

Session 1 – chaired by Dr Celia Bell

Janine Leach, Carol Fawkes, Adam Fiske and Vinette Cross

University of Brighton

Tackling The Darzi Agenda In Osteopathy: What Is The Optimum Survey Design To Investigate Patient Expectations Of Treatment?

The research question posed by the funder, the General Osteopathic Council (GOsC) was to gain a reliable and detailed understanding of the expectations of patients seeking osteopathic treatment. As the Regulator of the profession, GOsC needs more information to fulfil its statutory duties, in the context of Professor Darzi's aim to provide patients information on quality of care which "include patients' own views on the ... quality of their experiences" and to provide services which are "fit for everyone's needs ... includes those people who find themselves discriminated against in some way"

Our successful bid for funding proposed a survey of a large sample of osteopathic patients, using a semi-structured questionnaire to gain both understanding and adequate statistics. The survey questions will be based on both a review of literature and on a series of patient focus groups with osteopathic patients. The Focus Groups will take place in seven locations, geographically and contextually diverse, including one large NHS practice, and selected patients will be diverse with respect to age, gender, ethnicity, disability, affluence, employment, and presenting symptoms. The interviews will explore issues such as expectations, satisfaction, and communication. The interviews will be analysed using qualitative methods to identify themes to explore in the questionnaire.

For the survey, osteopathic patients will be recruited via around 800 (20%) osteopathic practices. 8000 survey packs will be distributed, 10 per practices, and the osteopaths will invite both new and existing eligible patients, to participate. Eligibility is discussed below. A large sample size is needed to permit a multi-variate analysis of at least 8 patient characteristics.

The design of recruitment for the survey is challenging. The recruitment strategy needs to be both methodologically sound, and to achieve a reasonable response rate. Methodologically, we would like both a representative profile of current patients' views, and an insight into the views of minority groups. The majority of osteopathic practices are private, and the majority of patients are white, educated and relatively affluent. A systematic random sample of practices will reflect this polarised population. To gain understanding of the views of a diverse range of patients, we need to purposively sample practices and patients. We can open the survey to patients who wish to complain, or who want to be heard. The results will reflect a diversity of views but will not be generalisable. We are proposing a mixed methodology, in effect two parallel surveys. The optimal sample sizes for the two strands will be debated.

In terms of response rates, there are several factors. Some osteopathic practices are keen to participate in research, and can be targeted in the purposive sample. The generality of practices are not necessarily motivated towards research. Hence the recruitment strategy for the systematic random sample needs to be easy to apply within a practice – such as inviting all patients attending on a given day(s) to participate. It is hard to predict patient compliance, but that may well also reflect the attitude of the practitioner who invites them.

We would welcome the opportunity to explore this design.

Session 2 – chaired by Dr Hugh McPherson

Peter Fisher, Robert Mathie and Helmut Roniger

Royal Homeopathic Hospital

A Strategy to Research the Potential of Homeopathy in Pandemic Flu

The possibility of a global pandemic of H5N1 avian influenza is a major public health concern for international and national public health bodies. To date all cases of H5N1 infection in humans appear to have been transmitted from animals, but mortality is high (254/407 laboratory confirmed cases worldwide).¹ It is not known when the next pandemic will occur but the scientific consensus is that the probability is high.² The 1918-19 influenza pandemic killed 20-40 million people; pandemics in 1957 and 1968 killed around 1 million in each.

Although homeopathy is currently mostly used in high-income countries and as a complementary treatment for chronic complaints, its initial rapid growth was associated with its success in epidemics including cholera and scarlet fever and the 1918-19 influenza pandemic. There is little doubt that the results achieved by homeopaths were superior to those of conventional treatment, but there is debate as to whether this was due to the effectiveness of homeopathy or the avoidance by homeopaths of harmful treatments.

The neuraminidase inhibitors Oseltamivir and Zanamivir are effective in treatment and prevention of 'ordinary' epidemic flu, but the US Centers for Disease Control and Prevention recently reported that 98.3% of flu viruses were resistant to Oseltamivir,³ and neuraminidase inhibitors will be in short supply in a pandemic. A strain-specific vaccine is unlikely to be available during the initial wave of a pandemic, and current global manufacturing capacity means it too would be in short supply. According to a Cochrane Review, the homeopathic medicine *Oscillococcinum* (*Anas barbariae* hepar et cordis extractum HPUS) is effective in shortening the duration of flu, though not, on current evidence, in prevention.⁴

In response, the International Foundation for Clinical Homeopathy, Royal London Homeopathic Hospital, European Council for Homeopathy, American Institute of Homeopathy and the Indian Institute of Homeopathic Physicians organised a meeting in Paris in November 2005.⁵ This gave rise to the International Scientific Committee on Homeopathy & Influenza (ISCHI), of which the authors are members. So far 4 projects are agreed for funding or under development:

- Development and in-vitro testing of a biotherapy from H3N2 influenza viruses
- An international data collection project on homeopathic treatment of flu
- A randomized placebo-controlled clinical trial of *Oscillococcinum* in treatment of epidemic flu
- A pilot randomized placebo-controlled clinical trial of *Oscillococcinum* in prevention linked to the trial above.

References

¹ http://www.who.int/csr/disease/avian_influenza/country/cases_table_2009_02_11/en/index.html (accessed 18.02.2009)

² Li KS, Guan Y, Wang J, et al. Genesis of a highly pathogenic and potentially pandemic H5N1 influenza virus in eastern Asia. *Nature* 2004; **430**: 209–213.

³ www.cdc.gov/flu/weekly/ (accessed 18.02.2009)

⁴ <http://mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD001957/frame.html> (accessed 18.02.2009)

⁵ <http://www.world-medical-homeopathic-observatory.com/Accueil/ISCHI.aspx> (accessed 18.02.2009)

Session 2 – chaired by Dr Hugh McPherson

Lesley Wye, Elizabeth Thompson, William Hamilton, Richard Fordham, Tim Wye; Academic Unit of Primary Health Care, University of Bristol

Resource Utilisation and Outcomes of NHS Patients with a Homeopathic Package of Care: A Pilot Population Based Case Control Study

Background: Increasingly, Primary Care Trust commissioners require information about the costs and cost savings generated by particular services to inform their commissioning decisions. To date, very little economic evaluation of NHS Homeopathic Hospitals has taken place. We propose a pilot study to test the suitability of a range of methods, including standard utility and stated preference discrete choice modelling, to economically evaluate homeopathic packages of care delivered at the Bristol Homeopathic Hospital (BHH).

Research question: What are the best methods and best outcome tools for undertaking a large scale economic evaluation of a cohort of homeopathic patients compared with a matched control group not using NHS homeopathy?

Setting: Bristol Homeopathic Hospital

Design: Mixed methods study - prospective cohort with matched control group and qualitative interviews. Twenty BHH patients, with first appointments in August 2009, will be recruited consecutively and offered homeopathic packages of care for a 12 month period (initial consultation plus 3 follow ups). They will be matched with three controls on the basis of presenting diagnosis at BHH, age within five years, gender, general practice and rates of consultation within the practice for the previous 12 months (within two consultations).

Data collection and analysis: We will collect and analyse quantitative data for both cases and controls from:

- a patient resource questionnaire administered every 10 weeks
- EQ-5D (wellbeing) and condition specific outcome tools (where existing) administered at baseline (pre-initial consultation) and follow up (after 12 months)
- BHH records (where appropriate) and general practice records (e.g. prescription costs, GP and nurse consultations, secondary care consultations, tests and investigations, sick notes) for 12 months before and after initial consultation

Data from cases and controls will be compared using conditional logistic regression, to obtain an understanding of the differences in costs between the two groups.

The aim of the qualitative interview study is to identify 'attributes' for a discrete choice model and explore patients' decision making around accessing conventional and BHH services. The qualitative data will be analysed thematically.

Potential outcome of study: If the results of this pilot study suggest that we can apply robust, acceptable and feasible methods to economically evaluate the homeopathic packages of care delivered at the Bristol Homeopathic Hospital, we will then design a larger study to investigate the difference in resource use between BHH service users and non- BHH service users.

Study status: This study is funded by The Blackie Foundation, The British Homeopathic Association and The South West GP Trust. It is currently under ethical review.

Session 2 – chaired by Dr Hugh McPherson

Clare Relton and Kate Thomas

School of Healthcare, University of Leeds

Evaluating Healthcare by a Homeopath for Chronic Widespread Pain Using the 'Patient Cohort' RCT Design

Background

To assess the feasibility of an RCT design for patients with Fibromyalgia Syndrome (FMS) an open pragmatic RCT design was conducted. Adults with a diagnosis of FMS were randomly allocated to usual care or usual care plus healthcare by a homeopath. The primary outcome measure was the difference in FIQ Total scores at 22 weeks. Drop out rates in the usual care group were higher than the homeopath care group (8/24 vs 3/23). Adjusted for baseline, there was a significantly greater mean reduction in the FIQ Total score in the homeopath care group (-7.62 vs 3.63) and significantly greater reductions in the homeopath care group in the McGill VAS pain score, FIQ Fatigue score, & Tiredness upon Waking score. We found a small Pain effect size of 0.21 (95%CI -1.42 to 1.84); and a large Function effect size of 0.81 (95% CI -8.17 to 9.79). There were no reported adverse events.

Given the acceptability of the treatment and the effect sizes found in this feasibility study, there is a need for a main study. However, the pilot study identified three problems: I) slow recruitment rate, II) high drop out rates in usual care group and III) hope and disappointment for those patients randomly allocated to the usual care group. The research question for the proposed main study is "What is the clinical and cost effectiveness of treatment by a homeopath for patients with FMS?"

Methods

In order to answer the research question and address the problems met in the pilot study, we propose to use an ultra pragmatic RCT design, the 'Patient Cohort' RCT design, to randomly select patients to be offered the treatment (or not) and to broaden the condition to Chronic Widespread Pain (CWP). All FMS patient have CWP but FMS needs a diagnosis in secondary care, whereas CWP can be diagnosed using patient questionnaires. These three changes to the piloted design will enable:

- a) 'with need' patients to be quickly identified (the Patient Cohort)
- b) potential RCT patients to be identified without having to offer patients the possibility of a new treatment which they then may not receive, thus avoiding hope/ disappointment and minimising drop out rates in the no offer (TAU) group.

Patients with CWP who are eligible for the intervention being trialled will be identified using GP databases and postal questionnaires. A proportion of these CWP patients will be randomly selected to be offered the intervention. The outcomes of those randomly selected to the offer group are compared to the no offer group in order to assess the effectiveness of the offer of treatment by a homeopath + TAU compared to TAU.

Information will be collected from both groups at 6,12,18 & 24 months by postal questionnaires. For cost effectiveness analysis we will be using EQ-5D and resource use data will be collected to estimate cost differences between the groups.

We plan to calculate the sample size using the Pain effect size found in the pilot. As large numbers of patients will be recruited to the CWP cohort, unequal randomisation will be used when estimating the sample size. We anticipate that 60% of patients randomly selected to be offered the treatment will accept, this 40% non acceptance rate needs to be factored into the sample size calculation.

Discussion

Questions remain as to the usefulness of a diagnosis of CWP for patients and GPs, the ethics of not informing the no offer group as to the existence of the trial, the rate at which patients will accept the offer of treatment by a homeopath, and the impact of the non acceptance rate on sample size calculations and any Intention To Treat analysis.

Session 3 – chaired by Professor Nicola Robinson

A. McVicar, C. Greenwood, F. Fewell, V D'Arcy, S. Chandrasekharan and J. Alldridge
Faculty of Health and Social Care, Anglia Ruskin University

Evaluation of Anxiety, Salivary Cortisol and Melatonin Secretion Following Reflexology Treatment: A Pilot Study in Healthy Individuals

This pilot study sought to identify an appropriate methodology to investigate the impact of reflexology in healthcare setting. The study involved healthy volunteers to prevent unnecessary intervention to individuals who may already be experiencing health related trauma. Thirty participants underwent either reflexology or no treatment (control), in a cross-over experimental design. Self-reported anxiety (Spielberger STAI), cardiovascular parameters (BP and pulse rate) and salivary cortisol and melatonin concentrations were assessed before and after reflexology. Control data were obtained at the same time points in identical settings.

Reflexology had a powerful anxiety-reduction effect ('state'; $P < 0.001$) but no significant effect on underlying anxiety ('trait'). Cardiovascular parameters decreased ($P < 0.001$). Baseline salivary cortisol and melatonin were not significantly correlated with STAI scores and did not change significantly following reflexology. Reflexology reduced 'state' anxiety and cardiovascular activity within healthy individuals, consistent with stress-reduction. Considering the connection between stress/anxiety and well being, the effects of reflexology may have beneficial outcomes for patients. These findings will be transferred to a study involving breast cancer patients where effects may be more pronounced particularly since cancer patients display dysregulation of cortisol and melatonin secretion.

Lessons learned

- Potential limitations of this pilot are encompassed in the reliable measurement of salivary hormones. It is important to note that in healthy individuals changes in cognitive stress perceptions may not be simultaneously translated into endocrine responses. The lack of correlation between hormone concentrations and state or trait STAI scores could also support dissociation with cognitive appraisal, but 'spot' hormone concentrations at specific time points may not be an accurate evaluation of stress-related secretion. It is also of note that baseline measures and the application of reflexology were at a time when secretion rates of the hormones were already low and hence any responses consistent with a reduction in stress might not be discernible. These time points were considered the most acceptable when considering a methodological design to be transferred into the study using cancer patient. A major consideration for the follow-up study involving cancer patients will be that changes in secretion may be more pronounced as chronic stress levels appear to alter the secretion patterns of stress-related hormones.
- The range of time points, information on food intake and health behaviours helped to minimise the propensity for variation in cortisol and melatonin between individuals.
- It was not ascertained in this study if the effects observed resulted from the impact of reflexology or massage *per se*. The additional benefit of thigmotropism (i.e responding to physical contact) which may also have an effect in reducing anxiety was not specifically controlled for but will be addressed in the future study. However, the study does exclude the significance of the therapeutic relationship that builds over time with one practitioner, as each participant only received one reflexology treatment.

Session 3 – chaired by Professor Nicola Robinson

Sarah Price, Kate Thomas, Andrew Long, Mary Godfrey;

School of Healthcare, University of Leeds

Getting Inside Acupuncture Trials- Unpacking the Theory in a Complex Intervention to Expose the Underlying Causal Process of Change

Background

Problems exist with systematic reviews of acupuncture. Acupuncture trials produce variable results that are sometimes difficult to interpret and the mechanism of acupuncture, that is the process by which change is effected, is often un-stated, implied or not known, thus raising questions over the validity of the acupuncture intervention itself. The STRICTA guidelines were published in 2001 with the aim of improving reporting of acupuncture trials, the first item of which requires information on the theoretical basis for the acupuncture intervention. We conducted a systematic review of published acupuncture trials for a cluster of symptoms common to breast cancer patients including fatigue, nausea, depression, anxiety and vasomotor symptoms. Our aim was to surface the theory implicit behind the choice of acupuncture points and treatment approach.

Methods

Using the logic of realist evaluation we searched nine databases with inclusion criteria. An analytical framework was developed to extract data relating to theory, treatment and outcomes.

Results

More than half the identified 27 trials could not be categorised in any formal theoretical model. Where the symptom in question has an unknown biomedical mechanism such as fatigue, understanding the causal link between acupuncture treatment and outcome can be problematic, as different notions of causality are implicit within the theory of an intervention.

Conclusion

This paper creates a framework that allows the diversity of the theoretical underpinnings of acupuncture to be identified; and in turn exposes gaps in the knowledge for a large number of trials of acupuncture. The theory and rationale underlying acupuncture interventions tested in clinical trials is often either poorly described or absent altogether in published accounts. It is important that authors of acupuncture trials report the intervention in a way that the theory and consequently the process by which change is effected is explicitly described. We recognise that the gaps in information identified in published trials may be due in part to the publishing process (word limits and editorial expectations), rather than the authors being unable to give a clear account of the theory underlying the intervention, and we therefore urge that the STRICTA guidelines be enforced more conscientiously by editors and that they require this aspect of reporting to be made explicit. This will enable a much more accurate interpretation of the results of any a trial. This work suggests the need for the STRICTA guidelines to give more weight and clarity to the theory underpinning the intervention.

Session 3 – chaired by Professor George Lewith

Trina Ward, Volker Scheid and Veronica Tuffrey

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London Women's Mid-Life Health Experiences as Chinese Medicine Patterns

Objective: 1) Identify cross cultural variations in symptom prevalence for mid-life women comparing with studies undertaken in Japan, China, Canada and the USA. 2) Identify symptoms and their grouping that correlate with menopausal status for London's multi-ethnic urban women aged 45-55 years. 3) Map factors to Chinese medicine treatment strategies.

Design: Cross-sectional self-administered postal questionnaire of women aged 45-55 years in London, UK (N1115), recruited from 7 general practice lists. Participants recalled 37 general symptoms. The chi-square test and logistic regression were employed with significance set at ≤ 0.05 . Principle component analysis and varimax rotation were carried out. Patterns thus identified are matched with Chinese medicine treatment strategies according to both Chinese medical historical literature sources and our clinical experience.

Results: London women experienced high levels of general symptom reporting. Tiredness was the most prevalent symptom (65%) followed by aches or stiffness in the joints (54%). The prevalence of seven symptoms varied by menopausal group, only the two vasomotor symptoms varied by age. Tiredness, insomnia and irritability varied by ethnic group. The pattern of symptom reporting for the London cohort was more similar to women in Beijing, than to the cohorts in Manitoba, Massachusetts and Japan. Vasomotor symptoms (hot flushes and or sweats) represent a Chinese category of 'bing' (Disease), which through factor analysis differentiates into four groupings that were mapped to Chinese medicine treatment strategies.

Conclusions: Symptoms experienced during the menopausal transition arise through a complexity of factors, which are not simply hormonally or ethnically derived; geographic location, local culture and temporality are factors that also need to be taken into account. Having identified locally experienced symptoms, factor analysis is a useful tool to identify patterns that aid in the translation to relevant Chinese medicine treatment strategies. Our data supports the existence of a dialectic between culture and biology. TCM textbook accounts of menopause have limited relevance to our population. Such findings challenge the universal relevance of such accounts, and offer a route to designing treatments that can be tested in randomized controlled trials.

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Session 3 – chaired by Professor George Lewith

Anna Cheshire and Lesley Powell

Coventry University

Evaluating a Massage-Based Intervention for Mothers and Their Children Who Have Been Sexually Abused: Challenges and Implications for Future Research

Introduction/background

The Mosac Massage Programme (MMP) is specifically designed for mothers and their children who have been sexually abused. The aims of the research were twofold, firstly, to ascertain the acceptability of the MMP to families, potential benefits of the MMP, and suggestions for improvement; secondly, to test different evaluation strategies to determine the best way to evaluate a larger study of the MMP. Two MMPs were delivered consecutively over a 10 months period.

Participants

Eight mothers and their children who had been sexually abused participated; four in each Group. Mothers only participated in the evaluation. Mothers were recruited through Mosac, a charity for families affected by sexual abuse.

Methods

A mixed methods approach was adopted. MMP1 was a qualitative design. Interviews were conducted with mothers and the MMP therapist immediately before and after the MMP. In addition, the MMP therapist's observations of sessions were collected. Data were analysed using thematic analysis. MMP2 used a pre-test, post-test quantitative design. Mothers were mailed a questionnaire to complete immediately before and after the MMP. The questionnaire included validated measures of family functioning (e.g. McMaster Family Assessment device), and mother and child well-being (e.g. Parent Emotional Reactions Questionnaire, Parent Report of Posttraumatic Symptoms). Measures reflected emergent themes from the MMP1 evaluation. In addition, researcher observations of three sessions were conducted.

Results

A total of 7 mothers completed the MMP. Interviews, therapist's session notes and researcher observations were each found to be successful evaluation methods. In particular interview data provided rich insights into mothers' experiences of the MMP. However, the effectiveness of the questionnaire was more limited; there was a low response rate and mothers' answers to open-ended questions included on the questionnaire did not reflect the richness of responses obtained by interviews. Mothers' comments regarding the questionnaire included: it was too long, brought up difficult emotions, and was difficult to know how to answer some of the questions regarding how their child felt. Mothers also provided feedback as to how questionnaire evaluations may be conducted more successfully in the future.

Discussion

The discussion will focus the best way to take forward the evaluation for future interventions. Contributions and discussion will be invited from the audience/ conference delegates.

Poster Presentations:

13.30-14.30: Hatchcroft, Ground Floor
Chaired by Professor George Lewith
(5 minute presentations)

- 1 Is There A Metabolic Effect Of Cinnamon On HbA1c And Serum Lipids In Type 2 Diabetes Mellitus?
Raj Akilen, A Tsiami, D. Devendra and N. Robinson
TVU
- 2 Childbearing Women's Use Of Homeopathic Arnica: Is There A Need For Maternity Services To Provide Information And Guidance?
Jenny Carter
King's College London
- 3 A Retrospective Examination Of The Appropriateness Of Grounded Theory Methodology For Investigating The Delivery Process Of Complementary And Alternative Medicine
Marcia Dixon
Granby Centre for Natural Therapy
- 4 Exercise And Manual Auricular Acupuncture For People With Chronic Low Back Pain: A Feasibility Study
Ruth Hunter, S.D. Liddle, D.M. Walsh, S. Dhamija, S.M. McCann, P. Glasgow, C. Paterson, G. Gormley, D. Hurley, A. Delitto, J. Park, I. Bradbury, G.D. Baxter, S.M. McDonough
University of Ulster
- 5 Primary Care Practitioners Attitudes To Traditional And Complementary Healthcare Approaches: Professional Or Personal?
Ava Lorenc and Nicola Robinson
TVU
- 6 Does Tasting Gentiana Lutea Affect Cardiovascular Parameters?
Michael McMullen, Julie Whitehouse, Gillian Shine, Anthony Towell.
University of Westminster
- 7 Towards An Abstract Geometrical Description Of Entanglement In The Therapeutic Homeopathic Process: Progress And Prospects
Lionel Milgrom
The Homeopathy Research Institute
- 8 The CAMEOL Project: Lessons Learned From A Large-Scale Review Of The Evidence
Karen Pilkington and Janet Richardson
University of Westminster
- 9 Randomised Control Trial and Evaluation of Influenza Using Chinese Medicine
Wenqing Li
Natural Health Clinic