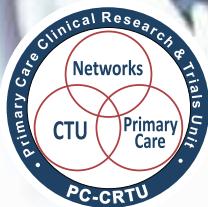




# PC-CRTU In Contact

AUTUMN 2012



**Studies in your area**

**Completed studies:**

BP-Eth and CATCH

# Recruit your trainee to research

Research and academic activity is the heading of one of the more neglected curriculum statements for GP training unless you are an academic trainee. It is recognised that all GPs require some basic research skills, and for a few GPs, early experience will fire a life-long interest in research. Some of the key skills include assessing evidence, basic statistics, significant event analysis and evaluation of performance. These, combined with the ability to think and reflect, are everyday processes in today's General Practice and Clinical Commissioning Groups.

As a Deanery we are encouraging all GP trainees to take part in research by volunteering to participate in one of the Primary Care Research Network studies. This is a win-win scenario with the practice being rewarded with a higher standard of care together with a financial reward for this important NHS initiative. Trainees register interest with the support of their trainer and practice. The trainee, university, practice, Deanery and NHS patients all benefit.

We have had a number of trainees take part in the 3-Cough study which identifies patients during a routine surgery. Trainees are often less busy than their GP trainers and more likely to identify and recruit appropriate patients. The training and experience provided by Warwick University is invaluable and 1-2 trainees have opted for further academic opportunities on completion. We have only had positive feedback from practices.

So the bottom line is, the Deanery approves of GP trainees taking part in PCRN studies, the practice gets paid for the time, and the trainee benefits from the learning experience. We will be promoting further opportunities to trainees in due course.

#### Dr Martin Wilkinson

Director of General Practice Postgraduate Education  
NHS Midlands and East

## Summary of RCGP and Primary Care Clinical Research and Trials Unit (PC-CRTU) Birmingham joint Research and Innovation Symposium 21st June 2012

### Background

This annual event rotates around the Midlands, two years at a time, between Birmingham, Keele and Warwick. 2012 saw it return to Birmingham where it was hosted by PC-CRTU. The event is supported by the West Midlands Deanery who fund free places for GP trainees and by the RCGP Midland Faculty who underwrite the event. Additionally the Faculty provides several prizes at the event. Some sponsorship money was successfully bid for and the Primary Care Research Trust of the Midlands (PCRT) kindly agreed to underwrite the event and to support PC-CRTU in turning the event into a showcase for local research to boost research capacity at Birmingham.

The organising was chaired by Helen Stokes-Lampard at Birmingham and the committee comprised admin and junior academic staff at Birmingham as well as the Midland Faculty of the RCGP team.

### Summary of the day

The event was held on 21st June at Aston Villa conference centre and was very successful in several ways:

- Of 61 completed evaluation forms, 53 delegates rated the day as good or excellent
- Over one hundred attended the event, a significant increase on recent years

- 28 abstracts were submitted for either oral or poster presentations, a significant increase on recent years
- There was an excellent mix of new and experienced researchers who presented on the day and some thought-provoking workshops which were well received
- Research teams who used the event to showcase their studies were very positive in the level of engagement they experienced with delegates
- There was a great atmosphere at the event and sponsors have asked if they can come again next year

### Looking ahead

Birmingham is hosting the event in 2013; the team who organised this event are anticipating organising the event again and have already approached new extra individuals to join them to ensure the event is fresh and new.

#### Dr Helen Stokes-Lampard PhD FRCGP

Clinical Senior Lecturer



# Welcome

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

I have recently taken over as the new Clinical Deputy Director at the PC-CRTU and would like to thank Dr Helen Stokes-Lampard for her sterling work in getting the Unit to this stage.

As we know, the NHS landscape is changing dramatically and we are beginning to realise some of the clinical implications of this with, for example, formation of CCGs. In terms of research, these changes bring many challenges and opportunities for CCGs, practices and professionals. There is a strong push from the Department of Health for increasing research activity in the NHS to improve patient outcomes and research is one of the CCGs priorities.

We can work together to address this and I would encourage you all to take part in one or more of the studies listed in this issue. Please contact the research team directly to register your interest. As always, participation is completely voluntary and practice costs are re-imbursed via research funding bodies.

**Dr Paramjit Gill**  
GP and PC-CRTU Clinical Deputy Director



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# New Studies



**Are you confident that your reception staff would know how to handle a call from a patient with suspected symptoms of stroke?**

Introducing the RECEPTS study (Receptionist rECognition and rEferral of Patients wiTh Stroke)

We will shortly be inviting practices to participate in a study to understand how GP reception staff recognise and respond to patients with stroke symptoms. We will use this information to design a Receptionist Stroke Symptom Protocol which all members of the practice are happy with. If successful this will be rolled out to practices nationally.

The study involves:

- Short questionnaire for GP receptionists
- Interviews and focus groups with GP receptionists and other practice staff
- Unannounced simulated patient telephone calls

Example of an unannounced simulated patient telephone call scenario



If your practice would like to be involved, or you would like more information on the RECEPTS study, please contact:  
**Janet Jones** (Project Officer)  
Tel: 0121 414 8901  
Email: [j.jones.5@bham.ac.uk](mailto:j.jones.5@bham.ac.uk)  
We'd love to talk to you about it



## The Preloading Trial Help your patients to quit smoking

Don't miss this opportunity to help more smokers in your practice quit. The University of Birmingham will soon begin recruitment on an NIHR HTA funded trial of nicotine patch preloading, and we are looking for interested GP practices to get involved by writing to smokers at their practice and offering them our support to quit.

Although participants who use the NHS Stop Smoking Service are four times more likely to quit than those that quit alone, the majority will still return to smoking. Therefore, we need to find new, effective treatments to help people to quit. Nicotine preloading is the use of nicotine patches by smokers before quitting, whilst smoking as usual. There are a number of reasons why this may help someone to give up smoking, including the following:

- 1) It may help to break the association between smoking and reward, making quitters less likely to relapse
- 2) If people feel less pleasure whilst smoking with the patch on then this may make them feel more confident that they can quit
- 3) Consuming nicotine through using patches and smoking (although not harmful) may result in some unpleasant sensations, such as nausea. This could lead to an association between smoking and negative feelings, making the smoker less likely to want to smoke
- 4) Using the patch before quit day could get the participant used to using the medication, so that they are more likely to use it successfully post-quit day

We carried out a meta-analysis to investigate whether nicotine preloading is advantageous, however this was largely inconclusive, with some studies finding a large positive effect and some not. Therefore, we concluded that more research is needed to investigate the treatment.

The Preloading Trial is a large multi-centre trial, recruiting through centres in the West Midlands, Nottingham, Bristol and London. We need GP practices to write to smokers registered with them to see if they would like to take part. Eligible participants will then be randomised, either to receive 4 weeks of nicotine patch preloading, or not. The research team will need to see participants for two weeks at their practice before referring them to their local NHS Stop Smoking Service (which could be a service already operating in the practice) for standard support. Our primary outcome measure is the participant's smoking status at 6 month follow-up. To collect follow-up data the research team will also need to see those participants claiming to be abstinent at 6 month and 12 month follow-up, at their practice.

Therefore practices taking part will be required to write to their list of registered smokers to invite them to the study and provide a room for use by our researchers one day (or morning/afternoon) a week. All of your costs in taking part will be covered, and the study could help your patients to give up smoking.

Therefore, if you are based in the West Midlands and would like to be involved then please contact:

**Carmen Wood** (Trial Administrator)  
Email: [c.wood@bham.ac.uk](mailto:c.wood@bham.ac.uk)  
Tel: 0121 415 8019  
or  
**Dr Nicola Lindson** (Trial Manager)  
Email: [n.l.lindson@bham.ac.uk](mailto:n.l.lindson@bham.ac.uk)  
Tel: 0121 414 2657

# Current studies

## 3C Cough Complications Cohort Study

Thank you to all our currently signed up practices and clinicians in Birmingham and the Black Country (BBC) for helping to recruit over 600 patients so far!

The 3C cough study is an observational cohort study being undertaken by the University of Oxford, designed to provide evidence to predict which patients presenting with acute or worsened cough, suggestive of a lower respiratory tract infection (LRTI) are at high risk of adverse outcome, particularly pneumonia. The target is to recruit 30,000 patients across the UK by spring 2013. The reason for the large sample size is because the adverse outcome is rare; therefore, we anticipate only 75 cases of subsequent proven pneumonia.

The main analysis will estimate the predictability of adverse outcome at first presentation and the extent to which this outcome is moderated by identified cause and treatment (i.e. antibiotics). The results should allow the development of a simple clinical prediction rule to help GPs restrict prescribing to those patients who are most likely to benefit from antibiotics. Adults aged 16 years and above; and children aged 3 months and above, are currently being recruited.

Patients will be given some written information about the study by clinicians at their consultation and consented to the study. Clinicians will ask patients about their signs and symptoms and use a simple online proforma to record these and some baseline observations. A consultation summary will appear at the end of the proforma which can be copied and pasted onto the practice's clinical system. Patients will receive a questionnaire through the post after 4 weeks to complete and return, and their medical notes will be reviewed 2 months thereafter.

The study has been designed to enable practitioners to recruit patients within their standard consultation time; therefore it can be easily managed within normal surgery times.

As one of our highest recruiters in Birmingham and the Black Country Primary Care Research Network (BBC-PCRN), Dr Shukla has helped to recruit over 85 patients at Eve Hill Medical Practice. We had the opportunity to meet with him to discuss his successful recruitment strategy and his experience of participating in the 3C's study.



### In the Spotlight: An interview with Dr Shukla

Q: How have you found the 3C study?

A: Participating in the 3C study has been very interesting and it is a good one to start off with if new to research. In respect of time, I felt it wasn't a major burden and recruiting children only required a few minutes more.

Q: What method did you employ when recruiting patients?

A: I usually undertake the patients' history and examination, explain the practice is taking part in the cough complications study and then allow the patient to read through the Patient Information Sheet (PIS). As this is different to the normal routine procedure, patients are always keen and don't mind spending the extra time to answer questions. I always manage to complete the online proforma live, as I have bookmarked the website on my computer. The ability to copy and paste the summary of the consultation into the practice computer system is very useful. I usually submit the proforma after the patient has left to save them sitting around unnecessarily.

Q: How have your patients responded to the 3C study?

A: Patients are very interested and cooperative and I have found it easy to engage children/adolescents.

### Dr Shukla's hints and tips:

- The practice employ a HCA who completes the medical notes reviews and which Dr Shukla oversees
- The 3C's manual is very comprehensive and explains everything
- GP registrars at the practice are also recruiting as they have more time during consultations
- The dummy proforma is a good way to get practising
- Once you are in the habit of recruiting patients then it becomes routine

If you are interested in this study please contact us or visit the study website: [www.primarycare.ox.ac.uk/3C](http://www.primarycare.ox.ac.uk/3C)

**Sabina Yasin**  
Research Facilitator  
Tel: 0121 414 8072  
Email: [s.yasin@bham.ac.uk](mailto:s.yasin@bham.ac.uk)

**Tina Sexty**  
Administrator  
Tel: 0121 415 8730  
Email: [sextyt@bham.ac.uk](mailto:sextyt@bham.ac.uk)



## Current studies continued

### A Study Promoting the Influenza Response in the Elderly

Influenza, commonly referred to as the 'flu', is a major health concern and the recent emergence of 'H1N1 swine flu' has increased the potential for a new pandemic. Although flu-vaccination is administered every year to people over the age of 65 years, many individuals fail to achieve a protective immune response to vaccination and this problem is seen commonly in the elderly.

One reason why the elderly can develop problems with their immune system is that they carry chronic viral infections such as cytomegalovirus (CMV) which is a herpes virus that infects the majority of the UK population and it can never be cleared from the hosts. Hence the immune system has to work hard to control these infections 'diverting' them away from new infections such as 'flu'.

ASPIRE is a Medical Research Council funded randomised clinical trial, which aims to investigate the use of antiviral medication 'Valaciclovir' to suppress the CMV-infection and improve the immune response to the seasonal flu vaccination.

The study is designed in two stages, phase 1 is a single blind trial to establish the optimum dose and duration of Valaciclovir which can help the immune system recover from the CMV-infection, so it can respond better to 'flu' vaccination. Phase 2 of the study will investigate the optimum dose of the drug (from phase one) against a placebo in its ability to enhance the immune response to 'flu' vaccine in elderly subjects seropositive for CMV.

For phase one, suitable healthy individuals over 65 years old are invited for screening with an aim of recruiting 50 eligible subjects after a blood test and are randomised into five treatment groups. Following recruitment, patients attend monthly appointments for 6 months and a follow up appointment at 9 and 12 months. Blood and urine samples are taken whilst and following cessation of treatment.

The study is led by Professor Paul Moss (School of Cancer Sciences, University of Birmingham, UK) and Professor Richard McManus (Department of Primary Health Care Sciences, University of Oxford).

We are now recruiting from practices within South Birmingham. If you are interested please contact:

**Dr Rhiannon Pursall**  
Trial Coordinator  
Tel: 0121 414 4707  
Email: [aspire@contacts.bham.ac.uk](mailto:aspire@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 1 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.

The aim of ExACT is to investigate extending treatment with oral anticoagulation beyond 3-6 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. It is hoped that the study will help to establish which patients are at greatest risk of developing a recurrent clot.

We are recruiting patients, aged over 18, with a first unprovoked VTE from secondary care anticoagulation clinics, but we hope to follow them up in the primary care setting. Patients will receive brief information about the study and be given a postcard to return to the research team if willing to take part.

Patients will be 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.

This study is now well under way but we still need more patients and help from GPs. We are in touch with GPs in your area asking for help with confirmation of patient's eligibility for inclusion into the study and provision of a room for the 2 year follow up. There is a reimbursement for these services. If you are already involved please don't forget to let us know if an ExACT patient experiences any adverse events.

For more information then please contact:

**Jayne Tullett** (Research Fellow)  
Tel: 0121 415 8092  
[J.M.Tullett@bham.ac.uk](mailto:J.M.Tullett@bham.ac.uk)





# FACE TIA (Functional, Cognitive and Emotional Outcomes after TIA)

## a prospective controlled cohort study to inform future rehabilitative interventions

The FACE TIA study is a prospective, controlled cohort study of functional, cognitive and emotional outcomes after Transient Ischemic Attack (TIA). A combination of postal questionnaires and the Birmingham Cognitive Screen (BCoS) are used to assess the long term impact of TIA on patient's mood, quality of life and return to usual activities/social life.

We are pleased to report that the study has recently received additional funding from the Stroke Association and we are currently in the exciting transition from the pilot study to the main study. As a result, the recruitment timeframe has been extended to December 2013 and the total sample size for the study has increased.

Recruitment of participants began in September 2010 and has been extremely successful with

1,222 participants recruited to date. The study is now actively recruiting from 30 TIA clinics across the Central England, Thames, Yorkshire and South West. We are also actively recruiting from 19 GP practices in the same regions to provide control participants. Controls are matched to TIA patients by age, gender and geographical location (deprivation score and urban/rural classification).

### GP Practices Wanted!

We are looking for GP Practices to recruit participants to the control arm of the study. Workload for Practices is minimal and consists of a one-off search of the patient register to identify eligible patients and the sending of postal invites to selected patients. The FACE TIA research team may also periodically require a room at the practice to conduct the cognitive

screen. Each Practice will receive NHS support costs for study related workload and resource use.

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.

#### Grace Turner

FACE TIA Study Co-ordinator  
Email: [TurnerGY@bham.ac.uk](mailto:TurnerGY@bham.ac.uk)  
Tel: 0121 414 5463

#### Sheriden Bevan

FACE TIA Study Co-ordinator  
Email: [s.bevan@bham.ac.uk](mailto:s.bevan@bham.ac.uk)  
Tel: 0121 414 8593

## Helicobacter Eradication Aspirin Trial



Helicobacter eradication to prevent ulcer bleeding in aspirin users: a large simple randomised controlled trial

**Principal Investigator Birmingham Region:**  
Prof Richard Hobbs

**Locations:** ~400 GP practices in Birmingham and Black Country, Worcestershire, Coventry and Warwickshire, Shropshire, Staffordshire, Herefordshire, Stoke, Telford and Wrekin, Wolverhampton, Nottingham, Durham, Southampton, and Oxford.

**Enrolment Period:** 2012 - 2014

**Participants:** Men and women aged 60+, infected with H. pylori, who are using aspirin <326mg daily

**Other Information:** This trial has been preceded by a successful pilot study, funded by the MRC. Practices will be reimbursed for their time.

Use of aspirin for cardiovascular prophylaxis is widespread and increasing. The main hazard is ulcer bleeding. This is usually associated with H. pylori infection. It is important to determine whether this can be reduced or prevented by H. pylori eradication. The trial hypothesis is that aspirin does not itself cause peptic ulcers,

but that it promotes bleeding of ulcers caused by H. pylori. Given the scale of aspirin use, its continuing increase and its contribution to ulcer bleeding, how to deal with this problem is arguably the most important question with regard to current iatrogenic medicine.

**Intervention and Clinic:** Suitable patients will be identified by their surgery, using an automated search, and then asked to attend an appointment with a University Research Nurse or Practice Nurse (relevant training will be provided) to consent to the trial and take a H. pylori breath test. Those with a positive result will be randomised to receive a one week course of either eradication treatment or placebo, supplied by the trial centre. No follow-up visits for the patients are required, but any hospital admissions for ulcer bleeding will be recorded over a period of 2-3 years by the trial centre.

**Further Information:** If you would like to find out more, please contact:  
Rachel Iles  
Trial Manager for the region  
Tel: 0121 414 2691  
Email: [r.iles@bham.ac.uk](mailto:r.iles@bham.ac.uk)

## GARFIELD

### Global Anticoagulant Registry in the FIELD

GARFIELD is an observational, multicentre, international registry of newly diagnosed Atrial Fibrillation (AF) patients with at least one additional risk factor for stroke. The purpose is to evaluate the management and outcomes of patients with newly diagnosed non-valvular AF at risk of stroke. The registry aims to enrol 55,000 patients at more than 1000 sites in 50 countries. Enrolment will take place in five independent, sequential cohorts and patients will be followed up for two years. Enrolment to the second cohort is ongoing; and in the UK GARFIELD is currently active in 110 practices in England, Wales, Northern Ireland and Scotland.

Thank you to all the practices participating in GARFIELD. If you would like further information about the study please contact:

**Patricia Apenteng**  
Email: [p.n.k.apenteng@bham.ac.uk](mailto:p.n.k.apenteng@bham.ac.uk)



## Current studies continued



### An Epidemiological Investigation of Motor Neurone Disease

This study is addressing environmental factors that are contributing to disease in individuals with Motor Neurone Disease (MND) with a view to enhance understanding of disease mechanism and improve treatment. Professor Karen Morrison's team at University Hospital Birmingham are recruiting patients with MND from outpatient clinics to then match the patients with Controls (no MND) from general practice, for age, gender, ethnicity and geographical region. We currently have some practices in Birmingham working with us to identify the Controls and so far we have helped to recruit over 30! If your practice would also like to get involved please contact the following for further information.

**Sabina Yasin**  
Research Facilitator  
Tel: 0121 414 8072  
Email: s.yasin@bham.ac.uk



### The REFER (REfer for EchocaRdiogram) Study

A Prospective Validation of a Clinical Decision Rule, NT-proBNP, or their combination, in the Diagnosis of Heart Failure in Primary Care

Heart failure has a major impact on patients and treatment costs are high, consuming almost 2% of total NHS expenditure. Diagnosis is particularly challenging because individual symptoms and signs are generally weak predictors of heart failure. A simple clinical decision rule could aid clinical decision-making, reduce variation in practice and prevent unnecessary echocardiograms.

We have developed a clinical decision rule (CDR) to help GPs diagnose heart failure earlier. Patients will benefit from earlier diagnosis and more appropriate referrals to Echo services should reduce demand and save substantial NHS costs.

This study aims to validate the performance of the CDR, a natriuretic peptide assay, or their combination, for diagnosing heart failure in primary care and determine if the CDR can be used in routine clinical practice to establish referral for echocardiography in patients presenting with symptoms suggestive of heart failure.

### OTCH

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

Care home and participant recruitment into the NIHR HTA-funded OTCH trial has now closed, having recruited 1055 participants. Three month assessments are complete and six and 12 months are ongoing. Occupational therapists have completed their work in the intervention homes and are now 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.

We would like to thank everyone involved in the OTCH trial for their help and contributions to date and for their continued support during the follow-up period.

We would all like to send our congratulations to Katie Stant on the birth of her daughter Isabel.

For more information about OTCH, please contact:

**Sheriden Bevan**  
OTCH Trial Coordinator  
Telephone : 0121 414 8593  
Fax : 0121 414 3759  
Email : S.Bevan@bham.ac.uk



Practices in Birmingham and Solihull are participating and enrolling consecutive primary care patients aged 55+, presenting with new onset symptoms suggestive of heart failure (i.e. breathlessness, lethargy or ankle oedema of over 48 hours duration). Patients then undergo structured clinical assessment, within seven days, and have an Echocardiogram, ECG, NT- pro BNP and creatinine performed and reported.

Patient assessment clinics and surveillance will be conducted between May 2011 and December 2013 at practices in Edgbaston, Aston, and Sutton Coldfield.

**At the present time the study is recruiting Birmingham and Solihull practices only (BEN, HoB, South Birmingham, and Solihull PCTs).**

For further study information please contact:

**Dr Lynda Tait**  
Research Manager  
Tel: 0121 414 8584  
Email: l.tait.1@bham.ac.uk

**Rachel Iles**  
Research Coordinator  
Tel: 0121 414 2691  
Email: r.iles@bham.ac.uk

# Size matters for sarcomas!

Soft tissue sarcomas present as a soft painless lump in virtually any part of the body. Approximately 2,000 patients are diagnosed with soft tissue sarcomas each year, with average survival currently 50% at five years. Patient prognosis and survival are closely linked to the size of the sarcoma at diagnosis, with smaller lumps being easier to treat effectively, leading to better patient outcomes. However, there are significant delays in diagnosis, with patients often reporting having seen their GP several times before suspicion of sarcoma was raised. Such delays mean that the average size of a soft tissue sarcoma at diagnosis is around 10cm. If the size of tumour at diagnosis was less than 50mm (around the size of a golf ball), it is estimated that cure rates would improve by at least 20%.

Sarcoma UK, in collaboration with the Royal Orthopaedic Hospital and the University of Birmingham are currently undertaking a 12-month feasibility



study within Birmingham to try and reduce the size of soft tissue sarcomas at diagnosis. The study is focused on raising awareness of lumps and bumps that may indicate sarcoma, by sending a golf ball prompt and brief written information intervention to all GPs in Birmingham. It is hoped that this intervention will facilitate earlier referral to the specialist sarcoma diagnostic clinic at the Royal Orthopaedic Hospital, and allow earlier sarcoma detection.

If you would like further details about the research, please contact:

**Dr Sarah Damery**  
Tel: 0121 414 3343  
Email: [s.l.damery@bham.ac.uk](mailto:s.l.damery@bham.ac.uk)



## STOP-CKD

Spironolactone to Prevent Cardiovascular Events in Early Stage Chronic Kidney Disease: A Pilot Trial (STOP-CKD):  
Call for collaborating practices.

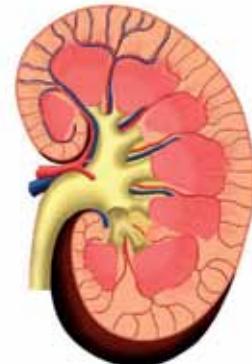
STOP-CKD is a double-blind placebo controlled randomised pilot study. We are looking for practices to collaborate with us to examine the effect of spironolactone in Chronic Kidney disease (CKD) patients on arterial stiffness, an important predictor of cardiovascular disease. If successful this would be important as CKD at least doubles the risk of cardiovascular disease.

Increased arterial stiffness is shown to be a crucial change in CKD and is strongly associated with cardiovascular mortality and morbidity and this risk factor and left ventricular (LV) hypertrophy are present in CKD patients independent of good blood pressure control. We have already shown in secondary care that spironolactone therapy in early CKD patients safely and effectively reduces LV mass and arterial stiffness.

As early CKD is common and most patients never attend a renal clinic, we wish to assess whether spironolactone reduces arterial stiffness in CKD stage 3 patients recruited in primary care and assess the safety of this drug, for example the rates of hyperkalaemia and deteriorating renal function. In addition, we will also evaluate patients' and healthcare

professionals' attitudes towards such treatment as a prelude to a much larger trial with clinical end points (cardiovascular events). This is a collaborative study between the PC-CRTU at the University of Birmingham and the Department of Nephrology at the Queen Elizabeth Hospital. As spironolactone is off patent and therefore of no interest to the pharmaceutical industry, we have gained funding for our study from the National Institute of Health Research (The NHS Research Funders).

We aim to recruit 240 non-diabetic patients aged over 18, with CKD stage 3. Patients will be randomised to receive either spironolactone 25mg once daily or inactive placebo and will be in the trial for 11 months. The patients will have regular monitoring of blood pressure, serum potassium, kidney function and proteinuria. All monitoring will be carried out by our research team that is led by Consultant Nephrologist, Dr Charles Ferro and Professor Richard McManus a local general practitioner, supported by two clinical nephrology registrars, Dr Khai Ng and Dr Poorva Jain, and a primary care research nurse. Participating practices will have the opportunity to have practice based renal workshops.



We are now recruiting practices within South Birmingham to participate in this important study. If your practice is interested and would like any information about the study, or would like to take part, please contact the team:

Email: [stopckd@contacts.bham.ac.uk](mailto:stopckd@contacts.bham.ac.uk)  
Tel: 0800 9230329  
Post: STOP-CKD research team, PC-CRTU, Primary Care Clinical Sciences Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT.

## In follow up

The TASMIN-SR study is now into the last 6 months and final follow-up clinics are starting to be completed. 59 surgeries nationwide are involved with this study and currently our follow up response averages 81%. This response rate represents a lot of hard work from all the surgeries and researchers

involved in the study and we would like to extend our sincere thanks and gratitude. We really appreciate efforts that colleagues are taking to see participants and keep them engaged with the study. Please keep up the good work for the final stretch. Results will be available in 2013.



## Preliminary findings

### CLAHRC-BBC Theme 7: Optimisation of the Management of Stroke and TIA

The NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRC) for Birmingham and Black Country is one of nine pilot CLAHRCs funded by the National Institute for Health Research (NIHR). CLAHRCs have been established to undertake high-quality applied health research focused on the needs of patients and to support the translation of research evidence into practice in the NHS.

**Theme 7: Optimisation of the Management of Stroke & Transient Ischaemic Attack (TIA)** is a longitudinal observational study with the aim of identifying current barriers to timely and effective treatment so that people in Birmingham who develop a stroke or TIA are optimally treated. Patients are being recruited from participating hospitals and GP practices. In order to link their stroke patient pathway, identifiable data from consented patients is being collected from records held in primary, secondary care and also the West Midlands Ambulance Service NHS Trust.

We would now like to share with you preliminary results from our research to date which relates to the hyperacute stroke pathway. The following groups of patients had significant delays in receiving optimum treatment:

- Patients who first contacted their GP (none of our patients in this group received thrombolysis)
- Patients who did not attend the hospital via the emergency services (i.e. calling 999)
- Patients who were FAST negative or where a FAST score was not completed
- Patients who did not have a documented symptom onset time

Delays in receiving treatment following the onset of stroke symptoms, especially thrombolysis (within 4.5 hours), result in a reduced quality of life for patients, higher treatment costs and a greater burden on families and healthcare services over the long term.

As a consequence of these preliminary findings, we are in the process of obtaining approval to set up a sub-study to understand how GP reception staff recognise and respond to patients with stroke symptoms. Further details about the RECEPTS study can be found elsewhere in this newsletter.

We wish to thank our partners, staff, Patient and Public Involvement representatives and patients who continue to support this project:

University Hospitals Birmingham NHS Foundation Trust,  
Heart of England NHS Foundation Trust,  
Sandwell and West Birmingham Hospitals NHS Trust,  
West Midlands Ambulance Service NHS Trust,  
South Birmingham PCT,  
Birmingham East and North PCT

Work will continue until 30 September 2013 and we will continue to keep you informed of our progress.

For more information about this project, please follow the link on the CLAHRC-BBC website [www.clahrc-bbc.nihr.ac.uk](http://www.clahrc-bbc.nihr.ac.uk)

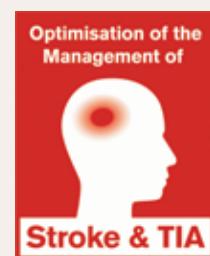
This article presents independent research funded by the National Institute for Health Research (NIHR) Collaborations for Leadership

in Applied Health Research and Care for Birmingham and Black Country. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

#### Publications:

BMJ Open. 2012 Jun 25;2(3). pii: e001430. doi: 10.1136/bmjopen-2012-001430. Print 2012. Protocol for an observation and implementation study investigating optimisation of the management of stroke and transient ischaemic attack (TIA). Sheppard JP, Mellor RM, Bailey SM, Barton P, Boyal A, Greenfield S, Jowett S, Mant J, Quinn T, Singh S, McManus RJ; on behalf of the BBC CLAHRC Investigators. Department of Primary Care Clinical Sciences, University of Birmingham, Birmingham, UK.

**Mrs Sheila Bailey**  
Project Officer  
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Tel: FREEPHONE 0800 408 9970





# Completed Studies

## BP-Eth

### Blood pressure Monitoring in Different Ethnic Groups

BP-Eth a mixed observational study completed in May 2012. The study was funded by the National Institute of Health Research, Research for Patient Benefit Programme (NIHR RfPB) to investigate variations in different measures of blood pressure amongst ethnic minorities.

BP-Eth recruited 720 participants from GP practices across Birmingham Black Country, Wolverhampton and Coventry, making it one of the biggest blood pressure studies in the UK comparing office, ambulatory and home monitoring blood pressure readings. The study will provide important new evidence regarding the comparability of the thresholds for diagnosis and monitoring of hypertension between White British and minority ethnic groups (South Asian, Afro-Caribbean and White Irish).



In addition, the completed survey responses along with the qualitative work undertaken will provide useful information about current patterns of and preferences for blood pressure monitoring by ethnicity groups. The results of the study will be available towards the end of 2012 and will be used for publications and presented in forthcoming conferences. GP practices involved in the study will be provided with posters with the findings for display in practices.

Thanks and appreciation to all the GP practices that supported the study.

Principal Investigator: **Professor Richard McManus**

## CATCH

### Constraint induced movement therapy. A randomised controlled Trial in pre-school Children with Hemiplegic cerebral palsy

Cerebral palsy is the most common cause of physical disability in children. Of those children affected, approximately one third has hemiplegic cerebral palsy and present with unilateral motor impairments. This can cause lifelong challenges to upper limb movement on the affected side of the body. Elective non-use may add substantially to the problem as children may disregard their affected hand even when the actual motor loss is mild.

Constraint induced movement therapy (CIMT) immobilises the unaffected hand and encourages mass movement practice of the affected upper limb. Experimental research with animal models and adult stroke survivors has shown that CIMT promotes functional use of the affected upper limb.

The aim of CATCH is to compare the functional outcome of the affected upper limb using two methods of CIMT. One method is prolonged restraint using a cast and bandage which is kept on for a period of time and the other brief, manual restraint. Both approaches could be transferable to current practice within the NHS.

Participant recruitment for this study which was funded by the West Midlands Strategic Health Authority has now closed having exceeded our recruitment target and recruited 62 participants. This was across

16 NHS sites. The ten-week follow-up assessments are completed and the 24 week postal questionnaires almost complete. Those participants who were randomised to the manual restraint group that requested prolonged restraint are now receiving that intervention.

A very big thank you to all of the therapists from the NHS sites for their support with the project. They not only recruited participants from their treatment databases but also carried out the intervention and supported participant follow-up.

For further information please contact

**Pauline Christmas**

Principal investigator

[p.christmas@nhs.net](mailto:p.christmas@nhs.net)



# 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](mailto:rdscentre@contacts.bham.ac.uk)

[www.rds-wm.nihr.ac.uk](http://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 primary care chronic disease management. The CPD team includes GP's, practice nurses and other health care professionals and as such we understand primary care educational requirements. We provide a wide range of CPD courses driven by demand from our students and continue to expand the subject area each year.



### Anticoagulation management in primary care

28 – 30 January, 17 – 19 June, 16 – 18 September or 2 – 4 December 2013  
£1500

This 3 day course aims to enable autonomous practice in dealing with both fundamental as well as more complex problems of oral anticoagulation management.

Learning Objectives include:

- An understanding of the theory underpinning anticoagulation management
- An understanding of the pharmacology of vitamin K antagonists and the relevant medication, side effects, antidotes, interactions and dosing
- A knowledge of the management of anticoagulation and prevention of complications on the basis of current guidelines and existing research evidence
- An understanding of the roles of the multi professional disciplinary team in managing anticoagulation safely
- An understanding of the requirements of clinical governance for anticoagulation management developing / adapting and applying audit tools with performance indicators

Lecturers include:

**Professor David Fitzmaurice**, GP and Professor of Primary Care, University of Birmingham; **Dr Will Lester**, Consultant Haematologist, University Hospital Birmingham

### Management of Hypertension in primary care

11 – 14 February 2013  
£500

This 4 day MSc accredited course is for GP's, nurses and other health care professionals aiming to acquire expertise and qualifications in Hypertension management in primary and community care.

Learning Objectives include:

- Demonstrate an 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

Lecturers include:

**Professor Gareth Beevers**, Emeritus Professor of Medicine, University of Birmingham  
**Dr Satinder Singh**, GP and Clinical Lead, University of Birmingham  
**Dr Una Martin**, Reader in Clinical Pharmacology and Consultant Physician, University of Birmingham

### Management of Heart Failure in primary care

26 February – 1 March 2013  
£500

This 4 day MSc accredited course is for GP's, nurses and other health care professionals aiming to acquire expertise and qualifications in Heart Failure management in primary and community care.

Learning Objectives include:

- 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

Lecturers include:

**Dr Clare Taylor**, GP and Clinical Research Fellow, University of Birmingham;  
**Dr Tom Marshall**, Senior Lecturer, University of Birmingham

### Management of Gynaecology in the community

22 – 24 April 2013  
£500

This 3 day MSc module is aimed at GP's and practice nurses working in the community required to develop competencies in the management of gynaecological disorders to an advanced level.

Learning outcomes include:

- Demonstrate systematic understanding of the theory and demonstrate ability to deal with complex issues underpinning gynaecological disease, prevention and management in the community
- Demonstrate knowledge of the aetiology, pathophysiology and presentation of gynaecological disorders and the diagnosis and classification of gynaecological disorders

Lecturers include:

**Dr Jennifer Byrom**, Consultant Gynaecologist, BWH  
**Dr Eki Sangha**, GP, BWH



## CPD Courses

### Understanding Haematology tests

#### – when to refer

5 February 2013

£150

This course is aimed at GP's and the following areas of haematology will be discussed; red cells and haemoglobin, white cells, platelets and coagulation, the common laboratory tests used, how to interpret them and parameters at which referral to a haematologist is indicated.

#### Learning Outcomes;

At the end of this course you will have:

- An understanding of the tests used in all areas of haematology
- An ability to interpret these results from these tests
- A knowledge of when to refer patients to a haematologist based upon abnormal laboratory test results

#### Lecturers include:

**Dr Gillian Lowe**, Clinical Research fellow and Haematology Specialist Registrar, University of Birmingham

**Dr Will Lester**, Consultant Haematologist, UHB and Birmingham Women's Hospital

**Dr Jim Murray**, Consultant Haematologist, UHB

### Oral Anticoagulation Management for Health Care Assistants and Assistant Practitioners

20 March, 10 July, 16 October 2013

£150

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 and protocol development.

#### Learning Objectives include:

- A basic knowledge of the principles of anticoagulation therapy, indications for its use, side effects and interactions
- An understanding of the principles of point of care testing, finger prick technique and quality control
- An understanding of the important components of a protocol for management of oral anticoagulation in primary care

#### Lecturers include:

**Professor David Fitzmaurice**, GP and Professor of Primary Care, University of Birmingham

**Mrs Dianne Kitchen**, Biomedical scientist, UK NEQAS for Blood Coagulation

**Dr Ellen Murray**, Senior Lecturer in Primary Care, University of Birmingham

### Management of DVT and Pulmonary Embolism within primary care

10 – 11 June 2013

£195

The course aims to provide expertise on the diagnosis and management of DVT within a primary care setting and to inform on major developments around VTE prevention for patients admitted to hospital.

#### Learning Objectives include:

- 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

### An Introduction to Oral Anticoagulation Management

2013 date tbc

£150

A 1 day CPD course for practice nurses which aims to provide an overview of the management of oral anticoagulation.



#### Learning Objectives include:

- Principles of anticoagulation therapy, indications for use, side effects and interactions
- Principles of point of care, INR testing and quality assurance
- Professional guidelines for management of oral anticoagulation, audit procedures and protocol development

#### Lecturers include:

**Professor David Fitzmaurice**, GP and Professor of Primary Care, University of Birmingham; **Mrs Dianne Kitchen**, Biomedical scientist, UK NEQAS for Blood Coagulation

**Dr Ellen Murray**, Senior Lecturer in Primary Care, University of Birmingham

**Dr Will Lester**, Consultant Haematologist, University Hospitals Birmingham



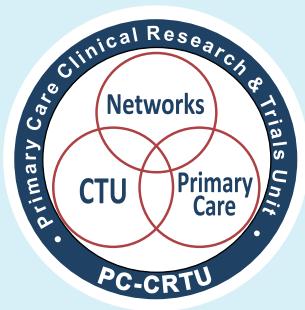
#### Upcoming courses in 2013:

- A guide to managing allergy within primary care – 17 April
- A guide to managing osteoporosis in primary care – 1 May
- A guide to the management of recurrent infections – is there an immunodeficiency? – 15 May

Details of all modules and CPD courses are available at [www.anticoagulation.org.uk](http://www.anticoagulation.org.uk) or from Amy Partleton, telephone 0121 414 2677, email [a.partleton@bham.ac.uk](mailto:a.partleton@bham.ac.uk)



# 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.

## Contact details:

Name:

Job title:

Practice address:

Postcode:

Practice code:

Email:

Your email address will only be used to send you details of studies being undertaken by the Primary Care Clinical Research & Trials Unit, Primary Care Research Network and Primary Care Clinical Sciences Department.

The Primary Care Clinical Research and Trials Unit (PC-CRTU) works in conjunction with the Primary Care Network for Central England (PCRN-CE), part of the NIHR 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 Portfolio of studies.

You can:

**Fax** back this form to **0121 414 2282** or

**Email** the details above to [pccrtu@contacts.bham.ac.uk](mailto:pccrtu@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.

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Visit our website  
[www.birmingham.ac.uk/pc-crtu](http://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