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## ABSTRACT

# Abstracts from the Developing Research Strategies Conference, March 2007, Northampton, UK

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This conference, held in collaboration with the Southampton Complementary Medicine Research Unit on 29th–30th March 2007 at the University of Northampton, was aimed at individuals and research groups interested in the methodological and political development of complementary and alternative medicine research. The aim of the conference was to enable the development of the CAM research community and provide opportunities for researchers to present ideas and work in progress.

### Oral presentations

#### Invited lecture: maximizing or minimizing non-specific effects in clinical trials

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In medicine there is still a strong demand that any treatment offered to patients should have more effect than a mere placebo. To ensure this, the randomised placebo controlled study has become the standard tool to evaluate new treatments.

The aim of such a study is to subtract the non-specific effect from the total effect of a treatment, thus demonstrating the specific part of the overall treatment effect. The size of this specific treatment effect is strongly influenced by the size of the non-specific effect, a fact that is often ignored. The size of the non-specific effect itself depends on various determinants (treatment and setting, patient, physician, and patient–physician interaction) that have an impact on the outcome through a number of mechanisms (such as expectations and conditioning). Studies on conventional pain treatment and acupuncture treatment studies have shown that patient expectations could have an impact on the treatment outcome. It might well be that

the answer to the question – which treatment is the most effective? – may vary between health care settings and, as, e.g., expectations or interaction styles might change, over time. The narrow interpretation of study results accepts only the so-called specific effects as relevant for decisions which treatments are best for a patient. It neglects the benefits from unspecific factors and is therefore not adequate for all situations.

Efforts are needed to develop reliable and valid, yet simple tools for measuring factors such as patient expectations in clinical settings.

#### A pilot randomised controlled trial of individualised homeopathy in children with severe asthma

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We will present a report on provisional results from a pilot randomised control trial of individualised homeopathy in children with severe asthma. We used a pragmatic design to preserve the homeopathic approach as a complex intervention. Recruitment to the trial was difficult and we gathered children from multiple sites within Bristol. For some families who were randomised to the standard arm they withdrew early on in order to pursue homeopathic treatment immediately rather than waiting the 16-week study period. Our impression of the trial at this time was that the complexity of the illness itself provides a dimension to running a trial that is challenging. This and provisional results will be discussed at the Conference.

With reference to the design of trials in the future, we will also review the complementary and alternative

medicine programme that has developed within the Bristol area within the past 5 years and our hope for future developments.

## Acupuncture in the treatment of schizophrenia

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In psychology, research on acupuncture in the treatment of disorders like depression and also insomnia has received increased attention both in and outside of China.

After having conducted extensive reviews in the field of e.g., acupuncture and schizophrenia, acupuncture and insomnia and fMRI results on acupuncture, the authors of this abstract have planned a thorough study of acupuncture in the treatment of a less investigated disorder; schizophrenia.

In the current presentation, relevant results from our reviews will be discussed. Moreover, a discussion on acupuncture research methods in schizophrenic patients would be highly welcomed and also relevant to other researchers, doing or planning experiments in patient groups.

The choice of good control groups and design is essential, not only for the reliability and validity of the results, but also to make acupuncture research taken more seriously and to make it more accepted and conclusive, both in the East and in the West, in the future.

## Nutritional medicine and lifestyle modifications (NMLM) to improve Hba1c level in patients recently diagnosed with type 2 diabetes mellitus

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**Objective:** To investigate whether dietary supplementation of fenugreek and cinnamon combined with lifestyle modification programme has the potential to improve HbA1c and serum lipids in patients recently diagnosed with type 2 Diabetes mellitus.

**Methods:** This proposed study is a randomised, parallel design, 4 arm pilot efficacy trial. A total of 60 patients recently diagnosed with type 2 diabetes mellitus, age over 30 years and treated only with oral anti diabetics or diet will randomly assigned to one of the four treatment arms; a control group, a Lifestyle Modification (LM) group, a LM and cinnamon group and a LM and fenugreek group.

Subjects in the control group will receive usual care of diabetes. Subjects in LM group will receive an intensive face to face diet and exercise counselling from nutritionist in addition to usual care. Subjects in LM cinnamon and LM fenugreek groups will receive the same treatment as those in LM group, but in addition they will receive a dietary supplement

of 4.5 g of cinnamon and 6 g of fenugreek per day for 6 months respectively.

A structured questionnaire will also be used to gather information on socio-demographic and lifestyle characteristics of the participants. The primary outcome of this study is change in HbA1c level. Secondary outcome measures include changes in glucose tolerance and changes in blood lipid profiles.

**Conclusion:** The hypothesis is that the three interventions may significantly improve HbA1c levels with greater changes expected in LM cinnamon and fenugreek groups.

## Space, place and complementary therapy within hospice care

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There is a small but increasing amount of research into the perceptions and experiences of complementary therapy (CT) users and providers within hospice care. However, no CT research has yet utilised the concepts of space, place and therapeutic landscapes as a means of framing questions about the perceptions and experiences of people using and providing CTs within hospice care and how CT may contribute towards the creation of a holistic care environment.

Hospice day-care patients, medical/nursing staff and CT therapists will be invited to participate in the study which uses photo-elicitation interviews (PEIs), whereby photographs are taken by the participants to record spaces and places within the hospice setting that they perceive to be particularly therapeutic, or that conversely create negative feelings. These will then be used to illustrate and inform the discussion of such phenomena while exploring therapeutic landscapes within the hospice. In-depth qualitative interviews, postcard diaries and observation will also be utilised to explore the perceptions and experiences of those using and providing CTs within a hospice environment.

This study aims to explore CT's contribution towards the creation of a therapeutic landscape and healing environment, while exploring ideas that the integration of CTs into healthcare settings can also be seen in terms of how CT practice 'fits' into the physical and psychological environment – its place in a geography of care – and how this may contribute towards creating a holistic care landscape.

## Acupuncture for irritable bowel syndrome: a pilot randomised controlled trial

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**Background:** The evidence on acupuncture for irritable bowel syndrome (IBS) is inconclusive. However many patients with IBS are self-referring for acupuncture. Therefore it is in the public interest to know whether acupuncture is effective or not. The aim of this study was to explore feasibility and design criteria for a larger-scale and more definitive trial.

**Methods:** A pragmatic randomised controlled trial compared 10 sessions of acupuncture plus usual GP care with usual GP care alone. Thirty patients were recruited from four GP databases in Birmingham, UK, and randomised two-to-one to acupuncture or usual care alone. The primary outcome was the IBS Symptom Severity Score (SSS) at 3 months (maximum score 500). Analysis was by intention-to-treat, and multiple imputation was used for missing data.

**Results:** From the databases, 189 patients with IBS were identified, of whom 30 were eligible and consented to randomisation. At 3 months, a statistically and clinically significant difference between groups of 138 points (S.D. = 90) in favour of acupuncture was observed on the IBS SSS (95% CI: 66 to 210;  $P=0.001$ ). For a full-scale trial, we estimate a sample size of 108 patients per arm, based on a minimum clinically significant change of 50 points, drawn from a primary care population of 140,000.

**Conclusions:** The results of this exploratory study suggest that more definitive research into acupuncture for IBS is merited. A pragmatic trial design will not be able to distinguish between acupuncture specific effects and placebo effects, however it is the design of choice to determine cost-effectiveness.

## Investigating adverse effects arising from CAM use in children with brain injury

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**Background:** Research suggests that although CAM use among children with brain injury is prevalent, there are few studies regarding adverse effects (AE) among this population. The term brain injury refers to any neurological disorder, and can include a wide range of diagnoses and severity. Adverse effects can be defined as direct, which might have been caused by the treatment administered, or indirect, which may, for example include delay in obtaining effective medical treatment.

**Methods:** This study will use the survey approach to measure AE. This type of approach is useful in establishing if safety problems within CAM exist. It aims to highlight areas for concern and thus target further investigation more effectively. However, caution needs to be exercised with these data when generalising findings, estimating prevalence and implying causality. Parents of children with brain injury will be recruited through Cerebra. There is evidence that individuals often do not report either their child's CAM use or AE associated with CAM use to their doctors. Thus, it was considered important to recruit parents directly to the study rather than healthcare professionals.

The research comprises three stages:

- I. To examine the range of CAM treatments used by children with brain injury through a cross-sectional survey of carers.
- II. To retrospectively investigate the 'nature' of suspected AE in relation to CAM use in children with brain injury through a cross-sectional survey of carers.

- III. To gain greater understanding of the 'experience' of suspected AE, via semi-structured interviews with carers.

## Development of simplified appraisal method of fatigue on sitting for extended periods by using finger plethysmogram

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By using an oscillation in the base line and the amplitude of a finger plethysmogram, a method was conceived for quantifying and indicating the degree of fatigue as a result of long term sitting in an automobile seat. When people get tired, disturbances of the biological fluctuation rhythm arise. People's homeostatic function works to correct this disturbance. Homeostatic function appears in biological fluctuation and autonomic nervous function as a compensation work. There is about hundred times difference in a fluctuation cycle between a finger plethysmogram and biological fluctuation to combat fatigue. So, an idea is proposed that a finger plethysmogram was converted into the gradient of comprehensive change to make those fluctuation cycle scales close and compare them easily. The gradients of the square of the finger plethysmogram amplitude were converted into the absolute values, the time series signals. Then, we drew a fatigue curve based on the results calculated by 18 s integrated values of the time series signals. This curve and the muscle fatigue curve by subjective judgement generally accorded. By using a finger plethysmogram featuring high sensitivity to fatigue progress, the differences in various subjects and seat performances can be found on this fatigue curve with only 30 min fatigue test. This method made it possible to shorten the measurement time from 3 h to 30 min to predict the fatigue level by a sensory evaluation.

## Posters

### The experience of spiritual healing

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**Background:** Proximate spiritual healing is commonly termed 'laying of hands', and includes therapeutic touch and Reiki. The exact mechanisms are not fully understood. Treatments for breast cancer cause bodily changes that negatively impact on women's quality of life. Women with

oestrogen sensitive tumours are prescribed hormone therapy for up to 5 years to prevent recurrence. Side effects include joint aches and pains, hot flushes, lack of libido and vaginal dryness. Anecdotal evidence suggests that spiritual healing can induce profound relaxation which alleviates stress, anxiety and perceptions of pain, and promote feelings of well-being. Healers make no claim to cure breast cancer.

**Aim:** The aim of this research is to identify any qualitative benefits of hands-on or proximate spiritual healing for women experiencing adverse reactions to hormonal adjuvant therapy, following potentially curative treatments for breast cancer. The research will investigate whether spiritual healing could support and complement the effective delivery of medical care for these women.

**Method:** This is a qualitative study, based on observations undertaken during and after a series of one-to-one healing sessions which will take place in the Wellcome Trust Clinical Research Facility. Twenty women will be recruited by their oncologist (or oncology nurse). Participants will be offered up to 10 free healing sessions over a 3-month period, followed by individual interview and focus group interview. Healing will be given by trained practitioners and will be recorded. Phenomenological and ethnographic methods will be used to analyse the data.

## 'Treatment appropriateness'—conceptualising the practice of medical pluralism

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**Background:** The majority of patients who use complementary and alternative medicine (CAM) practice 'medical pluralism', by continuing to utilise the services of conventional medicine. Studies have indicated that the decision to use CAM is a disease-specific one, so that medical pluralism has often been interpreted as a simple function of disease-specific choice for treatment.

**Aims:** As part of a broader study of beliefs surrounding the decision to consult a medical herbalist, the aim of this enquiry was to develop a deeper understanding of the practice of medical pluralism.

**Method:** A qualitative study was conducted, carrying out semi-structured interviews with eight individuals who had consulted a medical herbalist. Data were analysed using a simple substantive thematic analysis.

**Findings:** Forty-three themes were identified, a number of which presented contrasting views of herbalist and orthodox prescriptions and consultations, and beliefs about management of health and illness. 'Treatment appropriateness' emerged as a concept which explained medical pluralism as a product of the following beliefs: illness causality, bodily response to illness, treatment mechanisms, and responsibility for health.

**Discussion:** The concept of 'treatment appropriateness' and its underlying components enrich our understanding of medical pluralism and treatment choice. As medical pluralism continues to be practiced, and contraindications between complementary and conventional

medicines emerge, this understanding is of key importance to complementary and conventional practitioners alike, both in the patient consultation and in broader service delivery options.

## The effects of reflexology on pain threshold and tolerance in an ice-pain experiment in healthy human subjects

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Reflexology incorporates the use of specific pressure techniques to the feet, hands or ears. It has been claimed that reflexology is useful in the treatment of various conditions such as migraine, arthritis and multiple sclerosis. The aim of the present study was to investigate whether foot reflexology attenuates acute pain in human volunteers.

Ten healthy male ( $n=4$ ) and female ( $n=6$ ) subjects were each assigned to single treatments of both reflexology and sham TENS (transcutaneous electrical nerve stimulation; Control) administered in a cross-over design. Pain was induced in both treatment schemes by immersion of the non-dominant hand in crushed ice (1). Two measurements were taken (i) pain threshold (i.e. the time it takes for the subject to find the experience painful) and (ii) pain tolerance (i.e. the time it takes until the subject can no longer keep his/her hand in the ice water). Measurements were taken 15 min prior to treatment and at 30 min intervals for 120 min following reflexology or sham TENS. The data were analysed by two-way analysis of variance (ANOVA) with repeated measures on treatment and time and the Dunnett's *post-hoc* test.

ANOVA showed that there was a significant increase in pain threshold of the subjects following reflexology when compared with sham TENS control data ( $F_{(1,9)}=5.68$ ,  $P<0.05$ ). Thus, for example at 60 min, pain threshold increased from a control mean value (sham TENS)  $\pm$  S.E. mean of  $9.1 \pm 1.4$  s to  $15.5 \pm 2.1$  s following reflexology ( $P<0.01$ ). Similarly, there was a significant increase in pain tolerance ( $F_{(1,9)}=5.132$ ,  $P<0.05$ ). Thus, at 60 min, pain tolerance increased from a control mean value  $\pm$  S.E. mean of  $120.2 \pm 37.9$  s to  $171.4 \pm 42.0$  s ( $P<0.02$ ).

The results of this study show that reflexology increases both pain threshold and tolerance in human volunteers exposed to acute pain. These findings indicate the possibility of using reflexology in the management of pain.

## Research strategy for developing a standardised herbal antimalarial

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**Background:** Malaria is a major cause of morbidity and child mortality in Africa, and many areas cannot access

modern medicines, so WHO recommends home-based management of malaria. A new standardised herbal antimalarial is being developed in Mali, which can be grown and produced locally. This involved a new research strategy developed by Antenna Technologies in partnership with the Department of Traditional Medicine in Mali, and the Research Initiative on Traditional Antimalarial Methods (RITAM). Rather than starting with pharmacological screening of a wide range of plants (used in classical research methods on herbal medicines, with low rates of success) we started with clinical observations to identify the most effective remedy.

**Methods:** The first phase of research involved an ethnobotanical survey and a retrospective treatment-outcome study, asking patients about a specific illness episode and the outcome after a specific treatment. This was used to prioritise plants for further research, which included in vitro testing. The most effective plant was then tested in a prospective dose-escalating clinical trial, to assess safety and efficacy of different doses. Building on these results, a randomised controlled trial was conducted to compare two treatment strategies for home-based management of malaria: either herbal medicine as first line with modern medicine as second line; or modern medicine as first line.

**Results:** *Argemone mexicana* (Papaveraceae) was the plant most effective in the retrospective clinical study, and also in vitro. The dose-escalating trial identified the most effective treatment schedule as being one dose twice a day for 7 days. The RCT confirmed that this produced similar clinical results to a modern medicine, although a lower rate of parasite clearance.

**Conclusions:** A new appropriate research strategy has enabled the successful development of a standardised herbal antimalarial for use in the home-based management of malaria in Mali. This methodology could be applicable to a variety of other contexts.

### Using the existing research evidence and conducting your own research to gain acceptance for CAMS with severe and enduring mental illness

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The introduction of complementary therapies into UK mental health services began in the 1990s. It was a development that was requested by the service-user movement and was therefore in line with the Department of Health policy of putting users at the centre of services. However, introducing complementary therapies into mental health services has required those advocating these approaches to demonstrate that they are evidence based; with therapies having to establish their efficacy, safety and financial worthiness. Peterborough Mental Health Services introduced complementary therapies (Reflexology, Reiki healing, Indian head massage, Aromatherapy and Swedish massage) in response to the expressed needs of its service users. In addition

to presenting the existing evidence base, Service evaluation and Needs-led research have helped practitioners to overcome some of the challenges of introducing these new approaches, when demonstrating the evidence base and financial worthiness was key. The positive response received from service-users and refers as part of service evaluation has helped to maintain the service and informed service development. Currently, a research proposal is being developed to investigate the use of complementary therapies with people who experience psychosis. The complementary therapy service aims to maintain its passion for introducing complementary approaches into mental health settings, while not allowing critical evaluative abilities to be overcome by that passion, and in this endeavour a researcher-practitioner approach is vital.

### Assessing the outcomes of complementary therapy for palliative care patients across a variety of settings within North West Wales NHS Trust

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**Aim:** Complementary therapies such as: hypnotherapy, reiki, reflexology, guided imagery and aromatherapy are accepted in palliative care although evidence for their contribution to patient well-being is scarce. This study seeks to evaluate the contribution of complementary therapies towards patient well-being through the use of a self-reporting questionnaire.

**Method:** The Measure Yourself Medical Outcome Profile (MYMOP) is a patient generated instrument with known reliability and validity. The patient is required to respond to seven items, rating four items on a seven point 'Likert' type scale. Palliative patients newly referred for complementary therapy in three different care settings were informed about the study and invited to participate. Each patient completed the MYMOP measure at baseline prior to commencing therapy, followed by four weekly measures concluding with a final measure on completion of 1-month therapy (six measures of the same questionnaire). Three different settings offering complementary therapy were sampled, community clinics, day hospice, and one oncology ward. Therapists working at these settings received background information about the study and training in the administration of the MYMOP. All completed MYMOP schedules were centrally collected and analysed.

**Result:** At the time of preparing this abstract data was incomplete. It is expected that complementary therapy will be perceived to contribute positively to the palliative patient's sense of well-being, however there may be differences in this perception related to therapy setting and disease progress. Overall outcomes of this study will inform the on-going development of a holistic patient centred service.