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ABSTRACTS

Developing Research Strategies in Complementary and Alternative Medicine

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Introduction

This paper describes the annual conference, this year held in York on 24 April 2008, which brings together researchers from around the UK and beyond who have an interest in the development of strategies for research in complementary and alternative medicine. This year's event was held in York, and was attended by sixty academics, students and practitioners in the field. As in the preceding events in Northampton and Southampton, the plan for the day was that it be developmental for both the presenters and the audience. Therefore the papers presented were all at a stage where there was scope for audience input, for rethinking the future direction of projects and for developing creative solutions to some unresolved issues. Overall this created a supportive environment where speculation, innovation and creativity could flourish.

The keynote presentation was given by Professor Kate Thomas, and she set out her twenty years of experience

conducting research into complementary and alternative medicine (CAM). She has been at the forefront in documenting the levels of utilisation of CAM since her early study of CAM utilisation in the late 1980s. She has built on this with several other studies which together provide evidence of substantial use of CAM, which has largely been paid for out-of-pocket, rather than provided for within the National Health Service. Her research interest has extended to conducting pragmatic randomised controlled trials and exploring the policy implications of CAM being more widely available within the NHS, where the evidence for use justifies it.

What followed at the conference was a series of seven oral presentations, each one tackling a different challenge. The therapies covered included acupuncture, Chinese herbal medicine, chiropractic, osteopathy and homeopathy. Two presentations involved studies with multiple presenting conditions, while others had a focus on specific conditions, including secondary lymphoedema, infantile colic, endometriosis, and menopausal hot flushes. Methodologies discussed were wide-ranging, including randomised controlled studies, cohort studies, and cost-effectiveness studies, as well as the last paper which opened up discussion of the broader dimensions of the research culture within which we conduct our research.

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Two decades of CAM Research: a summary of the keynote presentation

Kate Thomas

Taking the long view of research in CAMs, two things strike me; firstly, the tenacity of a small research community and their refusal to give up on the difficult, and often disheartening, task of obtaining funding to build this area of research; and secondly the proof of the success of this doggedness that is demonstrated in this conference.

I have worked in CAM research since the late 1980s, and over this time my research has covered three main areas; utilisation and access to CAMs, NHS service provision, and effectiveness studies that aim to inform NHS policy. Early research into utilisation was aimed at providing much needed basic facts about who was using CAM therapies, for what reasons, and how this care was accessed. Much of this knowledge is taken for granted now, but robust, population-based data is hard to obtain. It was important to demonstrate that the media portrayal of the CAM user as middle aged, middle class, female, 'worried well' was far from accurate. In fact we were able to demonstrate that CAM was used by all age groups, both genders, and all socio-economic groups, and used for clearly described health problems. The biggest barrier to use appeared to be economic, with 90% of visits to practitioners being paid for out-of-pocket and just 10% accessed via the NHS. In 1998, we estimated that 22 million visits were made to CAM practitioners of the five main therapies (acupuncture, chiropractic, homeopathy, medical herbalism and osteopathy). In the same year the NHS estimated that 14 million visits were made to A&E departments in England. This single statistic has awakened many people to the fact that CAM use is a substantial element of health care behaviour and provision. While this research was being conducted, the political mood seemed to change. Thatcher's government took the view that patient freedom of choice was to be encouraged and urged the CAM professions to 'get their house in order' regarding regulation, and the BMA position moved from open contempt towards one of cautious acceptance. This was partly due to the GPs who knew their patients used and CAM, and sometimes offered it themselves.

In this more positive climate, it was possible to obtain policy research funding to explore provision in the NHS. We found many examples of pioneering GP services that were often championed by individual GPs, and sometimes involved local fundraising to keep them going. Such services often emerged when unrestricted funding opportunities arose, such as health promotion clinics and GP fundholding savings. Then, as today, such services were vulnerable and we witnessed many innovative services come and go before they could really prove themselves. Many people still quote our research finding that almost half the GP practices in England provided access to CAMs (via independent practitioners, GP provision and NHS referrals). What this figure hides is the fact that provision is very thinly spread, and sometimes amounts to no more than a once-in-a-year referral to a homeopathic hospital. GPs told us that they wanted these services to expand options for patients, and to ease their own workload. They also told us that they needed evidence of effectiveness to allow them to continue to sup-

port services which they believed their patients benefited from.

The rise of evidence-based commissioning made the need for evidence of CAM effectiveness urgent. The CAM community rose to this challenge very willingly, but was hampered by a lack of research experience and resources. Some learned to regret participating in research, particularly when they felt that their practice was not being given a fair test. In turn, the academic community was challenged by the requirement to design studies that reflected best everyday practice, while being robust and rigorous. The challenge of designing studies that assess the value of CAM as practised, taking into account both patient and NHS perspectives, continues today.

As we produce more evidence, the protests against CAM therapies seem to get louder. This suggests to me that we need to double our efforts at producing the kind of evidence that (i) focuses on patient groups that are recognised by policy makers as NHS priorities, (ii) remains true to the integrity of the interventions as they are practised, (iii) employs outcome measures that are relevant to patients, and (iv) assesses the relative cost-effectiveness of such interventions. Recent attempts to discredit the emerging evidence base for CAMs may turn out to be a positive sign after all; as Gandhi is reputed to have said 'First they ignore you, then they laugh at you, then they fight you, then you win.'

Northern Ireland complementary therapy pilot: March 07–March 08

Boo Armstrong, Donal McDade

Background: The Health Minister of Northern Ireland supported the funding of a pilot study to evaluate the provision of integrated complementary therapies in primary care. The service was provided in two cities in Northern Ireland and managed by Get Well UK, which specialises in integrating complementary therapies into the NHS.

Methods: Acupuncture and homeopathy were offered for mental health problems (depression, stress, anxiety), with the option of a complementary therapy alongside—massage, aromatherapy or reflexology. Acupuncture, chiropractic and osteopathy were offered to patients with musculoskeletal problems. Sometimes GPs wanted to refer to massage instead and so the pathway was adapted partway through to accommodate this. All patients completed Measure Yourself Medical Outcome Profile (MYMOP) forms and data was collected from the referring GP or prescribing nurse, as well as the complementary therapy practitioner after completion of treatment. Focus groups were conducted and a final survey of participants conducted in February 2008 by Donal McDade and colleagues from Social and Market Research.

Results: In the pilot, 700 patients were treated for either mental health or musculoskeletal problems. Many patients had both problems and often more as well. The level of illness and prescription medication was very high. The completed service evaluation will be available later in 2008.

Discussion: There are many points for discussion raised from the project, such as: What have we learnt from imposing service standards and imposing a service on an existing clinical team? What was it like for complementary

therapists to be recruited to the team? What are the challenges for a complementary therapist working in the NHS? Has the service had an impact on the whole health care system? What about health outcomes? Should capacity building happen before introducing a new service in primary care?

When the world is your oyster: taking a risk—acupuncture in the management of secondary lymphoedema

B. de Valois, T. Young, E.J. Maher

Background: The Medical Research Council (2000) advocates early stage exploratory research when designing studies examining complex interventions. As society develops “new” diseases, how do we develop and investigate treatments when no evidence base exists?

This presentation explores challenges and opportunities of conducting exploratory research into using acupuncture and moxibustion (acu/moxa) to promote well-being and improve quality of life in breast, head and neck cancer patients with secondary lymphoedema (SLE). There is little evidence supporting conventional treatments of SLE, and less for using acupuncture in its management. Funding from the National Institute of Health Research (NIHR) under the RISC programme enables Research that is Innovative, Speculative and Creative. Such funding seems ideal to explore complementary medicine, but how can researchers maximise the opportunity to develop treatment approaches and gather meaningful data? How do they ensure that research helps to improve the lives of patients suffering from a progressive, chronic, incurable condition?

Methods: This mixed methods study uses focus groups to identify the treatment priorities of SLE patients and their healthcare professionals. The research acupuncturist will seek to identify acu/moxa strategies to address these priorities, as well as appropriate outcome measures. The clinical phase, followed by further focus groups, will yield quantitative and qualitative data about patients’ responses and attitudes to acupuncture treatment, and their perceptions of its effects.

Designing the clinical phase may be the most challenging aspect of this study. With no evidence for treating SLE-related health issues in the canon of acupuncture, how can we establish optimum treatment? In an environment where much of the research agenda focuses on design methodology for randomised controlled trials, this study provides the opportunity to examine issues surrounding early stage exploratory studies.

Appropriate trial design for CAM and complex interventions? A preliminary study of a cohort with a nested RCT of homeopathic treatment for hot flushes

C. Relton, J. Nicholl

Background: Standard informed consent procedures for clinical RCTs communicate to potential participants both the *uncertainty* inherent in the research question and the *randomness* inherent in the randomised controlled trial (RCT) design. Knowledge of these two factors (uncertainty and randomness) can act as a barrier to participation in trials, as well as affect the delivery of interventions within trials,

especially complex interventions such as homeopathy and acupuncture.

Methods: A Cohort study with a nested RCT, was conducted in the Sheffield NHS during 2005–2008. Women with hot flushes were recruited to the Cohort and monitored over time. This observational study’s patient data was screened to identify women who met the trial inclusion and exclusion criteria (the ‘Trial’ group). These Trial group women were then randomised to be offered a 5-month course of ‘treatment by a homeopath’ (with homeopathic remedies prescribed as part of the treatment) or to form a control group. An estimate of the mean effect of offering the intervention was evaluated.

Results: 132 women with hot flushes were recruited to the Cohort. At 11 months there were 70 women remaining in the Cohort, of whom 48 women met the eligibility criteria for the ‘Trial’ group. 24 women were randomised to the offer of the intervention, of whom, 17 accepted and received the treatment, and the other 24 formed the control group.

Conclusions: The Cohort design with a nested RCT can enhance trial recruitment, as well as collect ongoing information on ‘treatment as usual’; thereby enhancing the external validity of the RCT. The Cohort RCT design minimises the amount of ‘uncertainty’ and ‘randomness’ communicated to potential trial participants by replicating (where possible), the types of information and consents given and sought in routine healthcare, thus reducing disappointment/expectation bias.

Proposed protocol for investigating the effect of cranial osteopathy for the relief of infantile colic: a controlled, randomised, multicentre trial

Brenda Mullinger, Clive Hayden

Background: Infantile colic is common although consensus on its aetiology, development and optimal treatment is lacking. Repetitive, inconsolable colicky crying distresses infants and parents alike, so many turn to cranial osteopathy for help. As evidence is limited, a prospective, pragmatic, double-blind multi-centre study is proposed to determine the effect of cranial osteopathic manipulation of infantile colic.

Methods: Healthy full-term infants aged <12 weeks, brought for osteopathic treatment of irritability, uncontrolled crying and poor sleeping will be assessed for colic (published definition) and randomised to treatment or no treatment. Parents will remain blind to allocation. Treated group: weekly osteopathic manipulative therapy (½h) for 4 weeks according to clinical findings; untreated group: no physical intervention but ideally equal time to be spent with all participants/parents. Active treatment offered to all at the end of the study. Starting 3 days before treatment (baseline characteristics), parents will complete a daily diary to record: time spent sleeping, crying inconsolably, being held/rocked and will record any unexpected changes (behavioural or pathological) in their infant during the study. Sample size: sufficient to detect a significant ($p < 0.05$) mean change from baseline in daily crying time of at least 50%.

Discussion: Many discussion points can be raised. Is a double-blind trial appropriate? Can it be achieved ethically?

If not feasible—what are the options? How to ensure all parents are given equal support but remain blind to treatment allocation? Would measuring 'quality of life' for the parents be relevant as an outcome measure? A positive study outcome will be an important step towards evidence-based practice by cranial osteopaths. If benefits are not demonstrated, such treatment (and attendant expense) will not be justifiable.

Acupuncture cost savings—lost in red tape

Gina Johnson, Adrian White, Ruth Livingstone

Background: Offering acupuncture in primary care may reduce referral rates to secondary care and the costs of prescriptions. The aim of this study was to test the feasibility of surveying national data on these topics.

Methods: All practices within three selected PCTs were sent an email asking whether any member of the primary care team offered acupuncture. Data on referral rates to orthopaedic, physiotherapy, pain and rheumatology clinics, and prescriptions were then sought for the acupuncture practices and for the PCT as a whole.

Results: Out of the 109 practices surveyed, a total of 14 (13%) offered acupuncture services to some extent. There was wide variation in provision. The eight practices which offered at least one appointment per week for every 2000 registered patients were selected for the analysis. Mean values (and SDs) for the PCTs and for the eight acupuncture practices respectively were as follows, for referral to various clinics: orthopaedic 32.3 (16.2) and 27.4 (10.87); pain 1.6 (1.3) and 2.8 (1.6); physiotherapy 13.4 (14.5) and 29.5 (10.0); and rheumatology 4.7 (2.3) and 6.4 (3.0). The mean values for costs of non-opioid analgesics were £1820 (£442) and £2008 (£762); and for NSAIDs were £4148 (£269) and £4476 (£1366), respectively. There were no trends towards reduction of clinic referral or prescription costs. Considerable difficulties were encountered in obtaining accurate data.

Conclusions: We have uncovered a wide variation in the availability of acupuncture in different areas. We have been unable to demonstrate any consistent differences in the prescribing or referral rates of such practices; a very large survey would be needed to identify it, but the practicalities of access to data and the problems with data accuracy would preclude this.

A full report of this study has been published and can be accessed on line: Johnson G, White A, Livingstone R. Do general practices which provide an acupuncture service have low referral rates and prescription costs? A pilot survey. *Acupunct Med* 2008;26(3):(in press).

A feasibility study exploring the role of Chinese herbal medicine in the treatment of endometriosis

Andrew Flower, George Lewith, Paul Little

Background: Endometriosis is a common and disabling gynaecological condition affecting an estimated 10% of women of childbearing age that is poorly treated by conventional medicine. Historical reports and clinical trials from China suggest CHM may be a useful treatment option for endometriosis.

Methods: A pragmatic, double blinded RCT feasibility study using individualised formulae of decocted Chinese herbs was designed to treat 40 women with endometriosis and to produce data to inform a power calculation for a larger, more definitive study. MHRA, Ethics, and NHS R&D approval was granted in October 2006. The study has three arms: active (Group A), placebo (Group B) or waiting list control (Group C). This enables an estimation of the specific (A–B) and the non-specific (B–C) effects of CHM intervention. Participants receive an individualised herbal prescription that is randomised at a distant herbal dispensary using a computer generated block randomisation code. Active herbs or a therapeutically inert herbal/vegetable placebo are pre-cooked and dispensed as a herbal liquid in identical sachets. Outcomes are weekly VAS pain scores, monthly MYMOP questionnaires and an endometriosis specific quality of life measure—the EHP-30.

Discussion: The trial will be completed in September 2008. The trial methodology is believed to be the first time that individualised decoctions have been used in a double blind RCT. This approach might offer a way of rigorously testing 'real world' clinical practice of CHM. Already many lessons have been learned relating to protocol development, MHRA/Ethics approval, developing a herbal placebo, recruitment, patient management, and the effects of an experimental design on the therapeutic relationship.

From hierarchies to process in Chinese medicine research

Volker Scheid

Background: Evidence-based health care (EBHC) is widely perceived as providing objective assessment of therapeutic interventions. The implication is that EBHC is free from subjective biases arising from culturally specific methodologies. In fact, it can be shown that EBHC is rooted in specifically Western intellectual traditions. The hierarchies of evidence and desirable action underpinning this view are almost opposite to those advocated by Chinese medicine (CM). Similar to proponents of EBHC, CM physicians established "gold standards" by which medical practice was to be guided, were focussed on evidence, and could become intolerant of those not sharing their ideas. Currently, advocates of EBHC and CM tend to see these differences as culturally incommensurable, leading to rejection of EBHC by CM proponents, or to destruction of individualised CM by EBHC standardisations.

Discussion: Utilising cultural theory, I argue that rather than seeing the incompatibilities between EBHC and CM as expressions of essential cultural difference, it is advantageous to examine what produces this difference. This helps us to see that while EBHC and CM share methods for managing knowledge and making health care decisions, they orient towards different types of preferred social organisation: individualist egalitarian culture in CM, and a tightly organised integrated social system EBHC. These orientations are reflected in distinctive processes by which knowledge is processed and made available for medical practice. Turning incompatible hierarchies into comparable processes allows us to see research not as un-biased evaluation but as knowledge construction that can proceed in different directions. This can assist researchers in becoming self-reflective about research processes, opening new avenues for how CM clinical research is conducted.