

PC-CRTU
In Contact
AUTUMN 2011



Studies in your area
Research: the GP's view
Are you research ready?

What is the PC-CRTU?

The Primary Care Clinical Research and Trials Unit (PC-CRTU) is the largest and longest-running academic primary care facility in Europe for clinical trials in the community. We have been conducting clinical studies since 1985 and have an excellent track record in designing, implementing, coordinating, monitoring, analysing and publishing trials.

Many of the studies that we are involved in are undertaken by researchers from Primary Care Clinical Sciences (PCCS), working in the clinical areas of Behavioural Medicine, Cancer and Chronic Disease, Cardiovascular Disease, Mental Health and Rehabilitation. PCCS is one of the divisions of the School of Health and Population Sciences, part of the College of Medicine and Dentistry at the University of Birmingham (see diagram).

Our trials are run by primary healthcare professionals and medical researchers in various primary care and secondary care settings, including care homes and pharmacies. Funding for research comes from various sources – most notably the NIHR, as well as the Medical Research Council (MRC),

Department of Health, medical charities and commercial investors.

The PC-CRTU has a team that combines clinical (general practice, nursing and other allied healthcare professions) and methodological (statistics, epidemiology, ethics) expertise, plus a range of technical skills (IT, research training, database management, clinical trial fieldwork and research administration).

We can help you and your practice develop research skills through taking part in studies – you can choose your level of participation and will be remunerated for any time spent on trials work. Research results can help to inform and develop clinical practice that will benefit your patients in the long term.

To find out more about us, visit our website at www.birmingham.ac.uk/pc-crtu



PC-CRTU

• Primary Care Clinical Sciences



In the News

BP Research shapes NICE guidelines

Research undertaken by the University of Birmingham and others is helping to shape NICE guidelines on blood pressure. The study, co-authored by Professor Richard McManus and published in *The Lancet* in August 2011, recommended that ambulatory blood pressure monitoring be used to diagnose high blood pressure. Researchers found that this method was both more clinically accurate and more cost-effective than clinic-based measurements.

Health interventions prevent deaths, save money

A modelling programme has shown that public health interventions that reduce cardiovascular risk factors, even by a small amount, would improve health, reduce cardiovascular events and save the NHS money. The study, led by Dr Pelham Barton, suggests a number of potential measures that could be of benefit – legislation to reduce intake of trans-fatty acids by 0.5%, for example, could potentially lead to a 570,000 life years' gain and generate NHS savings of £230m a year. The research was published in the *British Medical Journal* in July 2011.



Welcome

Welcome to the autumn edition of PC-CRTU In Contact.

Although this is my first contact with you via this medium, as the new Clinical Lead of Primary Care Clinical Sciences, you may be looking at the photo above thinking 'he looks familiar'. Having been involved in academic clinical research here in Birmingham since 1993, I will hopefully have already met many of you with an interest in cardiovascular disease – perhaps at the thrombosis and anticoagulation courses at the National School for Anticoagulation Training, or through your participation in research studies including SMART and BAFTA. I hope to meet many more of you in my new role, and that I, and my colleagues, can work with you on future trials.

My work has seen me heavily involved in the movement of anticoagulation management and self-management from secondary to primary care, and I continue to run studies in this area, alongside my work as a GP and as a reviewer for a number of journals. Of course, as a GP, I appreciate that we live in 'interesting times' – with NHS reforms and commissioning group confusion adding to our long list of daily challenges. Despite this, our commitment to our patients remains strong, and I am happy to say

that results from the studies you work on with us are helping to inform clinical practice and provide patient benefit through new and improved interventions.

Most recently in the news, research undertaken by Richard McManus and others at Primary Care Clinical Sciences has helped to shape new NICE guidelines on how hypertension is diagnosed and treated, through using 24-hour ambulatory blood pressure monitoring or home monitoring rather than relying solely on measurements taken in a clinical setting. We are particularly sad, therefore, to bid farewell to Richard, who is moving to the University of Oxford to take up a post in the Primary Care Department there. We wish him continued success and look forward to working on study collaborations with him in the future.

But we aren't prepared to rest on our laurels! We have many more studies in this newsletter that you can participate in, allowing you to develop or further a clinical interest and contribute to research that may benefit your day-to-day practice. Please do contact the



research teams directly if you are interested; participation in all studies is voluntary and expressing an interest does not commit you to taking part. For any research we support, practice costs are reimbursed comprehensively via the research funding bodies and the Clinical Trials Unit.

If you have any questions about the Trials Unit or any of the content of this publication, please do not hesitate to contact me or any of my team.

David Fitzmaurice

Clinical Lead, Primary Care Clinical Sciences
Deputy Head, School of Health and Population Sciences.

Contents



What is the PC-CRTU?	2
In the News	2
Welcome	3
Contents	3
New Initiatives	4
Interview – Dr Richard Edwards	5

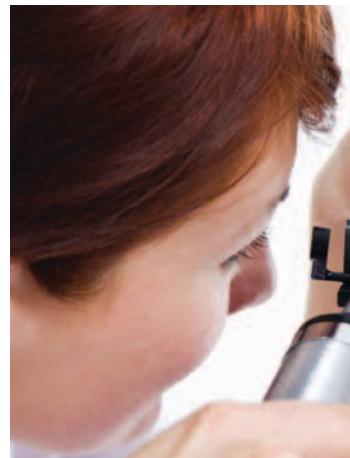
Current Studies

3C and OTCH	6
FACE TIA and ARTS	7
BLISS and EXACT	8
PATHWAY	9
GARFIELD and SCOT	10
PRIMIT and RRT	11

Completed Studies

CRC-IDA and HPV Core Messages	12
Research Design Service	13
CPD Courses	14
Keep In Contact	16

New Initiatives



Research Ready Self-Accreditation

Research Ready is an online self-accreditation tool which covers the basic requirements for undertaking primary care research in the UK. It has been developed in conjunction with the NIHR Clinical Research Network and the Primary Care Research Network.

Practices accredited under this scheme will be recognised by the Royal College of General Practitioners (RCGP) and receive a certificate stating this. They will also appear on a database available for viewing by the Medical Research Council, Universities and PCRN. Currently accreditation is free, but from 1st October RCGP will be introducing a fee of £150 to cover three years' accreditation. Therefore practices completing the process before this date will have the fee waived for one year at least.

For research active practices this is a useful tool to ensure that all the essential requirements

are being met and all staff are aware of their responsibilities.

If you haven't already done so, the practice will need to appoint a Research Lead who must be a doctor or nurse who agrees to do the following:

- Take professional responsibility for completing the assessment
- Deal with those questions directed at them
- Seek to involve all practice staff in the assessment process
- Take responsibility and lead the practice's response to any future assessor's visit

The process requires initial registration at this link: www.extension.rcgp.org.uk/researchready/survey.aspx

You will then work through the questionnaire answering 'yes' to all the questions and completing information on practice demographics and research interests. You may or may not choose to be accredited for undertaking Clinical Trials.

The main survey is available here: www.extension.rcgp.org.uk/researchready/practicelogin.aspx

For further information please contact:
Sarah Campbell
 Senior Facilitator
 PCRN-CE Birmingham Spoke
 Tel: 0121 414 3168
 Email: s.l.campbell.1@bham.ac.uk

Thinking about getting involved in industry studies?

The Primary Care Research Network (PCRN) is currently supporting 64 commercial research projects nationally. These studies are delivering high-quality commercial research in primary care.

All of the commercial studies that we support have been adopted onto the PCRN Portfolio and some studies are jointly supported, which means that more than one Network is engaged in supporting the research. Where this is the case, a 'Lead' Network is allocated. Benefits of joint support include cross-Network referral and patient identification: for example, a patient may be identified in Primary Care, but go on to receive treatment through the trial in a secondary care unit. The ability to work cross-Network really benefits industry as

it facilitates recruitment of participants across often complex treatment pathways.

The support of the Network with industry studies promotes effective communications between the company and GP practices and ensures consistent planning in order to achieve recruitment targets.

If you are interested in taking part in industry studies, or would like more information please contact Sarah Campbell (above).





Host Nurse Scheme

The Host Nurse Scheme was introduced two years ago to see if having a dedicated Research Nurse on site would give an effective resource to surgeries and enable them to be more proactive in research, thus facilitating an increase in research activity and leading to a wider range of studies and disease areas being investigated.

Since launching the scheme just eight practices have been involved and between them have assisted with an amazing 46 different studies. More than a quarter of all our recruited patients (accruals) across SBPCT, HoB and BEN have come from the Host Surgeries alone. This is a fantastic achievement and reflects perfectly the dedication and commitment of the surgeries involved as well as showing the programme to be successful.

PC-CRTU would like to thank Riverbrook, The Wand, Bellevue, Greenridge, Grange Hill, Ridgacre, The Vitality Partnership and Tudor practices for their continued help and support with making the programme work.

If you are interested in finding out more about the Host Nurse scheme please contact **Jackie Ingram**:

Tel: 0121 414 4791

Email: j.t.ingram@bham.ac.uk



Viewpoint on Research: the GP

Dr Richard Edwards of Eden Court Medical Practice in Castle Vale, Birmingham talks to us about his practice's experience of undertaking research.

When did you first start to take part in research?

When I first joined my current practice as a GP registrar my trainer was already involved in several research projects, one of which was a study into AF called BAFTA. I helped out with the work he was doing, enjoyed it, and then once I became a partner here I gradually contributed to more projects that were going on in the practice. Over time I was 'brave' enough to take the lead on new projects by myself.

What first got you interested in research?

I think seeing how easily a research project fitted into everyday practice, and realising how, for a small effort, I could help to answer important questions – which would hopefully reshape the way primary care was organised, or improve clinical care for my patients. As a doctor, there are still many unanswered questions, but it is satisfying to, at least in part, help to provide data which may lead to some solutions.

What kinds of studies have you been involved in?

We have contributed as a practice to a variety of studies over the years. We have been involved specifically with atrial fibrillation in the elderly, irritable bowel syndrome, menorrhagia, postnatal depression, sore throats, and, more recently, coughs and blood pressure control. A wide variety of topics really, which reflects the breadth of everyday general practice.

What types of activity did your research involve?

There have been a variety of styles and involvement, from passively providing

anonymised patient data, to actively enrolling and consenting patients. We have provided a base for researchers to use when seeing and assessing our patients, seen patients ourselves opportunistically and taken histories/measurements etc, and we have also provided some treatment options, such as coil fittings and distribution of probiotic yogurts.

Did you enjoy taking part in research?

I have enjoyed getting involved. Doing something a little bit different helps to re-energise my everyday work and keeps my mind active. I have never found the work onerous, and have enjoyed seeing the final results of the studies that we have contributed to, knowing that in a small way we had helped to make a difference.

What would you say to other GPs who might be considering taking part in research?

I have been surprised at how easy it has been to contribute to research, without taking on a huge burden, or without having to be a clever academic! These days we do a lot of searches and audits for various reasons, but at least for research purposes there is a point to the work and it leads to some intellectual satisfaction. In addition there is often a small financial benefit, and it certainly livens up and fills the section in my appraisal about research activities. Finally, as a training practice, our junior colleagues are often keen to get a taster of research and so an ongoing project helps us to satisfy that section of their teaching and education also. If you're thinking about research, I'd recommend taking on a small project as a practice and seeing where that leads.



Current studies

3C Cough Complications Cohort Study

The 3C study is an observational cohort study, being undertaken by the University of Oxford, designed to provide evidence to predict which patients presenting with an acute or worsened cough suggestive of lower respiratory tract infection are at higher risk of adverse outcome, particularly pneumonia.

This is a straightforward study in that patients are recruited within a typical consultation and once consented, the clinician will ask patients questions about their symptoms and fill in a short online form to record temperature, heart rate, pulse and blood pressure. This information will be recorded and the clinician will provide the treatment they feel appropriate.

The main concern that clinicians had when we began recruiting was that they would not be able to complete the consent process and the online proforma in the allotted consultation time. Feedback from one of our recruiting doctors is that, 'the study does take extra time during consultation, but improves with practise'.

The One a Week Plan

Taking this feedback into consideration we came up with the 'one a week' plan. If each clinician recruits a minimum of one patient a week we will soon make a dent in the UK-wide target of 30,000 patients, and our local target of 1000 patients recruited over winter 2011/2012.

We do not require every patient who fits the criteria to be recruited to the study, and one a week means that recruitment can be carried out at the convenience of the clinician.

A big thank you to everyone who has supported the study so far. We are actively recruiting across Birmingham and the Black Country area. So far we have 34 practices and 109 clinicians (made up of GPs and nurse practitioners), who have recruited 88 patients. The one a week plan attempts to make it easier for clinicians to make this research study part of their weekly regime and we are keen to recruit more clinicians. This study is ongoing until spring 2013 and patients can be recruited at any time throughout the year.

If you are interested in taking part in this study you will find information on the study website www.primarycare.ox.ac.uk/3C

Or please contact:

Sarah Campbell

Senior Facilitator

Tel: 0121 414 3168

Email: s.l.campbell.1@bham.ac.uk

Sarah Hadfield

Study Administrator

Tel: 0121 414 7182

Email: s.hadfield@bham.ac.uk



OTCH

A cluster randomised controlled trial of an occupational therapy intervention for residents with stroke living in UK care-homes (OTCH)

There has been a great deal of interest from care and nursing homes in the NIHR HTA-funded OTCH trial. This has resulted in over 85% of participants (residents with a history of stroke or TIA) being recruited to date.

Follow up assessments are being completed at three, six and 12 months and a number of participants have now completed the trial after their 12 month assessment.

Occupational therapists are actively working with participants living in the homes allocated to the intervention arm and are supplying appropriate adaptive equipment where applicable.

Work has also begun on delivering a training workshop to homes randomised to the control arm that have completed the trial.

Researchers are liaising with participants' GPs to confirm their stroke or TIA diagnosis and collect information relating to their current prescribed medications. Researchers may be in touch with your practice for confirmation soon.

For more information about OTCH, please contact:

Katie Stant

OTCH Trial Manager

Tel: 0121 414 6510

Email: k.e.stant@bham.ac.uk





FACE TIA Study

The FACE TIA Study is a prospective, controlled cohort study of functional cognitive and emotional outcomes after Transient Ischemic Attack (TIA). The study is funded by the NIHR National School for Primary Care Research and the West Midlands Strategic Health Authority, with ongoing support from the Stroke Research Network.

A combination of postal questionnaires and the Birmingham University Cognitive Screen (BUCS) is used to assess the long-term impact of TIA on patient's mood, quality of life and return to usual activities/social life.

The FACE TIA questionnaire assesses activities of daily living, anxiety and depression, economic cost and risk factors. It is distributed to participants at baseline, three, six and 12 months. The BUCS is an hour long cognitive screen that measures language, memory, perception and attention through a series of short tasks. BUCS is conducted at baseline and again at 12 months.

Recruitment of participants began in September 2010 and continues to go extremely well. Due to the popularity of the study the total recruitment target has been extended to 1,500 and the study has expanded outside the West Midlands. We are now actively recruiting from 11 TIA clinics in the West Midlands and four in Thames with a further two sites being set up in Thames, five in Yorkshire and one in the South West. The study is also actively recruiting from five GP practices in Central England to provide controls for the TIA patients matched by age, gender and geographical location (deprivation score and urban/rural classification).

We would like to invite GP practices to participate in the FACE TIA study to recruit participants to the control arm. Workload for practices will be minimal and consist of a one-off search of the patient register to identify patients matching the eligibility criteria and the sending of postal invites to the selected patients that are suitable matches. The FACE TIA research team will also periodically require a room at the practice to conduct the cognitive screen. Additional practice workload and resource use resulting from the study would be kept to a minimum and all costs would be recompensed.

If you would like to take part in this study, or would like more information about the research, please contact a member of the study team.

Jenny O'Donnell
FACE TIA Study Coordinator
Tel: 0121 414 5465
Email: j.e.odonnell@bham.ac.uk

Grace Turner
FACE TIA Study Coordinator
Tel: 0121 414 5463
Email: g.turner.1@bham.ac.uk

Sheriden Bevan
FACE TIA Trial Administrator
Tel: 0121 414 8593
Email: s.bevan@bham.ac.uk

Chief Investigator
Professor Cath Sackley



ARTS

Attentional Bias Retraining in Smokers Attempting Smoking Cessation

Although there are effective treatments to help smokers quit for a few weeks, most return to smoking within a year. There are currently no successful treatments to prevent this.

One reason why people start smoking again is because of triggers or cues related to smoking in the environment that remind them of smoking, such as a lighter or a packet of cigarettes. Previous research has shown that smokers have an 'attentional bias', where they tend to pay more attention to these cues related to smoking. This can cause cravings that lead people back to smoking again.

The National Institute for Health Research (NIHR) has now funded a three-year study to explore whether a computer retraining programme can change the way people process smoking-related cues while they attempt to stop smoking.

Smokers who would like to quit using the NHS Stop Smoking Services will be randomised to one of two groups, where they will either complete five weekly sessions of the computer programme with retraining or without retraining. All smokers will receive ongoing behavioural support and nicotine replacement therapy. We hope to recruit 200 smokers over 15 months.

We are looking to recruit more practices within Heart of Birmingham, Birmingham East and North and Sandwell PCTs who are prepared to write to, and invite, their patients to join the study. Any costs in doing so will be covered by us.

If your practice would like to take part, please contact:
Kathleen Waldron
Study Administrator
Tel: 0121 414 7895
Email: k.waldron@bham.ac.uk

Current studies *continued*



Birmingham Lung Improvement Studies (BLISS)

Chronic Obstructive Pulmonary Disease (COPD) affects 5–10% of people worldwide and the prevalence is rising.

COPD is a leading cause of mortality and is an increasing burden upon the NHS, accounting for 1.4 million GP consultations and one million in-patient days per year, resulting in a cost to the NHS of more than £800m per year. COPD is a significant health problem and the Department of Health has responded with its 2011 strategy. BLISS is a new programme funded by the NIHR which consists of two studies: 'The Birmingham COPD Cohort Study' and 'A Randomised Controlled Trial of Targeted Case Finding for COPD versus Routine Practice in Primary Care (TargetCOPD)', the former of which is due to start in January 2012.

There is a lack of information on the disease course of COPD, which limits treatment options, especially in people with mild to moderate disease. In order to test and develop means for evaluating how COPD can best be identified

and treated we are recruiting about 2,000 patients in the Birmingham COPD Cohort Study from GP practices in the West Midlands.

Approximately 60% of COPD sufferers are undiagnosed in the UK. TargetCOPD will evaluate the best methods for diagnosing COPD, with an aim to identify COPD in patients earlier in general practice. We will compare two diagnostic approaches for effectiveness and cost effectiveness, as well as taking into account the benefits of possible earlier treatment.

Thank you to all those practices that have expressed an interest in taking part in the BLISS programme. If any practices would like any information about the study, or would like to take part, please contact the team on bliss@contacts.bham.ac.uk



ExACT – Extended anticoagulation treatment for VTE: a randomised trial

Venous thromboembolism (VTE) comprising Pulmonary Embolism (PE) and Deep Vein Thrombosis (DVT) is common with an incidence of approximately one per 1,000 per annum. It is associated with significant mortality and morbidity, including post-thrombotic syndrome (PTS). There is an annual recurrence rate following a first VTE of approximately 10% per annum irrespective of the duration of warfarin therapy. This suggests that some patients should continue warfarin in the long-term however we are currently unable to identify this population.

D-dimer, a fibrin degradation product present in the blood after a blood clot, is used in conjunction with probability scores to determine whether further investigation is required for the diagnosis of VTE. Recent studies have investigated whether D-dimer can be utilised as a guide for determining who is at risk of recurrent VTE following treatment of the initial acute episode.

The aim of ExACT is to investigate extending treatment with oral anticoagulation beyond three to six months, for those patients with first unprovoked proximal DVT or PE prior to discontinuing treatment, in terms of reduction in recurrence of VTE and PTS.

We are now recruiting patients, aged over 18, with a first unprovoked VTE from both primary care and secondary care anticoagulation clinics. Patients receive brief information about the study and are given a postcard to return to the research team if willing to take part.

Patients are randomised to either continue or discontinue warfarin and will be followed up every six months for two years. We will be looking at D-dimer levels, the development of PTS and associated quality of life. We are also looking at the cost effectiveness of continuing warfarin treatment for these patients.

We really need your help! We are actively trying to recruit over 300 patients for this study so we have included a poster in this issue to raise patient awareness. Can we please ask you to display this poster in your waiting room, even if you don't run your own anticoagulation clinics. In addition, if you are interested in getting involved with this study or require further information then please contact:

Jayne Tullett
Research Fellow
Tel: 0121 415 8092
Email: j.m.tullett@bham.ac.uk





PATHWAY

We are inviting you to participate in the PATHWAY program comprising of three BHF-funded complementary studies which have been designed by eight senior investigators in the British Society of Hypertension specialists.

A total of 1400 patients will be recruited into the three studies, from ten study sites across the UK. Your participation can be in all three studies or any combination of them. A short summary of PATHWAY 1, 2 and 3 follows.

PATHWAY 1 – Monotherapy vs Dual Therapy for Initial Treatment for Hypertension

This study tests whether initial combination therapy with two drugs that are complementary in action is superior to the current stepped-care approach. Confirmation that patients starting on one drug 'never catch up' with patients starting on two drug therapy would have a major impact on hypertension treatment practice; possibly more than any previous study in hypertension.

PATHWAY 2 – Optimal Treatment of Drug Resistant Hypertension

The primary objective of PATHWAY 2 is to test a primary hypothesis which states that the commonest cause of resistant hypertension is excessive Na^+ -retention, and that 'further diuretic therapy', ie., spironolactone will be superior to other potential 'add-on drugs' for people with inadequate BP control despite treatment with optimal or highest tolerated doses of the three drug classes recommended by the BHS/NICE treatment algorithm, ie., A+C+D.

PATHWAY 3 – Comparison of single and combination diuretics in low-renin hypertension.

The objectives of this study are to ascertain whether potassium sparing diuretics improve glucose tolerance in patients with hypertension and one other component of the metabolic syndrome, demonstrate improved efficacy and tolerability of combining diuretics, compared to taking one class alone, and to establish a repository of pharmacogenetic samples and investigate relationships between genetic factors and pharmacodynamic responses.



Our Role

We will perform the patient search at your clinic for eligible patients, and provide the Research Nurse who will run all clinics at your surgery.

We would send all postal invitations to your eligible patients and, on their response, book them into clinics at a mutually convenient time dependent on your room availability.

We provide all equipment required for the study, and would simply require access to the patient records at each of their clinic visits.

Your Role

If our nurse found the patient to be eligible for the study, we would ask you to see the patient (and perform a short clinical examination) to confirm this.

You would be required to be present within the practice building whilst clinics are taking place, in case referral from our Research Nurse for management of any side effects arising from study medication is needed.

All blood results will be forwarded to you for assessment and action if required. Ensure a secure lockable cabinet is available for storage of study medication.

£150 per patient randomised will be paid to the surgery to cover GP time and room hire.

Any questions? Please contact:

Rachel Iles

Birmingham Site Trial Coordinator
Tel: 0121 414 2691

Email: r.iles@bham.ac.uk

or

Lucy Hughes

Birmingham Site Trial Administrator
Tel: 0800 694 0393
Email: l.v.hughes@bham.ac.uk



Current studies *continued*



Global anticoagulant registry in the field

The Global Anticoagulant Registry in the FIELD (Garfield) is a prospective, multicentre, international registry of patients newly diagnosed with atrial fibrillation (AF). Garfield is an academic research initiative led by the Thrombosis Research Institute, London. It is designed to determine in real-life practice the behaviour of newly-diagnosed patients with AF with at least one additional risk factor for stroke. The main focus of Garfield is to capture real-life AF management; it therefore includes male and female patients newly diagnosed with AF irrespective of whether or not they receive treatment. Garfield plans to recruit 55,000 patients in more than 1,000 sites worldwide. Patients will be enrolled as five sequential independent cohorts of 10,000 patients and the follow-up period will be two years for each cohort. An additional

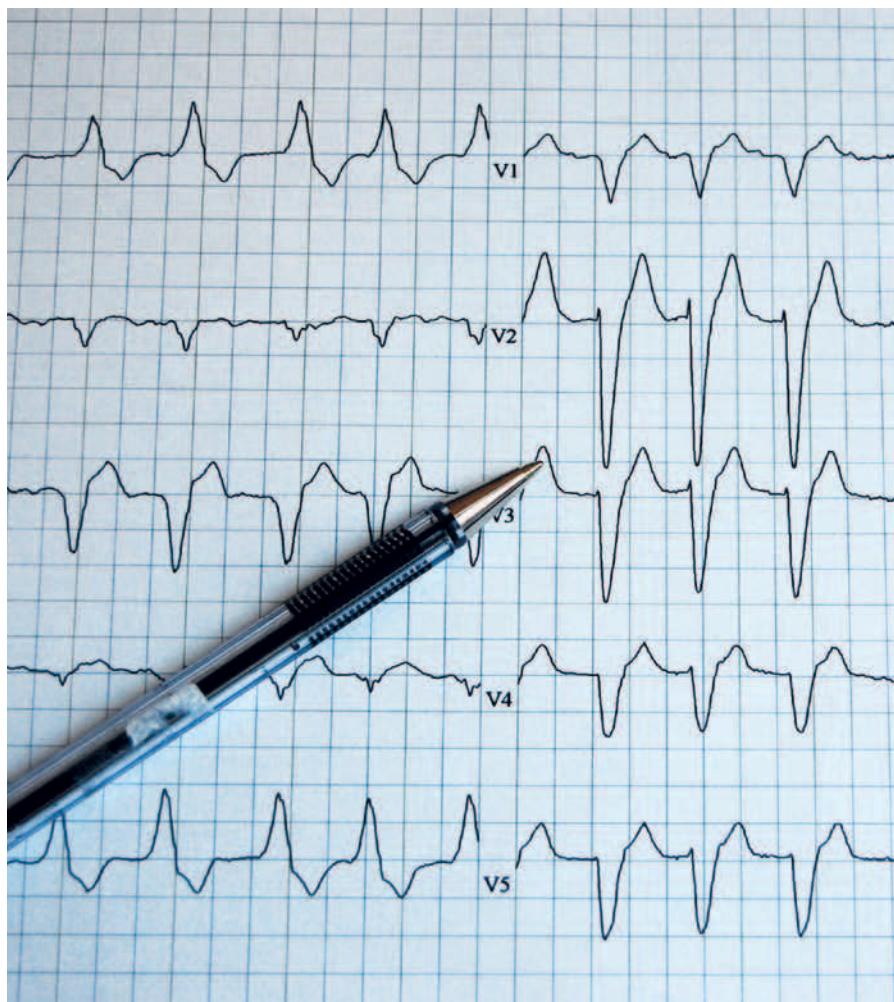
validation cohort of 5,000 patients will be recruited with the first cohort: these will be patients with a diagnosis longer than six months and no longer than 24 months before enrolment and with at least one additional risk factor for stroke.

Garfield is now active in 19 countries including the UK. In the UK Garfield is live in 75 sites across England and will now be extending to Wales and Northern Ireland. Cohort one is currently winding up and cohort two is due to commence in September 2011.

For more information please contact:

Patricia Apenteng

Email: p.n.k.apenteng@bham.ac.uk



SCOT Study

Standard Care Versus Celecoxib Outcome Trial

Your practice is being given the opportunity to take part in the SCOT Study, an RCT comparing the effects of older NSAIDs and 'Celecoxib' in people with arthritis.

We are looking for patients aged over 60 who are currently taking NSAIDs for arthritis.

- For every patient that completes the study the practice will receive £300 payment.
- The surgery will be reimbursed fully for prescription costs.
- Clinics will be hosted by University staff.

For more information contact:

Rachel Iles

email: r.iles@bham.ac.uk

or **Lucy Hughes**

email: l.v.hughes@bham.ac.uk

Tel: 0800 694 0393





A primary care trial of a website-based infection control intervention to modify influenza-like illness and respiratory tract infection transmission.

Can anything be done to stop RTI (Respiratory Tract Infection) and Flu (including pandemics) spreading within families? This study aims to get us nearer to answering the above question. The topic is important not only because of the normal winter pressures but also considering the ongoing risk of another flu pandemic.

An online intervention that provides people with tailored hygiene advice to lower transmission of colds and flu in their household has been designed. The study is a randomised clinical trial of this website. The primary aim of the study is to minimise contracting and spreading of respiratory viruses, including flu within homes. We intend to recruit 15,000 plus patients across England over two winters.

Patients will be recruited to login to the website by letter and they will be consented and randomised online. Patients will be allocated to intervention or control groups. The intervention group will access four different website sessions of tailored advice and complete a brief baseline and four, monthly, online questionnaires. The control group gets no access to the website sessions; however they will still complete a brief baseline questionnaire and four, monthly, online questionnaires. There is also the opportunity to take part in an optional viral sub-study and interview.

Practice involvement is minimal, the practice will help to generate a list of 2000 or more patients (depending on list size) aged 18 or over. Practices will then pass these details on to a secure mailing company that will carry out all the mailing, printing, compiling and posting. A Practice Nurse may be needed for one or two group meetings to explain the study or take nasal swabs if needed and the Practice reception staff will be asked to hand out free bottles of hand gel on request to participants. After the patient completes the study, a notes review will be carried out on their medical notes. The study proposes to recruit patients across two winters; 2011/2012 and 2012/2013. We will be mailing out invites to the patients between October and early January with a view to assessing patients' notes from May to September.

The research team is available to assist with all aspects of the study.

PRIMIT is funded by the MRC (Medical Research Council) and will be carried out in all BBC PCTs.

Service Support costs are available. Please note, there is a minimum commitment to contact 1000 patients. For any queries about PRIMIT please contact:

Deborah A Popoola

Trial Coordinator:

Tel: 0121 414 4839

Fax: 0121 414 3050

Email: primit@contacts.bham.ac.uk



Thank you for helping us help your patients to quit! The Rapid Reduction Trial:

In the last few issues of *In Contact* we have been exhorting practices in the region to join with us in our clinical trial to compare success rates between those who quit smoking abruptly and those who reduce smoking prior to quitting.

In this issue we will NOT be asking you to join in this trial as your response has been so good that we will achieve our goal of 700 recruits by the end of this year through the practices currently working with us on the trial.

The purpose of this short piece is to thank all those people, practices and PCTs who have worked so hard and willingly with us to achieve the research objectives of the study whilst, at the same time, helping hundreds of smokers to quit.

At the risk of sounding like an Oscars® acceptance speech, we would like to thank everyone who has contributed from within South Birmingham, Warwickshire, Worcestershire, Sandwell, Dudley, Heart of Birmingham and Solihull PCT areas including the research nurses, reception staff, practice managers and GPs together with the PCT Stop Smoking Service management teams.

Although this trial is coming to an end we have other quit-smoking related trials in train or about to start. So if you represent a practice which is keen to help your patients quit smoking, whilst also contributing to the body of knowledge supporting this key health initiative, please ring us to discuss the possibilities.

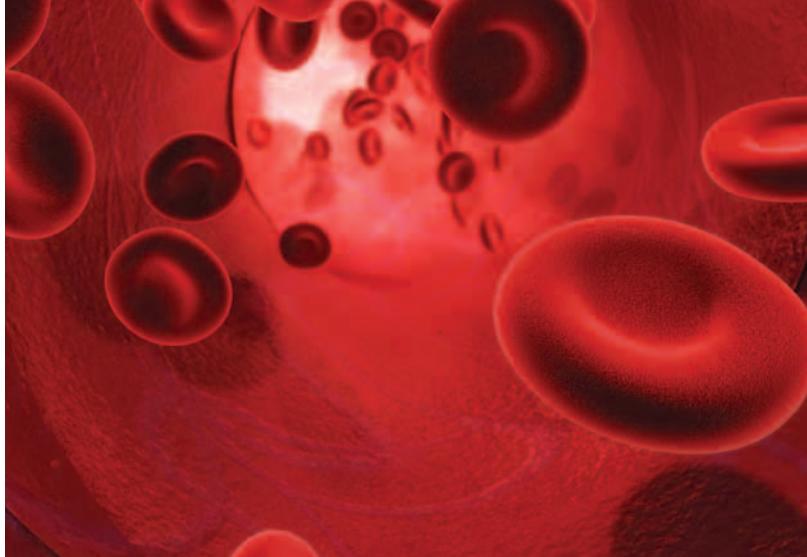
Contacts:

Kathleen Waldron

Tel: 0121 414 7895

Mike Healy

Tel: 0121 414 6422



Completed studies

Iron deficiency anaemia and delayed diagnosis of colorectal cancer

Despite a significant increase in colorectal cancer (CRC) survival rates over the past 25 years, primarily due to earlier tumour detection and improved treatment options, five-year survival for CRC in the UK remains below 50%, largely because of the advanced stage at which many cases are diagnosed. Earlier diagnosis could increase survival, improve quality of life, and reduce treatment costs. One factor that may contribute to poor performance in the early diagnosis of CRC in the UK may be a low priority given to iron deficiency anaemia (IDA) in primary care, despite IDA having been found to be a recognised presenting sign and an independent predictor of CRC.

In the case of CRC, distinguishing potential malignancy from more common disorders is a significant challenge, with the average GP seeing only one new case of CRC per year. British Society of Gastroenterology guidelines recommend both upper and lower gastrointestinal investigation in patients where IDA has been confirmed. However, the management of IDA is often suboptimal, with most patients being incompletely investigated.

This retrospective cohort study, funded by Cancer Research UK, used data from The Health Improvement Network (THIN) general practice database to identify CRC patients who had presented in primary care with IDA and to assess the referral pathway for each patient using the speciality of the first recorded GP referral in the three months following their IDA diagnosis.

The key findings of the study were:

- Time to diagnosis of colorectal cancer after a diagnosis of iron deficiency anaemia is significantly longer in patients referred to a speciality other than a relevant surgical speciality
- There was no significant difference in time to CRC diagnosis before and after the re-issue of updated NICE urgent referral guidelines for suspected lower gastrointestinal cancer in 2005
- A significant proportion of patients are still not managed within recommended care pathways to CRC diagnosis following a primary care diagnosis of IDA
- Improvement in education may be required to increase awareness of the risk factors for CRC at the primary care level in order to reduce the impact of GP delay in facilitating appropriate referral for patients with suspected CRC

The results of the study have recently been published:

Damery S, Ryan R, Wilson S, Ismail T, Hobbs FDR. Iron deficiency anaemia and delayed diagnosis of colorectal cancer: a retrospective cohort study. *Colorectal Disease*. 2011; 13: e53–e60.

For further details please contact:

Dr Sarah Damery
Research Fellow
Tel: 0121 414 3343
Email: s.l.damery@bham.ac.uk

HPV Core Messages: Development and evaluation of a set of human papillomavirus (HPV) core messages.

Little is known about attitudes towards, or knowledge about, human papillomavirus (HPV) vaccination in the UK. This study is a collaboration between the universities of Cardiff, Birmingham and Oxford. It aims to investigate current levels of knowledge and understanding about HPV in the context of the recently introduced vaccination programme in order to develop a series of evidence-based information messages that can support informed choice, minimise anxiety about HPV vaccination, and improve disease control in primary care.

The initial research phase, in which the views of vaccinated girls and their parents were investigated through a series of individual interviews, informed the development of a survey which focused on determining the views of primary care patients and healthcare professionals about the core messages that should accompany patient information materials relating to HPV vaccination.

The survey has now been completed, and the data from the responses is currently being analysed. The findings of this research will be important for all girls aged 12 to 13 years in the UK, and their parents or guardians. They will also be relevant to healthcare professionals involved in the delivery of, or education about, the HPV vaccination programme. We would like to take this opportunity to thank all the healthcare professionals – GPs, practice nurses and school nurses – who completed and returned surveys to us.

The Chief Study Investigator at University of Birmingham is Professor Sue Wilson.

If you would like further details about the research, please contact:
Dr Sarah Damery
Research Fellow
Tel: 0121 414 3343
Email: s.l.damery@bham.ac.uk

West Midlands Research Design Service



What is the RDS?

The RDS exists to provide help to people preparing research proposals for submission to peer-reviewed funding competitions for applied health or social care research. The RDS essentially consists of a team of methodologists based in universities and the NHS across the West Midlands, able to advise and provide practical support when you are developing your grant application. As the RDS is funded by the NIHR for this purpose, such help is provided free of charge.

Who can use the RDS?

The RDS will provide advice to NHS researchers, and others working in partnership with the NHS, who are developing research proposals for submission to national, peer-reviewed funding competitions.

For more information on West Midlands RDS please contact Melanie Guthrie on 0121 414 8533 or rdscentre@contacts.bham.ac.uk

www.rds-wm.nihr.ac.uk

How can the RDS help me?

The RDS can advise on all aspects of preparing grant applications,

- Formulating research questions
- Building an appropriate research team
- Involving patients and carers
- Designing a study
- Appropriate methodologies for quantitative research, eg, statistical issues, health economics
- Appropriate methodologies for qualitative research, eg, sampling, analytical strategies
- Identifying suitable funding sources
- Regulatory issues
- Writing lay summaries
- Identifying the resources required for a successful project

Advice and support is best provided face-to-face. RDS staff will be happy to meet with you at a convenient time and place to discuss your research. It is preferable to contact us at an early stage to discuss your ideas.

Courses

CPD courses available within Primary Care Clinical Sciences

The CPD team exists to try to meet the educational needs of health care professionals involved in all aspects of primary care chronic disease management. The current palate of courses has been driven by demand from our students. Details of all developments are available on www.anticoagulation.org.uk and information on a selection of the courses is given below.

MSc accredited courses

Anticoagulation management in primary care

28–30 November 2011 or
19–21 March 2012

This three-day course aims to enable autonomous practice in dealing with fundamental and more complex problems of oral anticoagulation management.

The programme is to include:
How warfarin works and the INR; anticoagulation guidelines; anticoagulant near-patient testing; quality control; CDSS/NPT workshops; case scenarios; litigation issues; stroke prevention and atrial fibrillation; patient self-management; protocol development and accountability; warfarin drug interaction; management of VTE; a typical primary care clinic; audit parameters and primary care management.

Faculty to include:

Professor David Fitzmaurice
Dr Will Lester

Prescribing: scientific principles and practice

27 January, 24 February and
23 March 2012

This three-day course aims to address the underpinning principles of prescribing practice as well as mechanisms and pathways to refine and optimise the prescribing process at patient, local practice and national levels.

The module is designed to be used as a self-standing unit to provide extended knowledge and understanding of the medical prescribing process: both for prescribers wishing to develop their knowledge base and those who do not necessarily prescribe but are involved with a medicines' management process.

Faculty includes:

Professor John Marriott
Professor David Fitzmaurice

Management of Heart Failure in primary care

31 January–3 February 2012

This course is suitable for GPs, nurses and other health care professionals aiming to acquire specialised skills and qualifications in heart failure management within primary and community care.

The programme includes: anatomy, physiology and function of the heart, echocardiogram, epidemiology and definition of heart failure, investigations, treatment, lifestyle, managing related clinical events, palliative care and the role of the specialist heart failure practitioner. Learning outcomes:

- Demonstrate ability to deal with complex issues underpinning heart failure management in primary care
- Evaluate critically the prevention of long-term complications according to current guidelines
- Understand the roles of the multidisciplinary team in heart failure care to improve health outcomes

- Understand the requirements of clinical governance for heart failure management

Faculty to include:

Dr Clare Taylor
Dr Ellen Murray

Management of Hypertension in primary care

5–8 March 2012

This course is suitable for GPs, nurses and other health care professionals aiming to acquire specialised skills and qualifications in hypertension management within primary and community care.

The programme includes: an epidemiological overview, measurement of blood pressure, factors controlling or raising blood pressure, organ damage of hypertension, CVD risk assessment, evidence based treatment, QOF and protocol development and referral pathways. Learning outcomes:

- Demonstrate ability to deal with complex issues underpinning hypertension management in primary care
- Evaluate critically the prevention of long term complications according to current guidelines
- Understand the roles of the multidisciplinary team in hypertension care to improve health outcomes
- Understand the requirements of clinical governance for hypertension management



CPD Courses

Liver disease in primary care

13–14 October 2011

A two day mini-conference organised in conjunction with Dr Phil Newsome, Senior lecturer in Hepatology, University of Birmingham and Honorary Consultant Hepatologist, QE hospital Birmingham.

The course aims to provide theoretical and practical knowledge of liver diseases and how to manage them in primary care.

Learning objectives include:

- An understanding of how to interpret liver function tests, when to investigate and when to consider referral
- How to identify the patients with chronic liver disease
- The community management of alcohol use disorders
- Developments in non alcoholic fatty liver disease
- Screening and community management of viral hepatitis
- Gall bladder disease – who to suspect and when to refer
- Vaccination and drugs in patients with liver disease
- An update on liver transplantation
- The National Liver Plan from the liver czar

Faculty includes;

Dr Phil Newsome

Professor Martin Lombard

Professor Peter Hayes

Professor James Neuberger

Oral Anticoagulation Management for Health Care Assistants and Assistant Practitioners

16 November 2011

This one-day course is aimed at health care assistants and assistant practitioners working within anticoagulation clinics. The course aims to provide a basic knowledge of point of care (POC) devices including blood-testing technique and quality control for oral anticoagulation management in primary care.

Reducing re-admission and saving lives. Management of PE and DVT

21 November 2011

The course aims to provide knowledge on the diagnosis and management of DVT within a primary care setting; to inform on major developments around VTE prevention for patients admitted to hospital and to discuss why it is relevant in primary care.

Learning objectives to include knowledge of the following:

- Aetiology and epidemiology of thrombosis
- Symptoms and signs of DVT
- Guidelines for treatment of thrombosis
- How to set up community management of DVT
- Major problem of VTE risk for patients admitted to hospital
- NICE guidelines for VTE prophylaxis and what can be done in primary care

Atrial Fibrillation – detection and treatment

2012 dates tbc

The aim of the course is to provide theoretical and practical knowledge of the condition of Atrial Fibrillation and an update of its management.

Learning objectives:

- Understanding the theory underpinning the disease of Atrial Fibrillation
- Understanding diagnostic and assessment criteria for Atrial Fibrillation, an ability in performing a good ECG and interpreting a normal ECG as well as irregular rhythms eg, AF
- Applying concepts appropriately in dealing with current evidence for treatment of AF
- Understanding the management of Atrial Fibrillation, when referral is appropriate, the roles of the multi-professional team in managing AF safely and national guidelines, quality and outcome framework aimed at stroke prevention

Anticoagulation in Practice 2011 conference

17–18 May 2012

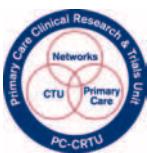
GPs, practice nurses, biomedical scientists, pharmacists and patients are all invited to attend Anticoagulation in Practice 2012 at the Wolfson Centre, the Medical School, University of Birmingham. Further details will be available on our website.

2012 courses

Dates tbc

- Management of Gynaecology in the community
- Effective commissioning within the changing organisation of the NHS
- Mental Health Care in the community

Details of all modules and CPD courses are available at www.anticoagulation.org.uk or from Amy Partleton, telephone 0121 414 2677, email a.partleton@bham.ac.uk



**National Institute for
Health Research**



Keep In Contact

Interested in taking part in research? We'd like to hear from you.

- You will always be able to choose your practice's level of involvement.
- You will be remunerated for practice time spent on research.

Name:

Practice code:

Practice address:

Postcode:

Primary Care Research Networks

The Birmingham, Keele and Warwick Primary Care Networks work in conjunction with the Primary Care Network for Central England (PCRN-CE), part of the UK Primary Care Research Network. Only studies which have been independently peer-reviewed and funded through national competition; and commercial research asking relevant questions will be adopted onto the PCRN-UK Portfolio of studies.

PCRN works with the following topic specific networks. Please tick if you have a particular research interest in any of the following subjects:

- Cancer
- Medicines for Children
- Mental Health
- Primary Care
- Obesity
- Stroke
- Other

You can:

Fax back this form to **0121 414 2282** or
Email the details above to pcrcrtu@contacts.bham.ac.uk or
Phone us on **0121 414 8843** for further information.

Alternatively, send the completed form to our postal address, as detailed below.

**UNIVERSITY OF
BIRMINGHAM**
 Edgbaston, Birmingham,
 B15 2TT, United Kingdom
www.birmingham.ac.uk

Primary Care Clinical Sciences
 University of Birmingham
 Primary Care Clinical Sciences Building
 Edgbaston, Birmingham B15 2TT

Visit our website
www.birmingham.ac.uk/pc-crtu

General Enquiries
 Tel: 0121 414 8843
 Fax: 0121 414 2282

Randomisation Service
 We now offer a telephone
 randomisation service for studies.
 Contact us for further details
 on 0121 415 8671