Complementary Medicine Research Unit

George Lewith

Community Clinical Sciences, University of Southampton, Southampton, UK

Why is Our Research Unit Important?

One in ten of the UK population use complementary medicine each year and ~50% are lifetime users. The recent House of Lords' Report has clearly defined a public need for further research into both safety and efficacy. The Department of Health research capacity building initiative is one of the first main responses to the Select Committee’s recommendations. We know that within this emerging field we have developed a unit with cooperative ventures within the university, both intra-faculty and inter-faculty. As a consequence, we have been able to draw in major funding along with a growing body of academic publications.

Our unit was established by George Lewith in 1995 with his appointment as Honorary Visiting Senior Lecturer. He now has a University contract as a Reader within the Department of Primary Care where the unit is located. The unit was initially provided with core funding by the Maurice Laing Foundation and has been able to generate substantial amounts of soft money funding for a number of minor and major projects from charitable (including Wellcome) sources as well as National Health Service Research and Development (NHS R&D) funding. Laing funding continues to provide our unit with an administrative core. Dr Lewith has been appointed as a Visiting Professor to the School of Integrated Health at the University of Westminster.

The Department of Health is now providing funds for research capacity building within complementary medicine and we have been successful in obtaining Department of Health support for two post-doctoral fellows (Peter White and Sarah Brien) and two PhD students during the first 2 years of the awards. The Department of Health is also funding complementary and alternative medicine (CAM) projects within palliative cancer care (£300 000) and we have successfully applied for this funding, in conjunction with Jessica Corner as the primary investigator. Wellcome is currently funding 37% of the applications it puts out for review in the field of CAM and is considering further initiatives in the light of the Department of Health proposals. The Medical Research Council has publicly stated that it welcomes quality applications in this area: our initial asthma and homeopathy study was alpha rated, the Alexander Technique study was alpha–alpha rated and funded. There is clearly now an opportunity for substantial growth in this area of research and the track record that we have developed in Southampton makes us well placed to capitalize on these initiatives.

Over the last 8 years we have created a unique multidisciplinary team (non-clinical post-docs, doctors, nurses, physiotherapists, pharmacists and health psychologists) in Southampton, which has developed considerable skill in primary clinical research within CAM. These studies have been directed at asking not only where complementary therapies may be most applicable but also whether and how they work. Furthermore, our research has led us to understand that the nature and content of the therapeutic relationship within complementary medicine is of paramount importance, and therefore we are in the process of developing clinical trial methodology that will allow us to look at the consultation independently from a particular therapeutic intervention, focusing particularly on the non-specific effects of homeopathy and acupuncture in chronic disease. The major studies in which our unit has been involved to date are as follows:

- Unconventional allergy testing (paper published; George Lewith/Jackie Broomfield).
- IIIPCOS-II. A study to evaluate the clinical effects and adverse reactions to homeopathy prescribed in general practice for upper respiratory tract and ear infections. This study was a multicentered, international study; our unit was responsible for three centers within the United Kingdom (study completed and data in the process of being analyzed; Sarah Brien/George Lewith).
- Asthma and homeopathy (paper published; George Lewith/Alan Watkins/Jackie Broomfield/Gina Dolan).
- Acupuncture for chronic mechanical neck pain (study completed, five papers published and two in press; Peter White).
• Acupuncture for stroke (study completed, two papers published and three in preparation; Val Hopwood).
• Enzyme potentiated desensitization for seasonal rhinitis—in conjunction with Michael Radcliffe (study completed, one paper published and one in preparation; George Lewith).
• Homeopathic proving: this study looks at some of the basic assumptions within the whole development of homeopathy (pilot study published, definitive study published with three additional publications in press or published; Sarah Brien).
• Gene expression in chronic fatigue syndrome in conjunction with Rob Powell and Wendy Barclay, University of Reading (pilot study completed and published; George Lewith).

Does the patient’s perception of the impact of Chronic Fatigue Syndrome (CFS) affect outcome? (study completed and paper in submission with Michael Hyland; George Lewith).

The Alexander Technique in low back pain (led by Paul Little) (study in progress; George Lewith).

The placebo effects of acupuncture (pilot study completed and paper in press; Peter White/George Lewith).

Acupuncture in disabling breathlessness (pilot completed and published, definitive study completed and paper published; Clare Hill/George Lewith).

The development of a validated questionnaire, which evaluates attitudes to CAM and health beliefs, important potential covariates in evaluating outcome in clinical trials—in conjunction with Michael Hyland (George Lewith).

The development of theoretical models (in conjunction with Michael Hyland) based on complexity theory that may underpin the basic mechanisms that underlie the clinical effects of CAM (paper published and further submission in progress; George Lewith).

Absent healing (study in progress in conjunction with the University of Freiburg, Germany and the University of Reykjavik, Iceland; George Lewith).

Why patients (re)turn to complementary medicine (a series of ethnographic and questionnaire based studies (5) in progress; Lucy Yardley/Felicity Bishop/George Lewith).

A study of the effects of a daily supplement of Siberian ginseng extract on well-being of young women with persistent fatigue of <6 months' duration—in cooperation with Ann Walker (study in progress; George Lewith).

A randomized controlled trial of Biobran for chronic fatigue patients (funded by Daiva, study in progress; George Lewith/Selwyn Richards/Clare McDermott).

An investigation of the ‘Candida syndrome’ using an explanatory Randomised Controlled Trial (RCT) in conjunction with laboratory investigations (protocol in submission with Michael Radcliffe) (George Lewith).

Bromelain, a herbal remedy for the treatment of osteoarthritis. A placebo controlled, randomized trial (study completed, publication and review paper in submission; Sarah Brien).

The specific and non-specific effects of acupuncture in chronic pain: a combined RCT and qualitative study (Clare Hill and Peter White, Department of Health Fellowship).

The placebo/Streitberger needle. A series of clinical trials and imaging experiments (PET) to evaluate its validity and the underlying mechanism of acupuncture (Peter White in conjunction with the Wellcome Imaging Unit, University College, London).

Research into the role of CAM in the care of patients with cancer (successful submission to the Department of Health, study in progress with Jessica Corner) (George Lewith).

Applied kinesiology; is it an effective treatment for back pain? (study in progress; Sue Hall).

Homeopathic remedies as a treatment for rheumatoid arthritis: is it the medication or the homeopathic process that benefits patients? (protocol completed, initial funding obtained, one publication published; Sarah Brien/Laurie Lachance).

The development of a practitioner scale to evaluate consultation content (in development; Sarah Brien/Laurie Lachance).

A qualitative study of the effects of acupuncture in chronic pelvic pain (in development; Will Stones, Clare Hill and Peter White).

Devil’s Claw and osteoarthritis of the knee. A Phase II RCT (protocol completed and funding obtained, data collection July 2004, one publication in submission; Sarah Brien).

A Cochrane systematic review of micronutrient supplementation for glycemic control in type II diabetes (in progress; Damian Smith).

Predictors of CAM use in asthma. Proposal in submission to Wellcome (Primary Investigator; George Lewith).

An investigation into how local ethics committees manage CAM submissions (in submission, The Nuffield Foundation; Gay Walker, George Lewith, Jane Maher).

The patient perceived value of a Traditional Chinese diagnosis in chronic pelvic pain (Clare Hill/George Lewith).

Endometriosis. We would like to look at how endometriosis is treated by CAM practitioners, evaluate how patients perceive CAM in the context of their endometriosis treatment and based on these more general investigations, develop clinical trial methodology to evaluate the use of Chinese herbal medicines and acupuncture as treatments, in both short-term and long-term, for endometriosis (Andrew Flower/George Lewith).

Experimental test of generalized entanglement as predicted by weak quantum theory. NEST-2003-1 Adventure submission (in collaboration with Harald Walach, Freiburg; George Lewith).

Whole systems research methods for the evaluation of CAM; learning from shared experience. European
Scientific Foundation (ESF) submission (in collaboration with Kate Thomas, Sheffield and Vinjar Fonnebo, Tromso; George Lewith).

- The use of intuition in clinical decision making in CAM (one paper in press, one paper in submission; Sarah Brien).

- Emotional and spiritual communication in the CAM consultation. A qualitative enquiry (protocol developed, funding being sought, paper in submission; Sarah Brien).

- Practitioners’ perceptions of effective consultations. Protocol in development. Sarah Brien in conjunction with Department of Health, PhD student.

- Developing research strategies for the future of homeopathy. Publication in submission (in conjunction with Faculty of Homeopathy, Royal London Homeopathic Hospital (RLLH) and University of Liverpool; Sarah Brien/George Lewith).

- A comparison of sensitivity to change of several outcome measures following treatment in a complementary medicine clinic (George Lewith/Michael Hyland).

- The superficial circulation in the skin: a comparison of acupuncture and non-acupuncture points. What does this tell us about the mechanism of needling? (Val Hopwood/Geraldine Clough/George Lewith/Martin Church).

- A randomized controlled trial of acupuncture for the treatment of hyperventilation syndrome (in submission, Physiotherapy Research Foundation; Denise Gibson/Anne Bruton/George Lewith).

- Complementary treatments for recurrent lower urinary tract infection in Primary Care (MRC submission; in collaboration with Paul Little).

- Nystatin and diet in polysymptomatic patients (in collaboration with Michael Radcliffe).

- Blood ergosterol as a measurement of Candida syndrome: a pilot project (in collaboration with Michael Radcliffe and others).

Each of these major studies is of substantial size and some plan to recruit 500 or more individuals. We have also been involved in a number of minor projects and have built close links with Professor Paul Little in Primary Care, Professor Lucy Yardley in Health Psychology, Professor Philip Prescott in Mathematics, Professor Jessica Corner in the School of Nursing and Debbie Layton in the Drug Safety Research Unit. Our external links include research cooperation with Ann Walker in the Department of Nutritional Medicine at the University of Reading, Ted Kaptchuk in the Complementary Medical Research Unit at Harvard, Michael Hyland in the Department of Health Psychology at the University of Plymouth, Peter Fisher and Robbert van Haselen at the Royal London Homeopathic Hospital, Janet Richardson at the University of Westminster where Dr Lewith holds a Visiting Professorship, Laurie Lachance, a visiting scholar from the University of Michigan, Ann Arbor, MI and Aslak Steinsbekk, supported by the Norwegian Medical Research Council. We have also been involved in cooperative publications with the Department of Complementary Medicine at the University of Exeter and Brian Berman’s Complementary Medical Research Unit in Baltimore, MD.

Teaching

We run a Special Study Unit on CAM familiarization for the third year medical students, chiropractic students and student nurses to give them a brief introduction to complementary and alternative therapies. This course includes placements with CAM practitioners. Lectures on acupuncture and pain are given for the School of Medicine Foundation Course and Term 4 teaching, and the fourth year projects on CAM supervised.

We also run an annual research strategy conference in conjunction with the Research Council for Complementary Medicine and regular critical appraisal courses for CAM practitioners.

Cooperation with Professional Organizations

The government is anxious to ensure that the provision of complementary medicine is evidence-based and safe. We have cooperated with a number of professional organizations in order to try and achieve this. These include the Society of Teachers of the Alexander Technique, the Acupuncture Association of Chartered Physiotherapists, the British Acupuncture Council, the Acupuncture Research Centre, the National Institute of Medical Herbalists and the Anglo-European College of Chiropractic. These initiatives have involved both regulation and specific research projects. Furthermore, George Lewith and Stephen Holgate have been involved in establishing a Royal College of Physicians sub-committee on complementary medicine. Our unit has played an active part in the House of Lords’ Select Committee Report on Complementary Medicine (2000) and three pages of this report are dedicated to the activities within Southampton. Southampton Medical School has also played an important role in the development of the Foundation for Integrated Health, particularly with respect to its research and development agenda. George Lewith is President Elect of the International Society for CAM Research and through that we are initiating a number of projects that include whole systems research workshops and regular annual international conferences. He is also a Director of the Marylebone Trust and Member of DH National Capacity Building Award Committee.

Research Supervision

George Lewith, Sarah Brien and Peter White supervise PhD students, Fourth Year Students and MSc Students from various departments within the University. Current and recent supervision are as follows:

2. Peter White, PhD (GL). A multicentre study evaluating the effects of acupuncture in chronic mechanical neck pain (completed 2002).
4. Felicity Bishop, Economic and Social Research Council (ESRC) Studentship. Why people (re)turn to CAM (GL co-supervisor with Dr Lucy Yardley).
6. Clare Hill, PhD (GL and PW). Non-specific effects of acupuncture (Department of Health Fellowship).
7. John Shao, MSc Rehabilitation (GL co-supervisor with Dr Alan Borthwick). The attitudes of acupuncturists to traditional acupuncture (2002).
11. Andrew Flower, PhD (GL co-supervisor with Dr Paul Little). The use of Chinese herbal medicines as a treatment for endometriosis (project awaiting approval).
12. Fiona Barlow, PhD (GL co-supervisor with Dr Jan Walker). The effects of Reiki on patients with cancer. A mixed methods evaluation (project awaiting approval).
14. Ron Feise, PhD (in conjunction with Maureen Simmonds, School of Health Professions). Formal and comprehensive comparison of disease-specific self-report measures and physical performance tests for low back pain.
16. Aslak Steinsbekk. The evaluation of homeopathy in the treatment of childhood upper respiratory tract infections (co-supervision with the University of Tromso and Visiting Research Fellow at the University of Southampton).

Grants Obtained To Date
1. The establishment of this unit in 1995 was generously supported by a 3 year grant from the Maurice Laing Foundation in order to pay university overheads, secretarial support and sessional salaries (£120000). Further grants have been awarded from the Maurice Laing Foundation for administrative expenses, nursing and statistical help until May 2006 (£603 073).
2. Smith’s Charity £100 000 for homoeopathy and asthma study.
3. Boiron Ltd £20 000 for homoeopathy and asthma study.
4. South & West Region £38 000 for homoeopathy and asthma study.
5. South & West Region £173 000 for acupuncture and stroke study.
6. Dorset Area HA £45 000 p.a. for complementary therapy outreach clinics and outcome audit.
7. Wiltshire Area HA £100 000 lump sum for complementary therapy outreach clinics and outcome audit.
8. South & West Region £1000 Delphi Project report on complementary medicine.
10. Quest £4000 for equipment purchased for aromatherapy study.
12. Unilever £5500 to investigate the autonomic effects of tea.
13. Maurice Laing Foundation £7500 salary support for Alan Watkins.
15. BMA Joan Dawkins Prize £10 000 to support third year undergraduate course.
16. Homoeopathic Research Foundation £3000 to support third year undergraduate course.
17. Smith’s Charity £109 000 to support acupuncture and chronic neck pain study.
18. Hospital Savings Association (HSA), Wessex MT and others £3500 to support PhD expenses for Peter White.
19. Persistent Virus Disease Research £10 000 to support chronic fatigue syndrome study.
20. Vega Grieshaber £3000 to support Vegatest study.
21. Asthma, Allergy and Inflammation Research (AAIR) £1000 to support Vegatest study.
22. The AIM Foundation; (AIM) £2000 to support Vegatest study.
23. Wellcome Trust £56 600 to support proving study.
24. South East Region £39 655 to support EPD study.
25. GUS Charity £50 000 to support EPD study.
26. University of Southampton £3200 p.a. to support third year undergraduate course.
27. European Union (EU) 5th frame £8565 to support European Healing Study (Total funding of project £489 000).
28. MRC £585 956 in cooperation with the Department of Primary Care to fund a clinical trial on the Alexander Technique.
29. Elizabeth, Lady Cowdray’s Charity Trust £5000 to support placebo study.
30. Boots the Chemist £5000 p.a. to support ESRC studentship.
31. Garfield Weston Foundation £25 000 to support breathlessness study.
32. Dr Susil Kumar & Jamila Mitra Charitable Trust £10 000 to support breathlessness study.
33. The Hospital Saving Association Ltd £60 000 to support Sarah Brien.
34. The Rainford Trust £1000 to support research fellows.
35. Daiwa Pharmaceutical Co. Ltd £49 000 to support Biobran and chronic fatigue syndrome study.
36. Southampton Comp Med Research Trust £20 000 to support Bromelain study.
37. Department of Health £98 936 to support cancer study (Primary investigator: Professor Jessica Corner).
38. Department of Health £181 496 to support Dr Peter White (Fellowship); to investigate the effects and mechanisms of acupuncture in chronic pain. Paired with PhD Fellowship (Clare Hill).
39. Department of Health £152 823 to support Clare Hill (PhD Fellowship); to investigate the non-specific effects of acupuncture.
40. Samueli Institute USA $70 000 to support homeopathy and RA study (R&D Poole General Hospital—funding research nurse 1 day per week).
41. Royal College of General Practitioners (RCGP) £1965 to support Dr Damian Smith (A systematic review of micronutrients for glycemic control in Type II Diabetes).
42. Southampton Comp Med Research Trust £201 464 to support Devil’s Claw study.
43. Pascoe Pharmazeutische Praeparate GmbH £58 857 to support GCP for Devil’s Claw study.
44. Department of Health £207 149 to support Dr Sarah Brien (Fellowship); to investigate the therapeutic relationship in CAM. Paired with PhD Fellowship (Caroline Eyles).
45. Department of Health £162 509 to support Devil’s Claw study.
46. Physiotherapy Research £15 000 RCT of acupuncture for the treatment Foundation of hyperventilation syndrome (Denise Gibson/Anne Bruton/George Lewith).
47. Acupuncture Association of Chartered Physiotherapists (AACP) £5124 Superficial circulation of the skin: a comparison of acupuncture and non-acupuncture points.
48. Garfield Weston £10 000 to support Department of Health Foundation acupuncture studies.
49. Primary Medical Care (PMC) Reserve £10 000 Herbal medicine project.
50. Allergy UK (co-applicant) £3500 Blood ergosterol as a measurement of Candida syndrome (Michael Radcliffe).

The Southampton Complementary Medical Research Trust was specifically established to raise money and aid the research development at the Complementary Medicine Research Unit at the University of Southampton. It is a charity registered in the United Kingdom (no. 1094802).

Personnel

(All still with the department unless otherwise indicated)

Dr George Lewith, Honorary Senior Research Fellow, Department of Medicine, 1995–98; Senior Research Fellow 1998–2005; Reader 2005– and Honorary Consultant Physician, Southampton General Hospital, 1998–

Mrs Felicity Bishop, ESRC Studentship, 2001–

Mrs Trish Boyle, Part-time Research Nurse, 2002–

Mrs Vicky Brickley, Part-time Research Assistant, 1999–99

Dr Sarah Brien, HSA Post-doctoral Fellowship, IIPCOS-2 study, Proving study, 1998–2002, rheumatoid arthritis and osteoarthritis studies 2002–04; Senior Research Fellow, The therapeutic relationship in Complementary and Alternative Medicine, Department of Health funded 2004–08


Mrs Jackie Burnham, Secretary, 1995–

Mrs Elaine Chivers, Part-time Research Assistant, 2000–01

Mrs Jane Cousins, Part-time Secretary, 2004–

Miss Gina Dolan, Research Assistant, 1996–98

Mrs Caroline Eyles, PhD student, Homeopathic practitioners’ perceptions of what makes an effective consultation, 2004–

Mr Andrew Flower, PhD Student, Chinese herbal medicine and endometriosis, 2004–

Mrs Sue Hall, Research Fellow, 2001–

Miss Clare Hill, Research Nurse, Acupuncture and breathlessness study, 2002–03; Research Fellow, 2003–

Mrs Val Hopwood, PhD Student, Acupuncture and stroke study, 1997–03; Research Fellow, 2004–

Miss Vicky Irwin, Research Acupuncturist, 2004–

Ms Christine Little, Systematic Reviews, 1998–2001

Dr Laurie Lachance, Visiting Scholar (Ann Arbor, Michigan). Developing randomized controlled trials to evaluate the use of homeopathy in rheumatoid arthritis, 2001–2002

Dr J Lorraine Low, Part-time Statistician, 1998–99

Miss Clare McDermott, Research Assistant, 2004–

Dr John McDonald, Part-time Statistician, 1999–2000

Dr David Owen, Member of the Faculty of Homeopathy, Teaching Module, 1996–

Professor Philip Prescott, Part-time Statistician, 1999–

Mrs Karen Prout, Part-time Clerical Assistant, 1996–97

Dr Damian Smith, Research GP Registrar, 2003–

Mrs Anne Smithson, Part-time Research Assistant, 2000–03

Mr Aslak Steinsbekk, Visiting Research Fellow and PhD student, 2003–04

Dr Alan Watkins, Locum Lecturer, Department of Medicine, 1995–98
Miss Hannah Watson, Part-time Research Assistant, 1999–2000
Mrs Fran Webley, Research Nurse, 2000–01
Mrs Chris Wheeler, Part-time Clerical Assistant, 1998–99
Mrs Julie White, Part-time Research Assistant, 1997–99
Dr Peter White, PhD student, 1998–2002; Research Fellow, 2002–03; Senior Research Fellow, Department of Health funded, 2003–
Dr Jinpan Zou. British Council Scholarship. Developing techniques to look at immunological markers which will elucidate the effect of acupuncture in asthma, and the development of an RCT protocol for evaluating acupuncture in asthma, 2002

Publications 2001–04
27. Lewith GT, Chan J. An exploratory qualitative study to investigate how patients evaluate complementary medicine.
30. Lewith GT. What complementary or alternative therapy is available for RA. NeLH Musculoskelet Dis VBL 2002.


### Articles in Press 2005


75. **Bishop FL**, Yardley L, **Lewith G** Developing a measure of treatment beliefs: the complementary and alternative medicine beliefs inventory. *Complement Ther Med*.


78. **Lewith GT**. The development of a multidisciplinary complementary medical research unit in the United Kingdom. *Semin Integr Med*.

79. **Lewith GT**, Godfrey AD, Prescott P. A double-blind, randomised, pilot trial evaluating the aroma of Lavandula augustifolia as a treatment for mild insomnia. *JACM*.

80. Borthwick A, Shao Y, **Lewith GT**, **Hopwood V**. Attitudes towards traditional acupuncture (TA) among acupuncture clinicians in the United Kingdom. *Evid Based Integr Med*.


### Articles Currently in Submission/Preparation

83. Hyland ME, Sodergren SC, **Lewith GT**. The role of positivity to illness in chronic fatigue patients. *J Health Psychol*.


86. Radcliffe MJ, Prescott P, **Lewith GT**, Church MK. Do incremental skin prick and conjunctival provocation tests predict symptom severity in seasonal allergic rhinoconjunctivitis?


91. Brien SB. Spiritual and emotional communication in CAM.

92. Brien SB. Intuition in CAM.


98. Lewith GT, White P. Imaging and acupuncture.


100. Lewith GT. Defining the effect of whole systems. Letter to the editor. Br Med J.

101. Bishop FL, Lewith GT. Who uses CAM? A comprehensive review of demographic characteristics and health factors associated with CAM use. JACM.


Books


Submit your manuscripts at
http://www.hindawi.com