to interrupt or answer for a child. This may have been discussed before the first appointment or by telephone. This was highlighted by practitioners as being more than about creating trust and engagement. It was also about getting the perception of the child rather than the parent, which was helpful in remedy identification. Even where the child is busy playing, the practitioner might ask the child for permission to talk to the parent.

Lilian: you know, quite often I'll say, are you really busy [when the child is playing], can I ask mum about it? And, you know, they're so busy, yeah, yeah and, you know, it keeps it kind of relaxed and not too challenging for them, bearing in mind that you obviously want to be - and also I find children are really good about saying to mum, no I'm not!

Here there is continued emphasis on the CYP as the focus of the consultation, they are given the option to answer the question if they choose to.

Creating a positive experience Some of the first session may be taken up with explaining the process and reassuring the child, and leaflets and booklets were also mentioned. Here the practitioner is preparing for the session and attending to the CYP's experience. They tell the child what's going to happen, and what's not going to happen! (oils/massage/herbs) Its also about letting the child know that there's no right or wrong answers - this suggests that the homeopaths are aware of the pressures on children to respond in particular ways, example of practitioner asking about the child's favourite food but making it clear "Ignore what you know is good for you" that they do not want a standard/expected answer.

Tilly: with a child I'll also explain to them why I perceive that they're there, you know, you mum says you've got a sore throat or you get tummy aches and we're going to talk about this and I can ask you some questions and ask your mum some questions. So I just run through how I'm going to work with them, they know that they can, you know, say something at any time and everything is as much out in the open as possible.

Most seemed to go to some lengths to ensure some understanding of the treatment process on the part of the CYP. This was seen as a clear way to facilitate a relationship via reassurance, setting out ground rules and expectations, and reassuring them that their views were very important.

Additionally, rather than pushing things to the point where the relationship might deteriorate, practitioners mentioned opting to use an alternative data collection methods such as asking the parents, or taking a short break. In some cases where the practitioner felt they had collected the key details, further questions might be dealt with over the phone.

Mary: If the child looks fed up, disinterested, whatever, then I'll finish the interview at that point and if there's more information that I need I'll ring the parent afterwards and get that.

Most practitioners said that they would try to avoid discussing anything particularly distressing which they could ask the parent about separately.

Tilly: like if there's things they need to say that they thought probably not best for the child to hear, then we either have a separate appointment or they can phone me separately and that's not to sort of collude or be secret from the child, that's more if the mother had a distressing pregnancy or something that might be upsetting for the child to hear

Practitioners reported an explicit desire to avoid unnecessary upset, or confirmation of existing negative patterns/stereotypes.

6.6.3 Building a relationship with the Parent/Guardian

The relationship with the parent was mentioned in relation to data collection, but also as a way to support them in their decision to use homeopathy. This was described as being more than politeness or explaining a model of health and treatment, but also incorporated building an atmosphere of trust to encourage the parent to persist with treatment. Practitioners made it clear that if the focus was consistently drawn to the adult then they would tactfully suggest a separate session.

Mary: because it's such a totally different approach to the conventional model. It's quite a leap of faith I think for a lot of them and they need a bit of support and just, you know, yeah okay are we doing the right thing here? If it feels right, it's right sort of thing.

Helping parents to understand why and when to give the remedy(ies) came through as being important for consistent treatment, as in conventional medicine, with ideas of compliance. Keeping the adults engaged with what could be a long process was acknowledged as important and without a relationship between practitioner and parent/carer it was felt it would be difficult to keep motivation going. Since conventional medicine is perceived to conflict with homeopathic remedies, a good relationship between practitioner and parent/carer was intended to help the parent keep in touch rather than opting for allopathic remedies at the first sign of problems.

Jean: So it (use of the remedies) really depends on parents being aware enough of how homeopathy differs from conventional medicine, so that we're talking the same language really.

In the same way that some practitioners will try to provide the child with some information around what to expect from homeopathic treatment, a similar kind of information was often sent out to parents in advance of the consultation. Practitioners reported speaking with the parent over the phone or sending out a basic health questionnaire. These tools seemed to serve a dual purpose of collecting initial information, but also starting the process off and establishing the relationship. It was felt that this helped the homeopath to establish the parent's perspective and opinions, and might encourage the parent to think more broadly about their child's problem.

Gloria: I'll have a conversation with the parent beforehand, how are you going to explain this to the child, what's the child expecting etc.

Rather than trying to explain homeopathy and associated concepts per se, the practitioners tried to give sufficient information to engage the parents/children with the consultation, help them to persevere through aggravations or the need for longer treatment without results, understand reappearance of old symptoms and decide when to seek conventional medical treatment. These explanations and discussions took place prior to or during the consultation, with information also being provided via websites, brochures or leaflets.

Symptoms were seen as the "finger prints" of the remedy. Jean described this as being both an integral part of the homeopathic understanding of health/illness and treatment, and also as an explanation she used to build engagement with the patient and parent. This was intended to help them to understand the type of questions that might be asked and getting them involved with the questioning process.

Jean: So I'll say things like we welcome symptoms because there are a unique way of our bodies saying that we're out of balance and it gives me a way of knowing that

3,000 odd remedies that we've got to the one that is unique as your finger print and it really engages them. I have a brochure that explains the sort of basics and even things like return of old symptoms

One practitioner raised the idea that the explaining and discussion might not occur at the first consultation. For her it was more of an ongoing process during treatment and follow-up visits. She gave an example where the discussion would be quite different depending on how the child was responding to treatment - again an indication of relationship building and development of trust although here not specifically about finding the remedy, but maintaining treatment.

The concept of conventional medicine suppressing symptoms and illnesses, and therefore true cure requiring the recurrence of old problems came up in discussion with these homeopaths and was something they might mention in the consultation. This was felt to have implications both in how the model of health is explained to parents especially for young children and the likely duration of treatment. For these homeopaths, they were not expecting instant cures, and would see a worsening of symptoms as a useful signpost. This was felt to be contrary to conventional medicine and would need to be explained in advance, particularly if the parent may resort to further conventional medication during homeopathic treatment.

6.6.4 When there is no relationship (with CYP and/or adult)

The lack of a relationship forming between practitioner and CYP or adult was felt to be a major disadvantage to homeopathic treatment, and many practitioners felt it could make it almost impossible to prescribe accurately.

Lilian: if I don't have a relationship with the child, I don't have a case even if they're all physical symptoms and you have a doctors report, I still don't think you're going to get the case. I think the relationship with the child is absolutely key, not only in the extracting of information, you know, that it facilitates the information coming across

Despite this, some practitioners also mentioned that the inability to communicate or build rapport as being a useful prescribing indicator. This perspective assumes the only issue is the child's failure to engage or talk, and this is a remedy indication rather than a reflection on the homeopath.

George: Whereas the one that sits mute in the corner, you know, will not engage despite your best efforts, that's really helpful too

Jean: Well that's information in itself and with the little ones it gives me information
- I don't know if you know the remedy called [unclear] that sort of clingy, cuddly to
mum stuff is an indication of the remedy straight away

Some of the responses pointed to differing ideas about what might be expected from children in terms of engagement relating to their age and developmental stage.

6.6.5 Summary

As the homeopath is ultimately interested in the perspective of the patient, rather than just the observable facts, the relationship with the child/young person may be more important than in some conventional healthcare settings. It was difficult for a homeopath to prescribe without data directly from the patient, and indeed some practitioners felt they would be unable to get to the heart of the case in such a situation. Perhaps because of this, almost every practitioner interviewed had a set of strategies or techniques which they explicitly employed to build rapport, focus on the patient and collect their personal perspective. Strategies relating to the child/young person were discussed in most detail and ranged from the initial greeting, through the handling of paperwork and directing of questions. The relationship with the parent or guardian was also reported to be important both in terms of encouraging compliance with treatment, but also to facilitate in collecting important information about the child/young person. Even in situations where there was little or no interaction with the child, this was still felt to be of value in choosing a prescription.

6.7 Collecting the Information

As has been discussed, the homeopathic interview is one of the main tools that a practitioner uses to collect information on the presenting symptoms and related information. Unlike in a consultation with an adult patient, CYP focused sessions required additional skills and methods, all of which were ultimately focused on helping the CYP to communicate with the homeopath. All of these components within a consultation also function to focus attention on the child or adolescent, prioritising their perspective and experience. The key techniques and concerns are dealt with in the following sections, based on data collected in interviews, observation sessions and discussions with Key Informants.

6.7.1 Information Gathering: Non-verbal strategies

It is impossible to get the symptoms and wants of a child except by interpreting its motions. An astute observer, one who has been watching children for a number of years, will understand the child and hardly have to ask the mother a question. He will know at once where the child is sick by what it does. pp 274 JT Kent

This theme contains information on the tools that homeopaths chose to use, how these were used and how they contributed to the consultation and information gathering process. On re-reading these sections none of this kind of information was mentioned in the trial reports.

Observation as a crucial skill

Observation skills play an important role in homeopathy regardless of age of the patient. The Sensation or Bombay school of homeopathy for example places considerable importance on the gestures made by patients. When working with younger CYPs including those who may be pre-verbal, observation was reported to be one way to balance the information from parents with a more direct perception of the CYP patient themselves. It was also suggested to be a way into understanding the younger child who does not yet use language as their primary means of communication. Lilian covered this in some detail in her workshop:

Lilian: you have to go and you do not speak the language, you don't know the cultural rules, you don't know the rituals. You do know them but they're an awfully long way back in your experience and they're a bit lost to time, so you have to watch and observe with huge respect and very, very keenly to see actually what's going on and see how it is

An associated challenge with the emphasis on observation was the need to avoid interfering unless absolutely necessary. This was reported to give the practitioner a chance to see how the parent/carer reacts, but might conflict with the homeopath's desire to preserve their consultation room.

Tilly: sometimes I have children who are sit and play quite happy and some just sit on mums knee and just suck their thumb and I've had others who run all around everywhere and have every tissue out of the box and I do my best not to say a word but sometimes it's quite tempting when things are being thrown against the wall but my job is just to observe them.

Observation took place generally throughout the session, as mentioned earlier the child which showed no inclination to engage with the environment was conveying valuable information, just as much as another child who is into everything in the room.

Tilly: when I'm working as a homeopath, the first thing I will start doing I suppose is just observing...(talking about later on in the consultation) So all the time this is going on and I'm talking to mum, I'm still watching the child

Observing Play/Using a toy box

Practitioners who used toys in the consultation seemed to fall into one of three groups

- those who provided the toys almost as a distraction for the children to keep them occupied during the session
- those who used play with the toys as a rapport building strategy
- and those who explicitly observed play behaviour and used this as further information when considering remedy choices

The following examples illustrate the kind of information that practitioners in the third group collect when observing children playing in a consultation. Violet ensures there are some toys in all of her practices and focuses on how the children interact with their toys - the emotional responses in particular. She is also conscious of not interfering or using the play in a developmental sense.

Violet: Any toys that they seem to be drawn to sometimes and how they use the space around them, whether they will leave the mother or the other carer. What their attention span is, how roughly or gently they treat the toys. What kind of toys they're drawn to. How quickly they get frustrated with things, even if their jaw drops open and they start dribbling when they're playing, do you know what I mean, anything?

Lilian has a wide range of toys scattered throughout her consultation room and stored in chests and multiple drawers which are left open to encourage children to access the contents. She commented that even the very young children of 18 months who are not yet talking will clearly pick out particular toys. Lilian mentioned that she found plastic food was particularly useful to ascertain preferences and she returned to the idea that *play therapy allows children to speak*

their own language. This practitioner emphasises the importance of such observations both in the way that children play, and their choice of toys in her consultation style, and teaches these ideas through workshops to her peers.

Lilian: they [the children] come back to a follow-up session going ooh and then they'll go over to that chest and out will come the same toys and its like "I'm going to tell you and I'm going to tell you and I'm going to tell you until you get it." I think children are very used to being misunderstood!

The degree to which practitioners actively joined in play sessions with the children seemed to be quite an individual thing. Some felt this was a useful way to engage with the child, but more often the idea was of the practitioner maintaining an observational distance from the child.

Self-expression (using art materials)

Practitioners who provided toys often made some kind of art materials available. Again there was a mixture of attitudes towards using artwork in the consultation ranging from uncertainty about how to interpret the results, to seeing drawings as a potential way to monitor progress. There was some awareness of the impact that developmental stage could have on drawings among other factors.

Jean: I actually prefer drawing more than play with toys because you've got something to take away with you that you can hang their own words on and therefore also something that you can monitor progress because I sometimes get the most disjointed pictures of really very primitive circles that are barely formed for quite old children, 6 and 7 when you would have thought they'd be onto faces with arms and legs and things and big smiley faces and sometimes children's original pictures are so dreadfully scribbled and chaotic and therefore over a period of time you can also see the child coming together as the pictures come together.

Drawings or paintings were used both to establish communication and again when seeking information for remedy choices. There was overall a clear sense that drawings were interpreted in the same way as dreams - that is not in relation to developmental goals or an underlying meaning, but followed through as the CYP told their story.

The homeopath who was less enthusiastic about using toys also expressed doubts about how to interpret children's drawings. Reference was made to the established tradition of using artwork with children but this was then contrasted with the lack of work on using art materials within a homeopathic consultation.

George: Sometimes I'll ask them to draw because I think that's, you know, that's established as a useful way of sometimes helping, particularly younger children express themselves. Now, I mean I was reading some stuff recently about homeopaths using children's drawings but there isn't a great deal of established work in using children's drawings in homeopathy

Another homeopath (Ruth) who was relatively new in practice had a full set of art materials out for use in her treatment room. Although they had not yet been used she was confident they would be useful based on her pre-homeopathy training and experiences having taken two summer schools in art psychotherapy at a local University.

6.7.2 Information Gathering: Verbal strategies

Verbal communication is often associated with homeopathy, because the essence of classical or constitutional homeopathy is prescribing to the individual which includes their unique experience of their symptoms. Practitioners commented that it was difficult to collect the detailed sort of information they needed just from observation or second hand reports, therefore the direct questioning used with adult patients was also part of consultations with children.

George: I would ask the kinds of questions I ask for any homeopathy appointment where the purpose of the questions is to get as much information as possible about what's going on.

Practitioners asked about likes and dislikes (called generals in homeopathic terminology) throughout the consultation. This was both a way to encourage the child to talk more, and also because it helped the homeopath to understand the case better. The responses provided useful information when considering suitable remedies.

Morag: What do you mean by generals?

Mary: Body temperatures, food likes and dislikes, thyme, sage [unclear] is better, anything that affects the whole of them because they tend to be really important useful symptoms and I use them to confirm a remedy. Is that clear enough?

Morag: Do you ask about those things if it was an adult as well?

Mary: I will do but I tend to have less emphasis because I find I may get a clearer mental picture, you know, encourage them to talk about their mental state and with children it tends to be more my observations and the parents interpretation which is less sound.

Some practitioners felt that they might phrase these questions differently for children although the broad content would not differ, or more focus might be placed on general perceptions to make up for less mental state information. Factual questions tended to be directed towards the adult if present. Child directed questions included asking them about their likes/dislikes, favourite hobbies or films, which could lead into talking about imaginings, dreams, metaphors and other more abstract things. These questions are similar to what they would ask adults, only the language might be different, for example being aware that the presence of a parent may influence the answers to questions such as your favourite food/drink.

Ruth: So when I ask about food and drink. I say - Ignore what you know is good for you! If you could have any meal you want in the world what would it be? What's your absolute favourite? If you were at a mate's house for tea and the mum put food down in front of you what would they be that you couldn't eat even for politeness?

Lilian described bargaining to talk about difficult topics and negotiating a time limit to the conversation, while Jean opted to drop in and out of the more sensitive issues while talking about something that the child was passionate about. Honesty from the practitioner was seen as a potential strategy to encourage honesty and trust from the CYP.

Lilian: this is the cooking timer I use, and I'll bargain with a child, you know, I really do have to talk to you about the bed wetting? How long could you bear to talk about it and they'll say, 1 minute. Okay, can you give me 6 minutes, 4 minutes, 3 minutes and you bargain your way down and then I'll set it and I'll say, okay I'm setting it to 4 minutes and we agree that we're going to talk about it for 4 minutes, when the bell goes I'm going to shut up.

Asking about a favourite film or book was expected to indicate a like/dislike of violence for example. It was considered to be revealing in the way that the child talked about their favourite or most hated character - potentially describing facets of their own personality. practitioners reported that they felt this was easier for the child than asking them to talk directly about themselves ("language of metaphor").

Gloria: asking children about their dreams can be really useful, even quite young children, I ask them about their dreams and whatever they tell you is useful and if they go into their imaginings, you know, it can be really telling.

Dreams were a common topic of enquiry for adult homeopathy consultations and several practitioners mentioned they would also ask about dreams with CYPs. This was presented as a further way into the child's imagination and personal sensations.

Collecting information from other adults/school

Homeopaths varied in the extent to which they would seek out opinions and information from adults out with the main carer(s) with some expressing strong opinions both in favour and against the idea. Some explicitly said they would ask for school feedback when working with behavioural issues due to the unusual nature of the problem.

Ruth: You know I wouldn't ever contact somebody's school unless invited to do so by the parents really.

Mary: I often ask the mother to get some feedback from the school when its a behavioural thing.

Of those who would seek opinions from other adults, there appeared to be an awareness that this was filtered information and would be considered cautiously as a result.

Gloria: But you would have to bear in mind that it's somebody's view so you have to sort of make sure that that's not in anyway biased or manipulated, that they're telling you the information as it is rather than interpreting it

6.7.3 Information Gathering: Data collection tools

Two of the participants in this project have developed their own picture and activity based tools for use within the homeopathic consultation: Case Taking Tiger Flash Cards; and the "Hopes, Dreams and Feeling Faces" activity pack. These tools were developed by the practitioners originally for personal use, but in both cases have been made more widely available to fulfil a perceived need for other homeopaths. Both practitioners alluded to children preferring to communicate in non-verbal ways (as in the previous categories) and they used these tools to collect more detailed information which allows remedy choices to be more precise.

The Tiger Cards were developed by a practitioner with previous experience with children who has also studied play therapy (Lilian). The Tiger Cards seem to be well known in the homeopathic community, and several of the interviewed practitioners (experienced and novice) mentioned using them, or brought them out to show me. The cards seem to provide a useful structure to use with the children, a way of collected the detailed information that otherwise can be difficult even with an adult. The cards were reported to offer an easy way to initiate and deepen the communication, although one practitioner felt they were relatively superficial.

Tilly: I've got the Tiger Cards there, so I can say to them, if they're sort of very young children or children who don't know how to articulate how they feel, I can say when you've got a cough which tiger are you and they can point and, you know, if you're hot or cold and get them to point.

The "Hopes, Dreams and Feeling Faces" pack came out of the second practitioner's previous work in childcare dealing with abused children (Jean). Various expressive faces are used to help the children answer specific questions, plus there are activity sheets for body drawing, hobbies and a genogram or family tree. Both tools bring the focus directly onto the child without the practitioner sitting opposite firing questions out, while the activities in the "Hopes, Dreams and Feeling Faces" pack could lead onto more information being volunteered about family relationships.

Jean (from article): The shared activity (filling out the genogram) takes the spotlight off the family, yet apparently incidental revelations about, for instance, their unique coping strategies and who the child most closely resembles, provide the insights we need in order to prescribe effectively. It is rarely necessary to ask 'how do you feel about that' because it is volunteered as part of the spontaneous interchange.

All [of these activities] reinforce the sense of the child as expert, whilst giving the parent the scope to add their perspective. Most importantly, concrete physical modalities emerge that prove so valuable when differentiating between remedies.

An excerpt from the Tiger Cards is presented in Appendix 15 (pg 461).

6.7.4 Summary

Non-verbal data collection methods such as observation were considered to be crucial in a homeopathic consultation. When working with CYPs, and especially with the very young patients, non-verbal strategies became even more informative. Observation was felt to be an important skill, and there was an awareness that adults observing children are in some senses outsiders who have to be careful to avoid making premature judgements. The use of props such as a toy box and art materials were covered in some detail - attitudes among practitioners ranged from being unsure of how to use these tools, to being interested in the specific toys that were chosen, or focusing on the way the child interacted with the items.

Verbal strategies were overall reported to be similar to those used when working with adults, although the depth of conversation might vary with age of the patient. The common elements

were asking fairly direct questions about feelings and reactions to the weather, situations or foods. Questions about dreams were also common in both adult and CYP consultations. Talking about favourite book or comic characters was more associated with CYP patients, and negotiating time periods to discuss awkward subjects was mentioned only in the context of children and adolescents. As elsewhere, practitioners demonstrated awareness of social pressure which might affect CYPs answers, so some of the direct questions such as what are your favourite foods were deliberately phrased to encourage an honest answer rather than what the parent might be expecting the child to say.

Two of the interviewed practitioners have developed data collection tools which use a mixture of verbal and non-verbal communication to explore how CYPs feel about their health and other preferences. Both tools are intended to offer structured and easy to understand channels of communication that can be used with pre-verbal children as well as those who are less confident about voicing their opinions.

6.8 Balancing parent and child perspectives

This category starts to draw out some of the ways in which working with CYPs may differ from treating adults - although what is not clear from the data is how many of these aspects are unique to homeopathy, and which might be shared by CYP oriented healthcare services more generally. These practitioners' experiences of working with children in the past, and the types of training they have received influenced their attitudes to collating information from parents and children, including the emphasis which they placed on both sources. The way in which adult and child perspectives were sought, evaluated and incorporated into the homeopathic consultation can be seen as sitting within the category of data collection. It has been drawn out into a separate category due to the importance given to these ideas by the homeopaths I interviewed.

6.8.1 Talking to the child and/or the parents

Consultation focus

Practitioners clearly had different ideas about the ages at which generally children could be used as a good source of information, although I wondered if perhaps those who were happy to rely on less verbal or less articulate responses were thinking of the younger age groups. These quotes seemed to be more about the age at which children actively participated in the consultation rather than when they might be considered to be reliable sources of information.

Tilly: Two, three years - older ones yes, you know, four years onwards they'll often speak to me, you know, it might just be a small amount but they will contribute.

Anne: Teenagers, again you would say that they will behave differently if the parent is in the room or if they're not. Again I would treat them as an adult to be honest, a 12 year old child it would just be case taking to perceive what their problem to be and talking about it.

Clearly interaction and information is expected even from the younger children but full verbal engagement may come later, and sometimes this was initiated by the child themselves:

Lilian: I think from around about 10 years they're beginning to realise that the point of the conversation is between me and them and they will set aside their toys in order to make the contact because they feel quite strongly that they don't want somebody to talk on their behalf all the time.

The survey used a closed response question aimed at establishing the overt focus in a consultation. The majority of respondents reported directing questions to both the CYP and parent (63%) while a substantial proportion (34%) asked mainly the CYP. See Table 6.11.

Table 6.11: To whom questions in a homeopathic consultation are directed (survey results)

	Frequency	Percentage
Mainly CYP	13	34%
Both parent and CYP	24	63%
Mainly parent	0	0%
Missing	1	3%

Presence of child/young person and adults

Table 6.12 on the next page provides details of who was likely to be present in a homeopathic consultation based on the survey responses.

Based on survey responses, the parent(s) and CYP would be present for most first consultations when the child was 5 years or younger (79%). Examination of the free text comments indicated that sometimes other people might also be present (grandparents or nanny). Phone

Table 6.12: Child and parental presence in homeopathic consultations

	Initial Consultation Freq (%)			Follow-up Consultations Freq (%)		
	0-5 yrs	6-12 yrs	13-17 yrs	0-5 yrs	6-12 yrs	13-17 yrs
Present	0 (0%)	0 (0%)	4 (11%)	0 (0%)	0 (0%)	8 (21%)
CYP only	30 (79%)	29 (76%)	18 (48%)	30 (79%)	28 (74%)	16 (42%)
Parent and CYP	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Parent only	4 (11%)	7 (18%)	12 (32%)	4 (11%)	8 (21%)	9 (24%)
missing	3 (8%)	1 (3%)	3 (8%)	3 (8%)	1 (3%)	4 (11%)

The table represents respondents who clearly ticked one option. Where the respondent ticked multiple boxes, this was classed as though they had ticked 'other'. Phone consultations were available as an option for first and follow-up contact but were not selected as the main form of contact by any respondents.

consultations or face-to-face contact with the parents only was also mentioned, particularly if the visit would deal with sensitive issues (i.e. behaviour) or the child might be uncomfortable with the topic. Parent only contact was also mentioned if the child was described as “uncooperative, uncommunicative or secretive”.

The usual pattern was for both parent(s) and CYP to be present for the follow-up visit (79%). Some variations were mentioned such as the use of telephone or face-to-face follow-up with the parent only (but only if child has been seen previously), or a telephone check-up with the parent and a later full follow-up in person with both parent and CYP. Regular phone consultations between actual appointments were also mentioned.

A similar pattern was observed for children aged between 6 and 12 years. The majority of respondents said that they would see both CYP and parent together for the first and follow-up appointments. The free text responses indicated that there was the possibility of seeing the child on their own for a portion of the consultation. Any time alone with the child would be discussed and agreed with the parents, one response stating that it would only be used if felt to be beneficial. If the child was seen on their own the parent would usually be in the next room. Again other family members or close adults (e.g. nanny) might be present, and respondents said that they might speak with parents only before seeing the child in sensitive or embarrassing cases. Telephone follow-ups might be used with parents, but potentially the CYP would be included in this. Follow-up with parent only would only be used where child had been seen in a first visit, but might be useful for example if the CYP was of school age to make attending appointments easier.

With older children and young people aged between 13 and 17 years, the most common response was still to see CYP and parent(s) together at a first consultation (48%). Seeing the CYP alone was mentioned more frequently than in the previous age groups. Many of the ‘other’ responses described seeing both parent and CYP initially with a portion of the consultation on CYP alone. Some respondents said that they preferred to see CYP alone for at least part of the consultation, although some CYP’s preferred to have parent (s) present, while some respondents said they would rarely see CYP’s alone. As before, seeing CYP alone was something that was discussed and negotiated by all involved parties.

Answers to the question about follow-up consultations gave a much stronger sense of seeing the CYP on their own, whether this was for the whole consultation or for a substantial part. Many practitioners would still see CYP and parent (42%), but of these some might see the CYP on their own within the consultation. One respondent reported that they would see CYP alone after the first 10 minutes of a consultation. CYP alone was mentioned particularly for teenagers,

but this was still a negotiated decision. Parents might still attend alone or be contacted by telephone to discuss the CYP in more depth.

Seeing the child or young person without the parent or other adult present was brought up as a potential strategy in the interviews as well, although feelings about this tended to vary considerably between practitioners with some preferring NOT to see the child alone (Mary). One practitioner mentioned using an initial information leaflet as a way of introducing the idea of seeing the child on their own to the parents (another way of building the relationship with the parents too). As in other areas, the idea of seeing a child on their own was also framed in terms of what the child might want to do rather than being an essential component of the session.

Tilly: I sent a little leaflet out to parents explaining I think it's good if I can see the child on my own, if the child and parent are comfortable with it and they can wait, you know

Lilian: it's more that's what they want, they want to have a talk on their own. I think it's a huge thing for a child to sit with a homeopath on their own actually

Value of seeing child/young person alone

Seeing the child on their own was felt by some homeopaths to potentially represent a valuable source of information which could clarify the issues as perceived by the child, without any modification to take account of the parents or other adults present. Practitioners clearly acknowledged that in some situations the children might respond quite differently to some questions without an adult present, or might feel able to offer different information. This was felt to be particularly important when treating older children/teenagers.

Jean: in that, what less than 5 minutes there's plenty of time for children to say, well actually this is what's going on, so it can work out quite well. Because I think the problem is, children have really well developed antennae of what is going to be acceptable to the parent sitting there and they really don't want to add to any existing problems

One practitioner in particular raised the issue that sometimes there may be too many adults in the consultation, and in these instances seeing the child alone can provide a useful contrast.

Violet: Quite often you'll get a mother and a grandmother, for example, so you've got, you know, a way too load of adults in there, sometimes the mother and father together.

Ethical constraints

Ethical issues were discussed in the interviews and those practitioners who saw CYPs on their own were clear about how they would then handle sharing that information if needed. Where possible the child would be encouraged to then talk to the parent in the presence of the homeopath, partly so the child then feels supported and empowered.

Jean: teenage girls in particular just pour out their hearts but then the problem is that I then have to get their permission to say to their mums, look they're feeling suicidal and the mums then beat themselves up for it because they hadn't realised or get very angry because they think she's just being a drama queen, but either way, you know, it seems to be very critical of the parent.

Issues of ethics were also raised by respondents in the survey. Several homeopaths mentioned needing criminal records checks to enable them to see children under 16yrs on their own, or seeing teenagers on their own only if the parent was in the building, or not being allowed to see under 16's on their own at all. Phone consultations with parents only were mentioned if the CYP themselves was secretive or uncommunicative during the face to face session.

For some practitioners the relationship itself might need to develop before the child would feel comfortable being on their own with the homeopath - so it was not necessarily a strategy that could be used straight off. The balance of time spent with adult and/or child also may shift between initial and follow-up consultations.

Tilly: Follow-up they might spend longer with me and mum will spend less time. As the relationship develops, they're often more comfortable spending longer with me and start telling me more.

Those homeopaths who did not see the children, either alone or sometimes at all, explained this in terms of sparing the children's feelings, avoiding confirming negative labels or stereotypes. One practitioner mentioned that she found it very difficult to interact with children who were firmly set in a 'bad child pattern'. Although one practitioner (Mary) felt seeing the child was less important than voiced by other respondents, she framed this in terms of avoiding needless upset to the child, avoiding the associated risk of damaging the relationship between CYP and homeopath.

Mary: I often find it's unnecessarily uncomfortable for the child, and I think you'd do as well just seeing the mum.

6.8.2 Disagreements - *it's all information*

In a consultation which involves more than one person or perspective, and particularly where there is a child/parent dynamic present, disagreements occurred when answering questions or even prioritising problems/symptoms.

Ruth: it's quite often interesting the difference between what the parent has said on the phone and the child's understanding of why they've come, there's often some disparity between the two

Resolving or at least dealing with these disparities can be challenging in any healthcare situation, particularly where the child is intended to be the focus of treatment. Since homeopathy is very much about understanding the individual's perceptions, feelings and reactions, gathering this information through the inevitable filter of a parent or adult is likely to create new challenges. The following paragraphs outline some of the strategies which practitioners mentioned in interviews when asked about dealing with these disagreements or disparities.

Seek further information To overcome disagreements between children and parents, one favoured option was to take the initial piece of information almost at face value, and seek further details. This was expected to identify if there was a real contradiction, if the child was contradicting as part of a behaviour pattern (therefore useful for remedy choices), or if there had been a misunderstanding.

Gloria: it's difficult to know whether they're contradicting because they can or, you know, the contradiction is true. I would probably ask for some more information from the child, if they're willing to give it. And try and work out what was fact or not and if I wasn't sure may not use that information if I was totally unsure about it.

Treat the disagreement as information In situations where there continued to be a disagreement between adult and child, and no further information was available or helpful, the practitioner might choose to proceed with caution and treat all the data as information. The opposing points of view are filed away for information, and the practitioner might reaffirm that the reality they are most concerned with is that of the child themselves.

Anne: Proceed with great caution [laugh]! I suppose in very gently and very diplomatically hint that the reality that I'm concerned with is that of the child and not anybody else's.

George: Well it's all information [laugh], you know, I make a note of that and I suppose you make a judgement about, you know, how to get very different information about what's going on and be aware of.

With older children, or where the disagreement seems to be particularly difficult or important for the child, some homeopaths would see the child on their own at the next appointment for a short time to allow open discussion of the child's opinions.

Using own judgement Almost all homeopaths also gave examples where they had to use their own judgement as to which version of events to believe, or use in choosing remedies. This usually occurred after talking through the issue in some detail. It also was affected by how well the adult was felt to know the child, or how observant the homeopath felt the adult was.

Violet: what you're doing is working out how well the adult knows this child and some of them don't perceive accurately - so that will vary from situation to situation but I try to believe the most credible in my own experiences and perceptions.

Remain aware of social pressures The idea that both children and adults may adjust their answers according to social pressures was present in the interviewed homeopaths responses. This was reported to be a complicating factor as either or both child/parent could be influenced, and therefore the information may be less reliable. If the homeopath felt certain that the child was answering in a particular fashion that did not represent their true feelings, the practitioner has to decide if this is being done purposely, due to social/cultural pressures or reflects real lack of awareness.

Jean: children have really well developed antennae of what is going to be acceptable to the parent sitting there and they really don't want to add to any existing problems and it's not that they're being deliberately sort of deceptive it's just that children learn very early what is a social norm

Jean (who works with children in difficult situations via an adoption agency) also placed less emphasis on seeing the child herself, and mentioned that this was a shift from her usual practice [demonstrating learning and change via experience]. Again this was couched in terms

of minimising stress and avoiding any further confirmation of negative labelling which might already have occurred.

Jean: I don't always see the children and that would be because they've already been to so many psychological assessments, all kinds of developmental learning, behavioural tests that just throwing in another adult sort of confirms their low self esteem that there's something wrong with them.

6.8.3 Ideas of change after treatment

The idea of balancing between CYP and adult perspectives emerged again when considering follow-up visits and assessing change following treatment. This was often alongside feedback from the parent and could raise the challenge of conflicting reports. Here the homeopath had to decide which piece of information to place more weight on, including in situations where the child may not feel able to express their own opinions.

Anne: You've got to see for yourself and make your own opinion, you can't take the opinion of an adult, they can be too close.

George: it's trying to get the perception, your own perception and the perception of the parents and the child as to whether anything is different

As one practitioner described, at times the child may directly contradict the parent as to whether there has been any improvements. This was a sensitive area and as the quote below shows, it is the perception of the child which is ultimately of most importance to the homeopath.

Mary: Some of them [the children] are very forthright and they will contradict their mother and they tell them exactly, and they often get to the point where they are telling the mum when they need another remedy. So they are very clear themselves on whether this helps or not. It has to be handled quite delicately I suppose. I'll probably point out to the parent that if the child is doing well and the child thinks it's doing well, I could probably explain to the parent what a healthy response is and if the parent thought the child was doing well and the child didn't, I would probably think the child probably had more idea, so I'd question that further and try and make is clearer for everybody.

We can also see the suggestion of dissonance between the opinion of the homeopath and the parent in the following example. Gloria discussed a case where the young boy she was treating had various health issues, and was unusually careful of staying clean and tidy at all times. Following the initial remedy prescription, one of the first changes was a reduction in obsessive cleanliness which pleased Gloria who felt the boy was expressing more normal childhood behaviours, but not the parent, who was quite disappointed.

Gloria: I would think that's perfectly beautiful, you know, but the parent, who was totally fastidious, may think it's not good enough.

6.8.4 Gathering information from the parent/guardian - *your search lights on the child*

This theme tackled some of the more difficult issues in working with CYPs who are likely to be accompanied at most or all times by an adult. Practitioners suggested that the level of meticulous detail which a homeopathic consultation requires can be difficult for a CYP to sustain. Therefore having an alternative/additional source as well as the child can be very useful. The parents' perception of what is going on for the child was seen as valuable by the practitioners; some of the information collected from parents would be difficult or impossible to collect from the child (medical history, family history, pregnancy details) and this can be helpful in finding the right remedy. Some practitioners mentioned getting information before the first consultation involving a child in different ways and for different reasons. This might be by phone, email, letter/questionnaire, or the homeopath may prefer to see the parent on their own first.

Seeing the parent alone, or gather information from them prior to the consult was seen as valuable for the following reasons:

1. makes the consultation easier and does not take up valuable time with the child when the information is more routine (such as pre-birth info, vaccinations and reactions to daily life)
2. sometimes the problem that is to be treated or associated symptoms might be quite embarrassing for the child so easier to gather some of those details from the parent before or after the consultation
3. sometimes the practitioner may want information from the parent that is less appropriate to say in front of the child - Mary gave examples of some very direct questions about character and personality

Parents were seen as valuable observers and sources of information, Jean mentioned this in relation to her work with adoptive parents although she did distinguish them from average parents. In general the information collected tended to be of a more practical/factual nature in terms of family health history. Information that could not be gleaned from the child in terms of early life and pre-birth experiences was gathered via the parents or other adults.

Gloria: information about the pregnancy and the birth, how the child was as a baby those sorts of things and anything that the parent has noticed

Tilly: Then I'll run through things that make it better or worse, what the coughs like, the symptoms, how the child is with it, whether they're clingy or do they get angry and bad tempered and then I look at the bigger picture. . . I can then build up a picture of how their health has been from the day they were born and how they responded to vaccinations,

Where parents responded to questions with their own interpretation of events/causation the practitioner had to consciously try to separate out the facts from the interpretation.

Gloria: well for example a parent saying, she behaves like this because of this when it may not be because of that it maybe something very different, so the parents are making assumptions that the reaction is due to a particular stimulus when it maybe nothing to do with that, it could be something quite different

Parents could also provide a useful way of a child communicating difficult issues to a relative stranger as in the following example:

Lilian: you want to ask them about their fears but some children are really happy to whisper in mums ear and mum writes it down on a piece of paper and puts it in an envelope and gives it to me, its one of those sorts of little rituals, you know, and the mother is becoming a handy conduit to get the information across.

Here the homeopaths are using the parents to collect adult perceptions of the problem and information on the child's behaviour/temperament/preferences. Parents could provide a detailed history linking to the idea of using parents selectively where most beneficial. Taking a detailed history is one of the fundamental skills emphasised in homeopathic training and a patient's history is seen as very much influencing current ill-health and the choice of remedies. There has been an increased interest in CYP-oriented research generally in recent years, moving

from merely interviewing or observing children to using innovative research methods that encourage engagement (e.g. using disposable cameras) and involving the CYPs themselves in the research design stages. Although most of these homeopaths did not explicitly talk about addressing issues of power imbalances or lack of ownership, the way in which the consultation was conducted and the emphasis placed on the child's perspective strongly echoed these movements in research more generally.

6.8.5 Summary

Every homeopath who contributed to the project consistently talked about the need to take the child's views and perspective into account, although not all of them would want to see a child on their own. The parent or guardian was described as a valuable source of information, a search light, that could add in details relating to very early life experiences and reactions. The views of parents were taken into account, but the focus continued to be on the child's own perceptions and reactions. Where disagreements occurred a variety of strategies were employed to balance conflicting opinions and reach resolution.

6.9 Assessing change and progress

The way in which homeopaths assessed the impact of the remedy they have given follows from related aspects of Personal Style, Training and Background and Model of Health. Some of the material which demonstrated the principles of homeopathy - the return of old symptoms, treating layers of disease, increased resilience to illness - have already been discussed in terms of models of health and disease, but these also impacted on the assessment of change at follow-up appointments. The follow-up, whether carried out by telephone or in person, had the following functions: to establish if there has been any change in the presenting case; to look for improvements likely to be a result of the remedy prescription; evaluate if a further prescription is required - and if so are any changes to the remedy/potency/frequency needed. If it is a particularly difficult or intransigent case the practitioner may end up retaking the case if they feel there is important information still missing.

The potential for the return of old symptoms, variable response to remedies and the different perceptions of change are again all aspects of any healthcare interaction, but have particular resonance within homeopathy. As discussed in Models of Health and Disease, and again in Building Relationships with the Parents, the model of health that homeopathy operates on implies that symptoms may not improve in a linear fashion. This may be discussed again in

a follow-up consult to help the CYP and adults understand the process, and perhaps improve concordance. As in the category Balancing Perspectives the homeopath is still moderating between the feedback from CYP and parent or adults who may have a very different perception of the impact of treatment. Examples are given in the following sections where the practitioner has moderated the parental response with their own perceptions. Table 6.13 on the facing page sets out the contributions from each data set.

6.9.1 When to follow-up

In practical terms there appears to be a consensus around having some sort of contact after 4-6 weeks either by phone or in person. Only one interviewee expressed any particular reason for this duration, other than that it seemed to be a case of doing as taught and following convention within the homeopathic community. A couple of instances where this sort of protocol would not be followed were offered by practitioners, for example where money was an issue.

Violet: I usually make an appointment for a month's time. Four weeks is good, 10 days I think is too soon unless you're just having a check-in. Six weeks gives people time to forget what happened in the first 3 days so I would say 4 to 5 weeks is the optimum

Anne: Others I will say, if you need to come back, come back, you know, some people will say I've really saved up to come here, so again it's, you know, if they have any problems

The specific timing for a follow-up related to ADHD or working with children was raised where a faster response might have been expected. Although some practitioners such as Lilian reported that this would not change for children with ADHD, most homeopaths indicated they would want to see the child sooner than normal.

Mary: I'd probably see a child up to three weeks the first time, especially with attention deficit, you can get a short term improvement, and if you leave it too long the mother will have forgotten all about it.

For some practitioners it seemed particularly important that there was contact or at least the option of contact throughout the period between the first and second appointments. Reasons given for this included: gathering information about short term or immediate changes; providing reassurance for parents/children who may be nervous about the treatment process within

Table 6.13: Matrix of contributing data sources (Assessing change and progress)

<i>Assessing change and progress</i>	<i>Published Papers</i>	<i>Survey</i>	<i>Interviews</i>	<i>Observations</i>
<i>Timing of the follow-up</i>	Data reported	Data reported	Data reported	Data reported
<i>Questions asked</i>	did not arise	Specific questions asked with closed tick box and open options to answer	Targeted questions asked	partially addressed in workshop on CYP Homeopathy
<i>Perceptions of change</i>	did not arise	not covered	Emerged from discussions about how the practitioners judged if there had been a change	addressed in SoH conference and workshop on CYP Homeopathy
<i>Variable responses</i>	mentioned in some case studies as an illustration of having not yet found the correct remedy	not covered	Emerged from discussions about how the practitioners judged if there had been a change	touched on in all observation scenarios, constant across adult and CYP situations
<i>Formal assessment tools</i>	detailed in all of the clinical trials	Specific questions asked with closed tick box and open options to answer	specific questions asked about this: Tiger Cards came up most often	mentioned briefly in CYP Homeopathy workshop, noticeably absent from presentations at the SoH conference

homeopathy; dealing with the possibility of aggravations. Gloria raised the issue about having parents discuss any increase in symptoms or new problems with her before going to the doctor, which might from a homeopathic perspective cause a set back in the treatment. Two practitioners specifically mentioned that they encouraged contact from the children which was part of enabling them to take a more active part in the treatment - this links in to the building relationship and balancing child/adult themes.

Ruth: LMs act faster so would want more frequent contact and opportunity to change the remedy more often, as constitutional remedy can 'throw' out symptoms and cause confusion/worry. Contact would allow her to explain and reassure, also to deal with aggravations.

Gloria: Some people have open access to contact me at any point and emails really useful for that because I can whip off an email or make a decision if I need to speak to them or not.

Follow-up beyond the second appointment seemed to be a mixture of standard appointments at 4-6 week intervals, or simply as needed and judged necessary by patient/parent/practitioner.

At the Society of Homeopaths conference where two well known homeopaths who specialise in the treatment of ADHD and other behavioural problems were presenting, there was relatively little attention paid to the issue of follow-up, recovery time or quantifying the improvements.

Within the published case studies and theoretical papers, little information was reported on the follow-up schedule. The clinical trials reported timing of follow-up sessions in more detail.

The open label phase of the major Frei et al. (2005) trial used four-weekly follow-ups. An indefinite number of follow-ups were allowed at this stage and medicines could be prescribed or changed until a successful response was obtained. There were no follow-up visit during the randomised and blinded section of the trial. Most survey respondents (66%) felt they would use a similar follow-up duration to that used in the Frei et al study. Those who disagreed (21%) reported that they would not only use phone follow-ups, would follow-up at 4-6 weeks/2 weeks on phone, 4-6 weeks in person, see patient when remedy runs out, or see the patient monthly "for as long as it takes".

Lamont (1997) used an unusual process where following the initial prescription all follow-up was carried out by telephone around 10 days after the remedy was given, there was no further face-to-face contact. Strauss (2000), who used a formula medicine, followed up patients at 30 and 60 days in person where the child and adult completed relevant scales and tests. Survey respondents who rated this as similar to their practice (32%) said that they might follow-up

this soon if felt to be necessary, others said they would follow-up between 10-14 days after a prescription if needed. The majority of respondents reported this was dissimilar to their practice (60%), which would commonly involve follow-up after 3-4 weeks. Some said there might be contact before the one month mark if required, but this would not be a full follow-up appointment. Some said they would be unlikely to change the remedy so soon, and that the follow-up duration was too short to see any effect.

The final study by Jacobs et al. (2005) separated out follow-up visits where the purpose was to monitor progress using tests and scales from the 6-weekly homeopathic consultations where the practitioner operated as normal. Follow-up after 6 weeks was judged to be similar to 63% of survey respondents practice although they might see the child more frequently at the beginning of treatment when more support might be needed, and 4 weekly follow-up was mentioned. Those who rated this as dissimilar to their own practice (24%) commented that they would prefer closer contact as the symptom picture developed, probably at 4-weekly intervals or less, and that this approach was too rigid.

Within the published trials, follow-ups were carried out with the CYPs present in only one trial (Jacobs et al. 2005), in all other cases only the parent or relevant adult was either present or spoken to by telephone. Overall there was less involvement of the CYP in most of the trials, which is in clear contrast to usual clinical practice as described thus far in this project.

6.9.2 How have you been, and other questions

This category covers both the style of follow-up questioning used by homeopaths, and also what seemed to be a strong tendency to ask a general opening question and then follow this up with targeted queries. Practitioners usually started off by asking a general sort of opening question e.g. "how the child has been", aimed at parents and child (if present). Some homeopaths specifically asked the child first and then went on to ask the parents. The child may feel quite strongly about whether there has been a change to the point of contradicting the mother (see also 6.8.3)

All of the survey respondents said they used a general opening questions such as "how have things been?" and almost all would also review the symptoms discussed in the previous consultation. Much smaller numbers would use drawing or handwriting as an assessment tool and relatively few (7/38) looked at school diaries or report cards. This last option would only have been relevant for conditions that impacted on education so it is unsurprising that it was used less often.

When a parent or child reported that there had been no change, the homeopaths mentioned that this might mean any of the following: there may have been no changes at all; there may have been changes in symptoms other than the presenting complaint; or the change may have been short-lived and forgotten. If there seemed to have been no change then this was questioned as it was assumed to mean:

a) there has been improvement but the patient/parent has not noticed - this is part of a definition of health - not being aware of a problem

or b) there has been aggravation

Violet: So first of all I'm looking for any change, if there's been absolutely no change I will still go through the previous case, you know what they've told me because quite often there has been some change

Regardless of the patient's initial answers, the practitioners usually went on to ask about the symptoms that were recorded in the last consultation, going through the list. The subsequent queries were focused on the symptoms mentioned in the initial consultation - almost a brief re-taking of the case. This process could be interpreted as almost mechanical checking off of items, or a very personalised assessment of change which the MYMOP type outcome measures attempt to replicate.

Anne: I will check off everything they said, have you still got this pain, have you still got this discharge whatever and just go through everything they said and see what's gone and what's not gone, everything has gone, have new symptoms come up or whatever.

As one experienced practitioner highlights, people may simply forget about symptoms when they are alleviated and not report their absence.

Mary: . If they say there's been no change, I'll say okay, yeah, and then I'll go through the consultation, and after that it will be clear to me and them if there has been a change.

Practitioners were interested in the perceptions of the parent and the child as well as their own perceptions as a homeopath. Their views were based on observation of the child, both physical, emotional and energetic e.g. sleep, dreams, energy level, relationships with siblings/parents or friends.

Jean: I check with the parent, normally the mother who's phoning or seeing to say, do you think we've got to the root of it or do you think we've just sort of taken the steam out of it and that's my way of sort of talking about expression

The specific areas that the follow-up assessment questions targeted were broader than just following up on symptoms. Some practitioners specifically looked for changes in personal likes/dislikes as well as behaviours, or changes in reactions to sensations such as pressure. General energy levels came up as a phrase used fairly often, though it was difficult to gain clarification of exactly what this referred to.

Tilly: when they'd finished talking I might just say, well I noticed something last time you said something about pressure, can you tell me a bit more about what that meant or.

Beth: Knowing child is better when invited to parties!

Change was discussed in terms of the symptoms - this might be the presenting complaint but might be something else which at least shows they are on the right track. It was also mentioned in relation to the way the child perceived or reacted to the symptoms. The practitioners then tried to decide if these changes were likely to be a result of the remedy, or other situational factors. Practitioners who mentioned this were those working in particularly challenging situations such as adoption support where it might be expected there were other ongoing interventions. It is not clear from this data whether practitioners assumed that change or a lack of change were related to the remedy prescription, or if they routinely assessed the impact of other factors.

Violet: and then I have to decide whether or not that change is actually owing to the remedy or whether it's to do with other circumstances

There appeared to be an interesting dichotomy between homeopathy which claims to prioritise the patient experience, feelings and symptoms, versus the practitioner who selects symptoms of interest to prescribe on, who questions the patient's perception of change and ultimately decides if there has been a change or not.

Observation was discussed in most detail in the context of an initial consultation but came up again when assessing progress or change. As before, observation as a category covered both observing the child, and child-parent/carer dynamic in the consultation and gathering information from other sources such as school reports. Direct observation of the child was mentioned as necessary in some situations in order to disentangle the parent's case from that of the child.

There were no data on the types of questions used to homeopathically assess change reported in the published papers.

6.9.3 Variable progress

There was a sense of being prepared to go in for the long haul in terms of the treatment relationship, which for one practitioner (Jean) might mean using additional remedies alongside the main or constitutional to deal with immediate concerns. One particularly experienced homeopath (Lilian) highlighted that it may be difficult to see where the end of treatment is within an ongoing and changing relationship, and as Beth mentioned there was a compromise to be achieved between a good enough improvement and the cost and time investment involved.

Lilian: But, you know, we're not in the process of assessing for assessing sake, we're actually trying to work out where we go next like, you're doing so well, you know, well done, off you go or okay, I'm not happy with this, I need to work further on this and maybe that's the [unclear]. It's very hard I think, it's very hard to sign off actually.

Ruth described a case where there was a need to balance both the child/parent reports with her own judgement to decide how much improvement had been achieved.

Ruth: So if we're looking at somebody who was getting a lot of anger then you would look at it in relation to the amount of stimulus and then decide, you know, make some judgement I think [unclear] whether it was in proportion or not.

Lilian specifically brought up the issue of accidental antidoting which may have interfered with the activity of the remedy, and highlighted how this appeared to conflict with the experience and teaching of two specialists in the area of homeopathy for ADHD in children.

Lilian: I was very surprised because actually I asked them a question just because I do remember because I have heard them speak before, you don't always think of coffee being a problem because children don't generally drink it but he had some cappuccino flavoured ice-cream and he was just up the walls and he anti-doted the remedy very significantly so I had to slightly go back to square one and go on from there, so we did a big u-turn back. But when I asked that question they said no they didn't think actually that was an issue, but maybe they've changed their views.

6.9.4 Perceptions of change

One of the potentially challenging areas of assessing change in a child seems to focus around perceptions of change. When a homeopath is working with just one individual the ultimate arbitrator of success/progress is likely to be that person, in contrast working with CYP involves far more than just the child and decisions of treatment success may in fact be determined by the parent/carer. Almost all of the respondents have made it clear throughout their interviews how important it was to have feedback from the child themselves – in person, by telephone or by email.

Tilly: One thing that I've always felt passionate about, it's important for children to say how it is for them, you know, that's really important.

Ruth: with a child, I always ask the child first, I do usually then go onto the parents and ask the parents what their perception is of how the change has been, if any

A further challenging aspect to assessing change is that the patient's inability to express how they are feeling may in fact be seen as a further remedy indicator, particularly if the homeopath is working within a constitutional remedy framework.

Anne: again that's useful because again you're seeing something about their personality that needs help in changing because they can't move or they need to stay where they are in their heads, you know, they're too frightened of moving on so that's another symptom, so again there are no rules on that. You know, I might think it's done well and they might not or they might think they are almost better and they don't know what they're doing.

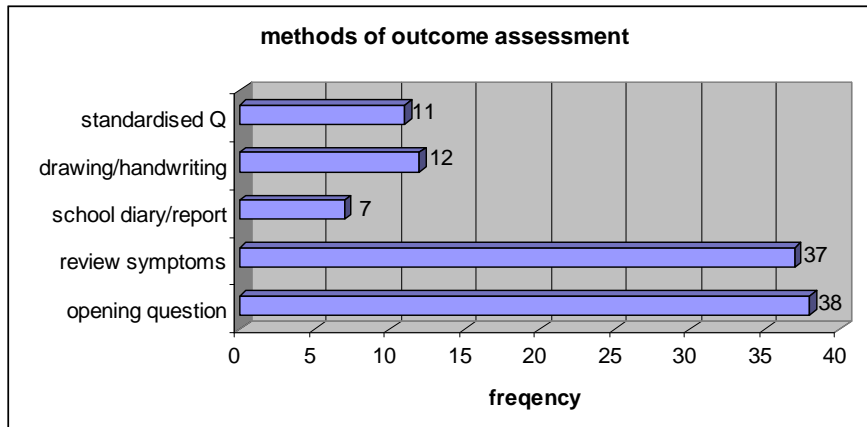
We can also see the suggestion of dissonance between the opinion of the homeopath and the parent in the example given by Gloria when talking about the tidiness of the child's room and their general appearance - the practitioner felt the child had improved dramatically, and actually by being less obsessively tidy was expressing more normal childhood behaviours, while the parent was quite disappointed by this change (see 6.8.3).

6.9.5 Formalised Assessment

Twenty-nine percent of the survey respondents said they used standardised questionnaires to monitor change, see Figure 6.3 on the next page. Most of these practitioners using MYMOP,

although some said they used it infrequently. Individual practitioners also used generic 1-10 rating scale or the SF-36 as part of their practice. The use of MYMOP is not unsurprising as the largest registering body for professional homeopaths (Society of Homeopaths) at whose conference this survey was distributed has heavily promoted MYMOP as a tool for practitioners in the previous 4 years.

Figure 6.3: Monitoring change in the homeopathic treatment of children



Eleven homeopaths said they used a standardised outcome measure, two of these respondents did not indicate what they used. Of the others, seven respondents said they used MYMOP, with some commenting that they used it infrequently. One respondent used a generic 1-10 rating scale and asked patients to rate various aspects of energy/health/pain using this. One respondent used the SF-36 as well as MYMOP as part of their standard practice within a community CAM service.

This proportion of homeopaths using formal assessment tools was largely reflected in the responses from those who took part in the interviews. Almost all of the interviewees had heard of MYMOP, and a couple of practitioners almost apologised for not using it. There seemed to be a perception that most other homeopaths were using these tools, although this assumption was not borne out by the survey data. None of the homeopaths who were formally interviewed or who were approached at any of the workshops formally assessed their practice or used auditing. The practitioners with specific experience of using MYMOP regularly or the SF-36 were also involved in research, or as part of a regularly monitored service, but did not use these in their personal practice.

Mary: No, sorry. I did use MYMOP for a while, but I stopped doing that. Yes, I found it very useful. I often use scales anyway. If I am finding it hard to tell if there's been an improvement or not, I'll say what number would you put that at now and what number would you put it at last time. So I did find that really quite useful.

Despite the relatively low numbers of homeopaths who reported regularly using MYMOP or similar tools, all of those with experience reported it had been useful in summing up the consultation and highlighting what the most important symptom was for the patient.

George: I think the most striking thing was a realisation that at times what a person felt to be the most important thing wasn't what you perceived to be the most important thing

It is worth noting that in all cases (survey and interview) participants were asked about their use of MYMOP or other tools when treating children. MYMOP has not been validated for use with children whether completed directly or by a proxy such as the parent. Based on the research workshop discussions, it appeared that those who were using MYMOP were not necessarily following the original format or instructions whether treating children or adults (e.g. talking to the patients and then completing the form as the practitioner). This is unlikely to be different from any healthcare professional who begins to use a tool, and then later adapts it, however it does have implications for the larger scale auditing exercises such as those promoted by the Society of Homeopaths.

George: But I moved away from that and I think I just felt happier actually asking the questions because I just sense you get more from a direct conversation rather than just standard answers on paper.

The published papers on ADHD and Homeopathy varied in their use of formalised outcome assessment tools. The case studies and case series did not report using anything other than practitioner judgement, while the observational study by Frei et al and the main clinical trials all used a more structured approach. None of these papers reported using an outcome measure tailored to homeopathy, or one that had been assessed in relation to homeopathy. Three of the trials used a well-known validated outcome scale designed for assessing ADHD symptoms - the Conners' Ratings Scales. Strauss used an older version (Conners, 1973) while Jacobs and Frei both used the revised forms CRS-R (Conners, 2001). Survey questions directly asked respondents about their views on these assessment protocols and are outlined below:

Frei et al (2005) used the full Conners parent-rating scale in assessment and unblinded follow-up, with the primary outcome measure being the Conners' Global Index-Parent form (CGI-P) which is a ten item summary scale. The smaller proportion of survey respondents (16%) who felt their evaluation methods were similar to those used by Frei mentioned preferring face-to-face contact, and enquiring about overall change as well as symptoms. The majority of those who reported their practice differed (74%) from the Frei vignette in evaluation methods reported

that they would want face-to-face consultations (especially for a first follow-up) that included parent and child to facilitate observation of any changes. Many said that they do not primarily use telephone follow-ups (but might be available by phone as needed), and one reason for this was the lack of accuracy for assessing change, and lack of input from the child. Some said they used rating scales, others said they never used scales, and one mentioned focusing more on well-being than just symptom improvement.

Jacobs et al (2005) used both the CGI-P and the CRS-R parent forms throughout their study yielding the most detailed outcome data. Most survey respondents felt that the face-to-face evaluation which incorporated a rating scale was similar to their practice (66%) - some commented that they also used a rating scale while others did not use any scales. Those who said this was dissimilar (18%) reported that they did not use rating scales, or that they assessed progress overall using the opinions of the primary carers.

Lamont (1997) used an unpublished 5-point rating scale of change in hyperactivity. Three trials reported using child-performance tests to assess attention and impulsivity. None of the case study reports or the community project reports indicated having used any kind of formal evaluation tools. Evaluation for this study was carried out by telephone with parent/carer using a scale of hyperactivity symptoms. The few survey respondents who said this was similar to their practice did not give any reasons for their decision (13%). The majority felt this was dissimilar (71%) and almost all of these commented on the lack of face-to-face contact. *"I would use proper face-to-face follow up"* They wanted to see the child again and ask broader questions. Some mentioned that they thought the rating scale might be useful but only in addition to other assessments.

6.9.6 Summary

This section has outlined the factors which constituted a follow-up consultation with a homeopath. The timing of the follow-up was discussed because although there appeared to be a fairly broad consensus of contact after 4-6 weeks, this differed markedly from some of the published trials. Homeopaths in the interviews and workshops mentioned the option of between-appointment contact, and that in conditions such as ADHD the follow-up might need to occur more quickly. Seeing the CYP on their own or only with the adults/parents present was covered in the survey, interviews and some of the workshops, as might be expected there was slightly more focus on seeing the CYP in follow-up sessions, particularly with older adolescents and teenagers.

The questions asked in a follow-up consultation were markedly more limited than in a first visit. The focus shifted from open associative style questioning that explored around symptoms, preferences and experiences, to working through a list of previously discussed symptoms. Where new symptoms emerged this was explored as in the first visit. Otherwise the focus was on an initial “how are you feeling” type question, followed by a careful analysis of the known problems. Interestingly most of the practitioners talked about taking the response to the initial question and placing it to one side before a judgement was made on the progress achieved.

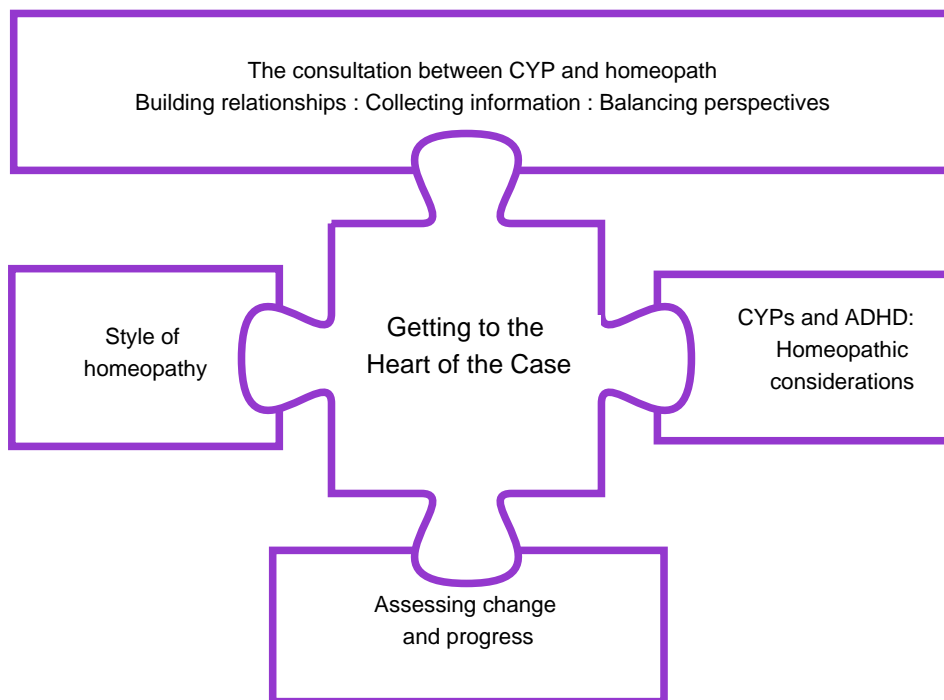
Across all the practitioners who contributed data to this study, there was relatively little awareness of or use of formal tools for assessment purposes. During interviews, the most recently qualified homeopaths mentioned being introduced to MYMOP during their training, although few went on to use it in their own practice. Homeopaths who routinely used formal tools were either operating within a clinical trial or working in a community health setting where tracking of patient data was prioritised. This picture was broadly mirrored in the published literature where only formal clinical trials reported using evaluation tools, case study reports tended to report an overall impression of improvement or the cessation of medication use. It is interesting that there appears to have been little uptake of structured assessment tools given the complex assessments and judgements being made in these follow-up consultations.

6.10 Discussion

The purpose of this section and analysis was to draw together data collected from primary and secondary sources that was largely qualitative in nature. Descriptive quantitative data were also included to assist in category development and demonstrate generalisability of the interview/observed populations. The process of model development has been described in the methods chapter and the introduction to this chapter. Grounded theory was used as a framework for the design, data collection and analysis of information relating to the practice of homeopathy, in particular relating to CYPs with ADHD. The systematic review and IPD analyses provoked additional questions around the practise of homeopathy, and provided some key topics to be explored (e.g. who is present during a consultation, what resources are used for prescribing, what is prescribed). While these topics informed the survey questions and initial interview questions, they did not limit the exploratory process. An organic evolution of data collection methods took place ensuring that as a question or area of interest arose, a suitable data collection method was adopted, for example observation was used to take advantage of a fortuitous seminar and to follow-up issues around how homeopaths dealt with research evidence.

This chapter has set out a comprehensive model that describes homeopathy in practice. It focuses on the homeopathic treatment of children and young people. It seems reasonable

Figure 6.4: Getting to the heart of the case (simple model)



however, that many of the elements of this model may be more widely applicable. The core concept according to grounded theory therefore is “getting to the heart of the case: how is homeopathy practiced”. A homeopathy which is practised by a heterogeneous group of individuals with a variety of previous experience, individualised in multiple ways to fit the needs of the presenting patient, and which is ultimately reliant on the subjective experiences of the patients themselves. Associated categories which contributed to this concept were: a personal or individual style of homeopathy; CYPs and ADHD in homeopathy; components of the relationship and assessing change and progress. Figure 6.4 provides a simple summary of this model.

One of the first questions was whether treating children and young people with homeopathy was different in any important way from treating adults. The initially confusing answer to this question was both yes and no. Yes, in the sense that the principles of homeopathy are believed to hold true regardless of age of the patient, or indeed species of the patient. The ideas mentioned under the sub-category of “model of health and disease/basic principles” such as the similia principle, smallest possible dose and the materia medica and repertories are still used for the prescribing of homeopathic remedies. However, most of the practitioners interviewed, surveyed and observed in this piece of research also felt there were important differences. These differences included the techniques used to establish focus on the CYP, the need to balance perspectives within the consultation, the methods used for collecting information and a lack of CYP specific repertories.

When treating CYPs with homeopathy is different - this raised the question of where does

the knowledge, expertise and information come from which allows the practitioners to do this. The category “style of homeopathy” illustrated that homeopaths draw on their pre-qualification experience where relevant, the limited training given (dependent on availability of specialist tutors) and textbooks or articles. The resources available to help with prescribing decisions appear to be relatively limited, provings and materia medica are often generalised from adult data to cover children, and the few CYP specific texts such as “Children’s Types” by Douglas Borland are collections of remedy pictures based on clinical experience. The use of a variety of prescribing resources has implications in terms of whether users will end up selecting the same remedy, the two published papers looking at agreement between homeopaths suggest that practitioners rarely agree on remedy choices, or methods of case analysis even when dealing with the same written information (Brien, Prescott, Owen and Lewith, 2004; Burch, Dibb and Brien, 2008). It seems unlikely that a similar study using CYP patients would produce any more reliable results.

The sub-category of “what shapes and changes practice” was particularly important for this project as it has implications for the education of homeopaths, design, construction and dissemination of trials in homeopathy, and ultimately how homeopathy will continue to exist in an increasingly evidence-based world. As has been highlighted throughout this thesis, very few of the challenges homeopathy faces within research are unique to this therapy. Equally the reactions of practitioners, and the way in which homeopaths make use of evidence is not unusual, and similar patterns can be seen in other healthcare professions. None the less, one of the key messages from this analysis has to be that the research which is being carried out on homeopathy for the treatment of ADHD does not in large part reflect homeopathy as it is currently practised within the UK, and perhaps not elsewhere in Europe or the USA. There was a broad range of opinions across respondents when asked if they would consider changing their practice in line with research on methods such as those adopted by Frei et al (minimal contact with the child, particular repertory and modified selection processes). Yet the positive result claimed by the authors will no doubt be cited by practitioners treating ADHD in a very different manner as an earlier example of practitioners citing the study by Lamont.

Trials which appeared to reflect more normal clinical practice failed to report the kind of information which this model suggests is crucial if we are to build an accurate picture of homeopathic treatment e.g. degree of focus on the CYP, relationship building strategies, data collection strategies and balancing of adult and CYP perspectives. Despite deliberately reading beyond the oft criticised clinical trials, the observational studies and case studies listed have also failed to report this information, while self-labelled experts in the area have not yet engaged with standard research procedures such as publishing case series.

A textbook which focused exclusively on case taking in homeopathy, encountered near the end of the synthesis, largely reflects many of the key categories which emerged from this model (Kaplan, 2006). This book was one of the very few to go into how homeopaths might talk to and communicate with children, and made it clear one of the main purposes was to “elicit reliable homeopathic data” (pp133). Dr Brian Kaplan also emphasised the need for more information on conversing with children in the homeopathic setting. The results from this section highlight the congruence between practical experience of important factors, and suggestions from authors like Kaplan. The synthesis also points to the varying attention paid to each factor by individual practitioners.

6.10.1 Limitations

Ultimately this project aimed to offer an insight into both the research around homeopathy for ADHD for CYPs, and the usual clinical practice of homeopaths. It was hoped to incorporate the perspective of the CYP themselves, however despite extensive recruitment attempts no such data could be collected. In an attempt to partially address this gap, the main discussion chapter includes data from qualitative studies of children with ADHD and those who have received conventional treatments. The main mixed-methods section of the research project was vulnerable to the following limitations. These are above and beyond the potential weaknesses inherent to the methods of data collection chosen which were discussed in Chapter 5 on page 115.

The majority of the interviewees, survey respondents and homeopaths taking part in the observed activities were based in the UK, and all but one were professional rather than medical homeopaths. It would be of benefit to extend this research to include medical homeopaths, in particular paediatric specialists, however there are very few such individuals and it was not possible to interview them for this research. Survey research by Anne Majumdar has suggested that while medically and non-medically qualified homeopaths (and acupuncturists) see similar presenting complaints, views on the effectiveness of CAM and conventional treatments vary significantly, with the non-medically qualified practitioners reporting higher levels of belief in the effectiveness of CAMs (Majumdar, Williams and Adams, in press). Non-medical practitioners also tended to see their patients for shorter consultations.

As mentioned previously, recruitment has been a significant challenge throughout this project. The response rate to the survey was disappointing, although it is unclear what more could have been done to increase this. At a busy conference it seems most delegates had neither the time or inclination to complete the forms. Despite a slow start, recruitment of interviewees largely met expectations and theoretical saturation did appear to have been met. It is undoubtedly true

that there were always interesting side-angles from the main research questions, for example the topic of how practitioners engage with and utilise research is very much deserving of further attention although this was not possible during this project.

The most challenging aspect of this section has been in relation to the synthesis of varied data sources. It has been methodologically difficult in the sense that this is a relatively new area of research and synthesis without a clear process to follow. The combination of primary, secondary, qualitative and quantitative data has increased the intensity of the well known 'drowning in data' phenomenon (Kelle, 2005). It has been important to keep track of the story running through the analysis, and to this end keeping a research diary and discussion with supervisors have been invaluable.

6.10.2 Strengths

This section in particular has tried to draw on a broad range of sources going beyond formal interviews, which have been subjected to a range of criticisms around the veracity of the information that can be gathered. Although it was not possible to observe any actual consultations, I did manage to interview practitioners across the UK including several homeopaths who have specialised in the treatment of ADHD and other behavioural conditions in CYPs. This has strengthened the model.

The inclusion and exploration of case studies and other published materials ensured that this was a less limited piece of research which might otherwise have excluded practitioner experience or the kind of resources most accessible to practitioners themselves. The use of grounded theory has provided a flexible framework to accommodate a variety of data types. It also facilitated integration across data sets which have allowed novel insight and understanding to emerge. In this way, and as discussed in Section 7.4.4, a deeper degree of integration across methods has been achieved.

Gaining access to two practitioner-oriented CPD workshops gave a unique insight into the areas of interest during development of the model and analysis, in particular relating to the use and understanding of evidence. Although the methodology was relatively complex, being able to return to key informants to discuss themes and categories during the analysis, access to two external advisors who are experienced in qualitative research in healthcare settings, one in a CAM therapy, and a supervisor with experience of mixed-methods research studies made the process relatively painless.

6.10.3 Quality of the research

The importance of attending to quality within qualitative and mixed-method research was outlined within Section 5.12 and will be considered more generally in 7.5 on page 278 for the project as a whole. The following paragraphs refer specifically to quality in relation to the mixed-method components.

As far as possible the project has worked to incorporate checks and balances during data collection and analysis periods. This section of the project has been guided by principles of good research design in the development of the questionnaire and qualitative data collection, and should be judged by the standards set by Spencer et al and Mays & Pope (Mays and Pope, 2006; Spencer, 2003) as discussed below.

Claim: The research has the potential to be contributory in advancing wider knowledge or understanding

Throughout Chapter 6 in particular, I have attempted to demonstrate how the findings are based on the collected data by presenting relevant quotations, questionnaire summary results and extracts from related documents. These findings are rooted in the raw data, but have also been discussed with key informants during the project to explore where the conclusions might resonate with or divert from their knowledge. Multiple sources of data have been used and in most cases serve to corroborate the findings.

A overview of the area followed by a detailed systematic review provided a clear picture of the existing knowledge base prior to beginning the mixed-methods phase, and the aims of the project were clearly grounded in the results of the review. The following chapter sets the findings from this project in the context of the attitude to homeopathy that now exists, and explores where further research is still justifiable.

An honest appraisal of the strengths and limitations to the project has been offered above. In terms of meeting the study aims and objectives, the project has produced a detailed and coherent model of how professional homeopaths interact with and treat children in their practices. Specific considerations relating to ADHD were drawn out, however the majority of the findings seem relevant across other medical conditions. This information can contextualise the results of the efficacy trials identified in the systematic review, and has relevance for homeopathy research in general since the majority of the data were collected from general practitioners and sources. The absence of the CYP voice in this research due to practical constraints has been noted. The lack of a synthesis of the qualitative research around CYPs with ADHD taking medication/receiving treatment is also clearly absent from the evidence base within conventional medicine, suggesting that our understanding of this angle is incomplete.

Claim: The research was defensible in design

As set out in Chapter 2, the design of this piece of research has been shaped both by emergent results and practical constraints. The choice to use Grounded Theory as an overarching framework reflected the topic area being relatively new, under researched and poorly documented - the structured methods were appropriate and could be implemented throughout.

Each of the data collection tools was chosen according to the available opportunities and the type of data being sought. For example, in-depth interviews with Key Informants helped to explore interesting aspects of homeopathic treatment relating to the published trials; documentary analysis was suitable for looking more broadly at the information available to practitioners; questionnaires allowed a broad sample of opinion to be collated; while multiple interviews with practitioners provided the opportunity to gather detailed information about individual practice characteristics, and participant observation permitted participation and insight into practitioner focused events.

The samples (of participants in each method, articles and book chapters) have been described in detail, and were chosen according to the method and data required. Within the documentary sources a relatively exhaustive process was used to identify as much material as possible, while the questionnaire was distributed to delegates at a relevant specialist conference, and a mixture of convenience and theoretical sampling was used to recruit homeopaths for interview. The concept of theoretical saturation was used to guide much of the sampling decisions, and while impossible to prove this was achieved, the main findings were well developed by the end of the process.

Claim: The research was rigorous in conduct

This principle has been addressed through transparent reporting of data collection methods, and analysis while adhering to best practice guidelines. Data collection processes have been described in the relevant methodology chapters utilising recordings during interviews, and detailed field notes. In retrospect it would have been helpful to record the participant-observation sessions as it was difficult to note sufficient detail and emotion within the discussions. The questionnaire was developed from initial interviews using best practice guidance and tested using think-a-loud procedures. There were some early problems with transcribing the depth interviews as mentioned in Chapter 5 (5.10.2 on page 146) where the transcriber omitted personal names and confused some of the homeopathic terminology. This was rectified as soon as possible, but has been mentioned for full transparency.

The potential impact of researcher identity was considered prior to beginning the research, and Section 7.6 on page 281 includes further discussion of where this may have influenced the available data. I have attempted to give an honest account of my experience of and beliefs regarding homeopathy, while listening with an open mind to all of the data sources.

The methods chapters provided examples of coding, and this chapter includes a matrix for each of the key areas indicating which data sets have contributed information. The use of detailed supportive quotations seeks to demonstrate that depth, richness and detail have been achieved. Where useful, additional information on the participants has been set alongside quotes, for example length of time in practice or school of homeopathic training. Negative case analysis was used where possible to interrogate the developing model.

Claim: The research is credible in claim

This piece of work has actively involved key members of the homeopathic community in design, data collection and analysis stages in order to promote resonance with the knowledge and experience of others. The use of a mixed-methods design helps to demonstrate consistency and boundaries of the findings and claims from the synthesis. These claims are discussed clearly with supporting evidence presented to help the reader evaluate the conclusions, while being cautious not to overstep the bounds of how far the results can be generalised. The settings in which the data were collected, and the cultural/social attitudes, are discussed in sufficient detail to allow an independent reader to evaluate the applicability of the findings.

6.10.4 Summary

This synthesis has presented an analysis of mixed-methods research which built upon the findings from a systematic review and exploratory IPD analysis. The central concept of Getting to the Heart of the Case helps us to better understand how professional homeopaths individualise their practice for each and every patient they treat, with particular reference to working with behavioural problems in children. The component categories have helped to define how this concept is developed for each individual homeopath, and how it is operationalised in practice, while reflecting on the presence and absence of these ideas within the clinical research literature.

The final chapter draws together the results and implications of the systematic review and IPD analyses alongside the synthesis which has generated this core concept. Key findings from the model are discussed with reference to the wider literature and implications for further research around ADHD and homeopathy, as well as homeopathy more generally, are presented.

Chapter 7

Discussion

7.1 Research aims and context

This programme of research sought to explore homeopathy for the treatment of ADHD in children and young people. The project has addressed the evidence for effectiveness, sought to describe what underpins such treatments, and describe how they are realised in practice. The research was commissioned during a period of strong interest in CAM research when homeopathy had been named as “one of the big five” in the House of Lords Report (2000). The five main therapies (acupuncture, homeopathy, osteopathy, chiropractic and herbal medicine) were earmarked for pump priming through the NCCRD. Reviews of ADHD at the time indicated that it was a condition with significant impact on the developmental progress of children, however the treatment options were relatively limited with little in the way of long term follow-up data, and an atmosphere of concern regarding the side-effects (NICE, 2000). An exploration of homeopathy for ADHD appeared to be both timely and to have the potential to affect NHS prescribing options.

The research aims for this project were divided between establishing the current evidence base in terms of RCTs, and exploring everyday clinical practice of homeopaths working with ADHD in the UK. As outlined in Chapters 1 and 2, these aims were based on an apparent lack of published evidence, the potential for RCTs in the area and keen interest by parents of affected children in finding alternatives to conventional medication for treating their children.

Homeopathy and ADHD: the research evidence

1. Describe the homeopathic treatment for ADHD as tested in clinical trials
2. Assess the efficacy and effectiveness of homeopathy as a treatment for ADHD/HKD
3. Evaluate the safety of homeopathy as a treatment for ADHD/HKD

Homeopathy for ADHD: clinical practice

1. How do homeopaths in the UK understand and treat ADHD in children/young people (CYPs)?
2. How do homeopaths assess the impact of their treatments on CYP's?
3. To what extent does the homeopathy practised in controlled trials of homeopathy for ADHD reflect usual practice for UK homeopaths?
4. Would UK homeopaths be willing to practice as per the controlled trials, i.e. would they change their practice?

During the five years of this research project, there were significant shifts in the attitudes to CAM research and homeopathy in particular. Two of the five NHS homeopathic hospitals have closed and there are significant threats to the continuation of the remaining three hospitals. There is no longer a CAM specific funding stream available within the Department of Health National Institutes of Health programme, meaning direct competition with more established conventional medical interventions and research teams. Some modalities appear to be weathering the changes, such as acupuncture which has relatively well accepted effectiveness in the treatment of musculo-skeletal pain. In contrast those therapies with less well established professional representation, and uncertainty around mode of action such as homeopathy, have seen a sharp decline in their fortunes. At the time of this project's initiation there were more than five university-based courses offering BSc (hons) programmes in homeopathy, plus several externally-validated courses which had been met with mixed reactions (Colquhoun, 2007). By 2011 it was reported by a well known science blog (David Colquhoun's "Improbable Science" <http://www.dcscience.net/>) that there were no BSc courses in homeopathy currently recruiting students (financial reasons were usually given by the universities), while the University of Wales had ceased to validate any external degrees after extensive criticism of their procedures (Colquhoun, 2011). Other universities such as the University of Central Lancashire and Thames Valley University continue to validate some courses offered by private colleges, but the overall number of courses available is much decreased.

7.2 Project Findings

7.2.1 Key finding: no significant benefits associated with homeopathic treatment for ADHD found in a systematic review

A detailed and rigorous systematic review with aggregate and IPD analysis failed to show any significant benefits associated with homeopathic treatment for ADHD. The IPD results strongly

suggest that the key factor in patient improvement was the baseline severity scores, rather than treatment per se. There was insufficient evidence to draw robust conclusions about the effectiveness of any particular form of homeopathy for ADHD given that only three randomised controlled trials had been carried out, and all trials were relatively small in size.

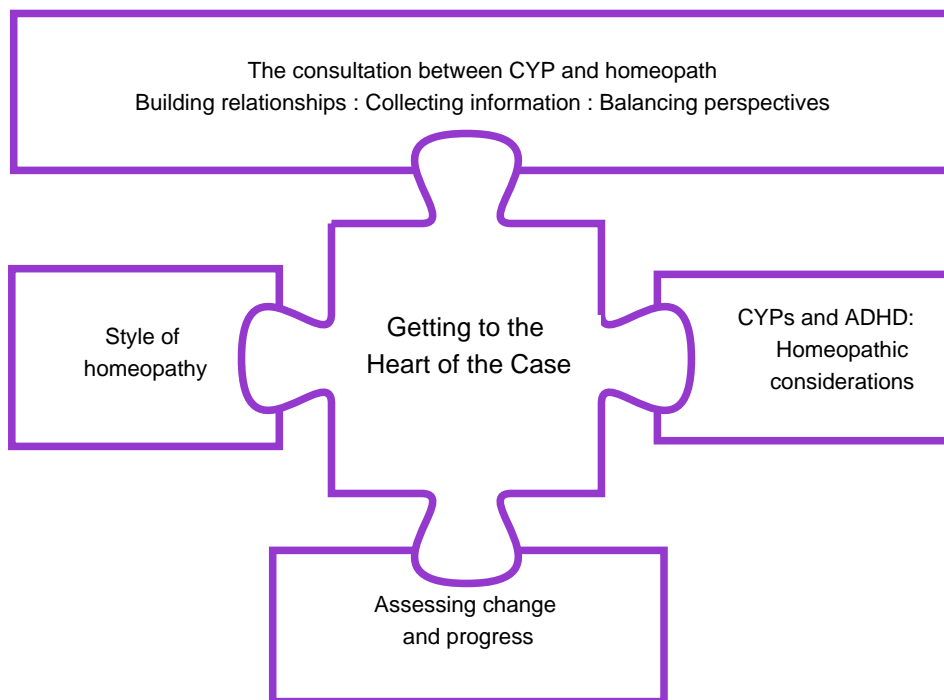
To restate the results in terms of homeopathic approaches; a trial of formula homeopathy found no difference between placebo and verum homeopathy (Strauss, 2000), a trial of classical individualised homeopathy that attempted to replicate usual practice found no significant difference between verum and placebo (Jacobs, Williams, Girard, Njike et al., 2005), and a trial of individualised homeopathy with minimised non-specific effects found a small but statistically significant benefit from homeopathy (Frei, Everts, von Ammon, Kaufmann et al., 2005). Even for those who might argue that it was inappropriate to have pooled these three trials, it is clear that the evidence base is uncertain at best about the impact of homeopathy.

7.2.2 Key finding: a model focused on “getting to the heart of the case” describes homeopathic treatment with children

A synthesis of data collected from primary and secondary sources that were largely qualitative in nature was used to develop a comprehensive model that described homeopathy in practice. It focused on the homeopathic treatment of children and young people, however it seems reasonable that many of the elements of this model are more widely applicable. The core concept was “getting to the heart of the case: how homeopathy is practiced”. The data suggested that homeopathy was practised by a heterogeneous group of individuals with a variety of previous experience, individualised in multiple ways to fit the needs of the presenting patient, and which is ultimately reliant on the subjective experiences of the patients themselves. Associated categories which contributed to this concept were: individual style of homeopathy; CYPs and ADHD; the CYP consultation: building relationships; and assessing change and progress (see Figure 7.1 on the next page).

There was broad agreement on the fundamental principles of homeopathy and a working model of health and disease, however each practitioner’s training, pre-homeopathy experience, personal preferences and further training affected the way in which these principles were implemented. As one key informant stated, homeopaths are often fairly independent individuals who dislike labels - attempts to draw together such individualised practices to summarise a treatment approach for ADHD can in retrospect be seen as unlikely to meet with success. While the homeopaths who contributed to this project were aware of ADHD and had a range of practical experience in treating this group, there was a lack of consensus about the details of treatment across practitioners. This was even more evident when bringing in documentary

Figure 7.1: Getting to the heart of the case: homeopathy in practice



sources such as textbooks, articles by well-known homeopathic experts in the area, and the published trial interventions. It was not useful or possible to try and describe what a homeopathic approach to ADHD would be in any detail. Many of the variables would have ultimately been labelled with “it depends”, which makes formal evaluation and documentation difficult.

7.2.3 Key Finding: the place of the child in homeopathy practice versus research is inconsistent

Whether or not we accept that a new social study of childhood emerged in the early 1990’s (Ryan, 2008; Christensen and James, 2000), it appears to be true that increasing attention has been paid to how we research with and on children and young people. Alongside the interest in the individuals experiences and a strong person-centred approach to health and social care, attention has also been focused on how this might apply to children. The Every Child Matters green papers (Education & Skills Committee, 2005) and Children’s National Service Framework (Department of Health, 2003) mention the importance of involving children in the design and evaluation of services.

Moving beyond an objective observational approach such as used by psychological research using tests of intelligence/ability, sociologists such as Proust, Jenks, James and Christiansen have promoted the use of varied research methods that allow children to contribute directly to research. Appropriate methods tend to be more qualitative in nature, however development

of pictorial health-report scales demonstrate that formulating the questions and responses in a manner that makes sense to children often enables them to give quantitative responses. The most common methods include: observation, interviews, creative methods, spontaneous narratives/elicited self-report; material props and visual prompts. Greene and Hill conclude their overview of the subject by emphasising that research with children is replete with similar challenges to that with adults, and should not be considered simpler or quicker (Greene and Hill, 2005).

Controlled trials of both conventional and alternative therapies for ADHD have generally relied on narrowly defined, symptom specific assessments without taking into account a broader perspective of expected change (Bjornstad and Montgomery, 2005; Heirs and Dean, 2007; King, Griffin, Hodges, Weatherly et al., 2006). Treatment which relieves ADHD severity is logically predicted to influence symptoms as well as peer relationships, emotional health and general well-being.

Reviews of outcome research in ADHD have called for a wider assessment of outcomes beyond diagnostic criteria (Schachar, Jadad, Gauld, Boyle et al., 2002; King, Griffin, Hodges, Weatherly et al., 2006). In the majority of trials of medication the outcomes have been assessed by a proxy such as a parent or teacher rather than directly by the child/young person. Although some symptom specific self-completion measures have been developed (such as the Conners Adolescent Self Report or parts of the Brown Scales) these versions are not commonly used in research, and self-completed quality of life measures are rarely seen in clinical trials of ADHD.

Research with children and young people has shown that they are capable of reporting accurately on their own health status from as young as 4 years (Eiser, Mohay and Morse, 2000; Riley, 2004), and their accounts may differ significantly from those of proxies in important aspects such as mood and social functioning (Verrips, Vogels, den Ouden, Paneth et al., 2000; Verrips, Stuifbergen, den Ouden, Bonsel et al., 2001; Eiser and Morse, 2001a). The literature around choosing outcome measures for trials involving children and young people strongly recommends that where possible multiple informants should be accessed including both the child/young person and main caregiver(s) or parent(s) (Eiser, 2004). Previous research has more than adequately demonstrated that children/young people (CYP) with attentional difficulties are capable of participating in both interviews and collaborative activities while articulating their experiences (Santoro, 2003; Brady, 2004; Clark, Kjørholt and Moss, 2005; Mukherjee, 2005).

The children and young people diagnosed with ADHD and receiving homeopathic treatment were clearly present within the survey, documentary sources and interview data collected for this project, although there was not necessarily consensus across all data sources. There was

broad agreement among the homeopaths and published papers that the heart of the case is focused around the child's unique experience of their symptoms. There was disagreement as to the most useful ways to tap into this information, and the extent to which the child themselves was the most important source of information. Practitioner attitudes ranged from one key informant who focused almost exclusively on the child during the consultation, allowing them to steer the conversation in large part and using a variety of communication modalities to encourage the child to express themselves. On the opposite end of the spectrum were practitioners who were interested in some physical observations but gathered the majority of their information from parental reports and interpretation of behaviour/emotional states. Parental reports were generally used to gather the factual information, but awareness of the potential for parents to subjectively interpret children's behaviour and responses varied across data sources.

The explosion of interest in research methods and findings within health sciences and CAM does not seem to have been replicated throughout homeopathy practice or research. Homeopaths are attempting to conduct interviews with CYP's and usually the parent or guardian present, exploring complex health states and symptoms with apparently little expert guidance or tuition. There appears to be an obvious opportunity to share information and techniques between social researchers and homeopathic practitioners, some of whom may be struggling with the challenge of collecting useful information, while simultaneously forming a bond with the child.

There was a notable lack of data collection from the children/young people themselves in the trials of homeopathy identified during this research. None of the studies reported using child-centred outcome measures or seeking the CYPs opinions on the impact of the treatments. Given the available research on the importance of including children's perspectives and opinions within their healthcare, and the ability of even young children to report on their health status and quality of life these issues should be addressed in any future research (Eiser and Morse, 2001d,a,c; Rebok, Riley, Forrest, Starfield et al., 2001; Wallander, 2001; Wallander, Schmitt and Koot, 2001).

Perhaps this should not be surprising given the lack of attention to CYP perspectives more generally within ADHD research, the homeopathy trials appear to have been modelled on similar pharmacological studies. Based on the most recent comprehensive review of treatments for ADHD (King, Griffin, Hodges, Weatherly et al., 2006): quality of life was most commonly measured using the Clinical Global Impression scale (CGI) or one of its sub-scales as completed by the clinician or physician although 38 out of the 65 papers included did not report any quality of life outcomes. Participant ages in these trials ranged from 5 to 18 years, though none of the assessments were completed by the CYPs themselves.

Overall, there was a clear discrepancy between clinical trials and reported practice when homeopaths work with children who have attentional difficulties. Although within practitioners there was a range of approaches all were clear that the child was the focus and priority. The trials of homeopathy were less clear cut with few details being reported on interactions with the children, with one trial (Frei, Everts, von Ammon, Kaufmann et al., 2005) explicitly trying to minimise contact with the children. Despite homeopathy usually being described as an individualised and person-centered therapy, there was relatively little evidence of this in the trials which followed the trend in conventional ADHD research by failing to include child-completed outcome measures or quality of life scales to capture the promised broader effects.

7.2.4 Key Finding: research may be poorly understood and strategically used by homeopaths

The topic of research within homeopathy is unusually sensitive compared with other forms of CAM, and conventional medicine. As outlined in the introductory chapter, research and evidence are not simple concepts and the implementation of evidence-based practice can face resistance from healthcare practitioners. This may be due to lack of understanding of the research, a desire to maintain autonomy in decision-making, resistance to perceived formulaic approaches to care among other issues. Research in and around homeopathy is intertwined with the fundamental conflict between allopathic/conventional and homeopathic models of health.

The introductory chapter outlined the development of homeopathy during a period when conventional medicine was largely unscientific, invasive and often dangerous. Homeopathy was built on a model of health in balance, and the principle of similars derived from clinical experience and observations. This contrasted with allopathic medicine which at the time took more of a deductive approach starting with unsubstantiated theories of illness and deriving treatments as a consequence. There was comparatively little understanding about the causes of disease, and the concept of mechanisms of action was not fully developed. While allopathic medicine has become increasingly focused on understanding the details of disease, and developing treatments based on this, homeopathy has continued to develop according to clinical experience and observation including provings of homeopathic remedies on healthy patients.

This lack of an apparent mechanism of action to explain how homeopathy might operate, and its effect on the debate around the effectiveness of homeopathy has been termed the plausibility bias. It continues to be debated both inside and outside the homeopathic community (Jutte and Riley, 2005; Milgrom, 2007; Rutten, Mathie, Fisher, Goosens et al., 2010).

The research around a mechanism of action for homeopathy is beyond the scope of this thesis, however it seems reasonable to note that there are still considerable numbers of conventional medical treatments which remain poorly understood, and estimates suggest up to 50% of these treatments are not based on evidence from RCTs (Institute of Medicine, 2007). Standard treatments offered across the NHS such as the use of SSRIs for depression appear to be effective, although the details of how this beneficial effect occurs are still under examination. The evidence-based movement within most healthcare professions has promoted research from lab-based through to clinical trials as a way to investigate tentative theories of disease and treatment, using research to promote understanding and produce effective treatments. Although there is evidence that the dissemination and implementation of best practice can be patchy within conventional medicine, the healthcare community as a whole is clearly involved with the evolving idea of evidence based practice.

In contrast, the findings from this project suggest that homeopathy is some way from this level of engagement with the evidence-based practice/research movement. As with most research, an open-minded approach and ability to tolerate ambiguity may be required to engage in and critique research findings. The changing state of knowledge about health, disease and treatments suggests that as in other areas of science such as physics, our current practices are based on theories built on observation and other collected data. Since our understanding is not complete, and new methods may revolutionise the available data, these theories are always open to adjustment, correction or even abandonment. Research within homeopathy may be characterised as falling into three camps: provings and case studies carried out by and reported for other homeopaths; lab-based research trying to show an effect of homeopathic remedies at a cellular level; observational studies and trials trying to show the effectiveness or efficacy of homeopathy in named conditions. The last category appears to be aimed at providing proof to the sceptics and healthcare commissioners, rather than truly testing if homeopathy is effective in these conditions.

Analysis of the interview and research workshop observation data in particular suggested that homeopaths were not particularly comfortable with the terminology around research. Concepts such as randomisation and the purpose of comparative studies were unfamiliar to most of the participants, though personal experience of teaching medical and nursing students suggests this is relatively common for healthcare professionals. The participants had limited access to scientific papers, journals and research oriented conferences with professional publications focusing on individual case studies, provings and discursive pieces. Research was seen as a way of providing answers to sceptics and the public, since practitioners knew homeopathy works anyway. During the follow-up interviews a scenario was posed where a good quality trial directly contradicted the homeopath's clinical experience, this provoked a mixed-response.

Some practitioners felt they would want to re-examine their own practice and carefully compare their methods with those tested in trials which points to an openness to reflecting on one's practice, however others felt that the trial would be too different and therefore not relevant.

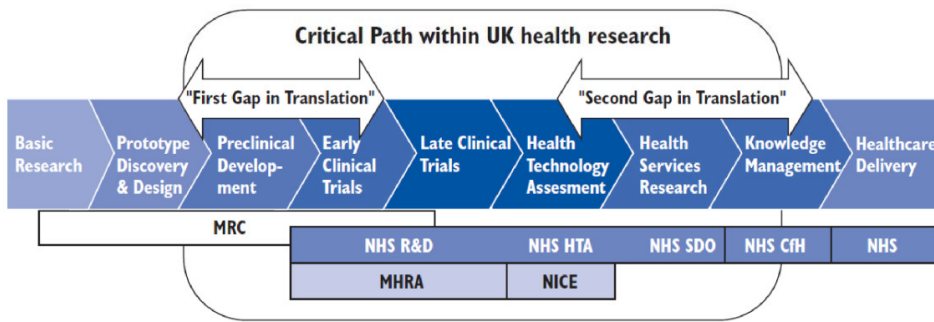
The workshop exemplified the use of research as a strategic tool by focusing on the problems of the classic placebo-controlled RCT which appeared to be set up for criticism rather than explored in detail. The evidence was presented as lists of studies with favourable results (lacking in critical evaluation) and de-constructing those trials which had less positive outcomes. The focus was explicitly on helping practitioners answer common criticisms, with little discussion of the implications of research findings for clinical practice.

This key finding suggests there are a number of ways that homeopathic research and teaching may develop in the future. The teaching of homeopathy has moved in recent years from private colleges towards further and higher education establishments, however this has taken the form of a physical movement/application for accreditation rather than a wholesale embracing of critical thinking and evidence-based teaching. Despite the current decline in university based courses, private colleges are still offering accredited degrees.

Personal experience suggests a contrast between the way EBM is being incorporated into teaching within conventional and complementary medicine. Medicine has been historically taught as a large, complex subject best learned through lectures and one-way provision of information. The newer approach to teaching such as that exemplified by the Hull York Medical School is problem-based learning with a strong patient focus (General Medical Council, 2009). Rather than expecting students to learn large quantities of information by rote, critical thinking and information finding skills are emphasised during sessions which help future doctors learn how to identify and appraise the available evidence when making clinical decisions. In contrast my experience of providing advice and supervision to several Homeopathy BSc level students suggests that the main teaching is still carried out in the direct information provision style with relatively little critique of the sources themselves. Students therefore may find it challenging when embarking on the newly introduced research methods module which demand rather different attitudes and skills.

The previous paragraphs have outlined the state of homeopathic engagement with research at the time of data collection in this project. There are clear breaks between the types of research being conducted, and a lack of relevance to and impact on practitioners. This idea is picked up again in the final section of this discussion where the future of trials in homeopathy for ADHD is explored. This situation has strong echoes of the picture painted by the Cooksey report of 2006 which reviewed the design and funding arrangements of the public funding of health research in the UK Cooksey (2006). Cooksey highlighted two "gaps in translation": the first gap refers to

Figure 7.2: Cooksey's gaps in translation



the lack of follow-through between basic level research and clinical trials; the second gap refers to where evidence exists but there is a lack of implementation in practice, see Figure 7.2.

These gaps have parallels in the homeopathic research world where the laboratory based research on molecular level action does not appear linked to clinical trials (for example see Lahnstein, Binder, Thurneysen, Frei-Erb et al. (2009)); and results of clinical trials do not seem to be disseminated to practitioners or implemented in daily practice. A feasibility trial looking at treating childhood asthma within an NHS homeopathic hospital concluded that although this condition represented one of the most common reasons for referral, the results showed insufficient benefit and any future trial should concentrate on primary care level referrals (Thompson, Shaw, Nichol, Hollinghurst et al., 2011). Interestingly, despite the lack of a cost-effective or clinically useful improvement in symptoms, the paper did not address the issue of whether children with severe asthma should continue to be referred to NHS homeopathic hospitals or other secondary care facilities. This recent paper exemplifies the apparent gap between research and impact on actual practice within homeopathy.

At present there is a lack of good quality research that progresses from case studies/series, through observational to clinical comparative trials. The homeopathic community is relatively new to the idea of a research culture, and to date has focused on the strategic use of results to shore up their position rather than reflecting on their own practice. In contrast, feedback from two homeopaths who have been involved in pragmatic trials suggested that the process of in-depth case discussion and reaching prescribing decisions helped to clarify the decision making processes, highlighted similarities across patients and may have increased consistency. Two small studies have previously suggested that homeopathic prescribing may not be reproducible across practitioners, clearly there is an interesting and clinically valuable research opportunity within this area (Brien, Prescott, Owen and Lewith, 2004; Burch, Dibb and Brien, 2008).

Homeopathy has long prided itself on a strong foundation of observed data from the original writings of Samuel Hahnemann, the application of critical appraisal and modern research me-

thods could be a natural evolution of homeopathy. Research around cognitive biases have helped to inform current research practices in medicine by highlighting the need to do more than rely on retrospective reports of health improvements or deterioration. Homeopathic teaching could take account of this body of knowledge when dealing with original sources rather than present the information as definitive. It seems essential that modern homeopaths understand the benefits and shortcomings of clinical research methods, rather than focusing on the placebo controlled RCT as being the only face of research. Ultimately, researchers need to acknowledge their own prior beliefs, and remain open to the possibility that the research data may require a change in attitude, beliefs and practice.

7.3 Grounded Theory

Grounded theory has been used as the overarching data collection and analysis strategy, and as discussed in the Methods chapters, constructivist grounded theory can be seen as a close fit with the pragmatic approach inherent within mixed-methods research. Although Glaser has continued to emphasise that grounded theory was never intended to be restricted to qualitative research, it is clear that the majority of published articles focus on qualitative grounded theory methods despite the publication of Glaser's guide to using grounded theory in quantitative research (2008). Searches of databases, textbooks and reference lists found few obvious examples of mixed-methods projects that reported using grounded theory even for the qualitative component of a single mixed-method study. For example the paper by Cresswell looked at five mixed methods studies in primary care and found that all had used a variation on thematic analysis (Cresswell, Fetters and Ivankova, 2004).

There are infrequent papers such as Losch (2006) which use grounded theory principles to guide exploration of quantitative data, and Martinez (2007) but overall this appears to be an under-developed aspect. As described in Chapter 2, Martínez (2007) used a form of mixed-methods research where initial focus groups were analysed using grounded theory, with a subsequent questionnaire and theoretically informed cluster analysis of the responses. In both Martinez and Losch, there was greater capacity for statistical analyses than with the survey data collected in this thesis.

Grounded theory is mentioned briefly in a key text by Pope, Mays and Popay (2007, Chapter 5) on synthesising qualitative and quantitative evidence in health care, but only in the context of synthesising qualitative studies. The authors state that it is unclear how grounded theory analysis might incorporate quantitative data from primary let alone secondary analyses (pp 74). The use of grounded theory within this mixed-method study, and across the multiplicity

of collected data has required: reflexivity; collaboration with colleagues; and an attempt to maintain a clear analysis trail.

The use of grounded theory across this project has been challenging at times, in part due to the lack of previous detailed examples to use for guidance when considering quantitative data. Nonetheless, the key principles of working from the data with an open mind and looking to identify emerging categories and concepts have been useful throughout. The grounded theory approach has facilitated considering data from all sources when balancing the trial reports with the comments from practicing homeopaths in the early stages of the project. The combination of incident by incident coding as proposed by Charmaz combined with the structure of open and axial coding from Strauss and Corbin helped to structure my reading and analysis of much of the qualitative secondary data. Martinez's (2007) research used a similar approach when coding free text responses from a survey that otherwise might simply have been added together to create frequency tables. Perhaps most crucially, the idea of analysing while still collecting data (constant comparison) not only helped the project to remain flexible to the changing circumstances, but also allowed me to take advantage of fortuitous data collection opportunities such as the workshop on research for homeopaths.

The aim of grounded theory is to move beyond description of the data towards generation of theory. This ultimate goal is often seen as the most challenging aspect of the methodology although some writers have acknowledged that it may not always be feasible (Becker, 1993; Charmaz, 2006). The analysis within this project has attempted to offer a theoretical model of the process of homeopathic consultations with particular reference to ADHD and children. It was difficult at times to find a single core category as is usually associated with grounded theory and, as can be seen from the overall model, there are still several areas deserving of further research. Overall grounded theory has been a useful framework for the research project, and has provided a number of valuable analysis techniques. Efforts have been made to move towards an explanatory theory, but this has been only partially successful and leaves the area primed for further in-depth analysis.

Grounded theory appears to have considerable potential as a framework when working with mixed-methods data. Despite the apparent paucity of guidelines or published work it has been informative and applicable in this project. Future research might usefully explore such applications and continue to experiment with process and methodology.

7.4 Mixed methods in practice

As previously discussed, this project was originally conceived of as a mixed-methods project based on a systematic review and a randomised controlled trial incorporating a qualitative com-

Table 7.1: Summary of data collected by type and method

	Primary	Secondary
Qualitative	Interviews with practitioners; interviews/discussions with Key Informants; participant observation at workshops; comments and free text survey answers	Research treatment protocols; background to the trial homeopaths; case study articles; expert opinion articles and textbooks on homeopathic methods
Quantitative	Survey data for most questions	Clinical trial results, aggregate and individual patient data meta-analyses

ponent to look at the usefulness of the outcome measures/patient experiences. Completion of the aggregate systematic review, and discussion of details of the research protocols resulted in a change of focus away from evaluating effectiveness, to stepping back to explore the intervention at a more general level. The mixed methods approach was still the most appropriate choice for exploring research versus practice in this context, however in this thesis the quantitative elements can be seen as supportive of the qualitative methods which has been noted as relatively unusual (O’Cathain, Murphy and Nicholl, 2007b).

7.4.1 Collecting and synthesising different types of data

The key debates around combining methods have been addressed in the Methods chapters, however it is worth reflecting on the additional challenges offered by using primary and secondary data. In most, if not all, mixed-methods projects (O’Cathain, Murphy and Nicholl, 2007b) researchers usually use a mixture of an evaluation component (often a trial) plus a survey/interview to capture patient experiences. Other common methods included case studies from the qualitative angle, and surveys, observation or economic analysis from the quantitative side. As is shown in Table 7.1, although qualitative data predominates, there is a considerable spread across the primary and secondary data types. It is useful to note that the quantitative data also breaks across this division, and while it may appear to be out-weighted in terms of sheer content by the qualitative, it made an equal contribution.

Potential complications of relying on secondary data are well acknowledged within the literature and include reliance on reporting by previous researchers, limitations imposed by the available data, potential mis-match between the question of interest and the focus of the original research among others. Researchers working in the synthesis of qualitative data have highlighted the

particular issues of working with a previously analysed data set when the researcher has access only to the chosen quotations and themes judged to be of importance (Britten, Campbell, Pope, Donovan et al., 2002). If this was a primary data collection exercise for example, the researcher could return to the participants or location to collect more information, follow-up leads and hypotheses and develop key ideas. Working with an established set of data, where there is little option to return to the scene, seems to require the researcher to be particularly conscious where there may be gaps or underdeveloped aspects of the concepts. The commonly quoted adage about statistical significance seems to be relevant here: no evidence of an effect is not evidence of no effect. In other words it was important to be clear that just because an aspect seen elsewhere in the primary data is missing from the secondary data, this does not necessarily mean there is a fundamental discrepancy between the two.

7.4.2 Resolving discrepancies in the data

Moffatt et al. (2006) have written about their experience of resolving conflicting results from the qualitative and quantitative components of a study looking at the impact of a welfare rights intervention. While their study was comparatively straightforward in terms of design, some of the steps suggested were helpful during the synthesis stages of this project. Discrepancies emerged between both qualitative versus quantitative, and secondary versus primary data types, although some of these conflicts were also present within each grouping of the data e.g. the trials were not always consistent. The key places where the data diverged can be grouped under: the position and importance of the child within homeopathic treatment, the individualisation of the remedy choices, evaluation of treatment effects and impact.

Starting points for exploring divergent data (adapted from Moffatt, White, Mackintosh and Howell, 2006)

- treating methods as fundamentally different
- exploring methodological rigour of each component
- exploring data set comparability
- collection of additional data
- exploring whether the intervention worked as expected
- exploring whether the outcomes in each component matched

Acknowledging the different contributions from each type of data/method employed was useful in clarifying that divergent findings may reflect different aspects of the phenomenon and be answering slightly different questions. Exploring methodological rigour was implemented by re-evaluating to what extent the project had adhered to the intended quality criteria - this has largely been discussed in the relevant sections, but it may be worth restating that best practice was followed in each method, and discussion of the findings with Key Informants, colleagues, mentors and supervisors provided a more external series of checks and balances. Data set comparability was not always easy to examine due to the use of secondary data sources such as trial publications which do not always report on the background of practitioners for example. Additional data was collected from trial authors where possible. The interviews were guided by an evolving topic guide which sought to probe some of the areas of apparent divergence between trial reports and clinical practice.

The last two stages were less relevant to this particular project, instead the interventions described in each data source were directly compared in an attempt to evaluate where there was missing information, and where there were direct disagreements between accounts. This process lends more confidence to the conclusion that published and unpublished trials and case studies do not always report the kind of information needed to compare the interventions with current clinical practice, and that there are real differences between the kind of homeopathy practiced across settings and indeed across trials. The evaluation of treatment impact has been dealt with in an earlier section, the finding that the outcome measures being used in research are unlikely and indeed unable to capture the kind of broad changes anticipated by practitioners appears to be relatively robust.

7.4.3 Structural issues

Mixed methods research has been studied in terms of barriers and facilitators (Bryman, 2007) with a further paper by O’Cathain (2009) suggesting that as a relatively novel research direction, it may face particular challenges. The structural issues identified by O’Cathain et al and Bryman (2007; 2009) are briefly outlined below with reference to the experience of designing and conducting this research project.

Funding bodies are generally recognised as shaping the form of research and there has been an increase in calls for mixed-methods research applications. Although seen as a facilitator, funders are not always seen as encouraging full exploitation of the method and the time constraints were suggested to be more likely to impact on a complex research design. This piece of research was funded by the-then Research Capacity Development scheme which was

certainly open to mixed-methods proposals, but appears to have favoured the prevalent model of qualitative to support a quantitative evaluation research.

Education and training have been highlighted by both Bryman and O’Cathain when looking at the experiences of mixed-method researchers. Bryman highlighted that having research team members with particular expertise could actually inhibit the integration in analysis, it was not sufficient to have qualitative and quantitative researchers to result in a truly mixed-methods project (2007). As a doctoral research project, this programme of research was less vulnerable to the impact of a research team where members may have preferred approaches. The design, data collection and analysis was primarily carried out by myself, a single researcher with a background in psychology research methods which included both qualitative and quantitative approaches.

O’Cathain’s findings emphasised the lack of awareness of published integration techniques in the researchers they interviewed, these individuals also struggled with a lack of good exemplars in the area of mixed-methods (2009). The interviewees’ knowledge and skills were based on practical experience rather than education and training. This was certainly borne out in my experience as a doctoral research student. An MSc in Research Methods in Psychology covered qualitative and quantitative methods but kept them clearly separate with only one series of seminars looking at integration via quantifying interview data. The research training for a doctorate in Health Services research between 2004-2006 required that I go out with the Health Sciences department to Sociology for more advanced qualitative training, although this has now been partially addressed in a new curriculum developed by the main supervisor for this study, Joy Adamson.

Publications were prominently mentioned in both Bryman and O’Cathain’s papers, in terms of the required format, restrictions on length and challenges with peer-reviewers. Mixed-methods studies are by their nature complex pieces of research and the description of at least two data sets, collection and analysis often requires greater length than is permitted. The Journal of Mixed Methods Research which was established in January 2007 allows 10,000 words for original research articles which is considerably longer than that usually given by journals, but indicates the necessity for additional content to fully exploit mixed-methods research. Although the challenge of publication has yet to be fully faced at the time of writing, the process of devising a suitable structure within the traditional PhD thesis to fully report a mixed-method, mixed-data type project has not been straightforward. Although the restrictions of length were less pressing, this thesis has not followed the usual chapter structure of a PhD in either qualitative or quantitative disciplines. Initial discussions around writing each data collection method up individually followed by a synthesis chapter were then abandoned as such a structure was

felt to falsely represent what has ultimately been a rather organic process of collection, analysis and synthesis.

The hierarchy of evidence, particularly within health services research, has been suggested to impact on how ethics committees approach mixed-methods projects. While not a major concern for this project it is certainly true that the qualitative aspects were subject to greater scrutiny and questioning than the survey forms. This may however have been a natural reaction of a departmental ethics committee to an ambitious project from a new doctoral researcher. Overall this project has faced many of the same structural issues and challenges identified by Bryman and O’Cathain, although it has also without doubt benefited from taking place under the guidance of a mixed-methods supervisor.

7.4.4 Evaluating level of integration

Regardless of the data type used, leading mixed-methods researchers have suggested a number of stages where integration can be observed (O’Cathain, Murphy and Nicholl, 2007a). A summary is presented below to demonstrate how this project has attempted to achieve maximum integration. Publications from the project are in the process of being written at the time of submission. To date several peer-reviewed conference papers have been delivered, all of which have clearly identified the data and results as coming from a mixed-methods research design.

Design

Integration at the level of design was an inherent part of this research programme. As explained previously, the systematic review was carried out as a preliminary step during the planning of a pragmatic mixed-methods RCT. The review was intended to inform the development of treatment protocols, outcome measure choice and interview schedules. The decision to not continue with the RCT was based both on the SR results, but also on discussions with the Key Informants as well as practical constraints. These discussions informed the decisions to explore the available data statistically (using IPD) but also to develop the full mixed-methods exploration of practice and clinical knowledge around homeopathy and ADHD.

Sampling

The extensive searches carried out for the systematic review provided a starting point in terms of authors and experts to contact for interviewing, although it was not always possible to locate

these individuals or carry out a formal interview. The interviews themselves provided names of possible experts and practitioners who had published on the treatment of ADHD, these were then followed up as far as possible. The participant-observation opportunities provided additional chances to distribute the survey, and facilitated identification of potential interviewees who ultimately were crucial in the development of several key categories.

Analysis

Four main strategies for analytic integration have previously been described (Caracelli and Greene, 1993). This project largely falls under the heading of data consolidation, whereby the qualitative and quantitative data are merged to create new variables for analysis, with some elements of typology development (analysis is carried out in an iterative process with each method informing analysis of the other). Other strategies include extreme case analysis (extreme cases from one method are used to interrogate the second method) and data conversion (quantitising or qualitisising). The aggregate meta-analysis was carried out independently as the first part of the project, but the larger set of mixed-methods data was used when exploring the IPD analysis - the extent to which this could be implemented was restricted by the available data unfortunately. During the rest of the analysis process, the data collected from each method was initially examined in isolation (light touch coding as it were), after which direct comparisons across methods were initiated and used to further deepen the analysis.

Interpretation

Findings from each method were integrated throughout the results chapter in this thesis with particular focus on areas of convergence, divergence and discrepancy - a process also termed crystallisation (Sandelowski, 1995). It was of particular concern to avoid the commonly noted trap of separating findings from each method and thereby risking losing the benefits of mixed-methods research.

7.4.5 Added value through using mixed methods

This project has, through the use of grounded theory and mixed-methods, achieved both more than could have been produced by a traditional systematic review/RCT design, and more than could have been learned through mono-method research.

The systematic review findings, if taken at face value rather than reflecting on the details of the intervention and assessment procedures, would have been used to design a typical style of

pragmatic RCT. Although this trial was intended to include an element of qualitative interviewing to capture patient experiences, it seems reasonable to anticipate that the main outcomes would have included:

- Equivocal findings
- Uncertainty around the appropriateness of the outcome measures
- A picture of one style of homeopathy (unlikely to be documented in detail) shaped by the lead clinician
- Failure to uncover the many differences and debates within the area itself

Mono-method research such as the survey would have indicated a lack of adherence to labels around homeopathy style, but would have been unable to explore the considerable heterogeneity hidden under those labels. Interviews would certainly have given a rich picture of how homeopaths claim to practice, but without the participant-observation the impact of practitioner beliefs could have been missed, and the perceptions of research by practitioners would have been seen as a relatively minor point.

Some of the key findings from the mixed-methods project are outlined below which seem unlikely to have emerged as clearly, if at all, from either the traditional review/trial methodology, or a mono-method project.

The individualisation and complexity of homeopathy in practice which emerged from the mixed-methods synthesis led to the re-examination of reporting of the intervention in the trials. It also highlighted the currently unexplored assumptions made by practitioners when working with children in particular. Consequences of this include potential problems with the black box approach to homeopathic research, and the need for clearer reporting by homeopathic researchers beyond the suggestions made by current guidelines (Dean, Coulter, Fisher, Jobst et al., 2007).

The presence or absence of research or evidence base in practitioner accounts, and indeed what these terms meant to homeopaths were ideas formed from interviews, key informant discussions, observations of practitioner workshops and reading of published documents. This is a key concept linked to a willingness to change practice. Research ultimately is intended to inform patients and service commissioners, as well as the practitioners who are being evaluated. This project has highlighted that research in this area may not have effectively evaluated

actual clinical practice. It has also demonstrated that homeopaths, like other healthcare practitioners (and CAM in particular where training curriculum are not necessarily required to include such concepts), struggle with the ideas of evidence-based practice as a strategy for growth and development rather than using it as a tool to reinforce current practice against criticism. The idea of a self-reflexive profession seems some distance from reality at this point - the mixed-methods data indicates that this is not just because practitioners are not interested, but also that their education is not offering this as a valid perspective, that they may not be learning valuable critical appraisal skills or have access to the published research in any case.

These findings have direct relevance toward how the future of homeopathic research in the treatment of ADHD might develop, as well as suggesting that the homeopathic community may face some specific challenges when trying to evaluate its own practices, or develop a self-reflective practice.

7.5 Quality of the research

7.5.1 Systematic review and IPD

The systematic review and individual patient data analysis stages of this project were conducted according to best practice both in terms of conduct and reporting. There are several well established requirements for systematic review methodology to be considered at low risk of bias which have been met by this research programme (Higgins and Green, 2005; CRD, 2009; Moher, Liberati, Tetzlaff, Altman et al., 2009). Specifically extensive database searches were conducted without language or publication type restriction; more than one reviewer was involved in study selection, data extraction and quality assessment; the IPD was checked for accuracy and errors; all studies were quality assessed and the quality information was included in the narrative and quantitative syntheses; the synthesis themselves were clearly described and justified; the conclusions were drawn from the available evidence with appropriate consideration of issues of generalisability and reliability.

These standard procedures are generally agreed to increase the reliability of systematic review results by reducing opportunities for language/publication bias and reviewer error, clearly detailing the quality and details of included studies, checking provided data for any errors and basing conclusions only on the data presented (CRD, 2009; Higgins JPT, 2008). Although there were only four trials available at the time of conducting the review, and IPD was provided by only three trials, these guidelines have been followed as far as possible, thus the limited conclusions are likely to be reliable.

7.5.2 Mixed methods

The topic of quality and rigour within qualitative and mixed-methods research is less clear cut than in areas such as systematic reviews, at least in part due to the range of opinions and methods. While the majority of the criteria detailed above are based on research which suggests that measurable bias may be introduced to a review where the processes are not followed, the same cannot be said to be true in mixed-methods research. Each field of qualitative research has traditionally used its own criteria to judge the credibility and reliability of research results, although at least within health services research there is an acceptance that quality appraisal is both useful and necessary (Pope and Mays, 2006). The framework proposed by Spencer, Ritchie, Lewis and Dillon (2003) was adopted for this project since it includes a range of generic and specific criteria. The main quantitative aspect, apart from the systematic review, came from the questionnaire data. The quality of this was addressed through rigorous development, targeted sampling and transparent reporting of the collected data.

The guiding principles (which include 18 specific questions) have been discussed in more detail in Chapter 6 (6.10.3 on page 256), and a summary is offered below along with a reflection on the success/failure in meeting them. As outlined in Chapter 2, these incorporate the suggested criteria from Charmaz specific to Grounded Theory (Charmaz, 2006).

The research should be contributory in advancing wider knowledge or understanding about a specific field: The thesis meets this broad criteria by having explored a relatively sparsely researched topic, and offering insight into how professional ho-meopaths work with children. In addition, the relationship between homeopaths and research came through as a theme worthy of future exploration. Results from the programme of research have been presented at conferences throughout the doctoral programme, and further papers and a book chapter are in process to continue the dissemination of the findings.

The research should be defensible in design and rigorous in conduct: The programme of research has addressed clearly stated research objectives using a range of methods in order to capture the broader aspects of the topic. Data collection methods were selected to inform each of the key research questions within an over-arching Grounded Theory approach. As far as possible the research methods and their implementation have followed best practice and been described transparently, including the ongoing evolution of the project according to practical constraints (see Figure 2.2 on page 39). The findings and analyses have been presented with sufficient rich quotations and other evidence to allow readers to judge their basis in the

data where possible. Interpretations have been drawn while bearing in mind the potential limitations of a largely UK based study focusing on professional practitioners and without a voice from the CYPs themselves.

The research should be credible in claim: It has been more challenging to ensure this criteria was met with respect to the mixed-methods component in part because of the range of data collection tools and breadth of the analysis. The multiple methods allowed for some triangulation, and the multiple interviews with practitioners and Key Informants permitted some degree of respondent validation. Negative case analysis was used deliberately to explore the robustness of categories and a range of data sources were used to support the model components. Nonetheless, this is the area that would have benefited from more detailed planning prior to beginning the research, and given more time it might have been useful to arrange for a presentation and discussion of the final model with the homeopaths who had contributed to the project.

7.5.3 Overview

In both of the main phases of this research, there have been challenges presented as a result of practical constraints and fortuitous opportunities. For example the change of project focus from nested qualitative study within an RCT to an exploratory mixed-methods Grounded Theory study has meant that the process has organically developed rather than following a clear a priori structure. The provision of additional data during the systematic review prompted the development of the IPD protocol and analyses, however there were some misunderstandings with the trialists which could have been avoided with better planning. In a similar vein, some of the participant observation opportunities, one of the interviews and the opportunity to distribute the questionnaire were informative but were indicative of taking advantage of opportunities for data collection rather than a prior planned activities. Nonetheless, where possible relevant best practice and quality guidelines have been followed. It was more difficult both to implement and evaluate quality criteria within the main mixed-methods component, and was perhaps one of the few time when the use of multiple approaches resulted in a disjointed feeling. Based on evaluating the completed research, it does not appear that there were any serious failures to meet the quality criteria as described above and a significant degree of transparency has been achieved across all the methods of data collection.

7.6 Reflexivity

Reflexivity, or attention to the researcher-participant relationship, has long been considered as key to qualitative research and a fundamental stage in enhancing the rigour of findings. Despite this, classical accounts of Grounded Theory which were rooted in the positivist tradition have tended to bypass reflexivity in their guidelines for new researchers. Strauss and Corbin addressed the effect of a researcher on the research process only insofar as the concept of theoretical sensitivity. The newer constructivist use of Grounded Theory has foregrounded the concept that interview and participant-observation data cannot represent the realities of informants in an uncomplicated fashion (Charmaz, 2005). Hall and Callery (2001); Mruck and Mey (2007) are among those who have argued that incorporating reflexivity into Grounded Theory better reflects the way these methods have developed, and takes account of the social construction of data.

Below I discuss how I may have consciously and unconsciously affected the data collection and analysis of this project in order to facilitate the reader's ability to judge the quality of the data, synthesis and conclusions. This section reminds the reader of my background and how I chose to present myself as a researcher throughout this project. The implications of the researcher identity for gaining access, data collection and how this has been both challenging and beneficial are discussed.

A deliberate effort was made to consider how I would present myself at the outset of the project. The focus was on coming across as a broadly aware and well-informed researcher who was interested in homeopathy, but without any strong beliefs around effectiveness. This position of an open-minded, agnostic researcher was an accurate reflection of my personal position. The research funding was accepted not from a strong desire to prove that homeopathy worked, but from my interest in research methods, background in psychology and professional experience of working alongside homeopaths.

7.6.1 Prior beliefs and bracketing

It is important to emphasise that I already had several years of experience working around homeopaths both as a remedial massage therapist in private practice in Glasgow, and working at Glasgow Homeopathic Hospital as a research assistant. I had not attended a homeopath for a personal consultation, but was probably more informed than the average lay person or researcher in the background, philosophy and treatments associated with homeopathy. This made it easier to connect with the homeopathic researchers and practitioners, many of whom would start conversations by asking if I was a homeopath or homeopathic student.

As a researcher my identity was clear from the University of York branding on all of the materials and consent forms, and I was comfortable to talk about my background and the research funding. The homeopathic community was relatively aware of the research programme as my position had been advertised widely across the CAM and homeopathy research communities, so simply having the funding spoke on my behalf as a researcher.

In Table 7.2 on the next page, I have summarised some of my prior beliefs which were discussed earlier in Chapter 2. I have included notes on the strategies adopted to prevent these beliefs unduly affecting my data collection and synthesis along side comments on their relative success or failure. The main strategy I employed across data collection modalities was that of phrasing my questions in an open-ended manner where possible without leading the respondent, followed by probes to explore the meaning behind any terms being used such as classical homeopathy. Across the project I would claim that these strategies were broadly successful, and had I not engaged in the bracketing process I would have certainly have risked missing valuable data. Bracketing is sometimes described merely as noting down one's prior beliefs, where as the more practical approach of recording the beliefs and considering how to avoid confirmation bias in the data collection and analysis phases was very useful.

In some senses the construction of my identity as a homeopathy 'sensitive' researcher was crucial in working through the systematic review and defending against criticisms based on my lack of understanding of the therapy when presenting at CAM focused conferences and events. As has been mentioned by other writers, examining one's own impact on the data collected is almost a separate piece of work in itself, and may often be overlooked when preparing publications for journals with restricted word limits. Examples are given in the following sections illustrating how I presented myself as a researcher, the outcomes of this both positive and negative, and other possible consequences on the data collection.

7.6.2 Negotiating access for data collection

In terms of how I as an individual affected the process and outcome when seeking access to collect these data, it seems reasonable to conclude that in the first year of the project (2005-2006) my background and self-presentation were helpful in easing the initial contact and build relationships. It also seems likely that any other researcher would also have been able to access these data having made the appropriate contacts. When introducing myself and my project during a practitioner CPD workshop (focused on new methods of case-taking and prescribing), there was a moderate amount of interest from the delegates with several approaching me during coffee breaks to ask for more information.

Table 7.2: Reflecting on prior beliefs

Prior Belief	Strategy adopted	Comments
<p>There are many different kinds of homeopathy but 'classical' single remedy homeopathy is the 'original' form</p>	<p>Ensuring that questions asked in both the interviews and surveys were deliberately open ended e.g. what kind of homeopathy do you practice? Followed up by appropriate probes to ascertain what classical homeopathy actually meant for each respondent.</p>	<p>It was helpful to identify my beliefs a priori, and the use of open ended questions plus probes generated descriptive and detailed data to avoid restricting responses. Remaining clearly neutral in terms of the types of homeopathy that might be used helped to clarify my position as an interested researcher.</p>
<p>Homeopaths will talk to the children more than parents, seeing the child as being the most important person in the consultation, they will demonstrate very child-centred practice.</p>	<p>As above, the questions used at interview and in the surveys were worded to ask the practitioner if they interacted with the child, and the level of interaction/reliance on their answers. While I had expectations of the answers, the questions and probes were worded in an attempt to avoid leading the participants.</p>	<p>As above, asking detailed questions helped to collect data that I might otherwise have missed through my own biases. In future I would be better prepared for the practitioner who did not particularly focus on the child as a source of information and have a further set of questions ready to explore this.</p>
<p>Homeopaths will agree on how to treat particular conditions or groups of patients</p>	<p>The original interview schedule included questions which were directed at collecting details of treatment protocols/remedy families. Most of these were eliminated after the first two interviews when discussion of the transcripts with mentors and supervisors indicated that these were not fruitful directions to pursue. The revised interview schedule steered away from this type of specific question.</p>	<p>The revised interview schedule worked well in opening up the conversation. The survey questions which asked about resources and methods used by practitioners had to be analysed as potential pointers to authors I might not have been aware of, rather than as a way to collect data on the way homeopaths were practicing. With hindsight I might have redesigned some of the questionnaire items, but I also think this is a fruitful area for further research and debate.</p>

The process of negotiating access in order to collect data was rarely straightforward in this project. Firstly due to the breadth of data collected, access was sought to trialists (and their records), workshops, conferences and seminars normally only attended by homeopathic practitioners/students, as well as individual homeopathic practitioners and their clinics. It is useful to recall that during this project homeopathy in general was under attack in the media more than was usual, and as a result there was a clear increase in levels of suspicion over time. Initial contact with homeopathic trialists was generally straightforward and positive.

Access to practitioner workshops where further recruitment for interviews took place was agreed following a short telephone conversation and confirmatory letter in late 2005, yet by 2007 attempts to attend a workshop on research in homeopathy nearly came to grief when the administration team outright refused. In the previous months some homeopathic colleges had reputedly been subject to undercover moles who were then reporting back to known, vocal critics of homeopaths. During the same period articles in the media had criticised the content of homeopathic training courses with a focus on the existence of BSc (Hons) Homeopathy degrees (Colquhoun, 2007; Corbyn, 2008). Access to the research workshop was eventually granted following discussion with the tutors (who were known personally to myself), however it was an interesting reflection of the levels of concern and suspicion at the time.

In later years of the project (2007-2009), against a background of suspicion, mistrust and feeling under attack, I am quite confident that access would have been considerably more difficult, and in the case of the research workshop observation entirely impossible, without both the existing relationship and researcher credentials.

Email text: I contacted XXX this morning about attending your research CPD event. I explained this would be as an observer (naturally given my background as a non-practitioner) and that I was interested in seeing how homeopaths think about and discuss research generally. This is an area that has developed from my interviews with practitioners and carrying out a systematic review. The office have told me that the organisers have concerns about my attending, and also feel the participants might feel uncomfortable with my presence. I wouldn't dispute that they might feel uncomfortable, but I have attended a previous CPD workshop as a non-practitioner. This was very acceptable to both workshop facilitator and participants, so I would be really grateful for your thoughts on this to help me understand the decision.

Access to the research workshop was ultimately possible after email and phone discussion with the tutors, whom I knew through a CAM research network, being part of a similar funding programme and contact at CAM conferences. I was also able to refer to my attendance at a

previous workshop (possibly setting a precedent, previous positive experiences), and having produced a systematic review in homeopathy for ADHD (being part of their community).

In many ways my unusual background of experience with the research and practice of homeopathy, without being a practitioner or having ties to a specific style, has been of benefit when approaching individuals and organisations. Only in the latter stages were there any particular challenges encountered in negotiating access for data collection in response to a general sense of being under attack (these sentiments were clearly articulated during the research workshop). The extent to which I may have influenced the actual data collected is explored below, the the impact of my research identity was overall positive in terms of gaining access and building relationships.

7.6.3 Collecting quantitative data

The collection of the trial data is an interesting area to reflect on because the initial interactions were very positive. All of the trialists who responded to initial contacts were encouraging and supportive of the systematic review, indeed one researcher provided their trial data without being asked. The process of gathering the relevant details has been dealt with elsewhere (difficulty of retrieving the relevant information, language complications, research staff having left or data being destroyed), however there was a particular concern around the re-analysis of the trial data which emerged during this project.

As explained earlier, IPD's are usually planned prospectively rather than as a follow-up to an aggregate review and involve substantial communication with the trialists to build cooperation and mutual understanding prior to data collection and analysis. These initial stages were not fully carried out during this project, which is undoubtedly a failing but has also been a useful learning opportunity. It is feasible that in a less controversial subject area fewer challenges may have been encountered. A covering letter and summary of the protocol was prepared and sent out to all of the relevant authors, including the trialist who had already voluntarily provided their data before the request. Although the letter explained that the data would be checked and cleaned, any apparent inconsistencies checked with the authors, and re-analysed before conducting a further meta-analysis, there may have been some misunderstandings as to the nature of these processes.

During the confirmation of the data analysis, it emerged that one group of researchers were uncomfortable with some of the exploratory analyses, particularly where these disagreed with the main findings from the published trial. Interestingly, the response of this research group was to respond with a litigious email which clearly stated that they would withdraw permission

to use their data unless the analyses agreed with their published results. It was possible via discussion to resolve the situation by emphasising that these were exploratory analyses not intended to invalidate or conflict with the main results, however the strength of the reaction points to an ongoing defensive attitude, of feeling attacked, as noted above even though this was not a UK based trial or research group.

The situation was partially resolved by clarifying the analyses and their purpose, but the formal replies from myself were deliberately sent on headed notepaper and co-signed by the primary research supervisor. Pains were taken to outline the particular reasons for having carried out the controversial analyses. This strategy was intended to reassure the research group that the project was a legitimate academic activity, and not aimed at discrediting their trial or publications. This particular trial was of an unusual design, produced a result that was only narrowly statistically significant, and has resulted in three peer-reviewed publications and a book chapter - suggesting that the authors were personally invested in the outcomes.

7.6.4 Collecting qualitative data

The influence of the researcher during data collection activities such as interviews has been widely debated, with experimental research from psychology showing clearly that differing styles of presentation, choices of clothes, and other factors can influence what participants are willing to share. Reflecting on my potential impact on data collection during the interviews is a useful step in increasing transparency when dealing with complex qualitative data, and is intended to help the reader further interpret the findings.

In the initial contact with potential interviewees, the focus of my presented identity was very much around that of an informed but impartial researcher as already discussed. This was reinforced during the introductions at the beginning of each interview, and in some cases participants would ask why I was interested in the area. At this point I usually outlined my experience as a therapist and work with the Glasgow Homeopathic Hospital, without going into my personal beliefs or feelings around homeopathy.

During the interviews however, there were occasions when it seemed both helpful and appropriate to reveal further information about my professional qualifications. An example is presented below which typifies the point in an interview where the homeopath would reveal something about their practice/approach and then looked uncertain about continuing. At first I attempted to use neutral prompts such as “could you tell me a bit more about that”, but after several interviews opted to deliberately reveal my own experiences in an attempt to encourage further

discussion. This strategy seemed to be most useful when practitioners were hesitant about discussing more alternative practices they might incorporate, or their opinions about the causes of behavioural conditions in children.

Donna: What I do sometimes is if I'm sending a remedy through the post, I might just give it some Reiki just really as an extra [looks uncertain].

Morag: [asked for an explanation of Reiki, Donna continued to look hesitant and the interview began to falter]

Morag: You don't need to be worried, I trained as a Reiki therapist some years ago...

Donna: well I was just wondering how to sort of put it. I know. If I feel, I mean I try and put Reiki into the room so it's a healing space. If I think a patient is and I wouldn't want to sort of obviously alter that picture but I suppose I might be sending out to them just to sort of give them strength to get through that.

It certainly influenced the data, in that the practitioners did not seem as comfortable discussing these issues when I did not use deliberate self-disclosure, and after the first three interviews it was a strategy which I used as and when needed. It was difficult not to appear to be agreeing with or encouraging, for example the use of Reiki alongside giving a homeopathic remedy, however I attempted to provide factual information about my qualifications and experiences rather than validation of their practices. Where practitioners directly asked me about my own personal use of homeopathy, I chose to answer this rather than avoid the question e.g. I have worked alongside homeopaths and my dog attends a homeopathic vet although I have not used it myself. The main advantages of these strategies appears to have been an increase in rapport, collection of additional data that may otherwise have remained hidden and providing a sense of honesty to the interview.

In contrast to the potentially positive impact I may have had on the data collection during interviews through deliberate disclosure, there were also occasions where assumptions of shared understandings may have reduced the explanations given by participants. When this emerged during the reading of initial interview transcripts, attempts were made to probe more deeply into homeopathic concepts. The two examples given here are both from interviews with one Key Informant whom I had co-taught with including a module introducing homeopathy to medical students. During this introductory course the key informant spent some time demonstrating and using a set of scales as a metaphor for the homeopathic model of health and well being. Despite this, in the interview there was a lack of focus on this metaphor. Upon reflection this seems to have been because a) the interviewee assumed familiarity with the idea, and b) I assumed I was familiar with their concept and example. In retrospect this may represent a partial failure in data collection.

One of the areas within the topic guide focused on the participants use of and familiarity with outcome measures. This was an area of particular interest to myself, however it was not until re-reading some of the early transcripts that a further way in which my identity may have influenced participant responses emerged. Some of the practitioners were almost apologetic about not using formal outcome scales, and it was unclear if this was an artefact of them speaking to a researcher rather than their actual feelings about the topic.

Morag: Do you use any kind of questionnaires or surveys or pen and paper methods for getting information, in your practice?

Mary: No, sorry, I did use MYMOP for a while, but I stopped doing that.

Morag: Could you tell me why?

Mary: Just lack of organisation because I do find it useful for two reasons, and the society (Society of Homeopaths) did push us to use it for a while.

As a result of this observation my introduction at the beginning of each interview was modified to explicitly reassure the participants that the interview was still useful if the practitioner was a novice or experienced homeopath, and regardless of their involvement or knowledge of research in general.

Other challenges which were documented through research diaries and memos included a personal feeling of responsibility to the homeopathic community, the conflict between being a student working on a PhD versus an identity as a knowledgeable researcher. This latter aspect surfaced during the participant observations of two workshops where my intention was to remain as silent as possible, but this raised challenges when my opinion was deliberately sought by the workshop leader. It was difficult at times to balance the desire to correct a perceived error such as the misreporting of the results of a review with the need to remain observant.

7.6.5 Summary

It has been helpful to reflect on the my prior beliefs, role and identity as a researcher both at the outset and during the project, and some effects were unexpected. It is impossible to separate self from the data as collected, therefore it seems vital to be both honest and reflective about the ongoing process of identity construction and how this may have impacted on the findings. Throughout the process I have remained curious about the potential impact of homeopathic remedies or consultations, while also sceptical as to the potential mechanism of action.

It was important to consider how I may have influenced the data collection, although this is less often seen openly discussed within quantitative traditions. This section has outlined the impact of the researcher on these data, both in positive and negative ways. It is difficult to envisage a situation where these effects were not present, however reflection allows for recognition and appreciation of their impact.

7.7 Further research

7.7.1 Homeopathy as a complex intervention

Homeopathy is one of several CAM modalities often referred to as a complex intervention. This term came into common usage within the research community following the report and BMJ paper of 2000 (MRC, 2000) which set up an idealised set of stages through which complex intervention research might progress. The definition of a complex intervention was agreed as:

a number of components which may act both independently and interdependently
(MRC 2000 and 2006)

The guidance was updated following a workshop in 2006 which set out to update and improve the framework. This more up to date document sets out a broader, more flexible and less linear idea of research development, and explicitly tries to move beyond the staged models used in drug development, although RCTs are still a key aim of the process.

The Norwegian National Research Center in Complementary and Alternative Medicine (NAFKAM Nasjonalt forskningscenter innen komplementær og alternativ medisin), has presented a linear approach to complementary and alternative treatment which appears to address the same question of evaluating complex interventions (Fonnebo, Grimsgaard, Walach, Ritenbaugh et al., 2007). The NAFKAM model is based on common clinical practice, with a focus on evaluating existing treatments. This model seemed helpful when developing the present research programme but following analysis of the collected data it is difficult to argue that homeopathy is being used for ADHD in a widespread and consistent manner.

Two key pieces of research have highlighted the complex nature of homeopathy: a case series carried out at Bristol Homeopathic Hospital and a grounded theory study by Caroline Eyles. Both studies used qualitative data to explore the homeopathic consultation and treatment process in detail (Eyles, Walker and Brien, 2009; Thompson and Weiss, 2006).

The Bristol case series deliberately focused on stages one and two of the original MRC model and studied the process of routine homeopathic care, focusing on the active ingredients and non-specific effects. Their findings highlighted a mixture of potentially contributory factors such as patient expectation; openness to a mind:body connection; empathy in the consultation; narrative within the homeopathic case taking; matching the remedy with the patient's lifeworld and the remedy as an active ingredient. As reflected in the data collected for the current project, there appear to be key aspects of the homeopathic consultation which are specific to homeopathy such as the matching of a remedy to a patient's often unusual symptom profile. If this is an 'active' ingredient then it may cast doubt on standard placebo controlled RCTs, as well as posing interesting questions about the design of Frei's ADHD trial which minimised this interaction.

Eyles et al.'s qualitative study comprising interviews, observations and diaries completed by homeopaths has presented a model of a UK classical homeopathic consultation. Within this model, the central process was 'connecting' which took place via four other overarching categories (exploring the journey, finding the level, responding therapeutically and understanding self). To summarise, although the expected non-specific activities such as listening and empathy were present, these took place in a distinctly homeopathic context and manner. They were also integral to the process of prescribing the homeopathic remedy. As in the Bristol study, the focus was on a face to face type of classical homeopathic consultation and treatment.

7.7.2 The evidence base for homeopathy and ADHD

The most reliable of the published trials assessing homeopathy for ADHD vary in the extent to which they appear to have been based on existing research, and to have followed the guidance set out by the MRC and NAFKAM.

Jacobs et al.'s trial used a well accepted design (parallel groups, placebo controlled) with appropriate outcome measures, however it highlighted potential problems with the included participants (may not have been typical ADHD patients, poor response). This trial was not developed from an observational study or similar information gathering process but drew on the findings from two previous studies: one using very different treatment style/methods, and a second which was poorly designed. There could have been a lack of model development prior to conducting the pilot RCT, and there was little in terms of describing the actual practice of the homeopaths, or how representative their practice was. The design itself may have been adequate but the duration was questioned following publication Frei, Thurneysen and von Ammon (2006). There was also a lack of information on how the practitioners felt working within

a placebo-controlled trial. The practitioners were in fact two well known homeopaths who were not named in the paper, nor have they mentioned the trial in presentations given since then.

Frei's trial attempted to balance the requirements of practitioners with the rigour demanded by clinical research. The resultant design had a number of unusual features including: participants has to respond to homeopathy, lack of a washout period, relatively short duration of cross-over arms - the outcome measure used actually asks about symptoms in the previous month while each arm lasted 6 weeks. In essence, by including responders after successful treatment, and without using a washout period, Frei et al made it harder to show a true difference in any direction. Additionally, due to the nature of the trial process the results may be more vulnerable to regression to the mean. Frei's trial was based on previous observational studies, but might have benefited from more developmental work (the length of the crossover arms was based on unpublished anecdotal observations following the uncontrolled observational study).

Comparing the current evidence base to the progression of research outlined by the MRC and NAFKAM (see tables 7.3 on the following page and 7.4 on page 293) within homeopathy for ADHD, it is clear that there has been a lack of research that explores or documents the actual practice of homeopaths working with this patient group. This is a scenario mirrored across much homeopathic and CAM research generally and may hamper developing an exploring the evidence base. From this it is clear that there are not inconsiderable gaps in the research literature, and future research should be best aimed at building a solid foundation alongside appropriate exploratory trials rather than moving directly to definitive RCTs focused on component efficacy.

It is worth noting that the majority of the existing observational studies and trials have not referred to the existing literature in their protocols or reports. There has to date been little published work that draws together the existing knowledge, and it is hoped that this thesis will serve as a useful resource for others considering research in this area.

Two pieces of research that I have been involved with on a supervisory level have begun to address some of these gaps in the research literature around homeopathy and ADHD: an observational prospective case series of homeopathic treatment for children at risk of exclusion (most have been diagnosed with ADHD) being carried out in London with supervision by myself Fibert (2012); and an undergraduate dissertation drawing together information on homeopathic remedies used for children with ADHD Fibert (2009). In addition, there is some further observational data that can be gleaned from McLean and Garland's observational study set within an English school working with primary-aged children at risk of exclusion (McLean and Garland, 2005), and Hughes, Bostock & Seymour's audit of a SureStart homeopathy project based in

Table 7.3: ADHD/Homeopathy research compared with MRC framework

MRC Stage	Theory	Modelling	Exploratory Trial	Definitive RCT	Long Term Implementation
Homeopathy and ADHD Literature	Twelve papers exploring the theoretical aspects of treating ADHD, remedy families and dosage ideas Two papers by the Frei team describing the development and implementation of their particular style of homeopathy.	One paper on modifications to the prescribing process in Frei's method of treatment. Nine case study reports that contain some information but were patchily reported at best One thesis by Kelly (1995) summarising case studies and remedy choices McLean and Garland (2005) observational study set within an English school working with primary-aged children at risk of exclusion Hughes, Bostock & Seymour (2004), an audit of a SureStart homeopathy project based in Calderdale (UK)	Jacobs (2005) placebo controlled pilot trial Frei and Thurneyssen (2001) open label observational study Two trials of complex homeopathic formulae (Strauss 2000, Hultzsch 2007) Lamont (1997) trial	Frei et al (2005) cross-over trial (although issues of carry-over and power)	No data found

Table 7.4: CAM systems research (NAFKAM) and the ADHD/Homeopathy literature

	Phase 1	Phase 2	Phase 3	Phase 4	Phase 5
<i>NAFKAM guidelines</i>	<i>Describe clinical practice in widespread use</i>	<i>Assess safety in routine practice: data collection (quality, quantity) observational studies</i>	<i>Assess the system effect (effectiveness of routine practice possibly using a pragmatic RCT)</i>	<i>Assess specific component effect (efficacy) principle method: explanatory RCT</i>	<i>Assess mechanisms of action</i>
ADHD & Homeopathy Literature	The survey reported in Chapter 6 of this thesis. Thesis by Kelly (1995) summarising case studies and remedy choices, all USA focused Thesis by Fibert (2009) updating Kelly's work and adding more UK data Two audit studies based on in the UK: McLean and Garland (2005); Hughes, Bostock & Seymour (2004)	Despite contacting prominent experts who run clinics specialising in ADHD it appears they do not routinely collect or publish safety data	Frei and Thurneyesen's observational study (2001) Fibert (2012)'s observational case series	Frei et al's cross-over trial (2005) Two trials of complex homeopathic formulae (Strauss 2000, Huitzsch 2007) Jacobs et al trial (2005) Lamont (1997) trial	Nothing found specific to ADHD but ongoing area of research for homeopathy in general

Calderdale (UK) which included some children with attentional difficulties and hyperactivity (Hughes, Bostock and Seymour, 2004). These pieces of work contribute to phases one and two within the NAFKAM structure by providing important observational data from the case studies, and by drawing together published information on current clinical practice, and could inform future trials.

7.7.3 Key ideas for an exploratory RCT

There are a number of factors that could be taken into account in future research. Good quality observational studies are crucial for the development of good quality trials. Such studies should document how homeopaths in the country of an intended trial actually practice, including time to see benefit and adverse events or side effects McCarney, Lasserson, Linde and Brinkhaus (2004). Subsequent trials should ideally take this information into account in the design phase, while recognising that homeopathy, particularly individualised homeopathy, is a package of care which potentially contains multiple active and interdependent ingredients as previously outlined Thompson and Weiss (2006).

A Canadian pilot RCT comparing homeopathic treatment with placebo for ADHD was still collecting data in November 2011 with analysis expected to complete in mid-2012. This trial was broadly based on the design used by Jacobs et al. and used the published Cochrane systematic review as a starting point, but unfortunately does not seem to have begun with good quality observational data. In contrast there is a small but growing set of data around UK homeopathic treatment for ADHD which could now inform future trials. The following paragraphs outline some of the key considerations for further research into the homeopathic treatment of ADHD and are informed by the findings from this research project.

Despite the current climate of anti-homeopathy sentiment, there is potential benefit in conducting an exploratory randomised controlled trial based on both the findings reported in this thesis and the data collected by the prospective case series and literature review mentioned in the previous section. In contrast to the previous trials, such research could draw on the information on current homeopathic practice presented here and by Caroline Eyles and incorporate appropriate mixed-methods data collection techniques to capture both process and outcomes.

As discussed earlier, homeopathy as currently practised in the UK by a professional or medical homeopath appears to fulfil the definition of a complex intervention. While a randomised controlled trial offers the most robust way to evaluate even complex treatments, using a placebo is likely to confuse the situation as the control arm are likely to still receive some of the 'active' components. Therefore a pragmatic randomised trial with two arms of active treatment is recommended. The question of interest is not about the homeopathic medicine in isolation, but

homeopathy as an alternative package to medication and its potential for provision within the NHS. In-depth consultation with both patient groups and clinicians at an early stage of this thesis suggested that it would be deeply unethical to offer a placebo treatment at this stage in the patients' treatment given that they may have been waiting several months for their assessment.

Within the UK the diagnosis and provision of treatments for ADHD varies across the country. Diagnosis usually occurs when the child is referred for assessment by an educational psychologist and/or to the Child Adolescent Mental Health unit, although it may be also be made by a GP. The proposed trial should be conducted in secondary care using mental health referral centres as a primary source or referrals. Other trials of homeopathy for serious conditions have used a mixture of self-referral and secondary level healthcare professional referrals Relton, Smith, Raw, Walters et al. (2009).

Proposed inclusion and exclusion criteria

Inclusion: The following criteria are suggested based on both previous research within CAM for ADHD and pharmacological trials in this area. Explanations for each item are given below.

Participants will be children or adolescents from 6-18 years referred to a child/adolescent mental health team or similar for assessment and diagnosed with ADHD. Participants should be diagnosed with severe or combined Attention Deficit Hyperactivity Disorder (ADHD) according to DSM-IV APA (2000) guidelines , this corresponds to the ICD-10 WHO (1992) diagnostic criteria for Hyperkinetic Disorder (HKD). This is the form of diagnosis commonly used in the UK and currently recommended by NICE for methylphenidate treatment. The diagnosis to be determined by a child/adolescent psychiatrist or paediatrician with expertise in ADHD.

The child/adolescent mental health team will have decided that pharmacological intervention is appropriate following the use of behavioural/education interventions as appropriate. In those centres which implement best practice treatment, behavioural and parenting interventions are almost always offered as standard first line and could not legitimately be withheld. Children with commonly occurring co-morbid conditions such as oppositional-defiant disorder or conduct disorder, will not be excluded provided these conditions are not seen as the primary diagnosis by the clinician. This allows for a more pragmatic trial since co-morbidity has been shown in a key trial to occur in between 30-40% of participants (MTA Cooperative Group, 1999a).

Exclusion: The following groups of participants would not be eligible due to being unsuitable for the treatments on offer, requiring additional treatment that may influence the outcomes of interest, or previous experience of homeopathy or medication.

Children/adolescents not suitable for methylphenidate or other treatment due to existing disorders: marked anxiety, symptom or family history of tics, hyperthyroidism, severe angina or cardiac arrhythmia, glaucoma or thyrotoxicosis (NICE, 2000). Children/adolescents with other serious conditions such as bipolar disorder, psychosis or personality disorder. Major neurological or physical illness. Previous use of homeopathy for ADHD. Previous use of medication for ADHD. No telephone [needed for ongoing follow-up]

Interventions

Individualised homeopathy Homeopathy itself has been defined as a complex intervention consisting of an in-depth consultation process and a homeopathic prescription which may consist of tablets or liquid. The homeopathic medicine should consist of “substances prepared according to the homeopathic pharmacopoeia” as defined by Emmans-Dean (2004: pp186) which includes a broad array of medicines. It is proposed that the individualised homeopathy will be delivered by non-medically qualified homeopaths (NMQ’s) although consideration should be taken of including medical homeopaths. The key issues around this decision centre on practicality and generalisability of the findings: there are considerably more NMQ homeopaths practicing in the UK, and such practitioners may be more likely to have the time/resource to deliver the chosen form of homeopathy.

Details of the individual practitioners, the homeopathic treatment and consultation would be recorded in line with RedHot reporting guidelines which have been established as an add-on to the CONSORT guidance when reporting controlled trials of homeopathy (Dean, Coulter, Fisher, Jobst et al., 2006).

Pharmacological therapy The suggested comparator intervention is based on current guidance for the NHS. Consisting of methylphenidate (Ritalin®, Equasym®) or dexamfetamine (Dexedrine®) – stimulant medications licensed for use in the over 6’s by NICE(2000). Delivered by Consultant Psychiatrist, dosage will be titrated for each individual child. Start with dexamphetamine and if no response move on to methylphenidate followed by alternative drugs . If drugs other than those listed above are to be used these should be agreed by a cross-site panel – these may include imipramine or clonidine (Royal College of Psychiatrists; 2004).

Protection from bias

RCTs are considered to be the most robust way of evaluating the impact of a defined intervention on a particular condition/outcome only so far as good practice is followed when designing

and carrying out such a trial. All forms of research are potentially vulnerable to bias, and despite the popularity of the RCT it is still unclear how different forms of bias can alter the treatment effect.

Remote random allocation administered by an independent source such as the University of York Trials Unit via telephone contact to prevent subversion. As recommended by Pocock (1983) randomisation should be balanced according to treatment centre so that each centre has a fair opportunity to try all treatments. Separate randomisation lists could be used for each centre since there are unlikely to be any other stratifying factors and random permuted blocks of 4, 5 and 6 used in their construction to reduce the chance of unequal allocation.

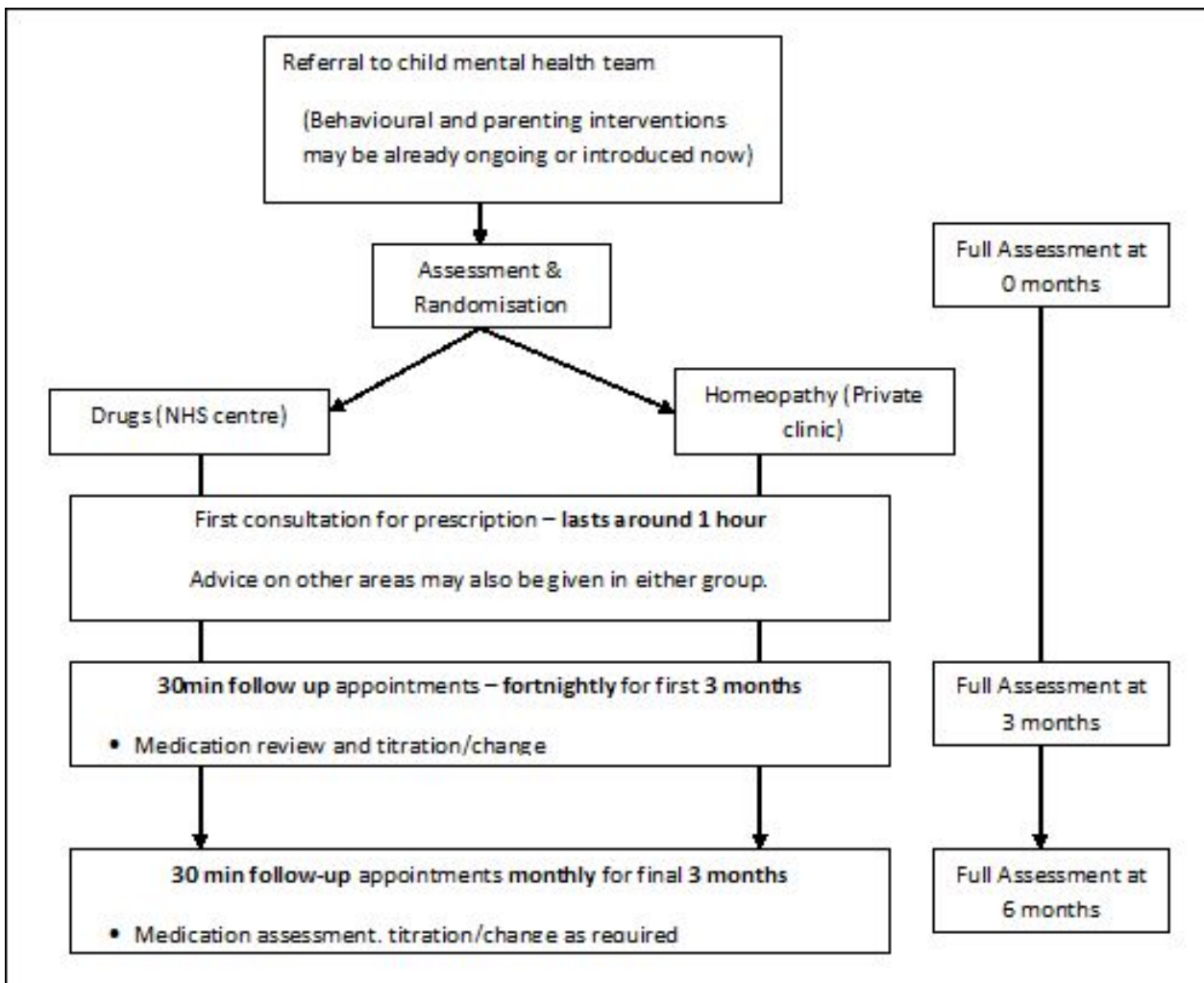
Selection bias occurs when there is a systematic difference in patients entered for each treatment and can result in exaggeration of the effect of a new intervention (Schulz, Chalmers, Hayes and Altman, 1995). It would be controlled for in this study by randomisation (doctors recruiting for the study will have no prior knowledge of the allocation) and scrutinising the rates of diagnosis versus being invited to take part in the study across sites.

Attrition bias is a potential problem for any trial. In this study measures are suggested to reduce this to a minimum and are based on the successful experiences of the MTA trial team. Careful monitoring is planned via review meetings every two weeks for both groups when dosage and other recommendations are discussed and compliance monitored. Should any meetings be missed the families will be contacted by the research assistant. In addition monthly saliva samples will be taken from each group – although not able to detect homeopathic compliance this method can adequately be used to assess medication compliance (MTA Cooperative Group, 1999a).

Reporting bias – where there may be systematic differences in the reporting of symptoms / side effects between the two active groups are possible. It is hoped this will be reduced by the use of a blinded assessor for most of the outcomes measures. Some studies have reported a lack of agreement between informants on the core symptoms of ADHD therefore to avoid bias and increase comparability with other papers this trial should use the full Conners Rating Scales (Revised)(Jadad, Booker, Gauld, Kakuma et al., 1999; Jadad, Boyle, Cunningham, Kim et al., 1999).

Detection and ascertainment biases can lead to differential misclassification of outcomes – the main outcome measure of ADHD symptoms in this trial is reported by parents, teachers and clinicians allowing careful comparison of results. Outcome data could be collected by a blinded research assistant which should also help to avoid this (Jadad, 1998).

Figure 7.3: Suggested Participant Flow



The flowchart in Figure 7.3 on the facing page illustrates the progression of patients through the two interventions and the follow-up details.

Throughout the trial one researcher will monitor attendance etc. and follow-up parents/carers if any of the monitoring sessions are missed repeatedly. Once treatment has begun patients attend a fortnightly monitoring meeting with either the homeopath or the clinician in charge of their case in the mental health team. Follow-up measures will be recorded at baseline, after three months and 6 months after commencement of treatment. An agreement has been reached with all centres that should homeopathy prove effective all parents will be given the option of continuing with the treatment under the NHS after the 6 months of the trial has been completed.

Outcome measurement

An earlier section in this discussion has addressed the relative absence of CYP focused outcome measures and why this may be particularly important for subjective symptom-based conditions such as ADHD. It is also evident from exploring the previous conventional and CAM research around ADHD that the outcome measures which are used are not always implemented/recorded appropriately resulting in data which may not be reliable and is difficult to compare across studies. Duration of follow-up is suggested to be very important in homeopathic research, and has largely been neglected in trials of conventional treatments for ADHD. Any future trials should carefully consider both the duration of the intervention arms necessary to demonstrate the presence or absence of a treatment effect, and include adequate follow-up to monitor long term benefits or side effects. By using the data being collected in the prospective case series Fibert (2012) ongoing, it should be possible to estimate the number of appointments needed to find the correct remedy/remedies and design a more realistic, pragmatic trial that reflects current homeopathic practice.

Primary outcome It is suggested that the primary outcome measure to be used for power calculations should be the Conners Global Index, a summary scale based on full symptom specific rating scales. This would facilitate comparisons across other CAM and conventional trials. The core symptoms (inattention, hyperactivity, impulsivity) would be measured using the full Conners Rating Scales – Revised (1997) (CRS-R) consisting of the Conners Rating Scale Revised Parent and Teacher forms and the Connors-Wells Adolescent Self Report; and Clinical Global Impression (severity and improvement sub scales) for clinicians. Full versions of the above forms would be used at the three evaluation points (80 items). A modified version of the Connors-Wells measure has been produced for use with ages 6-12 years and would be used for this age group allowing patient-reported outcomes to be recorded.

Quality of life This has been shown to be significantly lower in CYPs diagnosed with ADHD, and linked to a number of other adverse outcomes such as poor educational performance. These outcomes are rarely measured in the research literature, however guidelines on good trial design advocate the inclusion of such measures. Based on the findings from this project, and other published papers, homeopathy is frequently suggested to impact both on the identified symptoms but also more broadly on quality of life therefore it makes sense to try and evaluate these additional claims through appropriate outcome measures.

MYMOP The Measure Your Own Medical Outcome Profile (MYMOP) has been used in several homeopathic studies as a key outcome measure (Paterson, Ewings, Brazier and Britten, 2003; White, Slade, Hunt, Hart et al., 2003; Ludtke, Jacobs and Thompson, 2005; Relton and Weatherley-Jones, 2005) and has been adopted by the Society of Homeopaths for their national evaluation programme despite a lack of published work assessing its suitability for evaluating this therapy. MYMOP was developed by Charlotte Patterson to be a patient-generated and patient-centred problem specific outcome measure that allowed patients to select their most important symptoms while also asking about their general well-being (Paterson, 1996; Paterson, Langan, McKaig, Anderson et al., 2000; Paterson, 2004). At least 3 further variations on MYMOP 1 have been produced including the MYCaW ((Paterson, 2003)), the MYMOP pictorial ((Day, 2004)) and MYCHOPS (personal communication) - the latter is intended for completion by a child's main caregiver. MYMOP pictorial and the MYCHOPS are under-researched and there is little evidence of their validity or reliability in comparison with the original MYMOP format. The appeal of this measure may lie within the brevity and ease of administration, ease of use by practitioner-researchers and its use of patient-generated symptom descriptions rather than imposing diagnoses from western bio-medicine which may not be compatible with a complementary framework.

Although MYMOP may be a useful tool to include, depending on the burden imposed on participants, until further evaluation and validation is carried out there is no suitable version that can be completed by the CYP directly. In contrast the PedsQL is a well validated and rigorously developed package of quality of life outcome measures that includes the Generic Core Scales (parent and CYP forms)(Varni, Seid and Kurtin, 2001), a Family Impact module (parents) (Varni, Sherman, Burwinkle, Dickinson et al., 2004), and several condition specific add-on modules (Varni, Burwinkle, Katz, Meeske et al., 2002; Varni, Burwinkle, Jacobs, Gottschalk et al., 2003; Varni, Burwinkle, Rapoff, Kamps et al., 2004). Although there is no ADHD specific add-on, the Generic Core Scales have been evaluated in an ADHD diagnosed population and demonstrated minimal missing responses, good reliability and agreement between parent and child report forms and distinguished between CYPs with ADHD versus healthy children and children with other chronic conditions (Bastiaansen, Koot, Bongers, Varni et al., 2004; Sallee, Ambrosini, Lopez, Shi et al., 2004; Varni and Burwinkle, 2006).

The most commonly used QoL outcome for economic evaluations is the EQ-5D, while it can be insensitive to small changes in health states it provides well validated data J, J and M. (2002); J, M and C (1999). The standard EQ-5D has been evaluated in ADHD diagnosed populations, and there has been some work to develop a version which can be completed by CYPs (Badia Llach, Herdman and Schiaffino, 1999; Secnik, Matza, Cottrell, Edgell et al., 2005; Hennessy, Kind and Group, 2002). This may be a useful outcome measure to include, particularly if cost data are collected and cost-effectiveness is to be considered.

Adverse effects These are often not fully captured during RCTs, due to time constraints, but a suitable scale could be the Pittsburgh Side Effects Rating Scale (including loss of appetite, insomnia, headache, stomach ache and weight loss) measured using the (13 items rated as not present, mild, moderate or severe) (see Pelham 1993 for details). These items are rated by the parent or guardian, there does not appear to be a relevant side effects measure validated for completion by CYPs at present, although this would be of value.

Qualitative outcomes The experiences of practitioners, parents and CYPs during and after the trial could be explored most usefully through semi-structured interviews carried out by an independent researcher who was not otherwise involved with the trial. Decisions around the sampling of those to be interviewed should be considered carefully, and may be based on participant characteristics and/or treatment outcomes. The interviews themselves should be informed by existing qualitative research on CYPs with ADHD (all papers located in scoping searches focus on experiences of conventional treatment) and include questions about the experience of the condition, treatment related items and explore the outcome measures themselves. Interviewing children is an area that can be challenging and raises issues about consent, confidentiality and power balance (Lewis and Lindsay, 2000). The following paragraphs outline ways in which these concerns might be addressed and are offered as a useful starting point for researchers. The systematic review by Worrall-Davies et al of qualitative studies around how CYPs are consulted about their experiences of child and adolescent mental health services has also been used as a resource (Worrall-Davies and Marino-Francis, 2008).

It is suggested that parents be interviewed first prior to talking with the children. This would perform two functions; firstly it reassures parents as to the nature of the research while answering any outstanding questions, secondly it gathers information on the way each family referred to the attentional difficulties and related problems. CYP's would then take part in semi-structured interviews using activities, discussion and creation of an experience book to elicit their experiences and opinions about the treatment and the questionnaires. This would be based on work by Brady where the researcher successfully interviewed a number of children diagnosed

with ADHD about their experiences (Brady, 2004), while drawing on ideas suggested by Angela Veale (2005). Interviews could take place in the home without the parent present, provided both child and parent were happy with this. Previous research has shown that children and young people with attentional difficulties are capable of participating in both interviews and collaborative activities while articulating their experiences. The interviews would take advantage of this and engage the participants in creating something such as an “All About Me” book or folder to record their experiences in the trial (partially based on a similar idea from Harmin, 1978). This activity would provide a concrete talking point throughout the interview process and offer structure and consistency. Pages would include a space for the CYP to draw or identify themselves (Phillip, 1989), a page about the things they like and a page about what they might want to be different (Hobday and Ollier, 1999). The second interview could incorporate a more direct exploration of the outcome measures completed by the child in the study and draws on the previous work available to develop this methodology Rebok, Riley, Forrest, Starfield et al. 2001. The All About Me Book/Folder would be retained by the researcher throughout the study for review and preparation and then photocopied before being returned to the child/young person at the end of the trial.

The interviews will deal with important and potentially sensitive issues. Therefore it is recommended that at the beginning of each interview it is made clear to all participants that they have the right to stop at any point, take a break, not answer individual questions or withdraw without any repercussions. A simple red card/yellow card system could be used with the younger children to facilitate any desire to withdraw or pause the interview process. A yellow card indicates they do not wish to answer a question, the red card indicates that they wish to stop the interview – either for a break or completely. Where the interviewee appears to be distressed or uncomfortable a short break should be offered and verbal confirmation of a desire to continue with the interview obtained.

The children’s eagerness and willingness to talk about their disorder and being medicated for it, which they revealed during the interviews, clearly indicates that these children want to be heard and need to be heard. Clarke (1998)

The lack of research in this area asking children and parents about these outcome measures makes the topics important to include, and previous qualitative research with children diagnosed with ADHD (Krueger and Kendall, 2001; Santoro, 2003; Clarke and Eiser, 2004) has found that participants wished to talk about their experiences in detail.

Dissemination

The dissemination of research has often been seen as covered by the publication of a technical journal article although other forms of knowledge transfer are being used ad hoc by public health and health services researchers (Wilson, Petticrew, Calnan and Nazareth, 2010). As discussed earlier, such methods have some value but may not result in a reader-friendly paper nor reach the practitioners or relevant decision-makers. If the trial described above was to be conducted, then dissemination of the results and implications must extend to sharing information via practitioner organisations, and healthcare commissioners. Regardless of the trial result, it would be vital to establish external validity for such a trial by involving practitioner and patient groups from early on, and making use of this network when undertaking dissemination. This may involve making the reports and articles freely available on open-publishing sites, as well as developing tailored information releases similar to the Effectiveness Matters bulletins published by the Centre for Reviews and Dissemination, University of York. The incorporation of both any future trials, and the results from the ongoing study in Canada into the existing Cochrane systematic review would help to encourage cooperation and coherency within a challenging field of research.

7.8 Conclusions

Complementary and alternative medicine is increasingly evaluated from an evidence-based medicine perspective which includes clinical trials. As with conventional medicine the adoption of an evidence-based approach has not been straightforward with issues of power, professional identity and poor dissemination adding complexities to the situation. One of the oft-repeated criticisms of the evidence-based movement has been that randomised controlled trials rarely mirror clinical practice, either in terms of the the treatment or in the characteristics of the included patients. These challenges are most pressing when considering complex interventions for poorly understood, chronic, difficult to diagnose conditions, regardless of conventional or complementary medicine status.

Homeopathy for the treatment of Attention Deficit Hyperactivity Disorder has been used as an example to explore the overlap, dissonance and gaps between research trials and clinical practice. Homeopathy is a well known form of complementary medicine which continues to inspire strong feelings within adherents and sceptics alike. Despite a very mixed evidence base, and no accepted mechanism of action, homeopathy continues to be used by the general population, and chosen by parents and guardians to treat their children. Homeopathic practitioners have suggested they can effectively treat ADHD, among other behavioural conditions, without

the use of the strong pharmacological agents that discourage many parents from considering treatment.

A traditional aggregate systematic review was taken as a starting point and conducted according to best practice guidelines. The data set was then developed using individual patient data meta-analysis to explore questions about the individual trials. A comprehensive mixed-methods research design using the framework of Grounded Theory set within subtle realism has used primary, secondary, qualitative and quantitative data to further investigate homeopathy for ADHD in children. Grounded theory was selected as a suitable approach with well described methods useful for a relatively novice researcher and techniques that encouraged transparent reporting throughout.

Mixed-methods were used in an attempt to capture the richness of the area, practitioner knowledge and day to day practice. The most appropriate data collection and analysis tools were chosen pragmatically according to the available data rather than according to a particular paradigm with each offering an alternative perspective. The sources of evidence considered were deliberately broader than just randomised controlled trials and incorporated controlled and observational studies, case studies, reports of personal experience and expert texts. The reality of clinical practice was investigated via a range of qualitative and quantitative data collection methods, and led to the exploration of how homeopaths interact with and think about both research and evidence.

This project has explored the available evidence base and clinical practice, focusing on the UK context, and generated a synthesis that points to homeopathy as a process of individualisation. There was little reliable trial evidence that homeopathy can positively affect the symptoms of ADHD as measured using validated scales. Trials to date have not clearly reported details of the homeopathic intervention, and based on this synthesis are unlikely to have reflected clinical practice within the UK. The diversity of practice observed presents unique challenges for researchers who wish to improve the evidence base, and future publications should follow the RedHot guidelines where possible (Dean, Coulter, Fisher, Jobst et al., 2006).

A model of homeopathy as a process of individualisation has been offered as a starting point for future research both on the practice of homeopathy and on the effectiveness of the treatment. Practitioners appear to be conducting complex consultations with children/young people and their guardians where the homeopath must balance building rapport with accurate data collection leading to successful remedy prescriptions. Children seem to be quite clearly present in homeopathic consultations, both physically and in terms of practitioner focus. Future evaluative work in homeopathy might fruitfully include childrens' own perspectives through interviews

and outcome measurement. The outline of a future comparative trial has been provided which incorporates these ideas.

Homeopathy as a healthcare profession still has a difficult relationship with research. This research found there was a lack of engagement with evidence-based attitudes, and research was largely used as a tool for validation rather than improving practice. This is not unusual in marginal professions but may be more easily identified within homeopathy. There is therefore considerable potential to facilitate open-minded critical thinking in this field and encourage the open sharing of data for further analysis.

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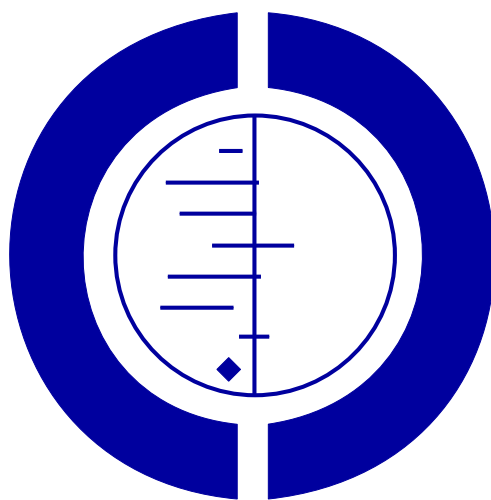
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Appendix 1

Cochrane Systematic Review Protocol

Homeopathy for attention deficit/hyperactivity disorder or hyperkinetic disorder (Protocol)

Dean ME, Coulter MK



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Homeopathy for attention deficit/hyperactivity disorder or hyperkinetic disorder (Protocol)

Dean ME, Coulter MK

This record should be cited as:

Dean ME, Coulter MK. Homeopathy for attention deficit/hyperactivity disorder or hyperkinetic disorder. (Protocol) *Cochrane Database of Systematic Reviews* 2006, Issue 1. Art. No.: CD005648. DOI: 10.1002/14651858.CD005648.

This version first published online: 25 January 2006 in Issue 1, 2006.

Date of most recent substantive amendment: 14 November 2005

ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

1. To assess the efficacy of homeopathy as a treatment for ADHD/HKD.
2. To evaluate the safety of homeopathy as a treatment for ADHD/HKD.

BACKGROUND

Background

Attention-deficit/hyperactivity disorder (ADHD) has only existed as a diagnostic category since 1980, with the publication of the Diagnostic and Statistical Manual (DSM) Version III (Barkley 1990). However, the syndrome has been under investigation since the 1900s, when a group of impulsive children was first identified in the UK whose marked behavioural problems were thought to have a genetic basis, rather than attributable to poor child rearing (Still 1902). Interest in the condition in the US followed an encephalitis epidemic in 1917-18, with the occurrence of persistent inattention, hyperactivity and impulsiveness in some of the surviving children. Brain damage following infection or trauma was regarded as the likely cause of the condition until hyperactivity syndrome began to be distinguished from brain damage syndromes in the 1960s. Since the 1970s hyperactivity syndrome has been closely associated with attention deficits, leading to wide acceptance that ADHD is a complex disorder with both developmental and biological underpinnings. Brain imaging and genetic research are current areas of interest, but observation of behaviour remains the basis of diagnosis in the absence of reliable tests for biological markers.

DSM-IV diagnostic criteria for ADHD include the 'core' signs of inattention, hyperactivity and impulsiveness. They also recognize three subgroups of ADHD: i) predominantly hyperactive-impulsive type (not showing significant inattention); ii) predom-

inantly inattentive type (not showing significant hyperactive-impulsive behaviour); and iii) combined type (displaying inattentive and hyperactive-impulsive symptoms) (APA 2000). Hyperkinetic disorder (HKD) is the term used in ICD-10 (WHO 1992), and refers to a more seriously affected subgroup, similar to patients diagnosed as having DSM-IV 'combined type'.

Diagnosis is usually determined by child/adolescent psychiatrists or paediatricians with specific expertise, and should have been made with reference to one of the aforementioned guides. For a diagnosis of ADHD/HKD these symptoms must have been present for at least six months, causing distress and in conflict with the child's developmental level, and impairment should present and be apparent in two or more settings. The symptoms should have been present before the age of 7 years, and should not be better explained by an alternative diagnosis.

Using ICD-10 criteria, prevalence has been estimated at around 1% of school-aged children in the UK, increasing to 5% if DSM-IV criteria are used. This translates to around 366,000 children in England and Wales (Lord 2000). A US population-based birth cohort study of 5,781 children estimated a prevalence of 7.5% at age 19 years using DSM-IV criteria (Barbarese 2004). Lower UK prevalence may be due to use of ICD-10 criteria, and to diagnosing the condition only after referral to secondary care, among other factors. ADHD can affect both males (more commonly) and females, of any ethnicity. The affected population has generally been defined as children and adolescents to age 18 years. After this point the patient is usually referred to adult services although in

some areas this occurs at age 16 (ADDISS 2003). ADHD persists in 30% to 70% of adults having had the disorder in childhood, and a self-report screening scale for detection of ADHD in general adult populations without a previous diagnosis is under development and has shown reasonable concordance with blind clinical diagnoses in a US community sample (Kessler 2005).

Interventions

Currently available treatments for ADHD include behavioural training for teachers and parents, and parenting skills classes. Drug therapy began in the 1930s (Bradley 1937), and started to attract attention in the 1950s (Laufer 1957). Since the 1970s, stimulants such as dexamfetamine, and methylphenidate have increasingly been used as the treatment of choice (Coghill 2004), but remain controversial (Timini 2003). More recently, the first licensed drug treatment claimed by the manufacturer to be a non-stimulant was atomoxetine.

Homeopathy

In recent years, homeopathy has gained general prominence as an alternative form of treatment. The therapeutic system originated 200 years ago with the German physician and pharmacologist Samuel Hahnemann (1755-1843). As codified by him, it has numerous features to distinguish it from botanical and conventional approaches to diagnosis and treatment (Hahnemann 1913). Its fundamental principle is treatment of 'like with like': any natural or man-made substance capable of causing specific disease states and symptoms in healthy individuals may be used to treat the same symptoms when they occur as part of sickness. During homeopathic diagnosis, each patient is considered uniquely, rather than as suffering with a fixed disease category. Information on qualitative aspects of the patient's experience of illness (for instance, emotions such as 'feeling forsaken' or symptom modalities such as 'restlessness increased after 1800 hours') is of particular relevance in determining treatment. Concomitant symptoms and co-morbid conditions are also included in the analysis, as part of a meaningful gestalt or 'symptom complex'. Homeopathic pharmacy involves a unique process in which the source material is serially diluted, with agitation. Called 'dynamization' or 'potentization', the process may be repeated many times until no molecules of the starting substance theoretically remain. During treatment, medicines, dilution, dosage and repetition may be changed in response to changes in the patient's condition.

Different homeopathic approaches have been tested in clinical trials, and categorized as 'classical', 'clinical', 'complex' and 'isopathic' subtypes (Linde 1997). Classical homeopathy is the complex intervention described above, involving an in-depth consultation and individualized analysis (Chapman 1999). Clinical homeopathy is not holistic treatment, but provides a standardized prescription for a predefined condition, based either on traditional recommendations, or new analysis of symptoms (Clark 2000). Complex homeopathy combines several clinical medicines into a single formula (Weiser 1998). Isopathic medicines are prepared

from known or presumed aetiological agents (Taylor 2000). Classical homeopathy can potentially include the other modalities, as part of an individualized course of treatment.

Several global systematic reviews and metaanalyses have evaluated all available trials of homeopathy meeting specific criteria, and found evidence of superiority to placebo (Linde 1997; Cucherat 2000; Dean 2004; Kleijnen 1991). A meta-regression of placebo-controlled homeopathy trials and randomly selected orthodox trials has claimed that specific effects of homeopathic medicines could be attributed to placebo (Shang 2005). In this study, the trials were matched for study type and condition, but not for study quality, homeopathy trials being significantly higher quality than the comparison trials. A systematic review of adverse effects of homeopathy reported that it is generally safe, but that adverse effects might be under-reported (Dantas 2000). Of several reviews of homeopathy for specific conditions, one did not find enough evidence to reliably assess the possible role of homeopathy in chronic asthma (McCarney 2004), while a proprietary formulation for influenza-type syndromes was found to reduce length of influenza illness by 0.28 days (Vickers 2005). To our knowledge no systematic review has been carried out on the safety and effectiveness of homeopathy for ADHD (Brue 2002), although at least two prospective randomized trials have been published where classical homeopathy was used to treat patients who fulfilled DSM-IV criteria for ADHD (Lamont 1997; Frei 2005).

OBJECTIVES

1. To assess the efficacy of homeopathy as a treatment for ADHD/HKD.
2. To evaluate the safety of homeopathy as a treatment for ADHD/HKD.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Efficacy: Randomised and quasi-randomised trials (e.g. by day of the week, alternate numbers, case number or alphabetical order) comparing homeopathy with no treatment, placebo, medication, behavioural or educational interventions, or other usual care. Quasi-randomised trials will be included in the review but not in any meta-analysis.

Safety: Any design including non-randomised controlled studies, cohort studies, case-controlled-studies, and case series.

Types of participants

Participants diagnosed with ADHD or HKD according to recognised criteria: DSM-IV (APA 2000) or ICD-10 (WHO 1992). Children and adults will be included, but analysed separately.

Co-morbidity: classical homeopathy treats 'whole patients', in addition to their conventional disease labels. Participants who, however, have a separate diagnosis of autistic spectrum disorder, learning disability, etc., will be analysed separately.

Types of intervention

Homeopathic medicines prepared according to national pharmacopeias, or other explicit protocols. Eligible comparisons for this review were compiled by consulting the relevant literature (Lord 2000; MTA 1999; CRD 2005) and include the following:

- Wait-list or no treatment
- Pharmacological treatment (e.g. methylphenidate etc)
- Usual care (if patient has not been referred to a secondary centre for assessment this will cover any intervention being offered by the GP, primary mental health worker or educational psychologist if involved)
- Multidisciplinary packages (secondary care: school-based interventions, behavioural training, parenting skills)
- Placebo (usually this consists of the patient participating in a normal homeopathic consultation but receiving placebo medication instead of the remedy).

The 'added value' of homeopathy (in, for example, trials of medication plus homeopathic treatment versus medication alone) will be considered.

Types of outcome measures

Trials reporting at least one of the following outcome measures will be included

- Overall incidence/severity of the problem behaviours
- Incidence/severity of the core symptoms
- School/academic performance measured via grades or teacher reports
- Depression/anxiety-related outcomes measured with appropriate scales validated for use with children and/or adolescents
- Conduct/oppositional disorder outcomes (as above)
- Adverse effects, measured with a validated scale (preferably based on parent or child responses) such as Barkley Stimulant Drugs Side Effects Rating Scale (Barkley 1990)
- Quality of Life
- Clinical Global Impression score changes (NIMH 1985)

Studies that report ADHD symptom improvement as a secondary rather than a primary outcome will also be included.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Developmental, Psychosocial and Learning Problems Group methods used in reviews.

Databases will be searched without language restrictions for any paper mentioning homeopathy and its synonyms (homeop\$, homoeop\$, homöop\$, omeop\$ etc.).

The records from each search will be compiled into a single EndNote library and de-duplicated. The library will then be searched, using the following disease- and population-specific terms:

- 1.Attention Deficit Disorder with Hyperactivity/
- 2.adhd
- 3.addh
- 4.adhs
- 5.hyperactiv\$
- 6.hyperkin\$
- 7.attention deficit\$.
- 8.brain dysfunction
- 9.or/1-8
- 10.Child/
- 11.Adolescent/
- 12.(child\$ or boy\$ or girl\$ or schoolchild\$ or adolescen\$ or teen\$ or young pe\$ or youth\$)
- 13.or/10-12
- 14.1 and 9 and 13

An RCT filter will not be used as a broad range of study designs will be evaluated (see Types of Studies above).

Published trials

The following databases will be searched from inception:

- Cochrane Central Register of Controlled Trials (CENTRAL), published in *The Cochrane Library*
- MEDLINE
- PreMedline
- AMED
- BIOSIS
- Centre for Complementary Medicine Research (University of Munich, Germany)
- CISCOM (Research Council for Complementary Medicine)
- CINAHL
- Dissertation Abstracts
- ECH (European Committee for Homeopathy thesis database)
- EMBASE
- ERIC
- HomInform (Glasgow Homeopathic Hospital Library)
- LILACS (Latin American database)
- PsycINFO
- Science Citation Index
- SIGLE (Grey Literature in Europe)

Ongoing research:
Clinical Trials (USA)
Current Controlled Trials (UK)
National Research Register (UK)

Conference proceedings etc:
ISI Proceedings
GIRI - International congress on ultra-low doses
Liga Medicorum Homeopathica Internationalis
SIGLE

Unpublished trials

We will request information on unpublished trials from authors of published studies, and experts and information groups in the areas of ADHD and homeopathy.

METHODS OF THE REVIEW

Selection of studies

Two authors (MKC and MED) will independently screen the titles, abstracts and keywords of all records using disease- and population-specific terms, and note their decisions on potential study acceptability. Copies of all selected articles will be obtained, and reviewed independently by the same authors. The reference lists of retrieved articles will be scanned to identify further trials. At all stages, reasons for inclusion and exclusion of articles will be noted. Disagreements will be resolved through consensus, or referred for arbitration by the editorial base of the Cochrane Developmental, Psychosocial and Learning Problems Group (CDPLPG) if needed.

Quality assessment

Two authors (MKC and MED) will independently assess the methodological and reporting quality of the individual trials using the Delphi List (Verhagen 1998). The checklist comprises the following 9 questions:

1. Treatment allocation
 - a) was a method of randomisation performed?
 - b) was the treatment allocation concealed?
2. Were the groups similar at baseline regarding the most important prognostic indicators?
3. Were the eligibility criteria specified?
4. Was the outcome assessor blinded?
5. Was the care provider blinded?
6. Was the patient blinded?
7. Were point estimates and measures of variability presented for the primary outcome measures?
8. Did the analysts include an intention-to-treat analysis?

Each question may be answered Met, Not Met, or Unclear. Disagreements will be resolved through consensus, or referred for arbitration by the editorial base of the CDPLPG if needed.

Data management

A standard data extraction form will be developed by both authors (MD and MC). Data on settings, populations, method of diagnosis, interventions, outcomes, and analysis will be extracted by one author and independently checked for accuracy by the second author. Data from studies with multiple publications will be extracted and reported as a single study. Subsequent versions of the form will include revision dates. Attempts will be made to contact authors for missing data, and all such correspondence logged.

Homeopathic treatments will be categorized as:

1. Classical
2. Clinical
3. Complex
4. Isopathy

Each trial will be independently assigned to one of these groups by the two authors. Disagreements will be resolved through consensus, or referred for arbitration by the editorial base of the CDPLPG if needed.

The results of the data extraction and quality assessment for each trial of clinical effectiveness will be presented in structured tables, derived from the data extraction form, combined within a meta-analysis if appropriate and possible, and further summarised in a narrative. The possible effects of study quality on the effectiveness data and review findings will be discussed and sensitivity analyses undertaken if appropriate (see below).

Data synthesis

Where sufficient data are available and statistical combination is appropriate, a meta-analysis will be undertaken, using RevMan 4.2 software (RevMan 2003).

Measurements of treatment effect

Where sufficient data are available treatment effects will be presented as relative risks (RR) for dichotomous data, weighted mean differences for continuous data or as hazard ratios where appropriate. If continuous outcomes are measured with similar, but not identical, instruments across studies, standardised mean differences will be calculated. Relative risks will be presented as Forest plots, but only pooled when this is statistically and clinically meaningful. Studies will be grouped according to the comparator used.

Heterogeneity

Heterogeneity between the included studies will be assessed by considering differences in (a) the study population, (b) intervention, (c) outcome measures, and (d) study quality. In addition, where pooling seems appropriate, two tests of heterogeneity will be performed. Additionally we will assess the variation of effects that may be due to factors other than sampling error using I^2 (Higgins 2002), available with RevMan software.

Sensitivity analysis

A sensitivity analysis allows for a measurement of the robustness of results in terms of *a priori* assumptions made at the outset of

the review. Sensitivity analysis will be conducted if appropriate for publication bias (published versus not published), trial quality (overall effects on trial quality), and treatment analyses (intention-to-treat versus non-intention-to-treat).

Subgroup analysis

Where sufficient data are available subgroup analyses will be used to investigate whether homeopathy has different effects in different populations. We are aware that reliance on subgroup analyses can lead to misleading conclusions (Oxman 1992; Yusuf 1991) and will conservatively look only for effects related to gender and age (patients), and homeopathic treatment type (interventions).

Assessment of bias

Where feasible, the possibility of publication bias will be investigated funnel plots (trial effect versus standard error) if sufficient studies are found, or Galbraith plots if not. Asymmetry could be due to publication bias, but could also be due to a relationship between trial size and effect size. In the event that a relationship is found, clinical diversity of the studies will also be examined (Egger 1997).

Time Frame

It is anticipated that the review will be completed within six months of the publication of this protocol. Following the publication of the initial review, we plan to search biennially for new evidence, and to obtain and analyse any new data that have been collected or published.

POTENTIAL CONFLICT OF INTEREST

MED is funded by the Department of Health (UK) as a researcher-practitioner of homeopathy.

SOURCES OF SUPPORT

External sources of support

- Department of Health UK

Internal sources of support

- University of York UK

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COVER SHEET

Title	Homeopathy for attention deficit/hyperactivity disorder or hyperkinetic disorder
Authors	Dean ME, Coulter MK
Contribution of author(s)	MD is responsible for the overall design and co-ordination of the review. MC and MD were jointly responsible for the development of the protocol. The literature search and screening of retrieved papers against the inclusion criteria will be undertaken by MD and MC. MD and MC will appraise the quality of the selected papers and extract data. Both authors will contribute to the analysis and interpretation of the data and the completion of the review.
Issue protocol first published	2006/1
Date of most recent amendment	16 November 2005
Date of most recent SUBSTANTIVE amendment	14 November 2005
What's New	Information not supplied by author
Contact address	Dr Mike Emmans Dean Department of Health Sciences University of York Seebohm Rowntree Building York YO10 5DD UK E-mail: med5@york.ac.uk Tel: 44 1904 321904 Fax: 44 1904 321388
DOI	10.1002/14651858.CD005648
Cochrane Library number	CD005648
Editorial group	Cochrane Developmental, Psychosocial and Learning Problems Group
Editorial group code	HM-BEHAV

Appendix 2

Contacts relevant to systematic review searches

ADHD Support Groups

ADDISS

ADDERS

Hyperactive Children's Support Group

National Attention Deficit Disorder Information and Support Service

Parentline Plus

The Paediatric Psychopharmacology Group

Medical/ADHD Specific Bodies

Association of Child Psychotherapists

Barnardo's

British Paediatric Neurology Association

British Psychological Society

Royal College of Paediatrics and Child Health

Royal College of Psychiatrists

ADHD Experts

Professor Eric Taylor

David Coghill

Homeopathy General Contacts

Some of this information was gathered from Google web searches, helpful listings were also provided by the Homeopathic Internet Resources List 1995-2005 [<http://www2.antenna.nl/homeoweb/organisations.html>] compiled and updated by E. van Galen.

Glasgow Homeopathic Hospital

Royal London Homeopathic Hospital

Bristol Homeopathic Hospital

Research Council for Complementary Medicine (RCCM)

Homeopathy Experts

Dr. Harald Walach

Jennifer Jacobs

Robert Mathie

David Reilly

Dr. Peter Fisher

Dr. Mike Emmans Dean

Homeopathic Professional Bodies & Organisations

The main bodies are listed below, but further organizations are listed at “Homeopathy Societies & Organisations” [http://www.drlockie.com/homp_org.htm].

UK Based Organisations:

Society of Homeopaths

The Faculty of Homeopathy

British Homeopathic Association

Alliance of Registered Homeopaths

USA Based Organisations:

American Institute of Homeopathy

North American Society of Homeopaths

National Center for Homeopathy USA

Dr. Alberto Espin Sabate American Institute of Homeopathy, USA

Australian Homoeopathic Association, Michael Tomlinson, PhD.

Europe and Rest of the World:

Academia Medico Homeopatica de Barcelona, Spain,

European Committee for Homoeopathy (ECH),

Dr. Ton Nicolai European Council for Classical Homeopathy (ECCH)

International Council for Classical Homeopathy (ICCH)

Homeopaths Sans Frontieres / Homeopaths without Borders. Dutch section: Dr. Martien Brands

International Network for the History of Homeopathy, referent: Dr. Martin Dinges

LIGA Medicorum Homoeopathica Internationalis (LMHI), Dr. Ton Nicolai,

Netherlands Osterreichische Gesellschaft fur Homoeopathische Medizin, Vienna, Austria

Syndicat de la medecine homeopathique (France)

Homoopathie-Forum Organisation Klassisch Homoopathisch (Germany)

Mailing lists contacted:

CAMRN mailing list which is moderated and run by the RCCM

Homeopathy List: unmoderated list for all aspects of homeopathy administrator: Jon Haworth
E-mail jon@cam.dungeon.com

ACHRN list: Alternative Complementary Health Research Network mailing list

Appendix 3

Data Extraction Form

Data extraction forms

General Information

Data extraction date:		ENL Ref:		Reviewer:	
Authors:					
Contact:					
Article title:					
Source (journal/conference etc):					
Year:		Vol:		Pages:	
				Country of origin:	

Eligibility

	Criteria	Yes	No	Eligible for:
Population	Children or adults diagnosed with ADHD (DSM-IV) or HKD (ICD-10)	<input type="checkbox"/>	<input type="checkbox"/>	Effectiveness? <input type="checkbox"/>
Intervention	Homeopathy: individualised, formula or isopathy	<input type="checkbox"/>	<input type="checkbox"/>	Safety? <input type="checkbox"/>
Outcome	Incidence/severity of key symptoms, school performance, depression or anxiety outcomes, adverse effects, quality of life	<input type="checkbox"/>	<input type="checkbox"/>	
Study Design	RCT, quasi or non randomised CT, cohort study, case-control study or case-series.	<input type="checkbox"/>	<input type="checkbox"/>	

Notes

Population and Setting

Target population:			
Inclusion criteria:			
Exclusion criteria:			
Recruitment procedures:			
Participation rates:			
Participant characteristics at baseline:			
Age:		Ethnicity:	
Sex:		Class:	
Other information:			
Numbers of participants per condition:			
Condition A		Condition C	
Condition B		Condition D	
Were intervention and control groups comparable:			
Notes:			

Methodological quality of the study

Design of Study:	
Randomised Controlled Trial <input type="checkbox"/> Quasi-randomised CT <input type="checkbox"/> Non-randomised CT <input type="checkbox"/> Cohort (matched concurrent controls) <input type="checkbox"/> Cohort (unmatched concurrent controls) <input type="checkbox"/> Cohort (historic) <input type="checkbox"/> Case-control <input type="checkbox"/> Case-series <input type="checkbox"/>	
Unit of allocation:	
Method of randomisation:	
If not randomised, method of allocation:	
Blinding:	

Cochrane Handbook Items

Item	Description (to be completed)	Met/Not Met/Unclear
Sequence generation adequate?		
Allocation concealment adequate?		
Blinding of participants, personnel and outcomes adequate?		
Incomplete outcome reporting adequately addressed?		

RedHot Details

REDHOT ITEM		Details	Reported Pg No
1. Rationale	Type of homeopathy (individualised/formula/isopathy)		
	Analysis strategy, tools, references		
	Evidence base		
2. Participants	Knowledge condition		
3. Medications	Manufacturer, pharmacopoeia		
	Potency and scale		
	Dilution method		
	Nomenclature (list of remedies or constituents if formula)		
4. Consultations	Dosage (dose, repetition, form)		
	Setting		
	Duration/frequency of consultations		
	Confidence in prescriptions		
5. Practitioners	Practitioners (number, experience, style)		
6. Co-Interventions	Co-interventions (included/excluded)		
7. Control Interventions	Active (rationale, references)		
	Placebo (manufacturing process)		
8. Adverse events	Aggravations		

Interventions:

Condition	Details of intervention	Delivery	Duration	Other notes
Condition A				
Condition B				
Condition C				
Condition D				
Intervention Site:				
Mediating variables:				
Type of homeopathy:				

Outcomes

Measured at baseline:	
Measured after intervention:	
Measured by:	
Primary outcome measure:	
Validation of tools used:	
Time intervals between measures:	

Analysis

Statistical techniques used:								
Adjusted for confounding:								
Unit of analysis:								
Attrition rate and method:								
Follow-up rates:	Condition A		Condition B		Condition C		Condition D	

Results

Variable		Condition A n=		Condition B n=		Condition C n=		Condition D n=	
		Mean	SD	Mean	SD	Mean	SD	Mean	SD
Var 1	Pre-test								
	Post-test								
	Difference								
Var 2	Pre-test								
	Post-test								
	Difference								
Var 3	Pre-test								
	Post-test								
	Difference								
Var 4	Pre-test								
	Post-test								
	Difference								

Effect size estimate:

Safety and Adverse Effects

Measurement tools used:	
Validity:	
Results:	
Other method of recording adverse effects:	
Results:	
Comments:	

Appendix 4

Risk of Bias Criteria

Outcome data criteria table (from Cochrane Handbook revised 2007)

Were incomplete outcome data adequately addressed?

Criteria for a judgement of MET (i.e. low risk of bias)	<p>Any one of the following:</p> <ul style="list-style-type: none">▪ No missing outcome data▪ Reasons for missing outcome data unlikely to be related to true outcome▪ Missing outcome data balanced in number across groups, with reasons for missing data having same profile across groups▪ For dichotomous outcome data, a proportion of missing outcomes compared with observed proportion of events not enough to impact on observed effect size▪ For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to impact on observed effect size
Criteria for a judgement of NOT MET (i.e. high risk of bias)	<p>Any one of the following:</p> <ul style="list-style-type: none">▪ Reason for missing outcome data likely to be related to true outcome, with either imbalance in number across groups or reasons for missing data having difference profiles across groups▪ For dichotomous outcome data, a proportion of missing outcomes compared with observed proportion of events enough to induce bias in observed effect size▪ For continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce bias in observed effect size▪ 'As-treated' analysis with substantial departure of the intervention received from that assigned at randomisation▪ Potentially inappropriate application of simple imputation
Criteria for a judgement of UNCLEAR (i.e. uncertain risk of bias)	Insufficient reporting of attrition/exclusions to permit judgement (e.g. number randomised not stated, no reasons available)

Appendix 5

Risk of Bias Assessments

Assessing Risk of Bias Tables

Risk of Bias (Lamont 1997)

Item	Description	Judgement
Sequence generation adequate?	This study was quasi-randomised using alternation	not met
Allocation concealment adequate?	Allocation was performed by the clinician who was also the researcher and performed the analysis. Assignments were easily predicted.	not met
Blinding of participants, personnel and outcomes adequate?	Participants (children) and their families/carers were blinded to the treatment allocation since they were not informed of the use of placebos in this trial. The study investigator who also collected the outcomes data was unblinded.	met for patients but not investigator
Incomplete outcome reporting adequately addressed?	Three children (out of 43) were withdrawn from the active intervention arm after changes to their stimulant medication following homeopathic treatment. These participants were not included in any of the analyses. No attrition or loss-to-follow-up was reported for this study.	not met

Risk of Bias (Strauss 2000)

Item	Description	Judgement
Sequence generation adequate?	The study was described only as randomised in the publication, personal communication with the author reported that a fellow researcher carried out the randomisation using a computer	met
Allocation concealment adequate?	Fellow researcher carried out the randomisation and then made up the verum or placebo medications appropriately (personal communication).	unclear
Blinding of participants, personnel and outcomes adequate?	Described as double blind in publication. Participants and families were blinded - being given verum or indistinguishable placebo medications according to treatment allocation. The investigator was blinded to allocation during the trial (known only to colleague). Investigator unblinded during analysis.	met
Incomplete outcome reporting adequately addressed?	Published paper reported 20 patients randomised to the study with no data on attrition or exclusion. Communication with author: of an original 22, one was withdrawn due to lack of compliance and a second was advised by their general practitioner to drop-out (Strauss 2007). No data have been presented on these patients, and they were excluded from all analyses.	not met

Risk of Bias (Frei 2005)

Item	Description	Judgement
Sequence generation adequate?	Allocation was based on stratified computer generated randomisation tables. Stratifying variables: age and symptom severity measured by CGI-P.	met
Allocation concealment adequate?	The randomisation tables were generated at the University of Berne, the treatment assignments were then sealed in consecutively numbered envelopes before being passed to the medication manufacturers. The manufacturers were informed by writing when a child was eligible to enter the cross-over trial with no other contact between any of the study personnel. Assignments are unlikely to have been predicted.	met
Blinding of participants, personnel and outcomes adequate?	During the screening phase all medications were sent straight from the manufacturer. On entering the cross-over phase the relevant medicine or placebo was sent out according to treatment assignment. Medication and placebo were indistinguishable. Neither child/family, clinician or investigators knew of the treatment allocation. Blinding was not assessed during this study.	met
Incomplete outcome reporting adequately addressed?	5 patients refused to enter the cross-over phase following open-label treatment. There were no losses or drop-outs during the cross-over trial, but four patients (out of 62) were withdrawn due to medical conditions (1 increasing tics, 2 behavioural disorders, 1 reactive depression). An ITT analysis was used and reported. Withdrawals after the first cross-over period were assumed to be missing at random by the authors.	met

Risk of Bias (Jacobs 2005)

Item	Description	Judgement
Sequence generation adequate?	Allocation sequence was based on computer generated blocked, stratified number generation algorithm. Stratifying variables: initial symptom severity and current use of stimulant medication	met
Allocation concealment adequate?	The sequence was passed to the distributing pharmacy. As each child began treatment, the homeopath would send in their prescription to the pharmacy to be posted out. The pharmacy filled the prescription with verum or placebo according to the randomisation sequence. There was no further contact between physician and medicine distribution or treatment allocation. Assignments are unlikely to have been predicted.	met
Blinding of participants, personnel and outcomes adequate?	Patients, care providers and outcome assessors were all blinded to treatment allocation. Care providers (homeopaths) performed no better than chance when asked to guess which treatment group patients were assigned to.	met
Incomplete outcome reporting adequately addressed?	Performed an intention to treat (ITT) analysis and reported loss to follow-up (one in placebo group) and missing values due to drop-outs (two in intervention, three in placebo). No further information available on reason for drop-out. They did not report what procedures they used to deal with missing data.	unclear

Appendix 6

IPD Protocol

IPD Meta-analysis Protocol 1.0

Background:

Attention-deficit/hyperactivity disorder (ADHD) has existed as a diagnostic category since 1980, with the publication of the Diagnostic and Statistical Manual (DSM) Version III (Barkley 1990). There is an ongoing debate around the social construction of ADHD as a disease category (Cooper and Bilton 1999; Brady 2004) and there is as yet no clear consensus on the underlying aetiology. Brain imaging and genetic research are current areas of interest, but observation of behaviour remains the basis of diagnosis in the absence of reliable tests for biological markers.

Using ICD-10 criteria, prevalence has been estimated at around 1% of school-aged children in the UK, increasing to 5% if DSM-IV criteria are used. This translates to around 366,000 children in England and Wales (Lord and Paisley 2000). A US population-based birth cohort study of 5,781 children estimated a prevalence of 7.5% at age 19 years using DSM-IV criteria (Barbarelli, Katusic et al. 2004). Lower UK prevalence may be due to the use of the narrower ICD-10 criteria, and to diagnosing the condition only after referral to secondary care, among other factors. ADHD can affect both males (more commonly) and females, of any ethnicity.

Survey research has demonstrated that a significant proportion of children diagnosed with ADHD will receive some form of non-standard treatment or intervention; for example data from Canada indicated that although the majority of a sample questioned were using medication (81%) for ADHD symptoms, around 50% were also using a non-standard treatment (Johnston, Seipp et al. 2005). Australian surveys have reported between 66-68% of children with ADHD have also been given non-standard therapy (Sinha and Efron 2005).

Non-standard therapy or intervention covers a wide range of alternatives from dietary changes, physical therapies such as chiropractic, herbal medication and homeopathy (Brue and Oakland 2002). Data on the current use of homeopathy for ADHD are limited. A survey from Florida, USA, found that around 3% of children diagnosed with ADHD in a school-sample were using or had used homeopathy (Bussing, Zima et al. 2002) while a study in Australia reported that of 67.6% of diagnosed children using non-standard therapy, 6% had tried homeopathy (Sinha and Efron 2005).

Aggregate review (Cochrane Systematic Review):

Given the increased use of CAM for ADHD, and claims by practitioners of homeopathy in particular to be able to offer a cure or at least alleviate symptoms (Ullman and Reichenberg-Ullman 1993; Brue and Oakland 2002), a systematic review of the research evidence was conducted. Twenty-four case reports/case studies, one observational study and four

randomised or quasi-randomised controlled trials were located. An aggregate meta-analysis was carried out on the controlled trials using summary data extracted from the published papers and supplemented by some additional data provided by the authors. This review has been presented at an international symposium (Coulter, Dean et al. 2006) and is in press with the Cochrane Library (Coulter and Dean 2006).

Pooling and analysis of these treatment estimates produced no significant benefits of homeopathy over placebo for ADHD. However as discussed in the aggregate review, these trials displayed significant clinical heterogeneity, and there was the potential to further explore the results thus informing both the current state of knowledge and future trial design.

Why further analysis?

Questions had been raised about the presence of statistical artefacts in Frei 2005 - it was possible that regression to the mean and/or carryover may have been present.

The most directly comparable trials (Jacobs and Frei) had not reported the same level of detail for the primary outcome measure meaning that only limited pooling was possible. Retrieval of more detailed data on the CGI-P would facilitate further analysis.

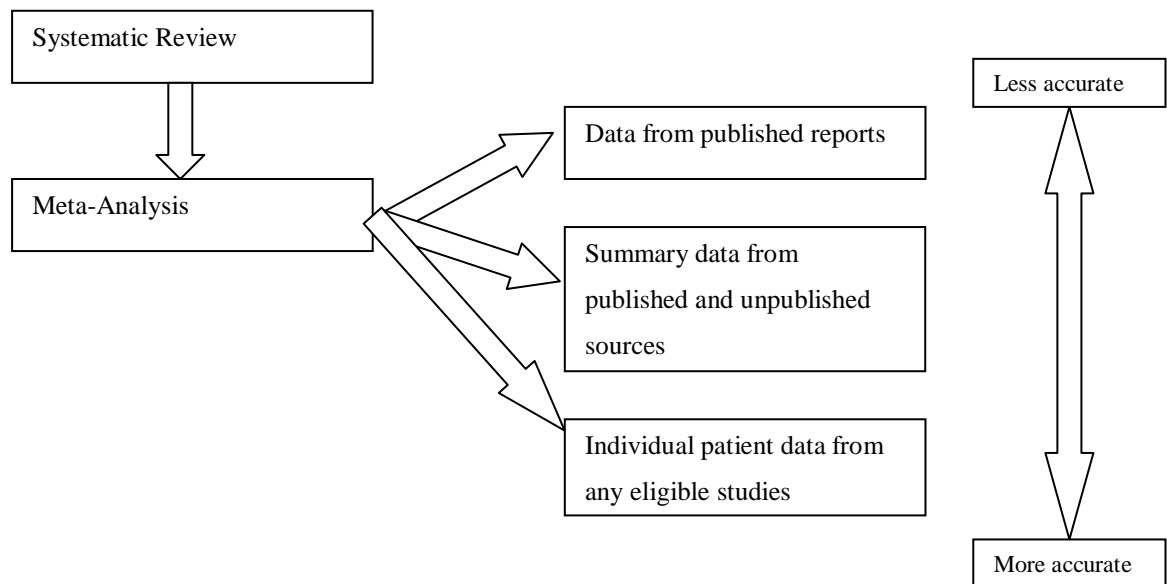
Inclusion of one trial in the aggregate review (Strauss 2000) necessitated requesting additional data from the author as the published figures were not amenable to the meta-analysis. Strauss generously provided an electronic copy of the original thesis from which the paper was written including raw data tables. Calculation of the summary estimates for the aggregate review highlighted some potential outliers within the data set which could be further explored.

Individual patient data (IPD) analysis has the potential to address all of the above issues, explore important covariates and provide updated, reliable treatment effect estimates.

What is Individual Patient Data (IPD) analysis?

IPD analysis involves obtaining the raw data on all randomised participants from eligible trials. This data is then screened, checked and verified with the authors, and re-analysed to produce summary statistics. The finalised summaries are combined to produce an overall estimate of treatment effect

Figure 1 (adapted from(Stewart and Clarke 1995))



Relying solely on data from published papers and reports can result in misleading and biased treatment estimates. The type of systematic review carried out by MK Coulter already, following Cochrane procedures, can be seen as taking up the intermediate position.

IPD methods facilitate checking the procedure and statistically examining the randomisation across treatment arms. Where information is missing or of poor quality the IPD approach of close contact with trialists is likely to increase the amount of usable data. Analysis by ‘intention-to-treat- principles is considered vital for good quality meta-analyses, and this is more likely to be possibly under IPD conditions. Trials may report analyses based on a proportion of the included patients and it can be unclear how many were excluded and why. IPD encourages re-instatement of excluded patients where appropriate and gives a fuller understanding of exclusions in each trial.

More sensitive analyses may be possible dependent on the data obtained, and alternative or more appropriate methods of analysis can be explored.

A summary of the potential benefits from IPD reviews can be seen in the table opposite (adapted from (Stewart and Tierney 2002))

Benefits of IPD meta-analyses

- Undertake subgroup analyses
- Carry out detailed data checking
- Ensure analysis is appropriate
- Update follow-up information
- More complete identification of relevant trials
- Better compliance with providing missing data
- More balanced interpretation of results
- Wider endorsement and dissemination of results
- Clarification of further research
- Collaboration on further research

Primary aims

1. Re-estimate the effect of homeopathic treatment on global severity, core symptoms and associated symptoms of ADHD by pooling the available IPD
2. explore the impact of selected baseline variables where possible

Secondary aims

(trial specific based on aggregate review)

1. Explore Frei 2005 data for evidence of period effect, carryover or regression to the mean, re-analyse and use any additional results in sensitivity checks
2. Extract, clean and analyse data from Frei 2005 on child completed tasks for potential pooling with Jacobs 2005 and Strauss 2000
3. Clean, check and re-analyse Strauss data to resolve any inconsistencies and produce summary estimates

Data checking and cleaning

A standard data checking procedure developed by the Cochrane Group and the MRC Clinical Trials Unit was followed for this meta-analysis (Stewart and Clarke 1995). Data is checked, not to discover fraud, but to improve accuracy and follow-up, ensure Intention To Treat analyses, facilitate the inclusion of all randomised patients, assess the quality of trials and assess the integrity of the randomisation procedure.

Preliminary checks

Preliminary checks are carried out by comparing the provided information with the variables of interest to ensure all requested variables are present and codes are interpretable. Where necessary clarification was sought and missing variables requested.

The following sections detail the main checking procedures carried out for each trial data set. Each check, the output, queries to trialist and responses were recorded.

Detection of duplicates

Patient identifier was used to sort the data (ascending) and the SPSS command 'identify duplicate cases' used. Data had been sorted and entered into SPSS such that no multiple patient identifiers were expected. Any duplicates were queried with the trialist. Any apparent missing values were also queried where the identifiers appeared to follow a sequence.

Date consistency checks

Date variables for each patient were checked for consistency according to the available data. Dates supplied were ordered in ascending sequence and checked for any unfeasible values –

where found these were verified with the trialists. Some dates were expected to occur subsequent to one another e.g. date of randomisation should fall before date of follow-up, where there was more than one treatment period these should follow chronologically. In both cases the earlier date was subtracted from the later date to give time elapsed, this variable was then ordered and checked as before.

Verifying integrity of randomisation

Fully randomised trials ought to have similar numbers allocated per arm according to the randomisation ratio, and randomisation to arm should be approximately evenly spread out across days of the week (depending on the days clinics were held). If patient identifiers follow a chronological sequence they ought to be parallel with dates of randomisation, and randomisation should approximately evenly allocate patients to each arm over time. These factors were checked in the following ways where data was available:

- i. Numbers allocated per treatment arm: taking the randomisation ratio into account, a table of number of participants per group was produced as well as a pie chart to check if numbers were as expected. Chi-squared test was used assess the statistical significance of any observed between-group differences
- ii. Days of the week randomised by arm: where date of randomisation was provided (or a suitable proxy) these data were converted to day of the week using the SPSS function. A table of participants allocated to each arm by day of week was produced along with a bar chart. This output was assessed to determine if differential allocation had occurred, thus indicating quasi-randomisation.
- iii. Sequence of patient identifiers: if patient identifiers were chronological, they were ordered by date of randomisation (or suitable proxy) and the sequence examined for any discrepancies.
- iv. Sequence of dates of randomisation by arm: a cumulative frequency plot was used to graph cumulative numbers of patients randomised by trial arm according to randomisation date. These plots should show similar allocation patterns with the potential for some crossing over. Other patterns (e.g. divergence, constant or no crossing) were noted for discussion.
- v. Check of dichotomous baseline variables by arm: a frequency table was produced, checked for unexpected codes and Chi-square test used to check for any statistically significant differences.
- vi. Check of continuous variables by arm: a table of summary statistics was produced showing mean, median, standard deviation, minimum, maximum values. These were

checked for any unlikely values. The data were checked for normality using graphs (stem and leaf plots, box plots) and statistical tests (Kolmogorov-Smirnoff). Normally distributed data was tested for any baseline differences using an independent samples t-test, non-normal data was tested using a Mann Whitney U test.

- vii. Patient age: where trials provide age, date of birth and date of randomisation an additional accuracy check was carried out. The reviewer calculated patient age by subtracting date of birth from date of randomisation, and checked this against the original age variable.

Assessment of follow-up

Follow-up should be consistent across treatment groups and correspond to the stated duration of the trial (as per published paper/protocol). Duration of follow-up was calculated by subtracting date of randomisation from date of last follow-up where available. Data were then ordered by duration of follow-up and patient identifier for each treatment group. This allowed checking of the expected versus actual duration, and if follow-up was similar across treatment arms.

Summary of primary and secondary outcomes

Continuous primary and secondary outcomes: summary tables containing mean, median, standard deviation, maximum and minimum were produced for baseline and final follow-up by arm of trial (placebo or verum).

Check excluded patients

Missing patient identifiers were compared with the known number of exclusions (based on published papers and contact with trialists). Where the numbers matched, this was verified with the authors, any discrepancies were forwarded for discussion. Reasons for exclusion by patient identifier were then requested and coded.

Check against main publication

The results of the data checking were verified against the relevant publication and any apparent discrepancies noted for discussion with the trialists.

Verification of data

A summary of the data checks, summarised baseline characteristics and a list of queries was supplied to each trialist with an explanatory letter. Trialists were asked to respond to the data checking queries and examine the supplied documents and report any inaccuracies. Updated and/or missing data was also requested at this point.

Baseline variables:

Baseline variables of interest to this IPD meta-analysis were largely based on findings from the MTA trial, one of the largest studies comparing medication, behavioural therapy, combined care or standard treatment on ADHD which attempted to explore longer term follow-up and a more pragmatic setting for treatments (MTA Cooperative Group 1999).

Age – with the knowledge that the trials eligible for inclusion in this review had used a fairly wide age range, this was included as a potentially important baseline variable.

Gender – gender differences in the prevalence of ADHD across cultures has been noted but there has been little exploration of sex-related responses to treatment to date.

Disease severity – Trials identified for this review have used varying inclusion criteria and it is possible that initial disease severity may be a factor in treatment response.

Previous psychostimulant treatment – The MTA study authors suggested that previous psychostimulant use may be associated with less favourable outcomes, and Frei et al have reported that such children took longer to respond to homeopathy (Frei, Everts et al. 2007).

Co-morbidity (specifically oppositional-defiant disorder and conduct disorder) – these conditions have been shown to have particular impact on the prognosis of treatment, possibly via their impact on peer and family relationships (Jensen, Martin et al. 1997).

Treatment acceptance and compliance – maintaining involvement has been suggested to be important for active treatments such as medication management or behavioural treatment in previous ADHD research, therefore this should be explored where data is available on acceptance and attendance at the scheduled sessions.

Outcome variables:

Outcome variables of interest were drawn from those examined in the aggregate review to focus on key areas.

The primary outcome of interest in this meta-analysis was global assessment of ADHD symptoms as assessed by parents. Core symptoms (hyperactivity, inattention and impulsivity), depression/anxiety, conduct/oppositional disorder and adverse events were included as secondary outcomes of interest as assessed by parent, teacher or child.

Analyses:

Intention to treat analysis which evaluates the average effects of treatment in a sampled population.

Subgroups defined by baseline characteristics may show difference response patterns – dependent on having sufficient numbers

Trials eligible for inclusion:

(Lamont 1997; Strauss 2000; Frei, Everts et al. 2005; Jacobs, Herman et al. 2005)

- Frei, H., R. Everts, et al. (2005). "Homeopathic treatment of children with attention deficit hyperactivity disorder: a randomised, double blind, placebo controlled crossover trial." European Journal of Pediatrics.
- Lamont, J. (1997). "Homoeopathic treatment of attention deficit hyperactivity disorder: a controlled study." British Homeopathic Journal **86**(10): 196-200.
- Jacobs, J., P. Herman, et al. (2005). "Homeopathy for menopausal symptoms in breast cancer survivors: a preliminary randomized controlled trial." Journal of Alternative & Complementary Medicine **11**(1): 21-7.
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- Jacobs, J., P. Herman, et al. (2005). "Homeopathy for menopausal symptoms in breast cancer survivors: a preliminary randomized controlled trial." Journal of Alternative & Complementary Medicine **11**(1): 21-7.
- Jensen, P. S., D. Martin, et al. (1997). "Comorbidity in ADHD: implications for research, practice, and DSM-V." J Am Acad Child Adolesc Psychiatry **36**(8): 1065-79.
- Johnston, C., C. Seipp, et al. (2005). "Treatment choices and experiences in attention deficit and hyperactivity disorder: Relations to parents' beliefs and attributions." Child: Care, Health & Development. **31**(6): 669-677.

- Lamont, J. (1997). "Homoeopathic treatment of attention deficit hyperactivity disorder: a controlled study." British Homeopathic Journal **86**(10): 196-200.
- Lord, J. and S. Paisley (2000). The clinical effectiveness and cost-effectiveness of methylphenidate for hyperactivity in childhood, Version 2. London, National Institute for Clinical Excellence.
- MTA Cooperative Group (1999). "Moderators and mediators of treatment response for children with attention-deficit/hyperactivity disorder." Archives of General Psychiatry **56**(12): 1088-96.
- Sinha, D. and D. Efron (2005). "Complementary and alternative medicine use in children with attention deficit hyperactivity disorder.[see comment]." Journal of Paediatrics & Child Health **41**(1-2): 23-6.
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Appendix 7

IPD Data Checking

7.1 Frei

Frei 2005: IPD Data Checking and Cleaning [October 2007]

Preliminary checks and queries

Variables received compared with those requested: colleague translated the data labels.

No duplicate cases were identified.

Consistency of Dates

Dates available for this trial:

- Date of birth
- Dates for four examinations
- Date of first examination used as proxy for DoRandomisation

Date of Birth: checked with age on entering trial by subtracting date of first examination from DoB given in data file. All matched.

Recruitment/entry dates: The trial recruited between January 2002 and September 2003, therefore all first examination dates should fall within these limits. Data from the excel spreadsheet was sorted by Phase 1 date and participant ID. First examinations were recorded as occurring between 06/09/2002 and 17/03/2004.

Examination Dates: checked by subtracting the earlier from the later date of examination. We have three approximately 6 week periods, date 1 = end of screening, date 2 = end of first crossover period, date 3 = end of second crossover period, date 4 = some point during open label follow-up which should have been 6 or 14 weeks, paper mentions two follow-ups.

*date 2 – date 1 problems: ID 22 (14 weeks), ID 26 (10 weeks), ID 63 (3 weeks)

*date 3 minus date 2: ID 48 (1 week), ID 26 (3 weeks),

*date 4 minus date 3: ID 48 (10 weeks),

ID's 40 and 47 – I think the date has been entered as 2003 instead of 2004

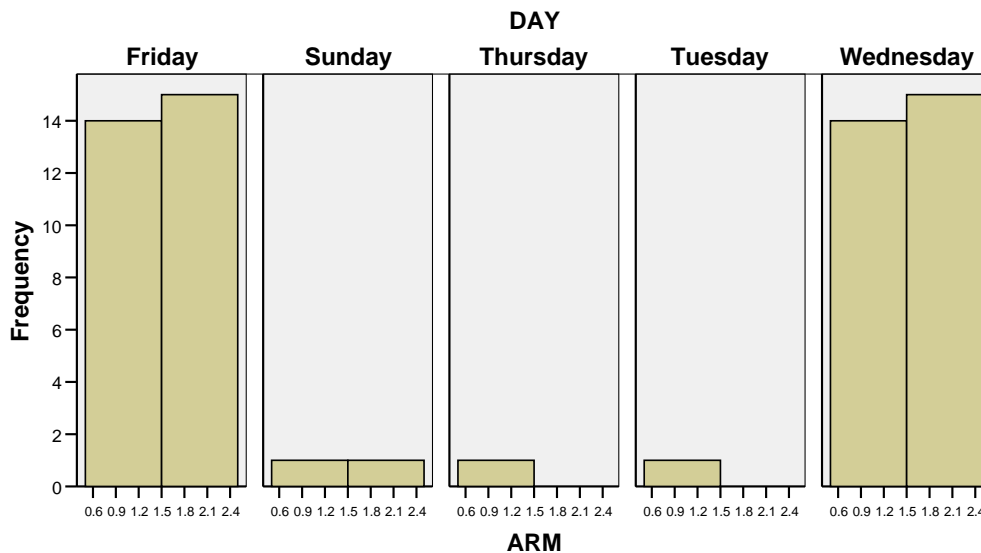
			Mean	Std Deviation	Median	Maximum	Minimum
Trial Arm (1= verum, placebo; 2 = placebo, verum)	verum then	date 2 minus date 1	6	2	6	14	4
	placebo	date 3 minus date 2	6	1	6	7	3
		date 4 minus date 3	6	1	6	8	5
	placebo then	date 2 minus date 1	6	1	6	10	3
	verum	date 3 minus date 2	5	1	6	7	1
		date 4 minus date 3	2	13	6	10	-46

Integrity of Randomisation

- Numbers in each arm: 31 per trial arm
- Days of the week randomised per trial arm

Authors were not able to supply date of randomisation but this was reported in an email as being “some days before the date of the first examination”. Using date of first examination as a proxy for the date of randomisation, these data were converted into week days using SPSS and the following graphs produced for the relevant participants. To be verified: two examinations on Sunday and general pattern (which seems pretty balanced across the groups).

Histogram of proxy day of randomisation by trial arm



Left hand column = arm 1

Right hand column = arm 2

Sex	female	Count	4	3	7
		Expected Count	3.5	3.5	7.0
	male	Count	27	28	55
		Expected Count	27.5	27.5	55.0
Total		Count	31	31	62
		Expected Count	31.0	31.0	62.0

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.161(b)	1	.688	1.000	.500
N of Valid Cases	62				

a Computed only for a 2x2 table

b 2 cells (50.0%) have expected count less than 5. The minimum expected count is 3.50.

Previous/current stimulant medication: previous medication use unknown, all concurrent treatment halted on entry to open-label treatment (phase 1).

Co-morbidity: no data but may have been ineligible for this trial.

Treatment compliance:

Two patients missed one assessment session during the crossover trial phase, one patient missed two assessment sessions. No data available for the open-label screening phase.

Continuous:

Age

Age in years at randomisation

Age at randomisation (approx)

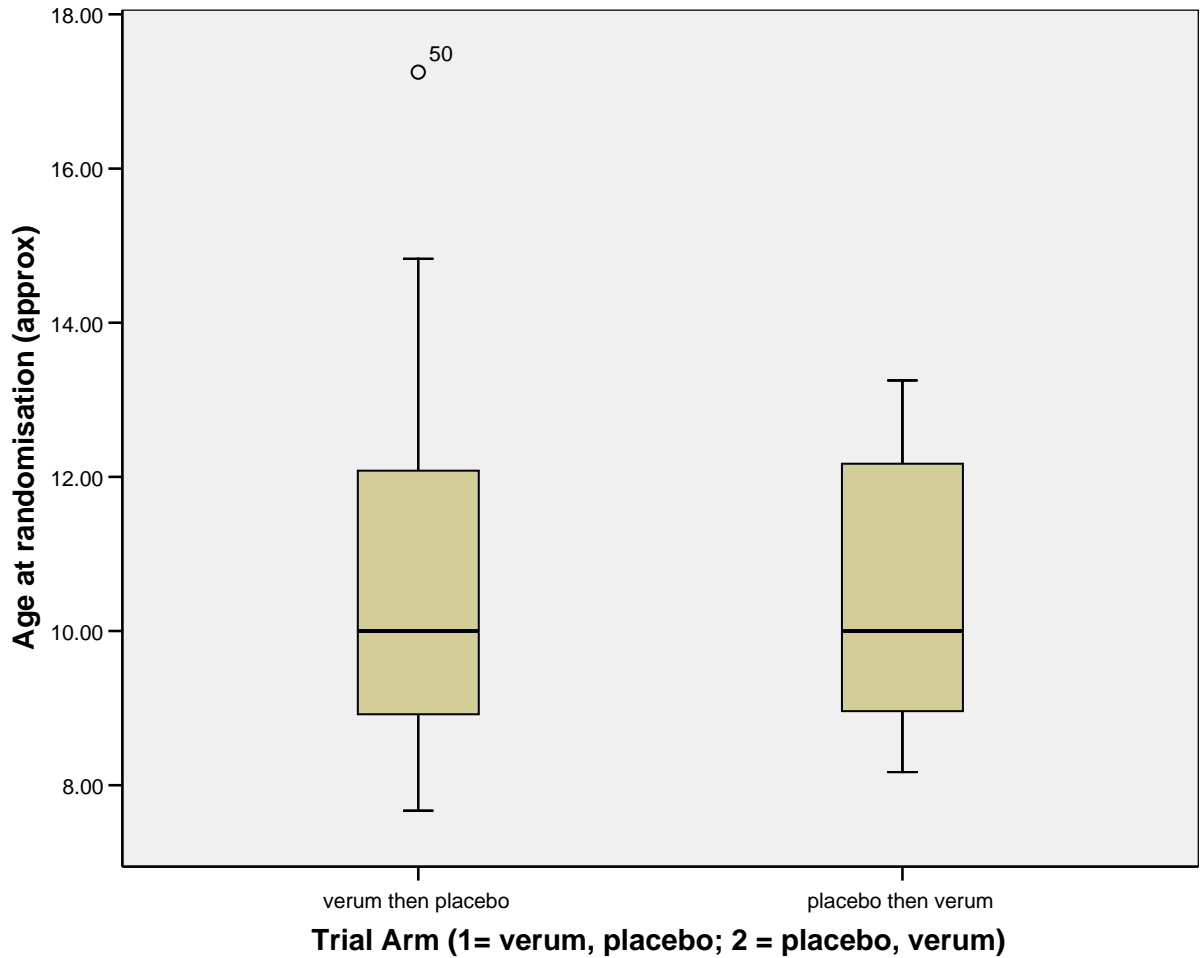
Trial Arm (1= verum, placebo; 2 = placebo, verum)	N	Mean	Std. Deviation	Median	Minimum	Maximum
verum then placebo	31	10.5968	2.26532	10.0000	7.67	17.25
placebo then verum	31	10.5384	1.64748	10.0000	8.17	13.25
Total	62	10.5676	1.96456	10.0000	7.67	17.25

Trial Arm (1= verum, placebo; 2 = placebo, verum)	Kolmogorov-Smirnov(a)			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
Age at randomisation (approx) verum then placebo	.121	31	.200(*)	.926	31	.035
placebo then verum	.144	31	.099	.924	31	.030

Tests of Normality

* This is a lower bound of the true significance.

a Lilliefors Significance Correction



Check of age

**verify ID 50 who appears to be older than the required age range (6-16yrs)

DoB: 21/10/86 1st examination 12/12/03

Reviewer calculated age at randomisation (based on DoB and DoRand) matched with the original ages provided by trialists.

Initial severity

Two checks were carried out here; severity measured by the CGI-P at entry to open label treatment, and severity on entry to the cross-over trial. The first check was carried out as this was a variable used to stratify the randomisation. The second check was carried out to ensure no unbalancing had occurred as a result of this choice.

- a) Severity at entry to open-label treatment (phase 1) [data extracted from additional information via email from Frei]

Pre-treatment CGI scores by randomised arm

pre treatment CGI

Trial Arm	N	Mean	Std. Deviation	Median	Minimum	Maximum
verum then placebo	31	19.6774	2.90272	19.0000	15.00	25.00
placebo then verum	31	19.0968	2.76110	19.0000	15.00	27.00
Total	62	19.3871	2.82469	19.0000	15.00	27.00

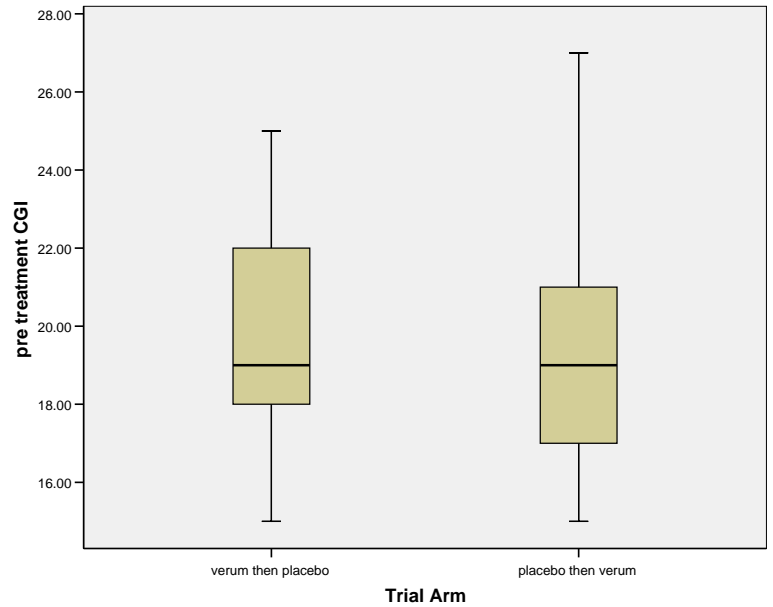
Minimum scores are above 14, the reported cut-off for entry.

Tests of Normality

Trial Arm	Kolmogorov-Smirnov(a)			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
pre treatment CGI verum then placebo	.117	31	.200(*)	.951	31	.171
pre treatment CGI placebo then verum	.127	31	.200(*)	.950	31	.153

* This is a lower bound of the true significance.
a Lilliefors Significance Correction

independent samples t-test showed no significant differences at baseline. $T(60) = 0.807$, $p = 0.423$.

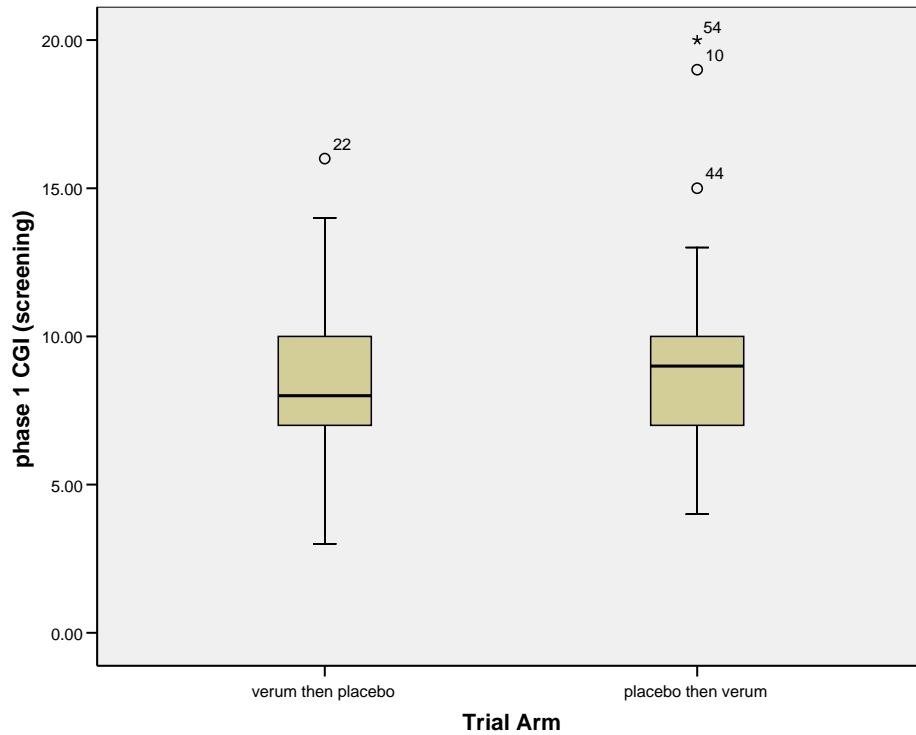


b) severity on entry to first cross-over phase and randomisation (CGI-P)

entry to crossover CGI scores by randomised arm

phase 1 CGI (screening)

Trial Arm	N	Mean	Std. Deviation	Median	Minimum	Maximum
verum then placebo	31	8.4516	2.85294	8.0000	3.00	16.00
placebo then verum	31	9.1290	3.71925	9.0000	4.00	20.00
Total	62	8.7903	3.30492	8.0000	3.00	20.00



Reflections: These scores should all have decreased by 50% or 9 points between entry to open label and entry to crossover period (randomisation). Checking the min/max scores and examining the box plots from both phases suggests there are a number of potential outliers or data entry errors:

ID	Trial Arm	Pre-treatment CGI value	Randomisation CGI Value (outliers)
10	2 (P, V)	19	19
22	1 (V, P)	23	16
44	2 (P, V)	23	15
54	2 (P, V)	20	20

Additional check: subtracting the entry to randomisation CGI-values from the pre-treatment CGI values ought to show the required 50% or 9 point drop. The researcher manually coded each participant as reaching eligibility or not (according to the data provided).

The additional data file containing starting CGI values also showed the progress of CGI values throughout the first six months of open label treatment. Successful treatment scores should then have triggered randomisation, so should be little difference between these values.

ID's not achieving 50% or 9 point drop in tx			Open label phase data	
Patient ID	CGI drop	(borderline)	last CGI	drop
9	5		6	13
10	0	Data entry error?	11	8
13	8		10	9
19	8		10	9
20	6		5	11
22	7		20	3
24	7		19	*increase
30	2		4	11
33	7		6	10
36	8	(needed 8.5)	5	12
38	6		18	*increase
39	8	(needed 8.5)	10	7
44	8		13	10
45	7		15	0
50	8		9	10
54	0	Data entry error?	22	*increase
55	3		12	9
61	8		9	9
63	3		5	9

Note that open label treatment extended beyond 6 months for some patients, and only 6 month outcomes were available to the researcher, therefore this data comparison is incomplete.

There may have been data entry errors, or a delay between successful treatment decision and actual randomisation ****to be verified****

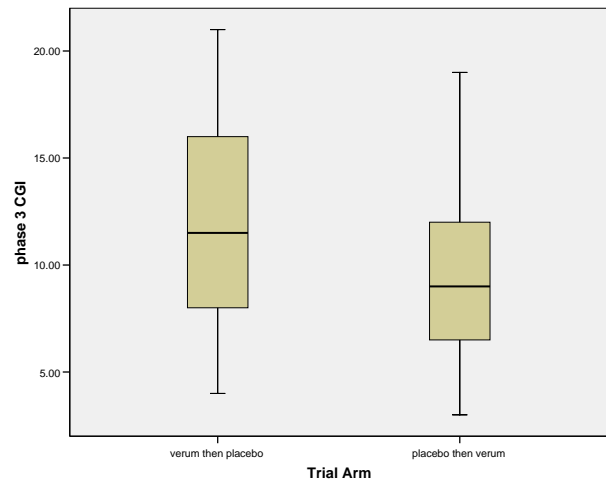
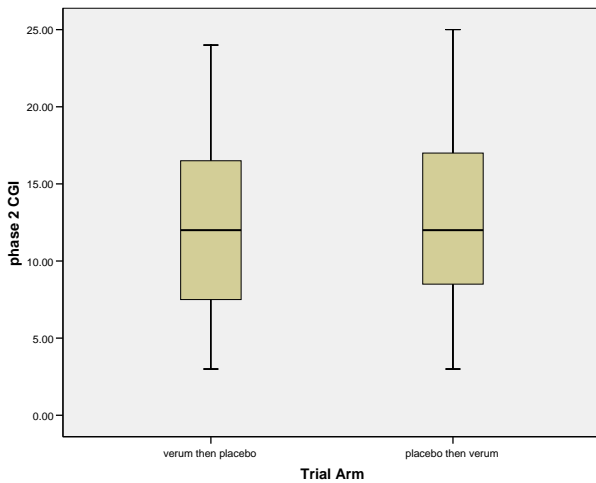
Assessment of follow-up

See 'consistency of dates' check section.

Summary of Outcome Variables

CGI-P Total Scores

			Mean	Std Deviation	Median	Maximum	Minimum
Trial Arm	verum then	phase 2 CGI	12.13	5.88	12.00	24.00	3.00
	placebo	phase 3 CGI	11.65	4.43	11.50	21.00	4.00
	placebo then	phase 2 CGI	12.76	5.56	12.00	25.00	3.00
	verum	phase 3 CGI	8.87	3.66	9.00	19.00	3.00



Child completed attention task (GO/NOGO from TAP)

Relevant TAP data provided: errors and omissions for Go/NoGo task which seems comparable to the Conners CPT task – gives data on impulsivity (errors) and inattention (omissions).

Data was examined on the errors (commission errors or false positives, responding to wrong stimulus) and omissions (false negatives, not responding) made by participants.

ID	Missing
1-4	Completely missing, ID's start at 5
19	Phase 4
20	Phase 3 & 4
25	Phase 3 & 4
23	All missing
50	All missing
54	Phase 2
55	Phase 2
56	Phase 1

Summary statistics were calculated for phase 1 (end of screening and entry to randomised trial), and phases 2 & 3 (the crossover periods) by trial arm. Data were provided as standardised T-scores (mean = 50, range = 1 to 100) and within the published article a mean of 50 +/- 10 was given as normal values.

	Arm 1 (V, P)			Arm 2 (P, V)		
	Mean	SD	Min, max	Mean	SD	Min, max
Phase 1 errors	22.08	6.02	16, 50	19.14	5.35	1, 27
Phase 1 omissions	46.58	30.18	1, 96	46.83	32.34	1, 96
Phase 2 errors	20.88	4.54	8, 38	19.34	4.89	7, 24
Phase 2 omissions	60.23	29.60	1, 98	59.59	33.68	1, 96
Phase 3 errors	19.88	3.83	7, 24	20.28	2.71	8, 24
Phase 3 omissions	65.92	30.77	1, 98	58.55	27.67	1, 96

Checks for excluded patients

Patient identifiers were checked to ensure all randomised participants were included.

Published paper reported that within the cross-over phases, 4 participants were withdrawn from the trial so incomplete data was expected. Patient IDs given for 5 – 67 in the initial data file received, ID's 1-4 and 23 were missing entirely. Incomplete data was recorded for patient ID's 19, 20 & 25. ITT analysis was reported in the original publication for 62 patients.

It is unclear which patients were withdrawn, and if follow-up data was obtained and entered to facilitate ITT, or if the missing data refers to non-withdrawn patients. An additional data file giving the dates of examination for each patient at each period includes data for ID's 1-4.

Check information is up to date

****check with authors if any additional data esp in relation to ID's 1-4 and 23****

No non-randomised patients were included.

Additional Checks for Frei et al:

Checked for normality: using tests for skewness and kurtosis, and Q-Q plots – all fine.

As explained earlier, it was decided to explore the possibilities of interactions and/or carry over effects in the data set before re-running the analysis.

Period effect: or does it matter whether patients received the treatment in phase 2 or phase 3. This was tested using a two sample t-test looking at the mean difference between phase 2 and 3 for each arm. If there was no period effect these mean differences should be similar.

Comparison between Arm 1 (verum - placebo) mean diff of 0.65 (SD 6.82) and Arm 2 (verum – placebo) mean diff of -3.75 (SD 6.04) was carried out using a two-sample unrelated t-test. This found a significant mean difference of 4.40 (SE 2.64) $t = 2.58$ (58), $p = 0.01$

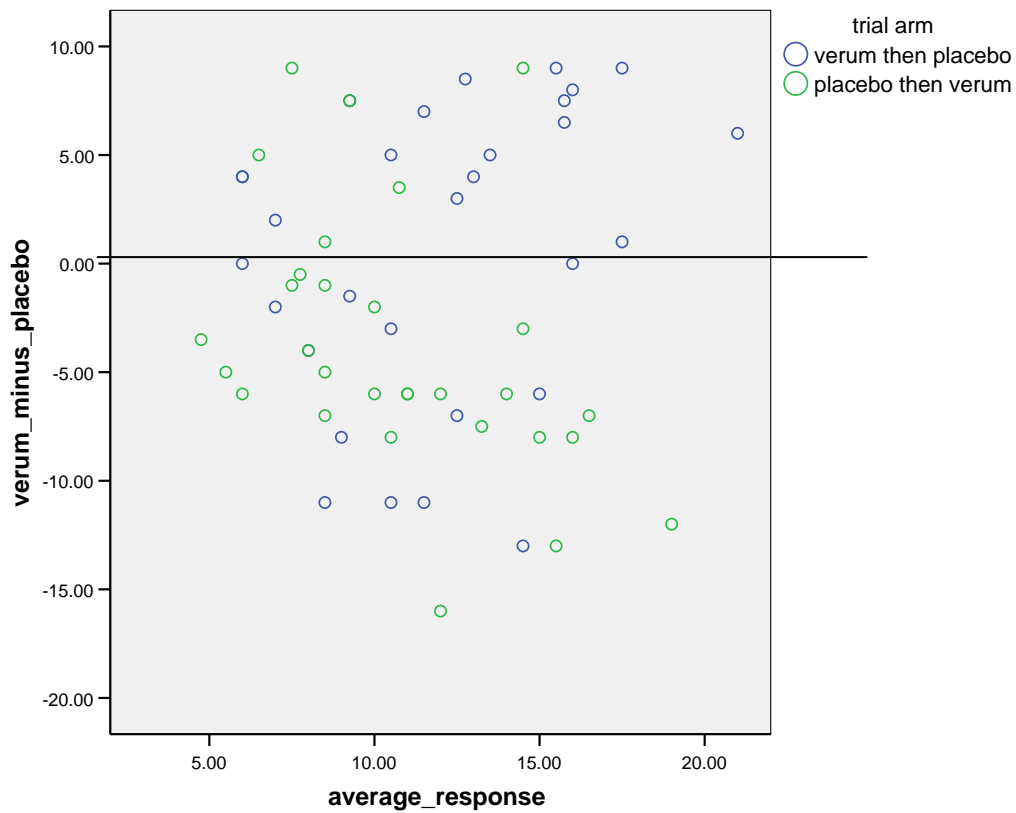
Treatment-period interaction: does it matter what order the patient receives the treatment in, usually a test for carryover. If there is no interaction the patient's average response should be roughly the same regardless of order of treatment. Carryover in this trial might be seen if the patients successfully treated with homeopathy did not worsen when moved onto placebo in the cross-over trial.

This was tested by comparing the average treatment response for each arm ([phase 2 mean + phase 3 mean] divided by 2) with a two-sample unrelated t-test. The average CGI score for arm 1 (verum then placebo) was 11.98 (SD 3.94), and for arm 2 (placebo then verum) was 10.74 (SD 3.63).

A two-sample unrelated t-test comparing the average treatment response found a mean difference of 1.23 (SE 0.98) which was non-significant, $t = 1.26$ (58), $p = 0.213$ Therefore there was no statistical indication of a carryover effect within the cross-over trial.

This test is known to have relatively low statistical power, therefore the existence of carryover was also checked graphically (see next page).

Double checked graphically as Altman points out that such tests are notes for their lack of statistical power: the scatter plot should, in the absence of an interaction, show no horizontal difference between groups and data should lie symmetrically either side of the line $y=0$



The graph demonstrates that there may well have been a carryover effect which has implications for further sensitivity analyses.

**Treatment estimate assuming no carryover as per Senn, adjusting for period effect
(observed by both MKC and Frei et al.)**

Continuing with the analysis, given the existence of a significant period effect, the method suggested by Senn was adopted: carrying out a two-sample t-test for the period differences which gives both a treatment estimate and a more accurate estimate of standard error while taking the period effect into account.

Independent two-sample t-test found $t = -1.86$, mean difference of -3.10 points (SE 1.66) (95% CI $-6.43, 0.23$) which was not significant ($p = 0.068$).

Pg 42 Senn – this produces an estimate of twice the difference, therefore need to divide the difference in means and SE by 2

mean diff = -1.55 (SE 0.83)

Comparison with published results

Frei used a linear mixed model (not adjusted for period effect) for their analysis reporting a significant mean treatment effect of -1.67 ($p = 0.0479$), and a significant mean period effect of 2.19 ($p = 0.0102$).

7.2 Jacobs

20TH DECEMBER 2007

Enclosed: IPD protocol
Data cleaning & checking report including Queries on the dataset

Dear Anna,

Please find enclosed a detailed report on the cleaning and checking procedures carried out on the data supplied previously (Access database and Excel summary sheets). Please find attached the full protocol document which details the cleaning and checking procedures carried out on all data sets. I would be happy to answer any further questions you may have.

The methodology I am using is that of Individual Patient Data (IPD) meta-analysis. This is a relatively new and improved approach to evidence synthesis of clinical trials. It has encouraged academics, commercial businesses and individuals to provide valuable raw data for exploration and further analysis in an attempt to draw firmer conclusions about particular interventions. It is not a commentary on any one study but a way of bringing together and taking stock of the knowledge base. It has been used very successfully in the cancer area, for example, to assess the effectiveness of cancer treatments where the evidence contains many different trials. It can be seen as analogous to the initiatives within the social sciences where large survey data sets are made publicly available via the internet, and can be accessed by researchers to answer a variety of questions.

Any publications based on IPD analyses are usually made in the name of the synthesising researcher and all collaborating trialists. Therefore, when the paper has been prepared to a draft stage it is then sent round to all trialists for comments and revision.

Please take the time to read through this document and the summaries I have produced based on your data. I would be appreciative of feedback around the summary statistics/means/standard deviations – do you agree with the values presented here. On the following page you will find a list of queries and questions about your dataset. I would be very grateful for any answers you or your colleagues can provide and look forwards to being in touch soon.

Kind regards

Morag Coulter

Queries on the dataset

Dates and Missing Values

1. When was the CGI-P completed? (the date associated with this variable does not match with other test or CPRS completion dates)
2. Was the 'test' date also when the CPRS was completed? This would allow me to fill in any missing dates.
3. Assessment date checks showed that patient ID 112 showed a difference of 10 weeks between week 0 and week 6: could the authors please verify if this was correct?
4. Patient ID 134 was identified as having duplicate baseline entry in place of week 18 for the CPRS test date and scores – could these values be provided please?
5. Days of randomisation: please check that the days of randomisation/first assessment match with those feasible according to the clinic opening schedule: most took place on Wed/Fri and Sat
6. From the published paper, six participants withdrew during the trial, could you confirm which patient ID's represented these individuals?
7. Incomplete data is presented for ID's 105, 118, 122, 125, 131, 137: they appear to have been randomised and received an initial assessment but no further data is given. Any clarification on the status of these participants, and any follow-up data would be very helpful.

Follow-up:

1. Possible data entry error for patient ID 154 where the 18 week test date is given as 27/05/1995

154	18wk	27/05/1995
-----	------	------------
2. Some patients seemed to have been in the trial longer than expected based on the protocol, Patient ID's and number of days between first and final assessment are given below for verification of any data entry errors (around 126 days was expected).

ID 112 – 153days
 ID121 – 133days
 ID 133 – 139days
 ID 134 – 141days
 ID 136 – 133days

Patient Identifiers:

1. When ordered sequentially the following were missing: What were the reasons for these missing values? Were they patients who were initially assessed or randomised who then refused to take part?

Missing ID's
109
116
119
120
129
130
143
145
150
151
152

2. Some patient identifiers appeared to be out of sync in comparison to others when looking at the date of first examination. Could these ID's and associated date of

ID	DORand	comment
106	23/10/2002	similar ID's in Sept
118	11/12/2002	similar ID's in Oct
126	13/12/2002	similar ID's in Oct
128	13/12/2002	similar ID's in Oct

examination be verified please? Alternatively were these participants identified and given an ID but not able to attend for assessment for some time?

Balance of baseline variables:

We would be very grateful if data on stimulant medication usage, either past or current, could be provided linked with patient ID's.

Summary of Variables (CGI-P and CPRS)

As you will see from the tables presented, the baseline summary statistics match your published figures while the follow-up values do not match exactly. I am unsure why this is, but would be grateful if you or your colleagues could detail exactly which data variables were used as the final measurement, or if your final value summaries were based on any kind of imputed data to make up for the missing values?

Summary of Variables (CPT)

I would be grateful for clarification of which variables your team used to assess inattention and impulsivity before providing summaries of these variables.

Looking at the available data for commission and omission errors (for Inattention) highlighted the following discrepancies where some data is missing or the survey period may have been wrongly entered. Any clarification on this subset of the data would be very welcome.

Discrepancies

ID #	Cohort	Tx_assnmt	Surv_pd		Com_t	Om_t
110	1	1	12		55.87	58.4
110	3	1	Baseline		49.53	56.31
110	1	1	Baseline		0	0
110	1	1	18 wk		43.18	48.64
121	2	1	Baseline		55.25	43.23
121	3	1	12 wk		30.95	43.23
121	2	1	Baseline		60.76	43.68
121	2	1	12 wk		58.11	42.76
144	4	1	6 wk		59.04	54.92
144	4	1	Baseline		60.63	53.52
144	4	1	12 wk		46.35	75.83

Additional queries:

In the published paper you report that the analysis controlled for severity of disease – I would be grateful if you could clarify which variable you used for this (clinical global impression, CGI-P or CPRS or another based on the diagnostic interview).

Jacobs et al 2005: Data checking and cleaning results

1.1 Preliminary checks and queries

Variables received compared with those requested: date of randomisation missing but clarified as same as week 0 assessment date, unclear about dates of outcome measurement, contacted to clarify.

Duplicate cases – none present overall, one noted in date of week 6 assessment

1.2 Date consistency checks

Dates available for this trial:

- no clear Date of Randomisation (DoRand)
- Date of Birth
- 6-weekly test dates (0,6,12,18 weeks)
- 6-weekly dates of CPRS completion (0,6,12,18 weeks) – same as above item
- weekly dates of CGI-P completion (weeks 1-15 detailed)

Test dates and CPRS dates seem to match perfectly in most cases. In some instances data is missing from one date variable but not the other.

DoB – checked with age reported on entry to trial by subtracting First Test Date from DoB. Matched with no discrepancies.

Dates of the four main assessment periods throughout the trial – dates were ordered by assessment period and values checked. All feasible dates (ID 134 as identified has duplicate baseline entry in place of week 18). Four assessment period dates were also checked by subtracting the later from the earlier (e.g. week 6 – week 1, week 12 – week 6 and week 18 – week 12), this gave the expected positive values around 6 weeks except where there was missing data.

**ID 112 showed a difference of 10 weeks between week 0 and week 6: verify

1.3 Integrity of randomisation

The randomization was done by the pharmacist ahead of time using a stratified system for gender and use or non-use of stimulant medication. Once a child was enrolled, the pharmacist assigned that subject to a group using pre-determined random number sequence within each strata. (from email)

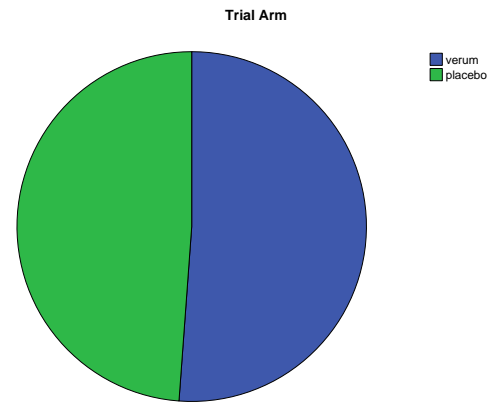
Based on above information and the published paper – date of randomisation is the same as first treatment. After consultation the prescription was faxed through to the pharmacy who then

randomised the child according to a pre-generated list. Pharmacy then sent out the appropriate verum or placebo. Dates of actual randomisation were requested from the pharmacy but have not been made available.

Randomisation in the figures/tables below was proxied by date of first test/assessment.

1.3.1 Numbers allocated per arm

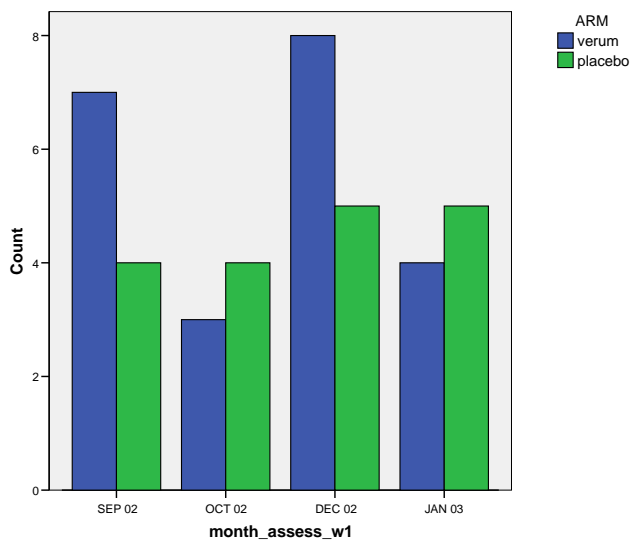
		Trial Arm			
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	verum	22	51.2	51.2	51.2
	placebo	21	48.8	48.8	100.0
	Total	43	100.0	100.0	



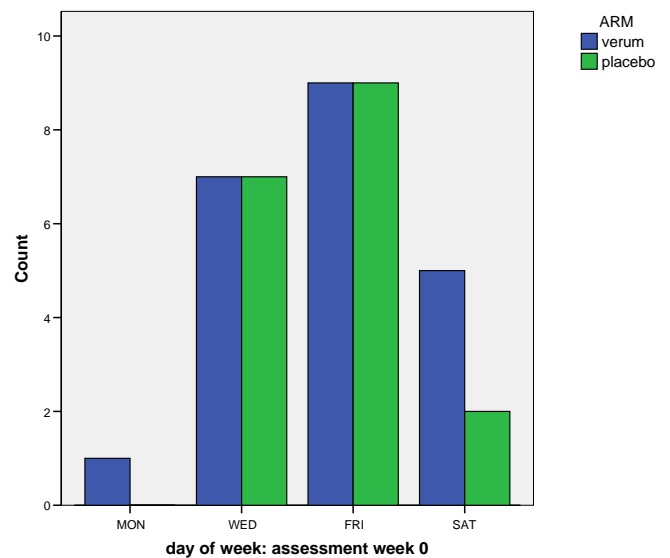
1.3.2 Days of the week randomised per arm

Histograms of:

month randomised per trial arm



day of week randomised per arm



1.3.3 Sequence of patient identifiers

Patient ID's ordered in Excel alongside DORand for the primary outcome variables of the trial (CGI-P). Consecutive numbers had been used.

Eleven missing ID's (see table), ID only for 105 (no further data, have tx allocation but no date of assessment or randomisation). No week 0 date available for ID 103.

Out of sync patient identifiers: **to be verified**

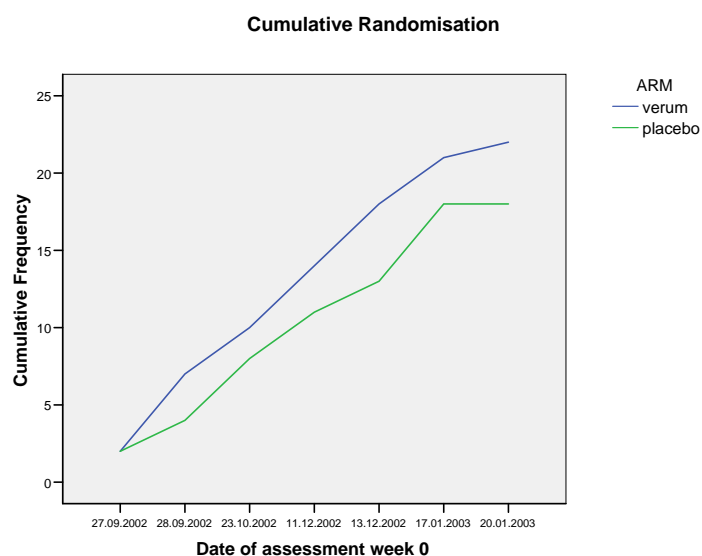
Missing ID's
109
116
119
120
129
130
143
145
150
151
152

ID	DORand	comment
106	23/10/2002	similar ID's in Sept
118	11/12/2002	similar ID's in Oct
126	13/12/2002	similar ID's in Oct
128	13/12/2002	similar ID's in Oct

When rechecked for the CPRS (containing secondary variables) ID 134 showed two baseline coded scores. Inspection of the original database showed doubled entry for baseline and no values/dates for week 18. **Verify with authors and request correct data.**

1.3.4 Sequence of dates of randomisation

Cumulative randomisation graph produced using SPSS syntax – lines lie close together with no crossing over.



1.3.5 Balance of baseline variables

Categorical

Gender – no sig diff although cells with less than 5.

Trial Arm * Sex Crosstabulation

Count

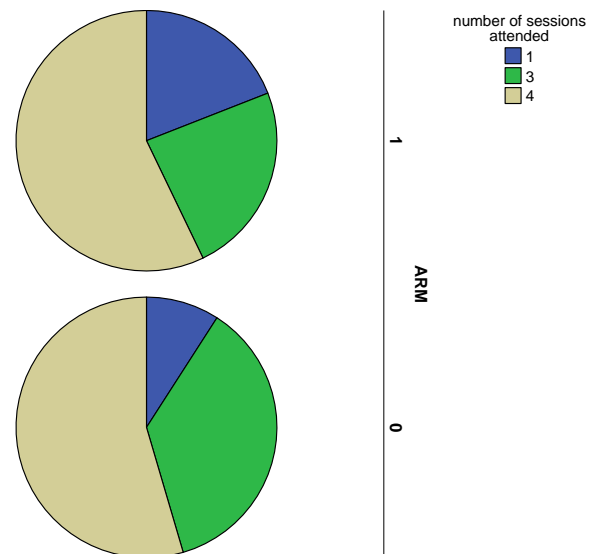
		Sex			Total
		male	female	missing	
Trial Arm	verum	17	5	0	22
	placebo	15	4	2	21
	Total	32	9	2	43

Previous or current stimulant medication use – not able to extract this data from Access file provided. [Check with trialist.](#)

Co-morbidity (intended to code as categorical, having additional diagnosis of oppositional-defiant or conduct disorders) – not relevant as such patients excluded.

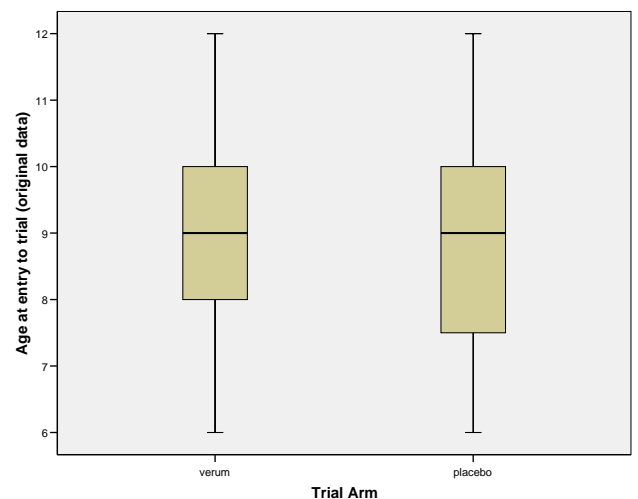
Treatment compliance, proxied by attendance at 4 weekly follow-ups during the trial. Using the CPRS rating scale data set, patients were coded as having completed week 0, week 6, week 12 and week 18. Frequency table below by trial arm

number of sessions attended	Trial Arm	
	Verum (1)	Placebo (0)
1	2	4
3	8	5
4	12	12



Continuous –

Age: Initial frequency table and boxplot showed no unexpected values or outliers. All looks fine and no sig departure from normality.



Age in years

Trial Arm	N	Mean	Std. Deviation	Median	Minimum	Maximum
verum	22	9.18	1.868	9.00	6	12
placebo	19	8.84	1.922	9.00	6	12
Total	41	9.02	1.877	9.00	6	12

Check of reviewer calculated age with given age – exact matches for all ID's.

Initial severity of disease: Measured by CPRS ADHD Index week 0 and CGI-P week 1:

Both variables missing data for ID's 105, 118, 122, 125, 131, 137

CGI-P week 1 RAW: No sig diff on t-test

Baseline Global CGI-P

CGI-Parent week 1 Global

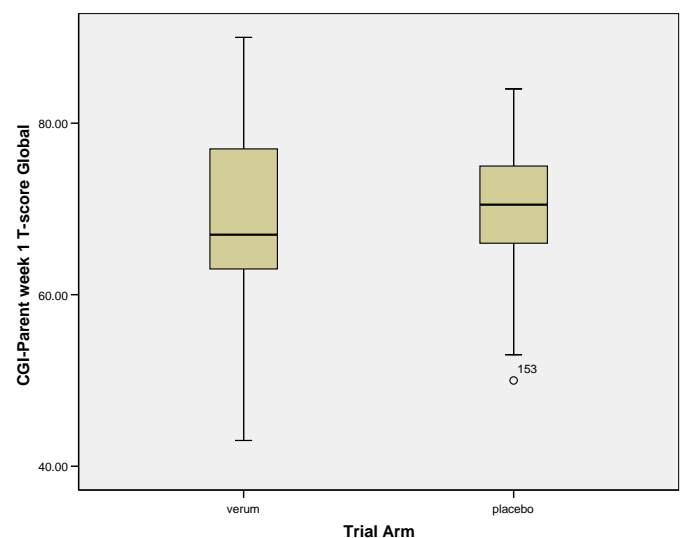
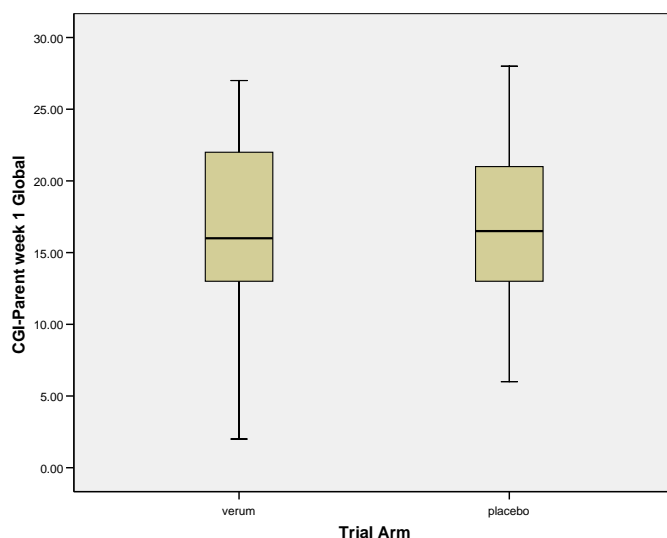
Trial Arm	N	Mean	Std. Deviation	Median	Minimum	Maximum
verum	17	15.5882	7.73029	16.0000	2.00	27.00
placebo	16	17.0000	6.34560	16.5000	6.00	28.00
Total	33	16.2727	7.01905	16.0000	2.00	28.00

CGI-P week 1 T-SCORE: generally fine, matches with published data, all normal. One possible outlier with ID 153 as marked on second boxplot. No sig diff at baseline.

Baseline Global CGI-P T-Scores

CGI-Parent week 1 T-score Global

Trial Arm	N	Mean	Std. Deviation	Median	Minimum	Maximum
verum	17	67.8824	13.76537	67.0000	43.00	90.00
placebo	16	69.8750	9.62549	70.5000	50.00	84.00
Total	33	68.8485	11.79810	69.0000	43.00	90.00



CPRS week 0 RAW: no sig diff on t-test

Baseline Raw CPRS Index

CPRS - ADHD Index Week 0

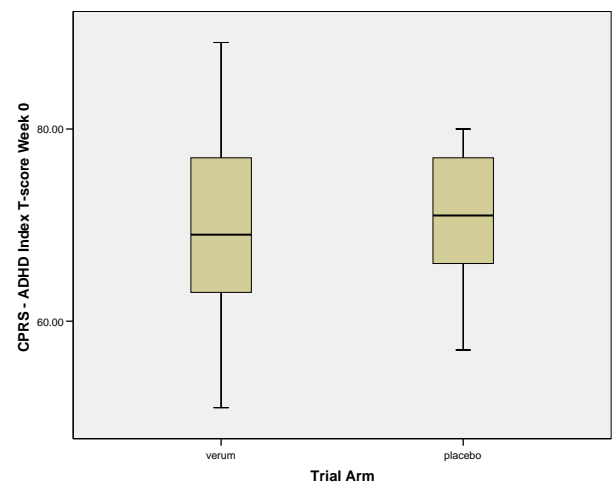
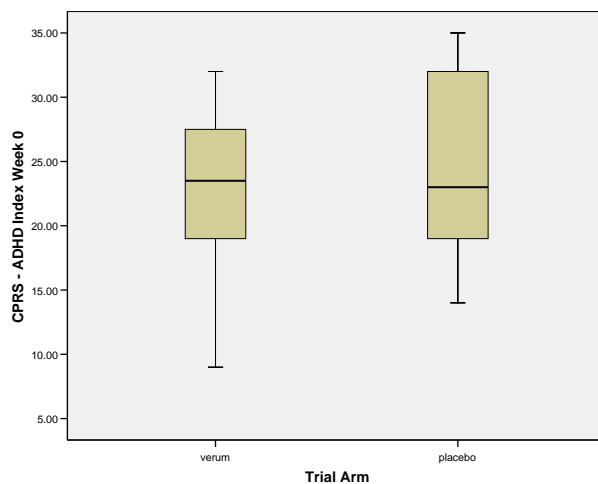
Trial Arm	N	Mean	Std. Deviation	Median	Minimum	Maximum
verum	20	22.8500	5.76080	23.5000	9.00	32.00
placebo	17	24.2353	6.82394	23.0000	14.00	35.00
Total	37	23.4865	6.22103	23.0000	9.00	35.00

CPRS week 0 T-SCORE: matches published data. no sig diff on t-test

Baseline T-Score CPRS Index

CPRS - ADHD Index T-score Week 0

Trial Arm	N	Mean	Std. Deviation	Median	Minimum	Maximum
verum	20	70.4500	10.65475	69.0000	51.00	89.00
placebo	17	70.4118	7.35747	71.0000	57.00	80.00
Total	37	70.4324	9.16376	70.0000	51.00	89.00



1.4 Further checks

1.4.1 Assessment of follow-up

Checked time elapsed between week 0 and week 18 test dates. Should be around 18 weeks matching expected duration of trial. Possible data entry error with ID 154. Suggested some variability around the actual final follow-up, so also graphed number of days in the trial. This figure should be around 126 days. Mean etc is okay but range and boxplot suggest some longer follow-up periods. Gave a slippage allowance of 4 days and checked how many patients were followed up after this – this left 5 ID's who according to test dates had been in the trial for more than 130 days. (ID's 112 – 23days, 121 – 3days, 133 – 9days, 134 – 11days, 136 – 3days)

1.5 Summary of outcome variables (parent rated)

CGI-P from week 1 – week 17 (using summary excel data file) in T-Scores

			Count	Mean	Std Deviation	Median	Maximum	Minimum	Valid N
Trial Arm	verum	CGI-Parent week 1 T-score Global	22	67.88	13.77	67.00	90.00	43.00	N=17
		CGI-Parent week 17 Global T-Score	22	64.31	15.93	65.00	90.00	41.00	N=16
	placebo	CGI-Parent week 1 T-score Global	21	69.88	9.63	70.50	84.00	50.00	N=16
		CGI-Parent week 17 Global T-Score	21	62.40	11.99	61.00	90.00	50.00	N=15

Restless/Impulsive from CGI-P for week 1 and week 17 (using summary excel data file) in T-scores

			Count	Mean	Std Deviation	Median	Maximum	Minimum	Valid N
Trial Arm	verum	restless/impulsive CGI-P T-score week 1	22	69.35	13.61	71.00	90.00	45.00	N=17
		restless/impulsive CGI-P T-score week 17	22	64.25	15.67	67.00	90.00	41.00	N=16
	placebo	restless/impulsive CGI-P T-score week 1	21	71.25	7.50	71.00	83.00	54.00	N=16
		restless/impulsive CGI-P T-score week 17	21	63.60	11.29	62.00	90.00	50.00	N=15

CPRS ADHD Index for week 0 and week 18 (using summary excel data file) in T-scores

			Count	Mean	Std Deviation	Median	Maximum	Minimum	Valid N
Trial Arm	verum	CPRS - ADHD Index T-score Week 0	22	70.45	10.65	69.00	89.00	51.00	N=20
		CPRS - ADHD Index T-Score Week 18	22	62.84	13.77	65.00	84.00	42.00	N=19
	placebo	CPRS - ADHD Index T-score Week 0	21	70.41	7.36	71.00	80.00	57.00	N=17
		CPRS - ADHD Index T-Score Week 18	21	60.63	8.01	57.50	74.00	49.00	N=16

Hyperactivity from CPRS for week 0 and week 18 (using summary excel data file) in T-scores

			Count	Mean	Std Deviation	Median	Maximum	Minimum	Valid N
Trial Arm	verum	hyperactivity CPRS T-score week 0	22	74.70	11.42	76.50	90.00	47.00	N=20
		hyperactivity CPRS T-score week 18	22	66.21	14.37	72.00	90.00	45.00	N=19
	placebo	hyperactivity CPRS T-score week 0	21	74.47	13.18	76.00	90.00	48.00	N=17
		hyperactivity CPRS T-score week 18	21	63.81	13.76	62.00	90.00	45.00	N=16

Inattention from CPRS for week 0 and week 18 (using summary excel data file) in T-scores

			Count	Mean	Std Deviation	Median	Maximum	Minimum	Valid N
Trial Arm	verum	inattention CPRS T-score week 0	22	67.55	14.02	67.00	90.00	44.00	N=20
		inattention CPRS T-score week 18	22	63.79	15.63	65.00	90.00	42.00	N=19
	placebo	inattention CPRS T-score week 0	21	69.35	9.53	71.00	80.00	48.00	N=17
		inattention CPRS T-score week 18	21	58.38	7.85	55.50	73.00	44.00	N=16

Oppositional from CPRS for week 0 and week 18 (using summary excel data file) in T-scores

			Count	Mean	Std Deviation	Median	Maximum	Minimum	Valid N
Trial Arm	verum	conduct/oppositional CPRS T-score week 0	22	64.55	14.77	61.50	90.00	42.00	N=20
		conduct/oppositional CPRS T-score week 18	22	63.63	13.40	62.00	90.00	45.00	N=19
	placebo	conduct/oppositional CPRS T-score week 0	21	63.53	12.46	66.00	80.00	40.00	N=17
		conduct/oppositional CPRS T-score week 18	21	63.56	14.34	57.50	90.00	40.00	N=16

*1.6 Summary of outcome variables (teacher rated)*CGI-T from week 0 – week 18 (using summary excel data file) in T-Scores

			Mean	Std Deviation	Median	Maximum	Minimum
Trial Arm	verum	teacher CGI global week 0	68.80	10.78	72.00	79.00	45.00
		teacher CGI global week 18	63.73	12.48	67.00	81.00	43.00
	placebo	teacher CGI global week 0	66.14	11.88	69.50	81.00	47.00
		teacher CGI global week 18	58.10	11.99	60.00	75.00	42.00

Restless/Impulsive (CGI-T) from week 0 – week 18 (using summary excel data file) in T-Scores

			Mean	Std Deviation	Median	Maximum	Minimum
Trial Arm	verum	teacher CGI Impulsive week 0	73.40	11.51	77.00	86.00	47.00
		Teacher CGI impulsive week 18	67.00	13.19	72.00	84.00	45.00
	placebo	teacher CGI Impulsive week 0	71.29	12.86	77.00	86.00	50.00
		Teacher CGI impulsive week 18	61.50	13.52	63.00	79.00	43.00

1.7 Summary of outcome variables (child performance based)

Inattention: data file has both comission and omission errors. Verify which used with authors.

Ordering the data by collection phase showed discrepancies as follows:

Discrepancies

ID #	Cohort	Tx_assnmt	Surv_pd		Com_t	Om_t
110	1	1	12		55.87	58.4
110	3	1	Baseline		49.53	56.31
110	1	1	Baseline		0	0
110	1	1	18 wk		43.18	48.64
121	2	1	Baseline		55.25	43.23
121	3	1	12 wk		30.95	43.23
121	2	1	Baseline		60.76	43.68
121	2	1	12 wk		58.11	42.76
144	4	1	6 wk		59.04	54.92
144	4	1	Baseline		60.63	53.52
144	4	1	12 wk		46.35	75.83

No further summaries were produced at this stage until these discrepancies are resolved.

Impulsivity: comission errors only, check of consistency showed no problems.

7.3 Strauss

Summary: Strauss 2000

Morag Coulter, Health Sciences, University of York, UK

Dear Dr Strauss,

In the following pages you will find a summary of the cleaning, checking and re-analysis of the data you have kindly provided. I would be very grateful if you could take the time to read through this information.

1. Do you broadly agree with the summary statistics/means/standard deviations etc ?
2. I have included some further questions on the data set in the final pages – the answers to these questions will be very useful in our analysis. Should you require any more details from myself please ask.

The authors of two other trials (Frei et al 2005 and Jacobs et al 2005) have also received similar documents. When we have these final pieces of information we will be ready to pool the results. At that stage you will again be sent the findings for comments. Any publications resulting from this work will be co-authored by all trialists who have provided data and be produced collaboratively.

With best wishes

Morag Coulter
Research Fellow, Department of Health Sciences, University of York, UK
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Included patients summary

Age at entry to trial - not yet compiled as still awaiting data

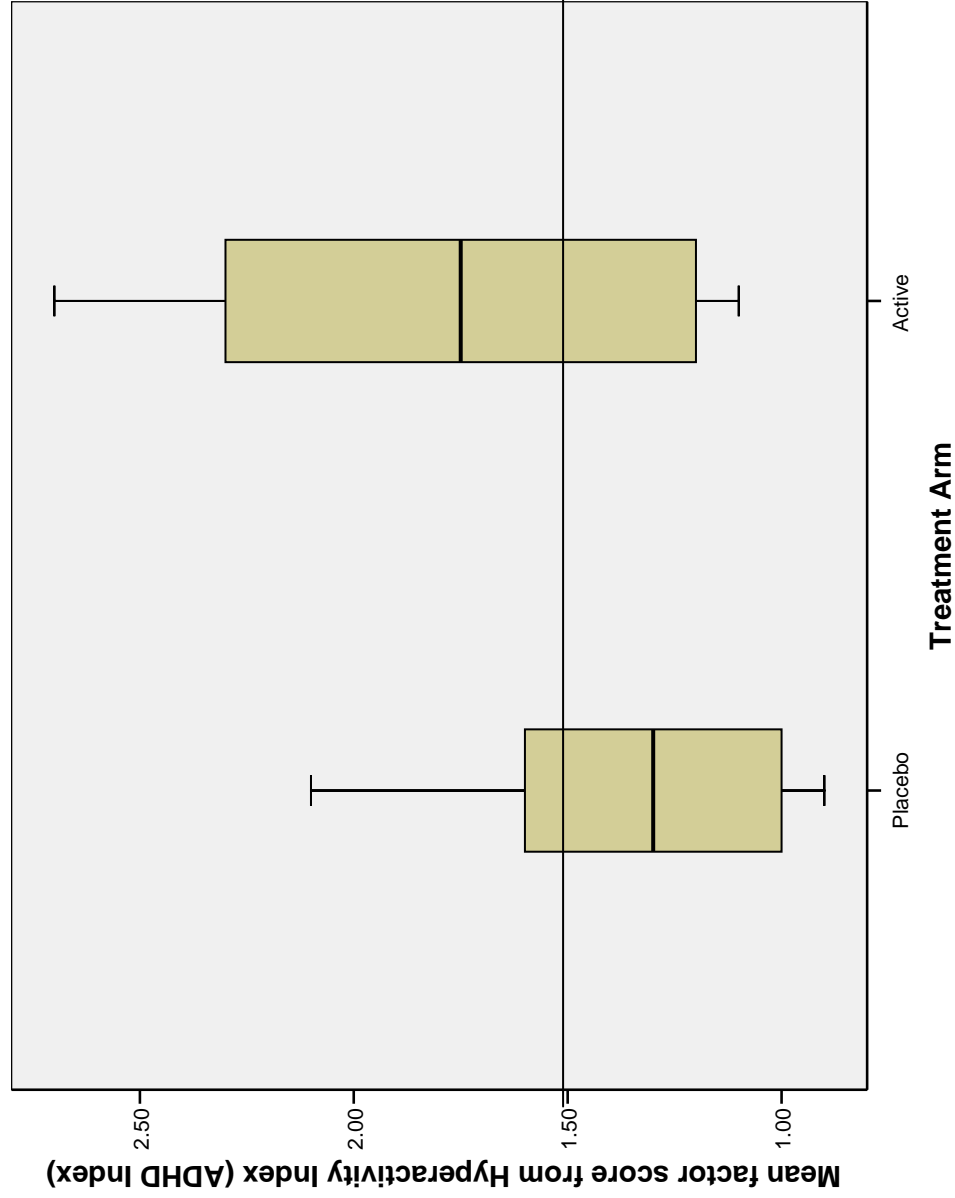
Trial Arm	mean	sd	median	min	max
Arm 1					
Arm 2					

Gender - not yet compiled as still awaiting data

Trial Arm	Male	Female	Total
Arm 1			
Arm 2			

Verification of randomisation using date of assignment - not yet compiled as still awaiting data

Baseline severity of patients using factor score for Hyperactivity Index variable



Trial Arm	mean	sd	median	min	max
Placebo	1.36	0.42	1.30	0.90	2.10
Verum	1.76	0.60	1.75	1.10	2.70

Line = factor score of 1.50 on Hyperactivity Index

PSQ variable summary

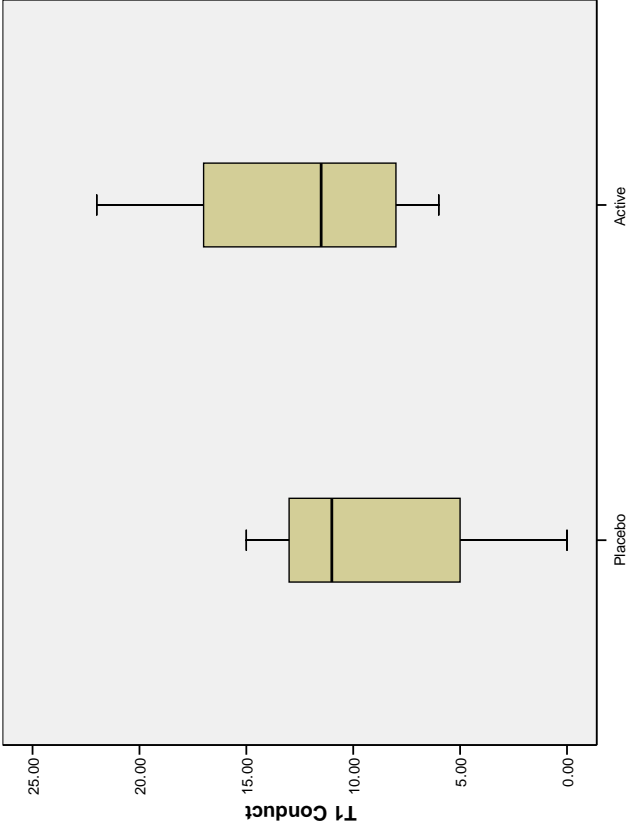
<i>Parent's Symptom Questionnaire</i>	Scale properties		
	No. Items	Max possible score	Min possible score
Scale			
ADHD index (previous Hyperactivity Index)	10	30	0
Impulsivity/Hyperactivity	4	12	0
Conduct problems	12	36	0
Inattention	4	12	0
Psychosomatic	5	15	0
Anxiety	4	12	0

<i>Parent's Symptom Questionnaire</i>	0 months placebo			0 months verum			3 months placebo			3 months verum		
	Mean	SD	Min/Max	Mean	SD	Min/Max	Mean	SD	Min/Max	Mean	SD	Min/Max
Scale												
ADHD index	13.60	4.17	9/21	17.60	6.04	11/27	10.06	5.19	3/20	9.60	6.15	2/23
Impulsivity/Hyperactivity	5.90	3.03	1/11	6.70	1.89	2/9	4.65	2.29	0/8	4.30	2.41	0/9
Conduct problems	9.30	5.52	0/15	12.40	5.19	6/22	9.20	8.48	0/29	7.30	5.45	2/17
Inattention	7.40	2.37	2/11	8.00	2.91	4/12	5.65	2.38	2/9	5.30	3.59	0/11
Psychosomatic	2.40	1.58	0/6	2.40	2.50	0/7	1.95	1.42	0/4	2.70	2.21	0/6
Anxiety	3.25	2.46	0/7	3.90	3.07	0/11	3.35	2.36	0/7	1.80	2.97	0/9

PSQ subscale outliers to be verified as accurate by author if possible

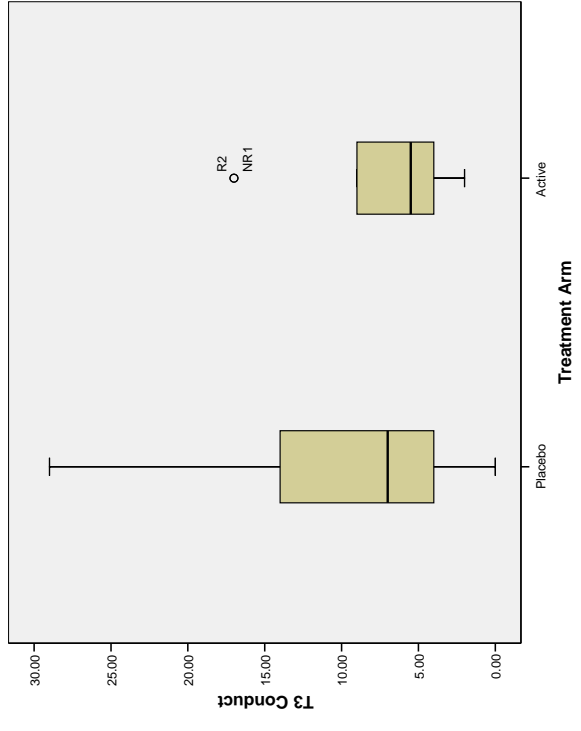
Variable	ID	Value	Treatment
Inattention 0 months	R6	2.00	placebo
Conduct 3 months	R2	17.00	verum
	NR1	17.00	verum
Impulsivity 0 months	NR1	2.00	Verum
Impulsivity 3 months	R9	8.00	Placebo
	NR4	1.50	Placebo
	NR3	0.00	Placebo
Index 3 months	R2	9.00	Verum
	R8	20.00	Placebo
Psychosomatic 0 months	NR2	6.00	Placebo
	R8	0.00	Placebo
Anxiety 0 months	NR1	11.00	Verum
Anxiety 3 months	NR 1	9.00	Verum

Pre-tx

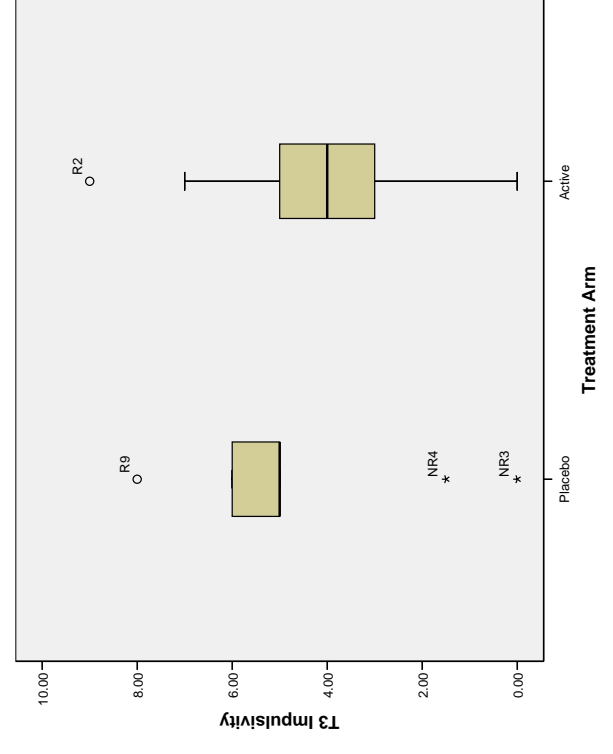
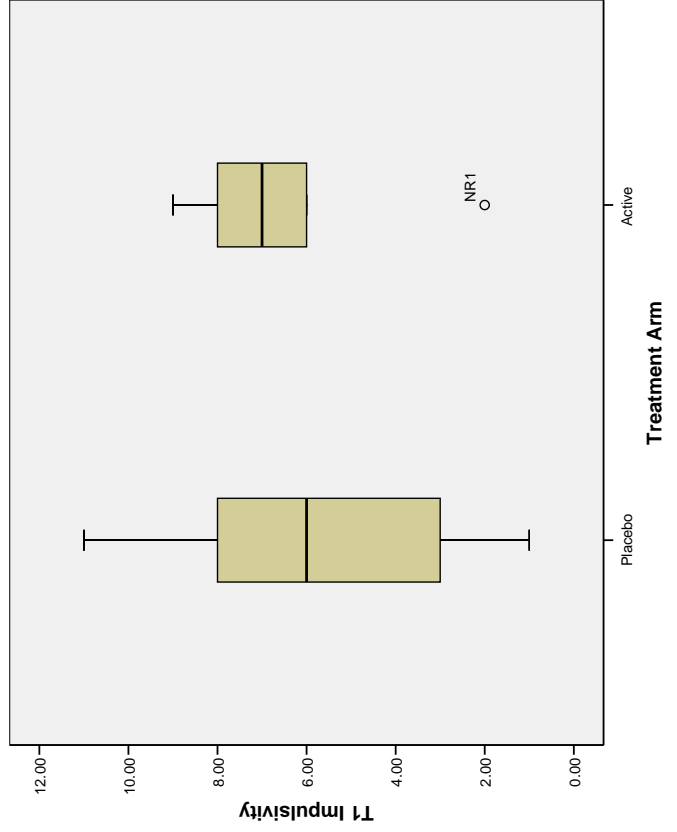


Conduct

Post-tx

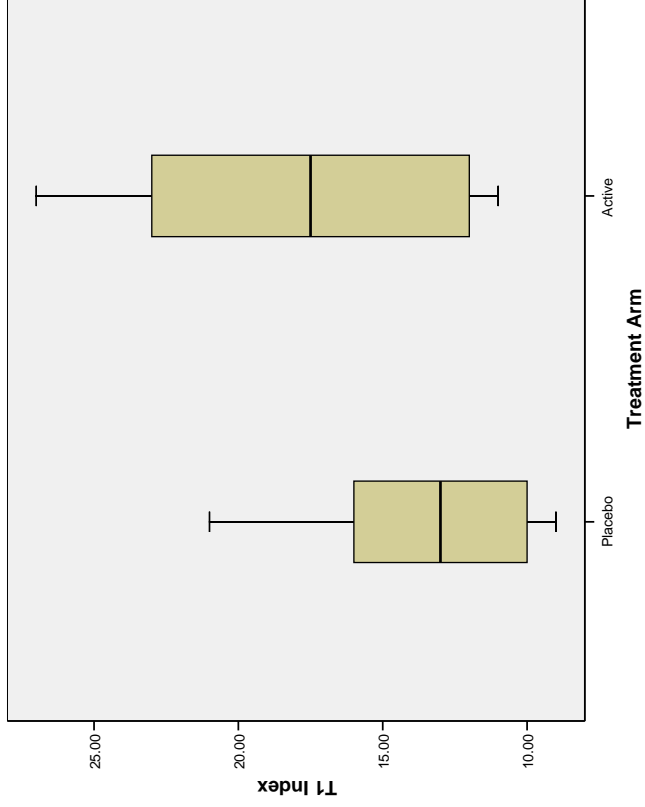


Impulsivity

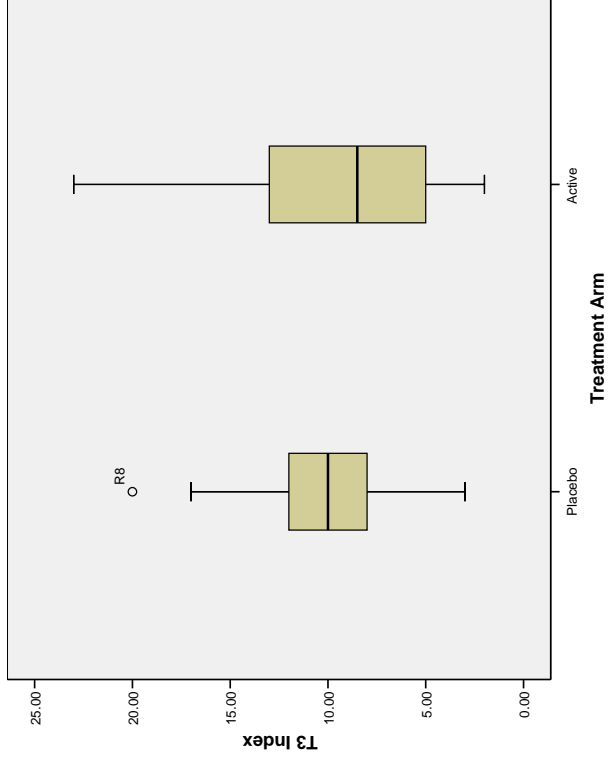


Index

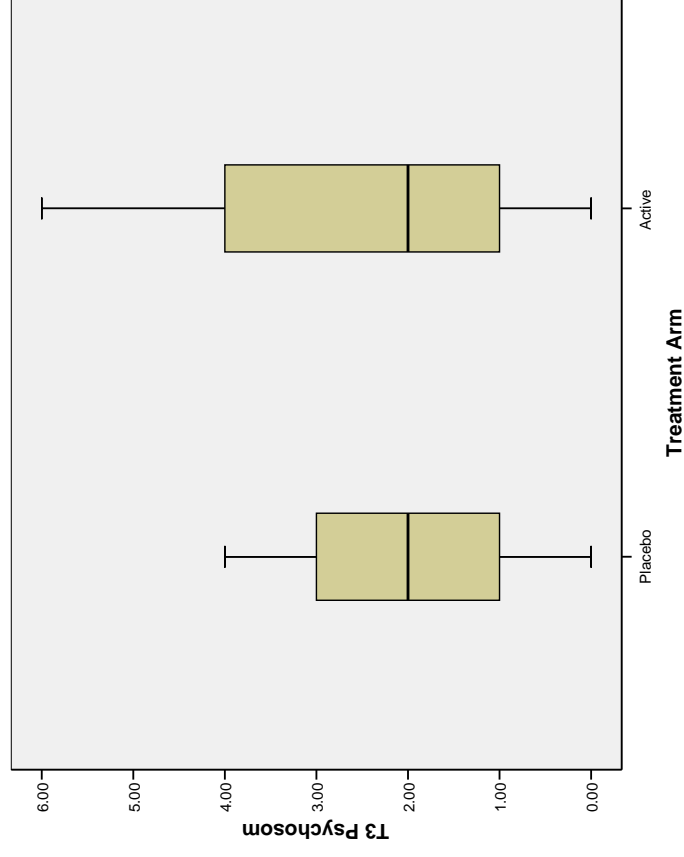
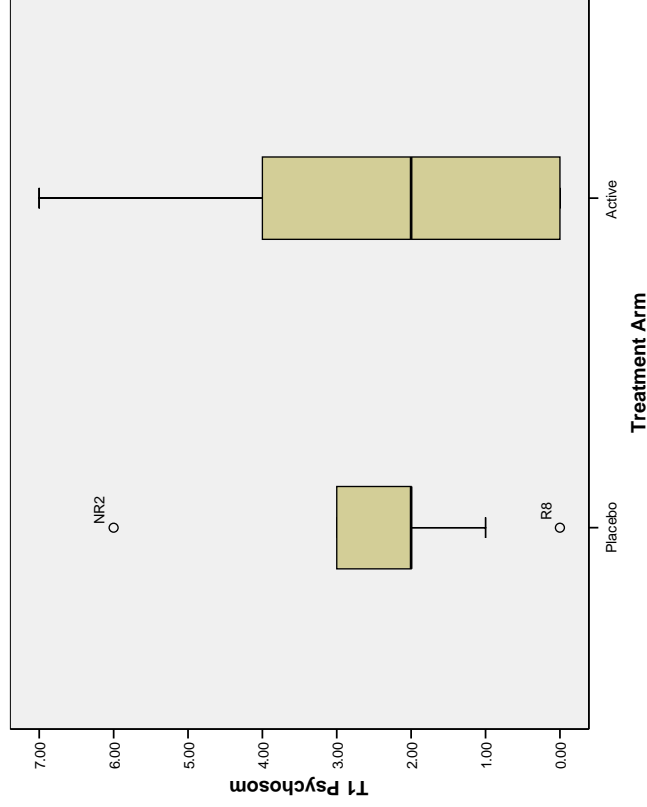
Pre-tx



Post-tx



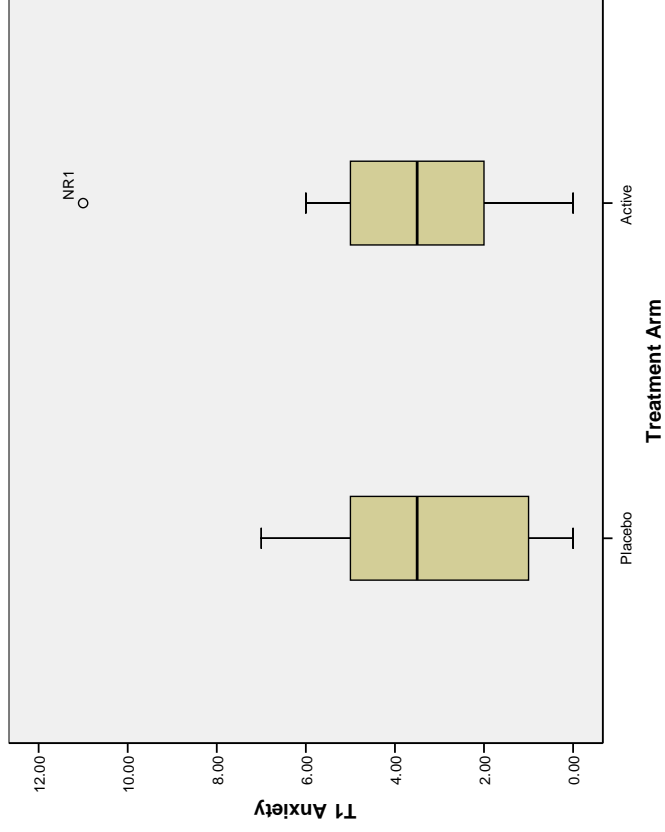
Psychosoma
tic



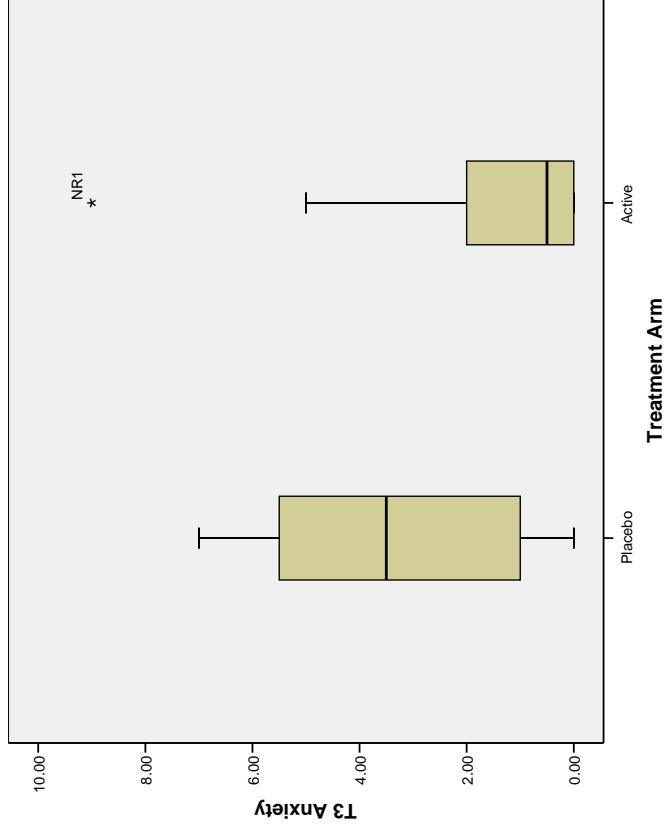
Strauss IPD ch

Anxiety

Pre-tx



Post-tx



Children’s Checking Task Summary

Data was provided in hard copy as appendices to the original thesis. The CCT consisted of four tasks where the participant was asked to demonstrate sustained attention by scoring through a specified target symbol/letter/number/word within a matrix of possibilities. This task can be scored for time taken and number of errors, but only number of errors was recorded and the data provided reported percentage correct per task.

Number of items presented and maximum number of matches to relevant target were derived from the appendices and used to re-convert the percentages into number of errors per task. Total errors per child were then calculated.

Task	Matches/Total items
Letter target task	78/336
Number target task	78/336
Symbol target task	78/336
Word target task	40/225
Total	274/1233

Task	Placebo			Verum		
	T1 Mean (SD)	T3 Mean (SD)	T3 Mean (SD)	T1 Mean (SD)	T3 Mean (SD)	T3 Mean (SD)
Letter target task	8.40 (9.96)	8.40 (15.61)	8.40 (15.61)	5.10 (3.28)	3.40 (2.41)	3.40 (2.41)
Number target task	12.20 (17.47)	12.30 (20.99)	12.30 (20.99)	5.70 (6.80)	4.00 (4.55)	4.00 (4.55)
Symbol target task	14.90 (23.81)	10.60 (17.67)	10.60 (17.67)	8.10 (6.67)	2.80 (2.10)	2.80 (2.10)
Word target task	4.30 (9.43)	5.40 (10.18)	5.40 (10.18)	2.50 (2.01)	1.70 (1.70)	1.70 (1.70)
Total	39.70 (58.26)	36.70 (63.57)	36.70 (63.57)	21.40 (11.12)	11.90 (8.95)	11.90 (8.95)

Further data requested:

- Date of randomisation by patient
- age of each patient
- gender of each patient
- In a previous discussion you informed me that two children withdrew from the study and were not included in the analysis. Could I request any data you have on these children to be sent via email or hard copy. It is important in Individual Patient Data analysis (being conducted now) that we have data from all of the randomised children if at all possible. This allows us to re-instate those patients and re-run analyses with a more complete data set. [query answered by email – many thanks!]

PSQ questions:

1. I have included a table with the participant values marked as being outliers by my statistics package. Could you confirm if these values are correct?
2. The graph on page three shows the starting mean factor PSQ score for Hyperactivity Index by trial arm. Page 44-45 of the original thesis states that a mean factor score of 1.50 is recommended as the lower limit for determining hyperactivity. You will see from the graph that a number of the participants did not score 1.50 or higher at baseline before treatment.
I wondered if you used alternative inclusion criteria or if you were not aware of this pattern in the data? I would be very grateful for your thoughts and opinions on this.

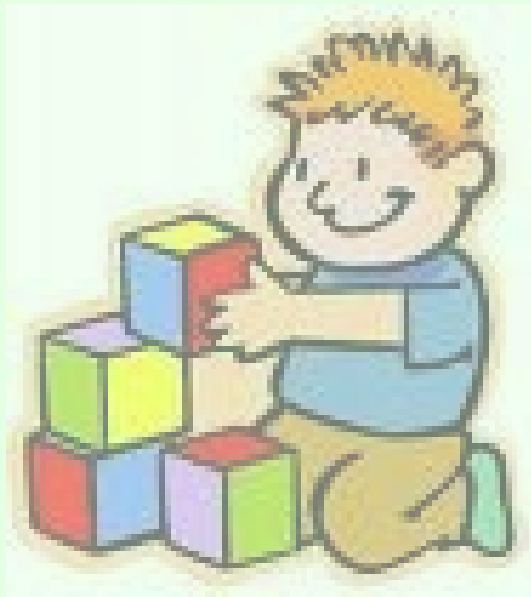
General Question:

In the thesis and published papers you did not seem to have directly compared placebo with verum, rather you calculated the change from baseline to follow-up in each group and then compared the p-values? Could you confirm if this was the analysis method that you adopted? [query answered by email – many thanks!]

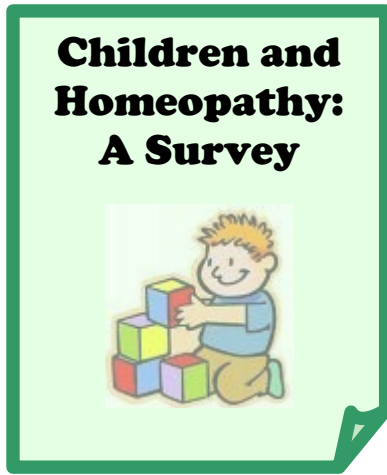
Appendix 8

Survey Instrument

CHILDREN AND HOMEOPATHY: A SURVEY



SOCIETY OF
HOMEOPATHS
CONFERENCE 2007



THE UNIVERSITY *of York*

DEPARTMENT OF HEALTH SCIENCES

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University of York
Heslington
York YO10 5DD

Telephone: (01904) 321 912
Email: mkc500@york.ac.uk
www.york.ac.uk/healthsciences

Dear Homeopath,

This survey has been designed to collect information on the approaches to treating children used by UK homeopaths. This is part of a research project being carried out at the University of York, Department of Health Sciences.

If you are **a practising homeopath who treats children or has treated children in the past**, we would be very grateful if you could fill out and return this short survey. It should take approximately 15 minutes of your time.

We are interested in what models of homeopathy you use and how you monitor changes/assess the impact of your treatments. The last section of the survey asks for your opinions on some of the ways homeopathy has been used in clinical trials for Attention Deficit-Hyperactivity Disorder.

It is up to you if you wish to take part and you are under no obligation to complete the survey. All participants will be anonymous and no-one will be identified in any reports that are written.

If you are interested in completing the survey please do so over the next two days and return all of the booklet to the collection box at the Research Desk. Alternatively you can post the survey back in the envelope provided.

The researcher (Morag Coulter) is available during the conference on the Research Desk to answer your questions.

With kind regards

Morag Coulter
Research Fellow
Dept Health Sciences
University of York
YO10 5DD

7. Who is present for follow-up consultations in your practice?

Please tick one box for each age group

0-5 yrs

6-12yrs

13-17yrs

- Parent(s) and child/young person present
- Parent(s) present only
- Child/young person present only

- Parent(s) and child/young person present
- Parent(s) present only
- Child/young person present only

- Parent(s) and child/young person present
- Parent(s) present only
- Child/young person present only

- Telephone follow-up parent & child
- Telephone follow-up parent only
- Telephone follow-up child only

- Telephone follow-up parent & child
- Telephone follow-up parent only
- Telephone follow-up child only

- Telephone follow-up parent & child
- Telephone follow-up parent only
- Telephone follow-up child only

Other (please detail below)

Other (please detail below)

Other (please detail below)

Further details here:

8. How do you usually monitor change/evaluate the impact of the homeopathy at your follow-up consultations?

Please tick all that apply

- General opening question e.g. "how have things been" or similar
- Review troublesome symptoms from previous consultation
- Look at school diary or report
- Drawings and/or handwriting
- Use a standardised questionnaire or outcome measure (please detail below)

Anything else (please detail below)

9. When asking questions; who are these directed to?

Please tick one

- Mainly the parent(s)
- Mainly the child/young person
- Both the parent and child/young person

10. If you work with 'difficult' children (ADHD symptoms, autism, aspergers, behavioural problems etc) is there anything that you particularly focus on in the consultation or when choosing a remedy?

Please tick all that apply

- Finding the root cause
- Identifying suitable nosodes
- Child's interactions with peers/parents etc
- Previous childhood ailments
- Pre-birth experiences
- Parental behaviour
- Others (please detail below)

PLEASE CONTINUE OVER...

SECTION THREE: PAEDIATRIC HOMEOPATHY IN TRIALS

There have been several studies evaluating homeopathy for children who have been diagnosed with **Attention Deficit-Hyperactivity Disorder**. We are interested in knowing what you, **as practitioners**, think about the way homeopathy has been used in these studies.

- You will find three short descriptions of different homeopathic treatments below.
- The numbers in superscript reflect the sentences concerning the questions below.
- for example: ¹ means this section refers to the source or repertories used

Study A

The first consultation in study A took place with parent(s) and child in a private homeopathic clinic. Single remedies were prescribed according to Boenninghausen (Allen's Edition with 125 remedies) and polarity analysis.¹ Liquid LM potencies² were given as daily drops³ to ensure more stable progress. Follow-up was carried out by telephone at 4-week intervals⁴ with the parent(s) using a symptom ratings scale.⁵ Remedies could be adjusted or changed at each follow-up until successful improvement of symptoms was noted, with no time limit.

i. How similar or dissimilar is this method of homeopathy to the way you practice? (please circle your answers)

	Very similar	Similar	No opinion	Dissimilar	Very dissimilar
1 The sources and repertories used:					
In what ways does this differ from your practice?					
2 The potencies used:					
In what ways does this differ from your practice?					
3 The frequency of remedies:					
In what ways does this differ from your practice?					
4 The follow-up duration:					
In what ways does this differ from your practice?					
5 The follow-up evaluation method:					
In what ways does this differ from your practice?					

ii. Would you be willing to practice homeopathy in this way within a clinical trial? (please circle your answer)

Very willing Fairly willing Neither willing nor unwilling Not very willing Very unwilling

Why?

iii. Any other comments on Study A?

PLEASE CONTINUE OVER...

Study B

The consultation was carried out with children and their parent(s) or carers in their home and remedies were prescribed based on classical homeopathy, HERSCU's remedy suggestions and using RADAR repertory software¹. Single remedies were used and given as 6x200c² pills taken daily for up to 5 days or until improvement was noted.³ Follow-up was carried out by telephone with parent or carer, 10 days after remedy prescription⁴, and any change recorded on a scale of hyperactivity symptoms.⁵ The remedy could be changed at follow-up and a maximum of two changes were possible. Overall the study lasted approximately two months.

i. How similar or dissimilar is this method of homeopathy to the way you practice? (please circle your answers)

	Very similar	Similar	No opinion	Dissimilar	Very dissimilar
1 The sources and repertories used:					
In what ways does this differ from your practice?					
2 The potencies used:					
In what ways does this differ from your practice?					
3 The frequency of remedies:					
In what ways does this differ from your practice?					
4 The follow-up duration:					
In what ways does this differ from your practice?					
5 The follow-up evaluation method:					
In what ways does this differ from your practice?					

ii. Would you be willing to practice homeopathy in this way within a clinical trial? (please circle your answer)

Very willing Fairly willing Neither willing nor unwilling Not very willing Very unwilling

Why?

iii. Any other comments on Study B?

PLEASE CONTINUE OVER...

Study C

An in-depth homeopathic consultation was carried out at a private homeopathic clinic with child and parent(s). The prescribing methods drew on the ideas of Sankaran and Scholten.¹ Remedies were given individually with freedom to vary potency and frequency. Briefly, single remedies in the 200 to 1M potency² repeated at 6-8 weeks³ were used for those not on allopathic medicine and more frequent low potency doses (30C² weekly³) for those taking stimulant medications such as Ritalin. Follow-up visits to the clinic were attended by both parent(s) and child at 6 and then 12 weeks after the first visit⁴ with the practitioners assessing any changes as in their usual practice. Practitioners also completed a global evaluation scale.⁵ Remedies could be altered at these visits allowing for up to two changes in the prescription. The study lasted a total of 4 ½ months.

i. How similar or dissimilar is this method of homeopathy to the way you practice? (please circle your answers)

	Very similar	Similar	No opinion	Dissimilar	Very dissimilar
1 The sources and repertories used:					
In what ways does this differ from your practice?					
2 The potencies used:					
In what ways does this differ from your practice?					
3 The frequency of remedies:					
In what ways does this differ from your practice?					
4 The follow-up duration:					
In what ways does this differ from your practice?					
5 The follow-up evaluation method:					
In what ways does this differ from your practice?					

ii. Would you be willing to practice homeopathy in this way within a clinical trial? (please circle your answer)

Very willing Fairly willing Neither willing nor unwilling Not very willing Very unwilling

Why?

iii. Any other comments on Study C?

PLEASE CONTINUE OVER...

**Children and
Homeopathy:
A Survey**



THANK YOU VERY MUCH FOR YOUR TIME

If you would be interested in being contacted for further research or for clarification of your answers please give your name and email/telephone number below:

Name:

Contact Details:

PLEASE RETURN THIS SURVEY TO THE RESEARCH DESK OR POST
BACK TO:

MORAG COULTER
2ND FLOOR HYMS BUILDING
UNIVERSITY OF YORK
YORK
YO10 5DD

Appendix 9

Interview Information and Consent



Homeopath Interview Information Sheet (Version 2.0)

I am asking if you would agree to take part in a research project about treating children with homeopathy, particularly children with Attention Deficit Hyperactivity Disorder (ADHD). Before you decide it's important to understand why the research is being done and what it will involve. So please read this leaflet carefully.

Thank you for reading this.

What is the purpose of the study?

I am interested in knowing more about what homeopaths think about working with children – is your consultation similar/different to treating adults, what kind of factors are important to you. I'm also interested in your opinions and perspective on children who have ADHD. I would like to understand more about how you as a professional make decisions about whether or not a child or young person with attention difficulties is improving or getting worse. I will also be asking you for your thoughts on the way homeopathy has been used in some recent clinical research.

Why have I been asked to take part?

You have been asked to take part because either 1) you had agreed to help recruit parents and children for an earlier project, or 2) I found your details through a professional register.

Ten homeopaths have been interviewed so far including specialists in paediatric homeopathy and newly qualified practitioners. I am interested in talking to a range of practitioners about their opinions and experiences.

Do I have to take part?

No! It is up to you to decide whether or not to take part. You are free to withdraw from the research at any time and without giving a reason.

Who is carrying out the research?

I (Morag Coulter) will be carrying out the interviews and analysing the information. I am a researcher at the University of York and also studying for my PhD. The study is funded by the Department of Health Research Capacity Development Awards scheme.

This study has been approved by the Department of Health Sciences Research Ethics Committee.

How will I benefit from this study?

You will not benefit directly from the study. The aim of the study is to document how children and young people are treated by homeopaths, particularly when they have ADHD type problems. It will also explore how homeopaths assess the impact of their treatment, and hence what might be missing from standardised outcome measures.

This research will inform the design of future trials and provide a practitioner perspective on the research that has been carried out to date.

Continued.....



Homeopath Interview Information Sheet cont.

What is involved?

You are invited to take part in an interview (60-90mins) during the research project at a convenient time. The interview can take place in your home, clinic or at the University – whichever is more suitable, or by telephone. The interview will cover your experiences with children and young people, how you usually assess treatment impact and your views on the types of homeopathy used in clinical research.

The session will be recorded.

What will happen to the information?

The results of this research study will be written up as a report and published in a journal. I will also write a summary report for the professionals who take part – this will be posted out to you at the end of the project. Some of the information will be used in a thesis. No-one will be identified in any of these reports or publications and all data will be anonymised.

What if there is a problem?

If you are worried about anything or are unhappy about the research study, you should ask to speak with me and I will do my best to answer your questions (01904 321 912). If things are not resolved you can complain formally through the University of York.

Will my taking part in the study be kept confidential?

Everything I discuss with you will be kept confidential. Your name will not be used when we write articles or reports. Project advisors from the University of York will see some of the information you give us to make sure the research is being done properly. Any information which is shown to anyone else will have names and address removed so that no one can be recognised from it. All information and data will be securely disposed of when no longer required. Our procedures for handling, processing, storage and destruction of your data are compliant with the Data Protection Act 1998.

What happens next?

If you would like to take part in an interview please complete the consent form and return it in the envelope provided. If you do not wish to take part please do not return the consent form. I will telephone to arrange the interview time and place.

Thank you for reading this,

Morag Coulter

Contact details:

If you would like to ask any questions or need to contact me, please use these numbers:

Morag Coulter 01904 321 912 or 07786 864 700



Practitioner Interview Consent (Version 2.0)

Tick a box

- Have you read the project information sheet?..... Yes No
- Do you know what taking part in the project means for you? Yes No
- Do you understand that you can change your mind about taking part at anytime? Yes No
- Do you understand that Morag will keep everything you say private, but responsible individuals from the University of York may need to look at the information once your name has been removed?..... Yes No
- Do you understand that Morag will record the interviews? Yes No
- Do you understand that information gathered during this project will be used to write research articles and reports? Yes No
- Do you want to take part in the project? Yes No

Participant Name

Date

Signature

Researcher Name

Date

Signature

PLEASE RETURN IN THE PREPAID ENVELOPE PROVIDED ☺

Appendix 10

Sample Interview Schedule



Topic Guide (Version 2.0)

Introduction and explanation of confidentiality

This project is focusing on how professional homeopaths treat children with homeopathy, and I am particularly interested in Attention Deficit Hyperactivity Disorder. I'm going to ask you some questions about the way that you practice homeopathy, and what you think is important when working with children.

Because there have been some clinical trials in this area, I'm also going to ask you what you think about these – you'll find the short descriptions on the sheets I sent out last week.

Our conversation will be recorded and transcribed. All the data will be anonymised and held securely in the University. Anything you tell me will be kept confidential and your name will not be attached to any of your statements if and when they are used in reports or articles. You'll receive a summary report of the findings at the end of the project.

Do you have any questions?

Are you happy to go ahead with the interview?

Your background and training in homeopathy

- Just to get us started, can you tell me a bit about where you trained in homeopathy please?
 - When was that
 - What kind of homeopathy would you say?
- How would you describe the homeopathy you practice now?
 - Style/potencies/methods
 - Anything else you use (bach remedies for example)?
- Did you have any specific training on working with children?



Your experience with children (and ADHD)

- In your practice how often would you say you see children or young people?
 - what sort of problems do they come with?

- Is there anything special or different about treating children rather than treating adults?
 - Anything that's easier? More difficult?

- Can you describe a first consultation for a child please, from when the appointment is made
 - Any contact with parent before you see the child – why?
 - Set up of the room – why?
 - See parent and/or child alone – why?
 - What sort of information do you get from the parents?
 - What sort of information can you get from the child?
 - Sometimes the parent and child might disagree – what do you do then?
 - What kind of questions – why?

- And now could you describe a follow-up consultation please
 - Time to follow-up
 - What kind of questions
 - Standardised questionnaire?
 - Questions to parent or child – why?
 - Is it important to see the child?

- How do you decide if a remedy has helped or not?

Communication and relationships

- One of the themes that seems to have come out of the research is about the process of establishing a relationship between the homeopath and the child/parent. Could you tell me a bit about that please?
 - Is it important?
 - What happens if you don't seem to be able to establish it with the parent / child?



ADHD

- Can you tell me a bit about what, as a homeopath, you think ADHD is?
 - What causes it?
 - How can homeopathy help it?
 - Could homeopathy cure ADHD, or might it be a maintenance treatment? – Why?

- Your experience of working with children with ADHD or behaviour problems
 - Do you see any children with ADHD or similar conditions?
 - What about working with a child with ADHD – anything specific that you look for or do in a consultation?
 - Any particular remedies or potencies that you might use? Why?



Your thoughts on research and homeopathy

- Do you think that the way you practice homeopathy has changed after reading something or attending a seminar since you graduated? Could you give me an example?
 - What sorts of things might convince you to change your practice?
- Do you think research into homeopathy is useful?
 - For practitioners? In what way?
 - For patients? In what way?

I know that as a practitioner you might not have access to journals and research articles (**pause for comment from participant**)

But in the next couple of questions I'd like you to assume that your association will have told you about these trials:

- If a research trial showed that a form of homeopathy different from your practice (say practical or clinical homeopathy rather than classical) **worked very well** for a condition, would you consider changing how you practice?
 - Why/why not?
- And if a research trial showed that, say classical homeopathy, **wasn't useful** for a particular condition or set of patients, what would you do then?
 - Why?
 - Would you stop treating those people? Why/why not?



Homeopathy for ADHD in Trials

I'm interested in your thoughts on the homeopathy used in some recent clinical trials – you'll need those three sheets that I sent out to you for this section.

Starting with Study A [Frei] could you read through the description for me. Feel free to ask about anything you're unfamiliar with.

Now I'd like you to tell me what you think about it:

- Positive aspects
- Any problems
- Anything you're not happy with

Moving onto Study B [Lamont] could you read through the description for me. Feel free to ask about anything you're unfamiliar with.

Now I'd like you to tell me what you think about it:

- Positive aspects
- Any problems
- Anything you're not happy with

And finally Study C [Jacobs] could you read through the description for me. Feel free to ask about anything you're unfamiliar with.

Now I'd like you to tell me what you think about it:

- Positive aspects
 - Any problems
 - Anything you're not happy with
-
- Would you be willing to practice like any of those studies? Why/why not?



Thanks for your time

You've been very generous with your time today, and your answers will be very useful in this research.

Do you have any questions for me?

I'll send out a form shortly for you to complete and then we can arrange a thank-you payment of £40.

Should you have any questions or want to contact me, all of my details are on the information sheet you received in the post.

Appendix 11

Interview Vignettes

Study A

The first consultation in study A took place with parent(s) and child in a private homeopathic clinic. Single remedies were prescribed according to Boenninghausen and polarity analysis.

Daily drops of liquid LM potencies were used to ensure a more stable progress.

Follow-up was carried out by telephone at 4-week intervals with the parent(s) using a symptom ratings scale.

Remedies could be adjusted or changed at each follow-up until successful improvement of symptoms was noted.

No time limit was placed on this study.

Prescribing methods - (Boenninghausen and polarity analysis)

Follow-up - by telephone with parent at 4 weekly intervals

Study B

The consultation was carried out with children and their parent(s) or carers in their home and remedies were prescribed based on classical homeopathy, the writings of Paul Herscu and using RADAR repertory software.

Single remedies were used and given as 6x200c pills taken daily for up to 5 days or until improvement was noted.

Follow-up was carried out by telephone 10 days after remedy prescription and any change recorded on a scale of hyperactivity symptoms.

The remedy could be changed at follow-up and a maximum of two changes were possible.

Overall the study lasted approximately two months.

Prescribing methods - classical homeopathy, Herscu and RADAR

Follow-up - by telephone with parent or carer 10days after prescription given

Study C

An in-depth homeopathic consultation was carried out at a private homeopathic clinic with child and parent(s).

Remedies were given individually with freedom to vary potency and frequency. Briefly, single remedies in the 200 to 1M potency repeated at 6-8 weeks were used for those not on allopathic medicine and more frequent low potency doses (30c weekly) for those taking an anti-stimulant medication. The prescribing methods drew on the ideas of Sankaran and Scholton.

Follow-up visits to the clinic were attended by both parent(s) and child at 6 and then 12 weeks after the first visit with the practitioners assessing any change etc as in their usual practice.

Remedies could be altered at these visits allowing for up to two changes in the prescription.

The study lasted a total of 4 ½ months (18 weeks).

Prescribing methods - Sholten and Sankaran

Follow-up - face to face with parent and child every 6 weeks

Appendix 12

Example Participant Observation Information Sheet

SoH Research Day - Manchester 23rd September 2007

Information about Morag's research

I am a researcher at the University of York and also studying for my PhD. The study is funded by the Department of Health Research Capacity Development Awards scheme to explore homeopathic treatment for children. As part of this research programme I am carrying out a systematic review of homeopathy for ADHD, interviewing practitioners about their practice, and collecting information with a survey.

One of the questions that has come out of my research to date is about homeopathic practitioners and how they access/use and understand research. I'm interested in how relevant they feel it might be to their practice, and their opinions on some of the research that's been published on homeopathy.

I am a lay member of the Society of Homeopaths and have attended several of their events to collect data and achieve more of an insight into the homeopathic community. I am attending this Research Day in Manchester to find out more about what homeopaths think about research, and how it relates to their individual practices. I will be taking part in discussions just like everyone else, and nothing is being recorded. I will be using some of my notes and personal reflections in the process of writing my PhD.

If you have any questions about my research or my presence at this CPD workshop please feel free to ask today, or contact me later as below.

Thank you for reading this,

Morag Coulter
Research Fellow

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Fax: 01904 321 920

<http://www.york.ac.uk/healthsciences/gsp/staff/mcoulter.htm>

Appendix 13

Homeopathic Models and Definitions of Health

Roberts E (2005) Homeopathy principles and practice (Roberts, 2005)

Principles: individualisation and treating whole person; minimum of interference to stimulate self-healing; potentisation of remedies; law of similars; Hierarchy of symptoms and being - spirit, mind, emotions, physical body; Vital Force.

Move towards health throws out disease away from vital organs. Direction of cure (detailed) not attributed to Herring - reads as integral to homeopathy?

Incorporates chakras, kingdoms of remedies. Immediate, maintaining and fundamental (miasmatic) causes of disease.

Lists various CAM modalities that may be used for diagnosis.

Actually much more focused on Kentian style homeopathy though not specifically attributed as such.

Ian Watson (1991) Guide to methodologies of homeopathy (Watson, 1991)

Main purpose of the book is to demonstrate the main ways the principle of similars can be applied in practice

Anthony Campbell (1984) Two faces of homeopathy (Campbell, 1984)

Basic idea is principle of similars, individual treatment, single medicines, small doses, repeated only when needed. mentions vital force, potency and chronic disease (miasms) as being from Hahneman but unscientific and meta-physical.

Hughes (1902) Principles and Practice of Homeopathy (Hughes, 1994 [1902])

Focuses on like cures like, mentions the use of infinitesimal doses is not a crucial part of homeopathy?! Talks about homeopathy as being a method that can be followed, rather than believing everything that Hahneman wrote without question. Also clearly mentions that the system might be expected to change, develop and improve.

Refers clearly to the evolution of The Organon through its five editions and points to the appearance of dynamisation (attenuation plus succussion) in the 5th edition, vital force is mentioned in 4th but only expounded upon in the 5th.

Totality of symptoms which reflects the inner patient. Clear suggestion that until the 4th and 5th editions, Hahneman's work is more clearly based on experimental evidence and observations.

Rajan Sankaran (1999) Spirit of Homeopathy (Sankaran, 1999)

Key principles are stated as like cures like, provers to generate symptom pictures and single remedy choice, potentization, healer within or the vital force, treatment for the individual who has a disease rather than the disease in isolation. Divides remedies into animal, plant and mineral kingdoms, disease products (nosodes), healthy tissues and secretions (sarcodes) and imponderables. Main focus is on mentals and generals - presented as being a discovery based on personal practice and lack of success in some conditions/individuals. Also termed the central disturbance.

key ideas: roots of disease, importance of and use of delusions and dreams, homeopsychotherapy, situational materia medica. Using the mentals and generals rather than the pathology, focus is on the psychotherapeutic benefits and ability to deal with inherited emotional states. Vital force ideas development coinciding with potentisation and dilution of remedies, no longer thinking only of material doses or effects. Less interested in prescribing based on pathology or local symptoms, suggesting that it is the central disturbance shown through mental symptoms that is of most interest. State of mind that is specific to each remedy. Critical of therapeutics.

Owen ed (2007) Principles and Practice of Homeopathy (Owen, 2007)

In terms of models of health and related prescribing, suggests 5 main areas (diagram on pg 7)

Pathogenic: causation: isopathic/aetiological

Biological: presenting symptoms: local/clinical/keynotes

Holistic: totality/constitution: three legged stool/mind body general/ morphological constitution

Holographic: essence/thematic: miasms/families/kingdoms/related remedies

Relational: reflective: Psychodynamic/emotional/intuitive

Suggests that homeopaths use all five models of health and move between them as needed

Life force and vitality

MD Dhawale (1985) Principles and Practice of Homeopathy (Dhawale, 1985)

Fundamental law of similars - an unchanging rule plus rules of homeopathic posology which have evolved through clinical experience as shown in the development of ideas in the various editions of the Organon. Idea of health as dynamic state of equilibrium, disease is disequilibrium we are aware of only via symptoms. Use of minimum force to help body reestablish equilibrium

Single remedy: minimum dose: minimum repetition.

Dismissive of alternating remedies, using combined remedies

Minimum dose though not necessarily infinitesimal

Guidelines given for choice of potency (pg 405)

States the basic stance of the Organon as:

diseases are a disturbance of the vital principle

Cure is dependent on strength of the strength of the vital principle, remedies should only be given that are known accurately and act dynamically

Law of similars must guide selection of remedies

dose should be sufficient to restore health without weakening, injuring or torturing therefore use small, minute dose

Potentiation increases the capacity of drugs to affect the life force (dilution, trituration and succussion)

individualisation

Symptoms: Elements of location/sensation and modality. Planes of mental/spiritual/physical. Common and characteristic/chief and concomitant/general and particular/incomplete and complete

Kurz (2005) Imagine Homeopathy (Kurz, 2005)

The law of similars

The totality - not an exhaustive list of symptoms but those which make the underlying totality apparent

Case Taking

Keynotes and characteristic symptoms/strange rare and peculiars

Individualisation - the asthma that Mr Jones has versus Mrs Wilson

State of being of the patient is an expression of the disease

Suppression of symptoms via allopathy

Poll of homeopathic practitioners came out with following definition characteristics:

1. law of similars
2. single remedy (one remedy of one potency given at one time)
3. minimum dose
4. Herings law
5. potentised substances as remedies (added in almost as an afterthought)

Kurz suggests that the core defining elements of homeopathy as the concept of a holistic and indivisible disease state observable through symptoms in sick individual. And the correspondence of each remedy to a holistic and indivisible state made observable through provings.

Therefore law of similars is used to find the drug that most closely matches the disease state.

Suggests that classical homeopathy uses remedies prepared by serial dilution and succussion as per Hahneman, whereas other practitioners are still homeopaths

Gives examples of miasms as chronic disease factors, mentions the recent expansion from the original three to 12 in one book by Sankaran.

Mike Dean (2005) Trials of Homeopathy (Dean, 2004)

Homeopathy post-Hahneman: different approaches can be seen as foci within the field of homeopathy that practitioners will move between as needed for each patient.

Hering, Boenninghaussen and Kent (purist? symptomatology focus and priority placed on mental/classical) versus Griesselich and Hughes (more scientific, correlating with physiology/clinical)

Appendix 14

Additional Survey Data

Survey Data: ICPC Categories and frequencies:

ICPC Category (plus notes)	Freq
A General & unspecified This category included recurrent infections (various), chronic fatigue syndrome, ME and concerns about vaccination or post vaccination treatment	21
B Blood and blood forming organs and lymphatics	1
D Digestive Given in survey as “digestive problems”, “bowel movements”, “IBS”, “constipation” or “diarrhoea”.	12
F Eye (vision)	0
H Ear (hearing) Ear infections or ENT infections were frequently listed, with more specific examples such as glue ear.	12
K Circulatory None	0
L Musculo-skeletal	1
N Neurological All responses in this category referred to migraine headaches.	3
P Psychological This category included enuresis (bed wetting) and behavioural disorders.	33
R Respiratory	27
S Skin	31
T Endocrine, metabolic and nutritional	2
U Urological	0
W Pregnancy, child-bearing & family planning	0
X Female genital including breast These codes were entirely made up of “menstruation problems” or “period problems”	4
Y Male genital None	0
Z Social problems None of the respondents reported anything that fitted this category	0

Survey Vignette Response Tables

Study A

	Vignette A 'source'		Vignette A 'potency'		Vignette A 'frequency'		Vignette A 'follow- up'		Vignette A 'evaluation'	
	Count	%	Count	%	Count	%	Count	%	Count	%
missing	3	7.9%	3	7.9%	4	10.5%	3	7.9%	3	7.9%
similar	6	15.8%	14	36.8%	16	42.1%	25	65.8%	6	15.8%
dissimilar	26	68.4%	17	44.7%	16	42.1%	8	21.1%	28	73.7%
no opinion	3	7.9%	4	10.5%	2	5.3%	2	5.3%	1	2.6%

Study B

	Vignette B 'source'		Vignette B 'potency'		Vignette B 'frequency'		Vignette B 'follow- up'		Vignette B 'evaluation'	
	Count	%	Count	%	Count	%	Count	%	Count	%
missing	3	7.9%	3	7.9%	3	7.9%	3	7.9%	3	7.9%
similar	20	52.6%	17	44.7%	12	31.6%	12	31.6%	5	13.2%
dissimilar	14	36.8%	17	44.7%	22	57.9%	23	60.5%	27	71.1%
no opinion	1	2.6%	1	2.6%	1	2.6%			3	7.9%

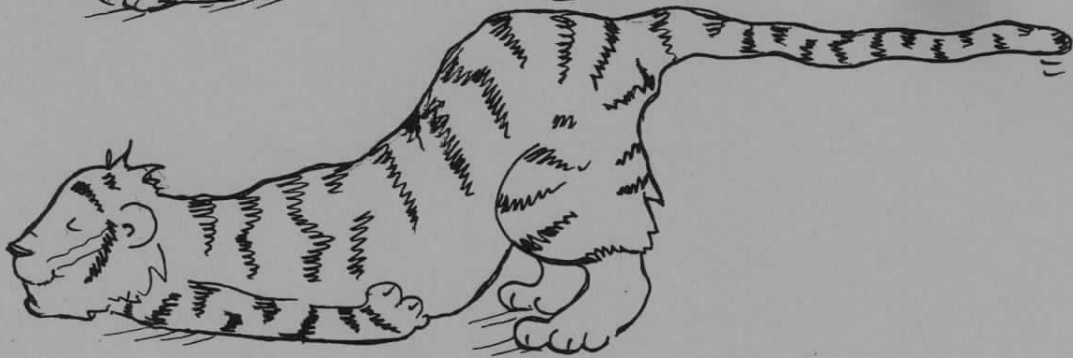
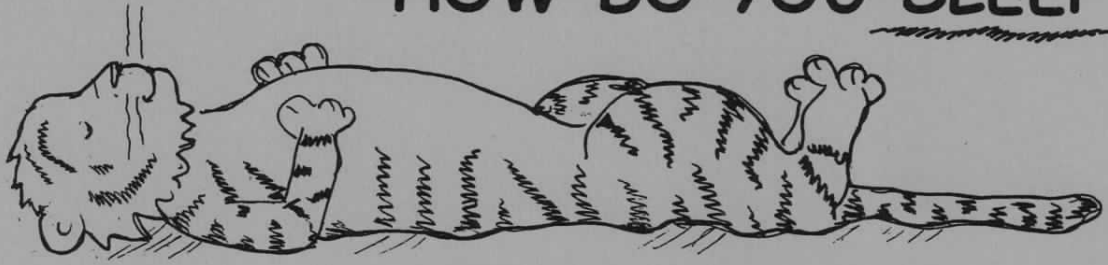
Study C

	Vignette C 'source'		Vignette C 'potency'		Vignette C 'frequency'		Vignette C 'follow- up'		Vignette C 'evaluation'	
	Count	%	Count	%	Count	%	Count	%	Count	%
missing	3	7.9%	3	7.9%	3	7.9%	3	7.9%	3	7.9%
similar	25	65.8%	31	81.6%	29	76.3%	24	63.2%	25	65.8%
dissimilar	8	21.1%	2	5.3%	4	10.5%	9	23.7%	7	18.4%
no opinion	2	5.3%	2	5.3%	2	5.3%	2	5.3%	3	7.9%

Appendix 15

Data Collection Tool Example

HOW DO YOU SLEEP ?



Do you grind your teeth ?

Appendix 16

Synthesis in Process

