

# PC-CRTU *in Contact*

Issue 14 – Winter 2006



## Annual Research Conference 2006

### Working together?

#### Date for your Diary

MidReC, The Royal College of General Practitioners (Midland Faculty) and R&D for Birmingham and Solihull PCT Consortium are holding their annual research conference on

**Thursday 27 April 2006**

City Hospital Postgraduate Centre  
City Road, Birmingham

The Annual Research Conference is an opportunity to hear about local research taking place by local researchers and is free of charge to all primary care practitioners working within the West Midlands

The programme includes:

- Presentations on local research projects
- Practical workshops on doing research
- Informative posters
- Practice Innovations
- 'Five Minute Ideas Workshop' – bring your research ideas to be discussed
- Keynote address by Professor Colin Bradley – Robin Pinsent Memorial Lecture

Booking forms can be obtained from: Sheila Bailey, PC-CRTU Administrator, Primary Care Clinical Research and Trials Unit, Department of Primary Care and General Practice, University of Birmingham, Primary Care Clinical Sciences Building, Edgbaston, Birmingham B15 2TT or email: [s.m.bailey.20@bham.ac.uk](mailto:s.m.bailey.20@bham.ac.uk) telephone: 0121 414 2845

Places are limited and will be allocated on a first come, first-served basis.

**PLEASE BOOK EARLY**

Welcome to the first edition of the *in Contact* newsletter for 2006. We hope you all had a wonderful break over the Christmas period and wish everyone a happy, healthy and prosperous 2006.

Change is a constant feature of primary care R&D and one with which we are all familiar. But during 2005 we all became aware that many more changes are on the horizon. The creation of the UK Clinical Research Collaborative (UKCRC) and the development UK Clinical Research Network (UKCRN) aim to provide a comprehensive infrastructure to support all areas of clinical research. There has been an announcement concerning the creation of a UK Primary Care Research Network and expressions of interest are currently being sought. If all this excitement wasn't enough – the new national research strategy for the NHS has been announced and reflects the messages of the Academy of Medical Sciences and Research for Patient Benefit Working Party reports which called for strengthening the UK capacity to recruit patients for clinical trials.

We have now received formal confirmation from the Department of Health that they will provide a further five years funding for our work related to **research capacity development**. This funding is for us to address the following objectives:

- increasing the number of individuals who are awarded national competitively awarded research fellowships
- providing the appropriate research infrastructure and co-ordinated programme of training required to generate increased research capacity within primary care
- increasing the volume of research proposals developed within primary care in the Midlands that attract national peer-reviewed funding
- increasing the volume of research outputs from within primary care in the Midlands

#### Studies currently open to recruitment include:

- CP450 study (variability in response to warfarin)
- TASMINH2 study (RCT of self management in hypertension)
- PSA and prostate cancer linkage study
- Genetics: primary care pathways (evaluating a new service development)
- MMP9 study, evaluating the accuracy of a potential serum marker for colorectal cancer

Further information about all these studies are included within the newsletter.

Finally we are pleased to announce that this year's annual conference is to be held in conjunction with the Royal College of General Practitioners (West Midlands) and R&D for Birmingham and Solihull PCT Consortium on 27 April at the Postgraduate Centre, City Hospital. We have an exciting programme which will include presentations on local research projects, workshops, practice innovations and keynote speakers. Invitations were sent out to all practices at Christmas, but if you would like more information, please see the advert for further details and how to register.

**Dr Richard McManus**  
Clinical Director MidReC  
[r.j.mcmanus@bham.ac.uk](mailto:r.j.mcmanus@bham.ac.uk)

**Dr Sue Wilson**  
Director, Research Support Facility  
[s.wilson@bham.ac.uk](mailto:s.wilson@bham.ac.uk)

#### Annual Report

##### Department of Primary Care and General Practice Annual Report

The 2004 departmental annual report is now available on the university website: [http://pcpoh.bham.ac.uk/primarycare/annual\\_reports.htm](http://pcpoh.bham.ac.uk/primarycare/annual_reports.htm)

#### Training

For details of research training, please contact Ben Cullen at South Birmingham PCT either via email: [benjamin.cullen@sbpct.nhs.uk](mailto:benjamin.cullen@sbpct.nhs.uk) or tel: 0121 442 3497, or Maggie Hope from the Birmingham Research Training Collaboration (BRTC) via email: [m.hope@bham.ac.uk](mailto:m.hope@bham.ac.uk) or tel: 0121 414 5346

# New Studies

## Follow-up after hysterectomy – an epidemiological survey

Full title: *Variation in NHS utilisation of vault smear tests in women post-hysterectomy: An epidemiological study, using routinely collected datasets, of the factors associated with variability in hysterectomy rates and follow-up afterwards by means of the vaginal vault Papanicolaou smear test, in the West Midlands 2002–2005.*

The aim of the study is to evaluate the follow-up of women after a hysterectomy and to provide evidence to support national guidelines. Twenty per cent of women in the UK have a hysterectomy but little is actually known about why and how they are followed up.

The study will use data that is routinely collected by hospitals about patient admissions (including dates of admissions, the precise operation that was undertaken, the diagnosis) and link it with nationally held data about these women's cervical smear tests prior to surgery and subsequent to surgery (how many smear tests and what were the results both before and after surgery), and routinely collected data from pathology laboratories to confirm the results of surgery (precise diagnosis from the hysterectomy specimen and precise results of all smear tests).

To get these data from three different sources and link it together will require some identifiable information (eg. name, date of birth). However as soon as we have linked the data and stored it on one database it will be **completely** anonymised before the analyses takes place.

The need for this study has been recognised by the local ethics committee and the Secretary of State (PIAG Approval) who have approved this work.

We appreciate that some women may not want their data to be used in this way and as such any woman who would like her data to be excluded from the study can contact the principal investigator (below). We must stress that once the anonymisation has taken place there will be no way for anyone to work out which information belonged to which patient. The only data to be held will relate to those women who had a hysterectomy in the West Midlands region, between 1 April 2002 and 30 March 2003.

**Helen Stokes-Lampard – Clinical Research Fellow and General Practitioner**

If you would like any further information about the study or would like to ensure that your personal data is excluded please do not hesitate contact me on 0121 414 2953 or via my email address: [h.j.stokeslampard@bham.ac.uk](mailto:h.j.stokeslampard@bham.ac.uk)

## PSA and prostate cancer linkage study

We will be carrying out a new descriptive study on PSA testing and prostate cancer over the next few months, recruiting practices in Birmingham and Solihull. The data required for the study will come from a simple search of patient records using the computer system in each practice.

This will provide information on PSA testing in primary care in the period before and after the introduction of the Prostate Cancer Risk Management Programme, the age and socioeconomic status of those being tested, and differences between general practices in their use of tests. We will also obtain records of prostate cancer registrations from the West Midlands Cancer Intelligence Unit and link them to the data from each practice to describe the treatment of and deaths from prostate cancer.

**If your practice would like to take part please contact Ronan Ryan on 0121 414 2690 or email: [r.p.ryan@bham.ac.uk](mailto:r.p.ryan@bham.ac.uk)**

## What is the optimum model of service delivery for Transient Ischaemic Attack (TIA)?

**This project has been funded by the NHS Service Delivery and Organisation R&D Programme and will determine what pattern of service delivery will best meet the needs of people who have had a TIA.**

Four different patterns of service provision will be assessed: current practice; enhanced primary care services; a '999' service and a rapid access neuro-vascular clinic. A mathematical model will be used to predict how many strokes will be prevented by each of these services and at what cost. We will be approaching 20 practices who are members

of MidReC to provide us with details of patients who have had a recent TIA so that we can send the patients a questionnaire to find out their preferences. The workload for practices will be minimal, so if this is something that your practice may like to consider, please contact **Dr Jonathan Mant on 0121 414 2657.**

## Department of Primary Care and the QOF

In early 2005, the NHS Employers were mandated by the DoH to review the GP contract, including the QOF, in conjunction with the General Practitioners Committee (GPC). As part of this process, they appointed an expert panel to support the review of evidence and good professional practice. This expert panel has been led by the Department of Primary Care at the University of Birmingham, working in partnership with representatives from the RCGP and the Society of Academic Primary Care. A Core Group, jointly chaired by Professor Hobbs and Dr Graham Archard from the RCGP was set up to provide a strategic overview of the process.

During the past 9 months, many members of the Department and other academic experts throughout the UK have been busy reviewing evidence in the four QOF domains (clinical, organisational, patient experience and additional services). In the spirit of transparency and equity, a widely publicised call for evidence with a 6-week time frame in Spring 2005 was also put in place. Although anybody could submit evidence to the electronic database held centrally at the University of Birmingham, a wide variety of stakeholders including professional bodies, clinical and research networks, patient groups and the voluntary and community sector were additionally targeted to submit evidence for both existing and new areas in the QOF. There were over 3100 web site 'hits' during the 6 week time period and 514 completed submissions received.

Each expert lead was asked to work with experts in their area initially by email and then with a face-to-face panel meeting where modifications to existing and new indicators could be discussed and recommendations made. The RCGP was asked to nominate an expert lead from a clinical perspective to work with each expert academic lead. Over 40 national experts were involved in the process and a series of interim and final reports for the negotiators were produced in all existing and new areas by August 2005.

Overall, 166 existing points were identified for redistribution by the negotiators, 138 of which were released for new work. From April 2006, there will be 15 new evidence-based indicators in 7 new clinical areas. They move QOF beyond a focus on chronic disease management towards, for example, recognising and rewarding excellence in holistic patient centred palliative care, flag up areas for future development such as learning disabilities and incentivise gold standard care in depression through the use of validated measures of severity. Where possible, points have moved to recognise outcome over process, payment thresholds have been informed by QMAS data and inconsistencies in wording and guidance have been clarified.

# UK Clinical Research Network

## Local Research Networks and the interface with primary care

### What is the UKCRN?

The UKCRN is a Nationally funded body that has been set up to support clinical research and to facilitate the conduct of randomised prospective trials and other well-designed studies. It is initially supporting the development of six Topic Specific Research Networks in the fields of cancer, dementias and neurodegenerative diseases, diabetes, medicines for children, mental health and stroke and, over time, will hopefully enable research to be conducted across the full spectrum of disease and clinical need. In doing this, the aims of the UK Clinical Research Network are to:

- Improve patient care and speed up access to the best treatment and care for people in all parts of the country
- Improve the coordination of research to provide an effective and efficient mechanism for conducting research in priority areas
- Improve the speed of research to increase the numbers of patients in research and the rate at which they are recruited
- Maintain and enhance the quality of research to provide the processes necessary for the development of high quality research protocols and the infrastructure to carry them out
- Improve the integration of research and to develop the link between research and treatment by speeding up the translation of research from the laboratory to the clinic
- Widen involvement in research and increase the number of NHS organisations, health care professionals and patients actively involved in research studies
- Strengthen links with industry to speed up, simplify and improve the quality of NHS structures to make the NHS one of the most attractive locations in the world for clinical trials and thus improve national health and increase national wealth.

The Department has received extremely positive feedback from the DoH and GPC about the role and guidance received from the Expert Panel. Strong collaborative links have also been made between the panel members. We hope to be able to build on this work in the coming year.

### What are Local Research Networks?

Local Research Networks form a key part of the UKCRN clinical research infrastructure and their specific objective is to lead, support and promote research in each topic area. The creation of an effective infrastructure for research within the NHS will be the cornerstone of the success of each Topic Specific Research Network. Each Local Research Network will have clinical and academic collaboration across an area that encompasses a wide variety of clinical services and patient populations, including primary, secondary and tertiary care.

The structure and organisation of each network will vary according to the demographic make-up of the local population and the nature of the service providers within it and networks will be expected to develop and build on links with existing clinical and research support services. Locally, networks are already in place for cancer, mental health and medicine for children and bids have been put in for dementia and neurodegenerative diseases as well as stroke and a generic primary care network. No West Midlands diabetes network was funded. MidReC and the PC-CRTU are involved in these LRNs and they provide an opportunity for practices to get involved in research around these topic areas.

### How can I get involved?

Plans are underway to develop capacity in terms of practices that have a particular interest in Mental Health and/or Medicines for children research. We are looking to find groups of practices that would like to be specifically involved in these kinds of research (which will not preclude you from other studies but will mean that you are first choice in the particular topic area).

If you are particularly interested in either Mental Health work or Medicines for Children then please contact Ros Salter in the first instance for further information. [r.a.salter@bham.ac.uk](mailto:r.a.salter@bham.ac.uk)

**Dr Richard McManus**

# News from the Cardiovascular Team

## Variability in response to warfarin

### A prospective analysis of pharmacogenetic and environmental factors (CP 450 Study)

**Rationale for the study:** There is a great deal of variability in the dosage requirement of warfarin to maintain the international normalized ratio (INR) within a target range. This is increasingly an issue for primary care. Recently, pharmacogenetic and environmental factors have been shown to affect warfarin metabolism and therapeutic dosing regimes.

**Aims:** The purpose of the study is to define genetic and environmental factors that determine variability in response to warfarin. The proposed outcome of the study would be the development of a clinically useful and practical algorithm (that takes into account the relevant genetic and environmental factors) that will help clinicians individualise anticoagulant therapy. The potential benefits of this would include improved safety of warfarin with reduced morbidity and mortality, improvement in patient quality of life, improvement in the cost effectiveness of warfarin therapy and improved uptake of warfarin.

**Study population:** A cohort of 400 patients who are to commence warfarin therapy will be recruited from about 100 practices in primary care. Our thanks go to all practices that have responded and are participating in this study. The first cohort of practices are trained and about to recruit the first patients. However there is still capacity for other West Midlands practices to be involved in this study. Training is being offered locally. Each patient makes four visits during a period of approximately six months, completing short questionnaires and giving blood samples. Data will be collected via an online secure database.

**For further information please contact Miriam Banting 0121 414 2956 or email to [m.v.banting@bham.ac.uk](mailto:m.v.banting@bham.ac.uk)**

# TASMINH

## TASMINH 2 – An RCT of Patient Self Management of Hypertension

**TASMINH2 is a DH-funded RCT comparing self management of hypertension (self monitoring plus self titration of medication following pre-determined GP instructions) with normal care.**

We will be looking for 14–16 practices to recruit a total of 480 patients (ie. 30–35 patients with poorly controlled treated hypertension per practice). We are currently busy piloting the methodology, but have delayed the start date because we have been recommended for a further £300,000 of funding to allow incorporation of telemonitoring and a qualitative evaluation. Once the funding has been confirmed, we hope to be able to start recruiting practices. In the meantime anyone potentially interested should contact **Emma Vince ([e.p.vince@bham.ac.uk](mailto:e.p.vince@bham.ac.uk))**



## BAFTA – Birmingham Atrial Fibrillation Treatment of the Aged Study

BAFTA aims to determine whether Aspirin or Warfarin is the best form of stroke prevention in people who are aged 75 years and over who have a diagnosis of atrial fibrillation.

Over 300 practices throughout England and Wales are taking part, and they managed to recruit 973 patients into the study – exceeding our 930 target! Recruitment ended in December 2004 and patient follow up will continue until the end of September 2006.

Once again we would like to thank everyone for their hard work – without it we would not have been able to recruit such an amazing number of patients. We'd also like to remind you to keep sending us the follow up information, as it is really important that we continue to follow up as many of the recruited patients as possible.

**Kate Fletcher – 0121 414 8091**

## MidReC Management Group Vacancy Practice Nurse Required

Sue Shortland, the Practice Nurse representative currently serving on the MidReC Management Group has completed her 3 year period of service and we are now seeking a replacement. Meetings are held on a quarterly basis and last for approximately 2 hours. Your practice will be re-imbursed for the time you are attending meetings. If you would like to become more involved in how research is managed and feel that from your nursing experience you would be able to provide the Group with help and advice then we would like to hear from you.

If you like to know more, please contact either Sue Shortland (0845 675 0563) or Ros Salter (0121) 414 6505.

We would like to thank Sue for all her hard work and commitment over the past three years.



# News from the Screening Team

## MMP9

### We are pleased to report that both of the MMP9 studies are progressing well.

**A prospective study to assess the value of MMP9 in improving the appropriateness of urgent referrals for colorectal cancer**

This study aims to assess whether MMP9 determination can improve the appropriateness of urgent referrals for colorectal cancer by comparing the MMP9 level of people who have been referred to a colorectal clinic at University Hospital Birmingham NHS Foundation Trust with the results of examinations and investigations done at, or shortly after their clinic visit.

Up to 2 December 2005 we sent information about the study to 1,682 new patients attending colorectal clinics. Almost half of these consented to participate (n=838) and provided a blood sample. We anticipate that recruitment will be completed by the end of February 2006.

The outcomes of the clinic visits (results from examinations and investigations) are being collected from patients' hospital records and will continue through 2006.

**Many thanks to all the clinics and staff that participated in this study.**

**Further information from Dr Sue Wilson, (s.wilson@bham.ac.uk) or Sally Warmington (s.a.warmington@bham.ac.uk) on 0121 414 8589**

**Study to evaluate the suitability and acceptability of measuring MMP9 as a screening test for colorectal cancer**

This complementary study aims to assess the accuracy and acceptability of MMP9 as a potential screening test for colorectal cancer. Participating patients provide a blood sample for MMP9 estimation and have a colonoscopy. Comparison of MMP9 levels and colonoscopy results (the gold standard) will establish the accuracy of this test.

#### **What does participation involve?**

Participating practices provide lists of patients aged 50-69 years, excluding people already under investigation or treatment for colorectal cancer or unable to give informed consent. Patients are sent a short symptom questionnaire by post. Responders, who report one or more lower gastrointestinal symptoms and who may be interested in taking part in the evaluation of MMP9, are asked to attend a practice based research clinic (staffed by departmental research nurses). Patients who provide informed consent have a colonoscopy and provide a blood sample at the Wellcome Clinical Research Facility (QE Hospital).

#### **How are we doing with recruitment?**

Nine practices have been recruited so far. Almost 4,000 patients have been sent symptom questionnaires and 65% have responded; 17% of these have been invited to attend a research clinic. About half of those attending are considered fit for colonoscopy and provide informed consent. We aim to recruit a total of 29 practices within travelling distance of the QE and are currently in our second phase of practice recruitment.

Any practices interested in participating or wanting further information about the study should contact either Dr Sue Wilson, (s.wilson@bham.ac.uk) or Val Redman (v.d.redman@bham.ac.uk) on 0121 414 2688

## Postnatal depression exercise study

**The feasibility and effects of exercise in women with postnatal depression: update on progress.**

This project explores whether exercise, which is recommended for mild-moderate depression, could be helpful for women experiencing postnatal depression. The study particularly focuses on promoting pram pushing. We are approximately half way through the recruitment phase of the study but are still looking for practices to help us recruit suitable patients. Patients randomised to exercise receive two individualized exercise consultations and support phone calls promoting exercise over the course of the 12-week period. Patients are also given a pedometer to help them monitor how much exercise they are doing each day. The control group are offered an exercise consultation after they have completed the study. **For further information contact Dr Amanda Daley (a.daley@bham.ac.uk: 0121 414 3762).**

## BeST Study (The Back Skills Training Trial)

**The BeST study is looking at the use of Cognitive Behavioural Therapy (CBT) in patients with low back pain. The University of Warwick is running the study and we are collaborating with them to recruit patients.**

The study is a randomised controlled trial comparing CBT with active management (normal care). Patients are identified by a search of the notes, and contacted with information about the study. Interested and eligible patients will then be assessed by one of our Research Nurses. Those patients that are randomised to CBT will be referred to a therapist and asked to attend a 6 week CBT programme.

We have successfully been running BeST in Heart Of Birmingham PCT since September 2005 and we will be extending the study into South Birmingham PCT in the near future.

We will be writing to all South Birmingham practices with further information regarding the study soon, but if you would like more information about BeST please contact **Jo-Anne Miles on 0121 414 3323 or email: j.m.miles@bham.ac.uk**

## Results from Completed Studies

It's great to see that Claire Asker (GP in Kings Heath) has published the work undertaken for her MSc in Community Gynaecology with the support of PC-CRTU. This is a summary of the work, which is soon to be published in The Journal of Family Planning and Reproductive Health Care: **What is it about Intra Uterine Devices (Coils) that women find unacceptable? Factors that make women non-users: a qualitative study.** *Claire Asker, Helen Stokes-Lampard, Jackie Beavan, Sue Wilson*

Increased patient choice regarding contraception has recently attracted media attention subsequent to the publication of the NICE guidelines on long acting reversible contraceptive products. There is a lack of published research into the perceptions of 'non-users' of copper intrauterine contraceptive devices (IUDs). Despite this being one of the most commonly used methods of contraception in other countries, only 5% of contraceptive users in Great Britain aged 16-49 years currently use an IUD. This study explored how women's lay beliefs and perceptions about IUDs lead to rejection of this contraceptive choice. One to one semi-structured interviews were conducted with 10 women of varying ages and parity recruited from an urban general practice. None of the women had ever used IUDs but all had used contraception in the previous six months. Data was subjected to qualitative analysis.

This study was innovative in seeking the views of non-users using a qualitative methodology. Five main analytical themes were identified: lack of objective information about IUDs, reported side

effects of IUDs, anxieties about the process of fitting an IUD, IUDs as an infection risk, and lack of personal control of an IUD, once fitted. Some of the themes identified mirrored those found in studies of user attitudes to and experiences of IUDs. Others, particularly the prominent worries about mess and embarrassment during fitting and the association between the hidden nature of the fitted device and unreliability, are new and need wider exploration. The beliefs that IUDs must be fitted during menstruation and that infection risk increases with duration of use are contrary to current medical opinion. The link between unreliability and the hidden nature of the fitted device was a new and unexpected finding.

A balanced and informed approach is needed when counselling women who might consider an IUD to allay myths and unfounded fears. Evidence exists that many women are dissatisfied with the level of communication within family planning consultations. Misunderstandings arise when clinician and client each assume that the other shares their own understanding. Accessing women's lay beliefs has enhanced our understanding of why women discount an IUD as a contraceptive option. We suggest that the findings of this study could form the basis for changes to written educational materials about IUDs, for both clinicians and potential users. Information about participants' fears could be presented in such materials in tandem with objective information about IUDs. Inclusion of positive personal narratives may help to counteract the negative impact of 'unofficial' information sources.

## News from the Exercise and Menopause Study (EAMS)

This study investigated the relationship between participation in exercise, and menopausal symptoms in women aged 46-55 years. Six general practices in the West Midlands participated in the study and over 1,200 women completed the study questionnaires. Analyses indicated that women who exercised regularly reported significantly lower depressed mood, somatic symptoms and attractiveness concern scores than those who exercised infrequently and who were sedentary. Additionally, obese women reported significantly higher vasomotor symptoms scores than normal weight women. We would like to thank those practices that helped us with this research. The findings from the study will be published shortly. **For further details about the results of this study please contact Dr Amanda Daley** ([a.daley@bham.ac.uk](mailto:a.daley@bham.ac.uk)).



The PROCEED Study concluded last year with the production of an educational package for health professionals working with people with cancer from ethnically diverse backgrounds. This consists of a manual for trainers and facilitators and a DVD which includes scenarios, interviews and resources that can be downloaded and printed. It costs £150.00 and is available from Cancer Research UK. There will be a formal launch on 22 March. If you would like further information, please contact **Jackie Beavan on 0121 414 3330 or via email [beavanj@bham.ac.uk](mailto:beavanj@bham.ac.uk)**

## Psychological stress and antibody response to vaccination in the elderly

**Main finding:** Bereavement is bad and marriage is good for the immune response to the annual 'flu vaccination. This suggests that people who have been bereaved, or who are not married have lower protection against 'flu. It is therefore especially important for people who have been bereaved recently, and those who are single, divorced, or widowed to have their annual 'flu vaccination.

This study initially was interested to see whether stress and other related factors affected the immune response to the 'flu vaccination given yearly. 184 elderly people (over 65 years) from five surgeries across Birmingham were recruited in 2002 at the time of their annual 'flu vaccination and gave a blood sample prior to vaccination, and

further samples at one and twelve months. Stressful life events exposure including bereavement, an event commonly experienced by elderly people, social support, marital status and satisfaction were examined using questionnaires which were later returned by the participants. Individuals' increase in antibodies following the 'flu vaccination, was measured. This is an indicator of how effective their immune system would be against real 'flu infection, where a higher increase in antibodies indicates a better response, therefore better immunity against 'flu. The number of stressful life events individuals had suffered in the year before vaccination, and their level of support received from close family or friends was not related to how well their body's immune system responded to the vaccination. However, having suffered

bereavement in the year prior to vaccination was related to a poorer immune response to the vaccination at the one month follow-up point. Being married and having a happier marriage was related to having a better response to the vaccination at one month. These relationships were not being affected by other health factors such as smoking, alcohol intake, sleep, exercise or diet, although older people and people with an ongoing chronic illness had a poorer response to the vaccine. This study is part of ongoing work at the School of Sport and Exercise Sciences, University of Birmingham into the effects of psychosocial and physiological factors on immunity. Thank you for taking part. **For further information you can contact Dr Anna Phillips at [a.c.phillips@bham.ac.uk](mailto:a.c.phillips@bham.ac.uk) or 0121 414 4398**

# Gut Directed Hypnotherapy for Irritable Bowel Syndrome : Piloting a Primary Care based RCT

Lesley Roberts, Sue Wilson, Sukhdev Singh, Andrea Roalfe, Sheila Greenfield

## Abstract

**Rationale for study:** Irritable Bowel Syndrome (IBS) affects between 10 and 30% of the population and has a significant effect on quality of life. It generates a substantial workload in both primary and secondary care and has significant cost implications. Gut-directed hypnotherapy has been demonstrated to alleviate symptoms and improve quality of life but has not been assessed outside of specialised centres.

**Aim:** To assess the effectiveness of gut-directed hypnotherapy as a complementary therapy in the management of IBS.

**Design of study:** Randomised controlled trial

**Setting:** South Staffordshire and North Birmingham, UK. Primary care patients aged 18-65 inclusive, with a diagnosis of IBS of greater than 6 weeks duration and having failed conventional management.

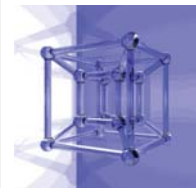
**Method:** Intervention patients (n=40) received 5 sessions of hypnotherapy in addition to usual management. Control patients (n=41) received

usual management alone. Symptoms and Quality of life were collected at baseline and again 3, 6 and 12 months post-randomisation.

**Results:** Both groups demonstrated a significant improvement in all symptom dimensions and quality of life over 12 months. At 3 months the intervention group had significantly ( $p < 0.05$ ) greater improvements in pain, diarrhoea and overall symptom scores. No significant differences in quality of life were identified. Between group differences were not maintained over time. Intervention patients, however, were significantly less likely to require medication, and the majority described improvement in their condition.

**Conclusions:** Gut-directed hypnotherapy benefits patients via symptom reduction and reduced medication usage, although the lack of significant difference between groups beyond three months prohibits its general introduction without additional evidence. A large trial incorporating robust economic analysis is therefore urgently recommended.

## More from the Screening Team



**CUBE is a MRC-funded national randomised controlled trial to determine the cost-effectiveness of *H.pylori* 'test and treat' compared with empirical acid suppression for dyspepsia in primary care. The trial is co-ordinated by the CUBE Trial Office at the University of Birmingham.**

The study comes to an end on 28 February 2006. Patient recruitment finished in February 2005, with 699 patients recruited. Follow-up on these patients is now complete and data is being analysed.

Since August, Practice Nurses have been undertaking a novel method of data collection, using an online database similar to that used when randomising patients to the study. We would like to thank the nurses who did this data collection for all their hard work.

For further information, please contact the Trial Administrator, Vivienne Tsimbili on 0121 414 3765 or email [e.v.tsimbili@bham.ac.uk](mailto:e.v.tsimbili@bham.ac.uk)

## Birmingham Primary Care Diabetes Management Training Courses 2006

- Are you involved in the management of diabetes in the community?
- Do you wish to learn more about current treatment?
- Have you considered commencing insulin?



### We have the course for you

This course has been produced to offer a practical understanding of knowledge and how to apply this to practice; a critical awareness of current problems and management issues and an understanding of new insights into the area of diabetes management.

Accredited by the University of Birmingham

### Spring course

**Venue:** Professional Development Centre, Birmingham Medical School

**Dates:** April 4, 5, 12, 26 then May 3, 10, 17 and 24

**Cost:** £1500

The course consists of eight days face-to-face teaching, starting with two consecutive days, then weekly on Wednesdays excluding Easter. Students receive pre-learning materials and six months clinical supervision.

### Autumn course

**Venue:** Professional Development Centre, Birmingham Medical School

**Dates:** October 16-19 then November 6-9

**Cost:** £1500

The course consists of eight days face-to-face teaching, in two 4-day blocks. Students receive pre-learning materials and six months clinical supervision.

### Enquiries and registration forms

Deborah Bird, Department of Primary Care and General Practice, Learning Centre and Primary Care Clinical Science Building, University of Birmingham, Edgbaston, Birmingham B15 2TT Tel: 0121 414 2677 Email: [birdd@adf.bham.ac.uk](mailto:birdd@adf.bham.ac.uk)

[www.anticoagulation.org.uk/training.htm](http://www.anticoagulation.org.uk/training.htm)

## The Rotavirus Incidence Study

**This study is looking to estimate the disease burden of rotavirus gastroenteritis in children under the age of 5. We are looking at incident rates, age distribution, severity and seasonal variations, along with economic costs (to include both parental and practice costs) and sibling transmission rates.**

The study is now up and running in 16 practices across Birmingham and to date we have seen 50 patients, unfortunately none have tested positive for Rotavirus!

We have a group of dedicated bank nurses who are seeing the patients. They will also be popping in to the participating practices on a regular basis.

We would like to thank all 16 practices that are continuing to inform us of all eligible patients. We really appreciate your hard work!

For further information please contact Jo-Anne Miles on 0121 414 3323 or email [j.m.miles@bham.ac.uk](mailto:j.m.miles@bham.ac.uk)

## Bursary Scheme for Pharmacists

The Pharmacy Practice Research Trust is inviting applications from community pharmacists for the 2006 Bursary Scheme funded by the Leverhulme Trade Charities Trust. Below is some information re. the funding arrangements and eligibility constraints.

The Bursary Scheme is intended to support community pharmacists who have an interest in developing their skills in conducting research relating to everyday practice. The Trust has £40K to fund a number of projects over the following levels of funding available:

**Level 1** – funding to undertake research modules and a small-scale project (supported by a research organisation, for example, a Higher Education Institute, Primary Care Research Network or Research and Development Unit)

**Level 2** – funding to upgrade a Diploma in Clinical/Community Pharmacy to a MSc, which usually involves undertaking a further two modules (one on research methods) and undertaking a project

**Level 3** – funding to undertake a non-pharmacy MSc

Applications are invited from community pharmacists, self employed (as locums or independent community pharmacists) or employed by a small chain of up to 60 registered premises, who demonstrate a real need for external support to develop their skills and careers in research.

The Bursaries include the following items of funding:

- Salary (pro rata for part time)/locum costs
- Course fees
- Research costs (up to a maximum of £250, to include printing, postage and travel)
- Supervision costs (either from a Higher Education Institution or from local Research and Development Unit/Network)

- Conference attendance (up to a maximum of £200 towards attendance and presentation of work at UK conferences).

The aim of the bursary scheme is to develop pharmacists who have basic experience and skills in health services research who will pursue research as part of their practice. The Trust is therefore pleased to announce that Ms Tabassum Jafri, 2003 Research Training Bursary holder is going on to undertake a PhD at the Engineering Department, Cambridge University (Lucy Cavendish College). The aim of Tabassum's project is to apply risk assessment practices to the medication provision process, either based on existing methods, or by adapting and tailoring new methods. A major case-study will be based around the provision of automation in hospital pharmacies.

Further details, application forms and guidance notes are available by contacting Beth Allen, Acting Research Manager, Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN (Tel: 020 7572 2466, email: beth.allen@rpsgb.org).

The deadline for completed applications is 9 June 2006 and interviews will be held in late July 2006 at the Royal Pharmaceutical Society of Great Britain's headquarters in Lambeth.

## Conference Bioethics: Past, Present and Future

A PhD student in the department of Primary Care and General Practice has recently been awarded £5,795 from the Wellcome Trust to run a postgraduate conference in Bioethics at the University in June this year.

The conference, entitled *Bioethics: Past, Present and Future*, aims to provide a forum for post-graduates currently working in Bioethics to share their current research and hear other professionals in the field talk about where they think the discipline is headed. The hope is that the conference will foster future interdisciplinary collaborations and methodologies.

A further innovation of the conference is that it is being run concurrently with a schools Bioethics essay competition, funded by the Researchers in Residence programme, the winner of which will be invited to present his/her work to the delegation.

Currently, speakers include Dr Lisa Bortolotti (University of Birmingham), Dr Andrew Edgar (University of Cardiff), Dr Adam Hedgcoe (University of Sussex) and Dr Jacinta Tan (ETHOX, University of Oxford). The rest of the conference will comprise of postgraduate presentations from delegates. All enquiries should be directed to Jonathan Ives in the Department of Primary Care (ivesjz@adf.bham.ac.uk)

This conference is one of a number of innovations with which the Centre for Biomedical Ethics is presently involved. *Ethics at Birmingham: Bridging the disciplinary gap* is a new lecture series, aimed at promoting interdisciplinary research in ethics across the University. For details on this, and other activities within the Centre, visit the website at <http://pcpoh.bham.ac.uk/primarycare/cbme/index.htm>

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