PC-CRTU *in Contact*

Issue 23 – Spring 2011

Editorial

Welcome to the PC-CRTU *in Contact* Newsletter for spring 2011.

After a long cold winter it is good to see the sun once more. The Primary Care Clinical Research and Trials unit (PC-CRTU) has been through a period of expansion over the past six months, with many new staff being recruited and trained. Some of them have profiles in this edition, the others we will introduce to you next issue. The result is that we are better able to support research activity in the region and are looking forward to a busy year.

At this time of change, with many new faces joining us, we say farewell to a familiar face, our Director Professor F D Richard Hobbs, who is leaving Birmingham after 25 years. Professor Hobbs helped establish the modern Department of Primary Care here and, having nurtured it from a fledgling, has seen it evolve into one of the premier academic departments of Primary Care in the world. He will be leaving us to take up a busy post as the Head of Department for Primary Care in the University of Oxford from mid-May 2011. We all wish him continued success there and look forward to closer collaboration between these two great departments. At the time of writing Professor David Fitzmaurice is acting Clinical Head of Primary Care. I will update you next time with any developments.

We have an expanding group of GPs affiliated to the PC-CRTU, who are tasked with engaging other GPs in medical research at a grass roots level: our GP Champions programme. This initiative was initially piloted in Dudley PCT, an area which has not, historically, been particularly engaged with research. Due to the successes of Dr Subdoh Jain and Dr Dalvinder Ratra in increasing the research profile in that area, Heart of Birmingham PCT have funded two GP Champions to work in their region. I am pleased to say that Dr Paramjit Gill and Dr Khasheen Alam took up their posts from 1 April 2011.

We are now looking ahead to a busy time as several new studies begin recruiting and we hope that many of you will become actively involved. A selection of these studies are outlined in this newsletter, please do contact the research teams directly if you are interested in taking part. Participation in all studies is entirely voluntary and making contact does not commit you to anything. I would reassure you that for any research we support, practice costs are reimbursed comprehensively via the research funding bodies and the MidReC Network.

Finally, if you have any questions about the PC-CRTU or any of the content of this publication, please do not hesitate to contact me: h.j.stokeslampard@bham.ac.uk

Best wishes
Helen Stokes-Lampard PhD FRCGP
Clinical Director of PC-CRTU

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Meet the team

Andrea Morcom is a Team Manager within Primary Care Clinical Research & Trials Unit (PC-CRTU) overseeing a team of Primary Care Network staff.

Her role at the PC-CRTU is primarily to manage the network staff that support MidReC/PCRN studies. The Network team that she oversees support largely academic studies covering a range of subjects from physiotherapy to cardiovascular studies. This support helps research teams recruit primary care sites and patients into research. Whilst all studies that are supported relate to primary care, due to the multi-disciplinary research teams that the PC-CRTU staff work with, there are cross-cutting themes allowing us to link into secondary care.

In addition Andrea takes a lead on overseeing the New Business Process for PC-CRTU. This involves coordinating new business applications and liaising with the relevant staff to ensure resources are in place to support Trials Unit and/or Network studies.

Andrea tells us what drew her to a career in primary care research
I started out doing a Medical Microbiology degree at the University of Wolverhampton. During my sandwich year I worked in a medical microbiology laboratory which sparked my interest in health research and I decided to pursue it as a career – although at the time I wasn't sure how! After graduating I went on to do a PhD at Aston University in Chemical Engineering and Applied Science, which I was awarded in 2004. At Aston I was the Biologist in a Chemical Engineering team looking at the medical applications of release mechanisms – artificial cells that release drugs in a delivered way, in this case specifically targeted towards cancer cells. In 2002, while still working on my PhD I obtained a Research Associate position at the University of Birmingham and that's what bought me to primary care.

In my Research Associate post I worked on various studies in the sexual health and cardiovascular fields. I remained within the research department for just over two years, and then moved to a Trial Coordinator position in the CRC Trials Unit. In that unit I worked as a Trial Coordinator on the aTTom study, which was a large, multi-centre, UK Cancer study which linked into a similar international study called the ATLAS trial.

In 2006 I left the University of Birmingham and went to work for a Clinical Research Organisation called SGS, which managed studies on behalf of pharmaceutical companies, for about a year. I then moved across to Quintiles, a similar company that contracts personnel out to pharmaceutical companies. In that time I worked for Novartis and Boehringer Ingelheim as a monitor, or a Senior Clinical Research Associate (CRA), monitoring clinical studies to check they were meeting regulatory requirements. I spent about four years in total in those positions. As a result of my work as a Senior CRA I took on more of a leadership role which I really enjoyed. I started to look for a position within a research setting leading a team on a day-to-day basis and returned to the University of Birmingham to take up this role as Team Manager in September 2009.

I hope to continue to bring these multi-disciplinary teams together to improve primary care research and engage primary care professionals.

There are a number of benefits for Primary Care Professionals interested in taking part in research. Not only financial benefits but also being involved in new research that will hopefully improve patient care in the future. Outside work life is busy too. I'm learning to play the flute and have just passed my Grade 1 Flute examination. I'm also into various adventure sports and outdoor pursuits.

Host Nurse Scheme

Since the start of the scheme in June 2009 we have maintained a total of seven active Host Practices and are very pleased that the scheme is now proving effective. We were sorry to lose our Host Nurse at Tudor Practice but do value the continued support of the surgery.

I would like to personally thank Tudor Practice, Riverbrook, The Wand, Bellevue, Greenridge, Grange Hill, Ridgacre and The Vitality Partnership for their help and support with the programme. I would also like to extend a special thank you to Julie Timmins, Somi Spannuth, Debbie Easlea, Susan Read, Sue Maiden, Maki Chermahini and Ann McDonald, who continue to work very hard to develop a research culture at their surgeries and support us to recruit successfully into an extensive variety of studies covering a wide range of disease areas. They are a dedicated team I am proud to be working alongside.

There has been a massive increase in identification of eligible patients for the portfolio studies across the Host Practices since their nurses came into post. Between the nurses they have identified 15,696 patients as potentially suitable for our studies, yielding 556 new study participants – an excellent 3.5% rate of conversion.

If you are interested in finding out more about the Host Nurse scheme please contact Jackie Ingram on 0121 414 4791 or email j.t.ingram@bham.ac.uk

Viewpoint on Research: The Researcher

Rachel Iles, Research Fellow at the University of Birmingham shares her daily routine with us and explains how research benefits patients and practices.

How did you get into research?
I worked at Good Hope Hospital as a cardiologist technician. When a position came up as a Project Officer at the University of Birmingham, doing echocardiography for a heart screening study, I applied and got the job. When that study finished I became involved in running the studies, rather than just doing the heart scans. I was a Research Associate, then a Research Fellow and I've been in this department ever since – this is my sixteenth year.

What kind of trials do you take part in?
I'm involved in non-clinical trials and also those involving drugs – CTIMPs (Clinical Trials of an Investigational Medicinal Product). I've got two studies at the moment that involve medication: a hypertension study and one for patients with arthritis, testing whether the drugs have any effect on cardiovascular disease. I have three others which are screening studies, they are nice and easy for the patients who don't need to do anything – they just have to have a screening. We're also looking at the prevalence of heart failure in the community.

Where do most of these studies take place?
All over the West Midlands: we have practices as far North as Stoke, around Birmingham, Dudley, Sandwell, South Staffordshire, Worcestershire and Warwickshire. We may well be getting a team in Colchester, Brighton and Hove as well to extend one study. We'll be reaching country wide.

Can you describe a typical day at work?
It's day-to-day running of the study – anything from speaking to the GPs and practice managers, dealing with queries from GPs and nurses, to arranging clinics. This morning I've been obtaining ethics approvals for an amendment to one of the studies and have had to update all the paperwork to ensure everyone is using the correct version. I spend a lot of time answering emails and queries and also do a bit of teaching. This morning I made a poster for a meeting, I'm writing a review of a paper and I'm doing a presentation for another meeting for GPs so it's quite varied. There's a lot of paperwork and problem solving – just to make sure everything runs smoothly.

How is a research study designed?
Drug studies and non-drug studies differ. The CTIMP studies need to go through a lot of regulations: there are pre-clinical laboratory-based studies, then four phases of controlled testing, ethical approval and regulated approval before a medication is used on the general population. By the time a study has reached the research department it's all usually gone through those phases and the drug has been declared safe.

With a non-drug study, you think of an idea (well that's how all studies start) and then you write a protocol explaining why you think the study would be useful, why you think it is needed and how you're going to do it. So let's say that you think of a question, eg. *A is better than B*: then you write a protocol, apply for funding, ethics and regulatory approvals. The non CTIMPs are a lot easier to design and write a protocol for, because obviously you are not putting a patient at risk.

If a patient is unsure or has questions about being in a study, what happens?
We have to make sure that the patient is fully informed about the study, so when we invite them to participate we send them a patient information sheet. Depending on the study they can be between one and ten pages long. We need to give the patients a certain amount of time to read the information through, so that they can discuss it with family and friends. If they are interested in taking part, we ask them to call back or send us a letter saying they'd like to take part. When they get to the study clinic, we go through the study again with them, asking if they have any questions and answering any questions they've got. We then ask them to sign a consent form saying they agree to participate. The consent form explains that they've had all their questions answered. If the patient decides to leave the study, they can withdraw at any point and it won't affect the way their GP interacts with them at all.

What are the benefits for practices who take part in research?
They get research experience for the practice, they can get involved. It all depends on the study, how involved they actually get – sometimes we go in and do everything for them, other times we ask for GPs to get involved. Depending on the study, practices may get improved or assisted clinical management of complex patients; they may also get access to tests that you don't usually see from primary care. In one study we're running, the patients get an echocardiogram, which they wouldn't usually get unless there was a clinical need and would have to be referred to a hospital. It might also help with gaining QOF points and may increase benefits for patients in the future, for example if we find a drug is safe or unsafe.

How do practices find out the outcomes of the study?
The results of the entire study are usually published at the end of the project. However on a day-to-day basis, if there's anything they need to know about their patients that would affect patient management, they're usually made aware as soon as possible. It wouldn't be fair to allow patients to wait.

Next issue
Viewpoint on Research: The GP

Current studies

ARTS – Attentional Bias Retraining in Smokers Attempting Smoking Cessation

Although there are effective treatments to help smokers quit, most return to smoking within a year. There are few 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.

'ARTS' (Attentional Bias Retraining in Smokers Attempting Smoking Cessation) is a randomised controlled trial which aims to explore whether computerised attentional retraining can help smokers stay quit 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.

The study has been set up in four practices within Birmingham Community Healthcare Trust and is in the process of recruiting the first set of patients. We will be rolling out the trial to additional practices and would be pleased to hear from practices within Birmingham Community Healthcare Trust. Interested practices will be asked to do two things:

- Identify current smokers from their patient records and send out letters inviting them to participate in the trial
- Provide a room one day of the week for our research nurses to provide the stop smoking clinic

We will cover the costs of your participation. Your practice can participate regardless of whether you already provide a smoking cessation service.

Please do contact us for further information on taking part:

Patricia Apenteng
Trial Coordinator
Email: p.n.k.apenteng@bham.ac.uk
Tel: 0121 414 9117

Rachna Begh
Chief Investigator
Email: r.begh@bham.ac.uk
Tel: 0121 414 3206

Blood Pressure Monitoring in Different Ethnic Groups

The National Institute of Health Research, Research for Patient Benefit Programme (NIHR RfPB) has funded a two-year study to investigate variations amongst ethnic minorities in different measures of blood pressure.

Three different methods of blood pressure measurement will be used in the study: home, office, and 24-hour ambulatory in 800 participants: 200 each drawn from the White British, White Irish, South Asian and African-Caribbean populations. Patient recruitment will be facilitated through an initial survey phase and qualitative analysis will elucidate patients' views on the different measurement modalities.

The study has been successful in recruiting a number of practices across Birmingham and has already screened several hundred individuals. We are particularly interested in enlisting the support of practices, in the Birmingham and Black Country area and Wolverhampton, who have a high ethnic minority population including White Irish, South Asian and/or Afro-Caribbean people.

The study is observational with no intervention, hence this is a great opportunity for practices that have previously been cautious about undertaking research, as well as suiting those familiar to undertaking research at their practice. It involves minimal work for practice staff and GPs.

The use of 24-hour ambulatory monitoring can help to improve the clinical management of hypertensive patients and all participants receive a comprehensive report of clinical findings which can aid QOF targets. With the new NICE guidelines recommending out of office measurement in the diagnosis of hypertension, this study can help you get ahead of the game.

If you are interested in the study, please contact us for further information.

Principal Investigator
Professor Richard McManus

Gurdip Heer
Research Nurse
Email: g.k.heer@bham.ac.uk

Amanpreet Johal
Research Facilitator
Email: a.johal.1@bham.ac.uk

Ramandeep Kaur
Study Administrator
Email: r.kaur.3@bham.ac.uk

Optimisation of the Management of Stroke & Transient Ischaemic Attack (TIA)

Part of the NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) for Birmingham and Black Country.

Optimal treatment of people suffering Stroke or TIA results in improved recovery and health outcomes. This study aims to identify barriers to timely and effective treatment by gathering information about symptoms and management of Stroke and TIA. Data will be collected from two Birmingham Hospitals (UHB and Heartlands), West Midlands Ambulance Service and local GP practices. Analysis of this data will allow service changes to be modelled and likely effects of these changes predicted.

Data collection for this study is now well underway. We are keen to invite practices from within BEN PCT referring patients with Stroke or TIA to Heartlands and/or UHB Hospitals, to participate. Workload for practices will be minimal and involves facilitating a search of records to identify patients who have had a Stroke or TIA. The study team will support practice staff to mail research invitations to those patients meeting our selection criteria.

Your practice can benefit from being included within our study as it is our aim to offer feedback in whatever way is most useful. This could include helping populate your QOF figures or identifying any instances of miscoding in your Stroke or TIA patient records. You are assured that all data generated in this way will be kept completely confidential between the study team and your practice.

The study invite will request permission from the patient to access and link their health records from primary and secondary care. This information, together with ambulance service records will create data on the patient pathway which will be used to identify barriers to treatment.

Results will be fed back to local care commissioners, GPs, specialists and patients in order to plan service improvements. Once interventions have been initiated we will perform repeat cycles of the investigative process to assess the impact on service improvement and patient care.

We would be very interested to hear from you if you would like to take part in this study. If you would like further details about the research please contact:

Mrs Sheila Bailey
Project Officer
Tel: 0121 414 7956
Email: s.m.bailey.20@bham.ac.uk

Principal Investigator
Professor Richard McManus

Metronome cued walking after stroke

Phase shifts in metronome-cued training of hemiparetic gait

Walking speed is decreased in stroke survivors, which may limit their participation and ability to carry out activities of daily living, such as negotiating a pelican crossing. Stroke survivors also demonstrate a less symmetrical walking pattern, with differences observed between the paretic and non-paretic side for step length and step time. The use of a metronome has shown some success in improving walking in stroke patients. The use of a variable rhythm in the metronome may have benefits for adapting walking in the community, where obstacles such as kerbs may impede the natural rhythm and result in the need for correction. The research involves a series of studies in Worcester and in Birmingham, designed to investigate the use of auditory cueing in walking in hemiparetic stroke survivors. This research involves a visit to a gait laboratory that uses specialised motion capture equipment to measure joint movement during walking.

If you would like to take part in this study or would like more information about the research please contact:

Dr Rachel Wright
Study Coordinator
Email: r.wright.1@bham.ac.uk

Principal Investigator
Professor Alan Wing

FACE TIA Update

FACE TIA is a cohort study of functional, cognitive and emotional outcomes after Transient Ischemic Attack (TIA). We started recruiting patients to this study in September 2010 and are now active at nine TIA clinics and one GP practice in central England, with several more in set-up. Recruitment is going well, with over 90 patients consenting to participate so far.

The Stroke Research Network and the Primary Care Research Network have had a huge impact on FACE TIA, resulting in more than 60 additional sites nationwide expressing interest in the study. We are now in the process of rolling out the study to other areas of the UK.

Thank you to all the practices and TIA clinics that are doing incredibly well with recruitment and contributing to the overall success of this study.

For more information, please contact:

Nicola Brittle
Study Coordinator
Tel: 0121 414 5483
Email: n.brittle@bham.ac.uk

Principal Investigator
Professor Cath Sackley

PAM-PeRS
(Effectiveness of exercise as a treatment for postnatal depression)

PAM-PeRS is an NIHR-funded study which aims to assess the effectiveness of exercise as a treatment for postnatal depression. The study has been recruiting since April 2010.

Currently 65 practices from SBPCT and BENPCT are helping us to identify mothers for this study. Practices from across Sandwell, Dudley, Walsall and Wolverhampton are also now helping with recruitment – a really big thank you to all of you. If your practice is not currently taking part and you would like to, please contact us, our details are below. The time commitment for practices is minimal and we will reimburse practices for their time.

We are also delighted to be receiving referrals from Health Visitors attached to practices across the West Midlands, so please continue to encourage health visitors linked to your practice to refer into the study.

If eligible, patients could benefit from one-to-one exercise consultations in their home and regular support to exercise over six months with a female physical activity advisor.

This study will recruit until December 2011.

If you would like more information, please feel free to contact:

Ruth Blamey
Trial Coordinator
Tel: 0121 414 6891
Email: r.v.blamey@bham.ac.uk

Principal Investigator
Dr Amanda Daley

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

Heart failure has a major impact on patients and treatment costs are high, consuming almost two per cent 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 (CDR) could aid clinical decision-making, reduce variation in practice and prevent unnecessary echocardiograms.

This study aims to validate the performance of a CDR, a natriuretic peptide assay, or their combination, for diagnosing heart failure in primary care and to 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.

Twenty practices in Birmingham have agreed to participate and enrol consecutive primary care patients presenting with new and recent onset symptoms suggestive of heart failure (new onset symptoms of breathlessness, lethargy or ankle oedema of over 48 hours duration). Patient recruitment will take place in two phases: with Phase I recruitment commencing 5 May 2011; and Phase II from 5 December 2011. Patient assessment clinics and surveillance will be conducted between May 2011 and December 2013.

For further information please contact:
Deborah McCahon
Research Manager
Tel: 0121 414 6784
Email: d.mccahon@bham.ac.uk

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

OTCH is an NIHR HTA-funded trial looking at the effects of a targeted course of occupational therapy for people with stroke living in a care home. It hopes to ascertain the effect of occupational therapy rehabilitation on the resident's mobility and independence in self-care activities of daily living.

The study has been recruiting since February 2010 and there are now 11 research sites involved from across the country. Researchers are currently working with over 100 care homes and in March 2011 we exceeded 50 per cent of our recruitment target with over 450 participants recruited.

Occupational therapists are actively working with participants living in the homes allocated to the intervention arm and are supplying appropriate adaptive equipment where applicable. The follow-up assessments are continuing at three, six and 12 months with some participants due to finish in May this year.

Researchers are liaising with participant's GPs to confirm their stroke or TIA diagnosis and may be in touch with your practice for confirmation.

For more information about OTCH, please contact:

Katie Stant
OTCH Trial Manager
Tel: 0121 414 6510
Email: k.e.stant@bham.ac.uk

Rapid Reduction Trial

Reduction versus abrupt cessation in smokers who want to quit

A lot of smokers find quitting smoking abruptly a scary prospect, and would like to reduce their smoking before quitting completely. The NHS Stop Smoking Service, however, offers smokers abrupt quitting only. We carried out a Cochrane Review, which was published in 2010, to challenge the conventional wisdom that the best way to quit smoking is abruptly. The studies included in the review all compared an intervention where participants were asked to quit abruptly, with an intervention where participants reduced the amount they smoked before going on to quit. The main finding was that quit rates were comparable whichever method was used – however few trials used behavioural support and nicotine replacement therapy, as would be used in the NHS. Furthermore, there was some variation in the results, which raised concerns that reducing gradually may in fact harm the chances of success. We obtained funding from the British Heart Foundation to run a trial where we compare reducing to abrupt quitting. If we show that reducing is just as good, it may encourage many reluctant quitters to give it a go and increase the number that try to quit.

We call the trial the Rapid Reduction Trial (RRT). Like the studies featured in the Cochrane Review the trial compares an abrupt and a gradual quitting method, whilst providing participants with nicotine replacement therapy and behavioural support both before and after a quit day. It will add substantially to the evidence in this area. The trial has been underway since July 2009 in South Birmingham, Solihull, Worcestershire and Warwickshire PCTs and has recently extended into Dudley, Sandwell and Heart of Birmingham. We are still looking for practices interested in helping their patients to quit smoking and we will contact practices in Walsall PCT to help reach our recruitment goal. We aim to recruit 700 participants, and currently have 424 (March 2011). A strong recruitment drive this year is necessary for us to finish in the required time.

Interested practices need to be prepared to send out a letter to their patients registered as smokers encouraging them to join the trial.

You will also need to provide the use of a room in the surgery where our research nurses will see your patients on a regular day or half day each week. We will reimburse your time and postage costs. The nurse will run clinics for your patients and provide the nicotine replacement therapy that they will use.

If you are interested in getting involved in the Rapid Reduction Trial then please contact:

Mike Healy
Trial Manager
Tel: 0121 414 6422

Full Review available at: Lindson N, Aveyard P, Hughes JR. Reduction versus abrupt cessation in smokers who want to quit. Cochrane Database of Systematic Reviews 2010, Issue 3.

SCOOP Study
Screening of older women for prevention of fracture

Follow-up data collection is continuing for the SCOOP study. The study (funded by the MRC and ARC) aims to assess whether a community-based screening programme for osteoporosis reduces the incidence of fractures in older women in a manner that is cost-effective, and acceptable to women and GPs.

Follow-up questionnaires are being sent to study participants on an annual basis, and the response rate from Birmingham has been good with 94 per cent of questionnaires being returned. Participating GPs have also been assisting in providing additional follow-up data collection. This will continue over summer 2011 and on an annual basis until the end of the study.

We would like to thank everyone for their continued support during the follow-up period.

For further information about SCOOP please contact:

Katie Stant
Tel: 0121 414 6510
Email: k.e.stant@bham.ac.uk

New studies

3C Cough Complications Cohort Study

Recruitment of practices in South Birmingham and Dudley is already underway and the study will be rolled out to practices across Birmingham and the Black Country in the next few months so watch this space!

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. At least 30,000 patients across the UK will be recruited and we would like a significant number of those to come from the West Midlands. The large sample size is necessary because adverse outcome is uncommon – for example, 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 (ie. 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 are currently being recruited and recruitment will be extended to children aged three months and above within the next few months.

Patients will be given some written information about the study by clinicians at their consultation, prior to providing consent for their participation in 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 four weeks to complete and return and their medical notes will be reviewed after two months.

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.

Congratulations to Maypole Health Centre and Northfield Health Centre for being our first two practices to recruit to this study! A big thank you to them and keep up the good work!

If you are interested in taking part in this study please visit the study website: www.primarycare.ox.ac.uk/3C

Or 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

The Active Women Study

Effectiveness of exercise as a treatment for menopausal hot flushes and night sweat symptoms

The Active Women Study is an NHS-funded study that aims to assess the effectiveness of exercise as a treatment for menopausal hot flushes and night sweat symptoms. To date 12 practices from Solihull and BEN PCTs have agreed to help us recruit menopausal aged women for this study – a big thank you to all the practices that have agreed so far, we really appreciate your support. We have just started recruiting, so those practices that have already agreed to help us can expect to hear from us again in the near future. This study will continue to run for the next 12 months, so if your practice is willing to help us recruit, please get in touch.

The practice workload for this study is minimal. We will ask you to generate a list of women in your practice who are between the ages of 48 and 57 and mail a study invitation letter and screening questionnaire to these women on two occasions. Those patients wishing to take part in our study will be asked to return a reply slip and questionnaire to the research team. We will pay practices a set-up fee and reimburse you for the time involved with helping us to screen these women. If eligible, your patients may benefit from one-to-one exercise consultations in their home and receive regular support to exercise over six months with a female physical activity advisor.

If your practice would like to take part or would like more information, please contact:
Dr Adèle Thomas (Trial Coordinator)
Tel: 0121 414 2666
Email: a.thomas.2@bham.ac.uk

Principal Investigator
Dr Amanda Daley

The Sociology of Prescribing

The Department of Pharmacy and Pharmacology at the University of Bath is looking for pharmacist prescribers working in a primary care setting, to take part in a study looking at the way different prescribing groups communicate with patients about medicines.

The study team is keen to hear from pharmacists in Birmingham and the Black Country who are currently running clinics as independent prescribers in primary care.

Participation in the study would mean that we ask pharmacist prescribers to audio-record approximately ten of their patient consultations that involve a discussion about medication. Consenting patients would also be asked to complete a questionnaire about their consultation. All information about you and your patients will be anonymised and kept confidential. We will also be able to offer you individualised feedback at the end of your involvement.

The patients will be approached by one of our researchers in the waiting room only if they have accepted information about the study from the receptionist. The patient will then receive more information from one of our researchers who will consent them into the study.

The study has been adopted on to the NIHR PCRN portfolio. The study has R&D approval for HOBT, Dudley PCT and BEN PCT and is ready to start.

There will be reimbursement for the practice's/pharmacy's participation.

If you are interested, or know someone who might be, and would like more information, please contact:

Deborah Popoola
Research Facilitator
Tel: 0121 414 4839
Email: d.a.popoola@bham.ac.uk

ExPeKT

An exploration of current knowledge and barriers to VTE prevention

Little is known about the role of primary care in thromboprophylaxis and the information high-risk patients receive prior to hospital admission or after discharge. The majority of VTE episodes occur days or weeks after a patient has been discharged from hospital. Primary healthcare professionals initially responsible for patient care often remain unaware that a patient has experienced an event. Coordinated care and the integrated management of thromboprophylaxis between hospital and the community are essential.

The National Institute for Health Research (NIHR) has funded a study to explore existing knowledge and the perceived role of primary care in thromboprophylaxis. The research aims to identify barriers to providing thromboprophylaxis in primary care and the results will be used to develop educational initiatives to help the adoption of safe practice outside the hospital setting. Primary health care professionals, patients, acute trusts and other relevant organisations will be recruited to take part in the study.

This mixed methods study is being conducted in conjunction with Oxford University and recruitment will take place in the Oxfordshire and South Birmingham regions. Patients will be recruited from medical, surgical and orthopaedic wards at Oxfordshire Radcliffe Hospitals, Nuffield Orthopaedic Centre Oxfordshire, Queen Elizabeth Hospital Birmingham and the Royal Orthopaedic Hospital Birmingham. Patients will be surveyed regarding their attitudes to receiving thromboprophylaxis and their awareness, knowledge and experience of VTE risk and assessment at each stage of their engagement with VTE prevention. A sample of patients will be invited to take part in an interview.

A purposive sample of consultants and registrars in the acute trusts and representatives from relevant organisations will be interviewed to explore the interface between primary and secondary care in terms of VTE prevention.

General practitioners and practice nurses in Oxfordshire and South Birmingham PCTs will be invited to complete a survey to assess their current use of VTE risk assessment and thromboprophylaxis, assess how they provide VTE risk and management education, and explore perceived financial or clinical barriers to use of VTE risk assessment. A sample of GPs will be invited to take part in an interview.

The research is expected to begin in April 2011 with the interviews of voluntary organisation personnel followed by a pilot trial of the questionnaire at the Nuffield Orthopaedic Hospital in Oxford.

If you would like further information or would like to contribute to the study please contact:
Lorraine McFarland
Email: l.a.mcfarland@bham.ac.uk

Jo Leggat, Project administrator
Email: j.leggat@bham.ac.uk

A Study Promoting the Influenza Response in the Elderly

ASPIRE

Flu is a major health concern and although the flu vaccination is given every year to people over the age of 65 years, a lot of people make a poor immune response to the vaccine.

It is now clear that one reason why older people can develop problems with their immune system is that they carry chronic viral infections such as cytomegalovirus (CMV). The immune system has to work very hard to control these infections and this 'diverts' them away from new infections such as flu.

ASPIRE is an MRC-funded study to explore the use of an anti-viral drug that is often used to treat diseases such as cold sores, to dampen down CMV and therefore allow the immune system to recover from fighting the virus. We anticipate that the efficiency of the immune response will then improve and make a stronger response to flu vaccination.

In the first part of the study we will find the dose of drug that is most effective in this effect and see how long it needs to be taken for. In a second section we will use this dose in a large cohort of elderly donors who are receiving their influenza vaccine. We will therefore test if this intervention is effective. If proven, this form of treatment could be valuable in a wide range of clinical conditions and help to promote healthy ageing.

We are looking to recruit practices within South Birmingham PCT who are prepared to write to, and invite, their patients to join the study. Any costs in doing so will be covered by us. We hope to start recruiting in May 2011.

If your practice would like to take part or would like further information please contact:

Dr Odette Chagoury
Trial Coordinator
Tel: 0121 414 9116
Email: o.l.chagoury@bham.ac.uk

CATCH

A randomised controlled trial to compare two methods of upper limb constraint induced movement therapy to improve functional ability in the affected arm in pre-school children with hemiplegic cerebral palsy.

Cerebral palsy remains a major cause of lifelong disability, affecting approximately two per 1,000 children. Of those affected, about 30 per cent have hemiplegic cerebral palsy (HCP), a unilateral impairment, which can often lead to major difficulties with manual dexterity and upper limb, functional ability and independence. Therapists employ a number of strategies in upper limb rehabilitation, however they are poorly understood and their efficacy has been questioned. Constraint Induced Movement Therapy (CIMT), which is a combination of restraint of the unaffected limb and intensive practice with the impaired limb, has been found to be an effective intervention with HCP. However its use in the pre-school child within an NHS setting has not been evaluated. Our aim is to compare CIMT using prolonged restraint, with CIMT using brief manual restraint which may be standard practice and acts as the control. This young age group has been targeted as there may be greatest neural plasticity and minimal disruption to compulsory education.

This is a multi-centred trial and we aim to recruit 60 participants from treatment databases of participating trusts. In order to do this recruitment has been extended beyond the West Midlands to Leicestershire, London and Devon. Participants will be randomised following baseline assessments which will include two upper limb assessments and a quality of life questionnaire for parents. The intervention period will be for six weeks, offered intermittently in two-week blocks, over ten weeks. Parents/guardians and possibly pre-school workers will be expected to carry out a therapy-guided programme. The amount of intervention and compliance will be recorded by parents/guardians and therapists. The primary outcome measure which focuses on upper limb function is carried out at ten weeks from the beginning of the intervention. Assessments for longer term follow-up will be repeated at 24 weeks. The results of the trial will contribute to the evidence of the effectiveness of CIMT in the pre-school child with HCP, and will also provide evidence on the implementation of CIMT delivery within current NHS therapy services.

Currently there are seven sites recruiting participants, of which eighteen have carried out baseline assessments and been randomised, and two have completed the ten-week follow-up assessments. Recruitment has been extended to an additional seven sites and it is intended that the recruitment period will continue for a further nine months.

For more information about CATCH, please contact:

Pauline Christmas
Email: p.christmas@nhs.net

CREDIBLE

CREDIBLE
ColoRectal cancer Early Diagnosis: an Information Based Local Evaluation

New scoring system helps GPs diagnose colorectal cancer

New research has developed a symptom-scoring system to identify patients with suspected colorectal cancer. The scoring system works significantly better than the existing NICE urgent referral guideline.

Researchers at University of Bristol and University of Birmingham used a large database of electronic primary care records to see which of three symptom-scoring systems was best at correctly identifying patients with colorectal cancer. They found that their newly-devised symptom-scoring system (the Bristol-Birmingham equation) performed best, closely followed by the CAPER score. Both scoring systems were much better than existing NICE guidance on urgent referral. NICE guidance was particularly poor at identifying colorectal cancer in patients aged under 50.

The results are important because they show that GPs still need to use their clinical judgement and not to rely solely on NICE guidelines. This is particularly the case with younger patients. They also show that existing guidelines could be greatly improved.

Dr Tom Marshall, the lead researcher, said: 'Our symptom scoring systems work better but they are too complicated for GPs to apply in a normal consultation. We need to programme these rules so that patients can be identified automatically from electronic medical records.'

A further research study is planned to do exactly this. The CREDIBLE study (ColoRectal cancer Early Diagnosis: an Information Based Local Evaluation) will get underway this year. This study, funded by the National Awareness and Early Diagnosis Initiative, will investigate the feasibility of using software to identify patients needing urgent referral for suspected colorectal cancer. The plan is to run the software weekly in practices and identify whether any patients meet referral criteria. The practice can review the patients' records, invite the patients for consultation or refer if there is a genuine need. The researchers will follow up identified patients to find out how many turn out to have cancer, polyps or other diagnoses.

A software company, MSDi has already added the symptom-scoring systems to its Clinical Manager software. Another company, Health Intelligence, will include the symptom scoring systems in its CDRIntell software in the near future. The software is expected to identify about one patient a week in a practice of 6000.

Dr Marshall said: 'It is not enough for us to develop a better scoring system. We have to find a practical way of making it work. That is why we want GPs to get in touch if they would like to take part.'

For further information, please contact:

Dr Tom Marshall
Senior Lecturer in Public Health
Email: t.p.marshall@bham.ac.uk

ExACT

Ex ACT

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 ten per cent per annum irrespective of the duration of warfarin therapy. This suggests that some patients should continue warfarin in the long-term, but 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 recruiting patients, aged over 18, with a first unprovoked VTE from both primary care and secondary care anticoagulation clinics. Patients will receive brief information about the study and be given a postcard which they should return to the research team if they are 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.

If you are interested in getting involved with this study please contact:

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

RedGP

Public policy and clinical treatment in tobacco addiction in the UK has focused on cessation – an abrupt attempt to stop all cigarettes. However, most other addictions are not treated this way and recent evidence suggests that allowing more gradual withdrawal from tobacco or even permanent partial substitution by nicotine replacement therapy (NRT) could lead to net benefits to public health. However, the benefits of smoking reduction policy are currently unknown: the effects of such policy need to be tested in a defined population.

In this trial, we are investigating whether providing a treatment programme for people who are not ready to quit will enhance or reduce overall smoking cessation rates. We also propose to examine whether GPs and their medical team can be trained to implement a reduction programme, how well they do so, and how this is received by smokers and by their primary care teams.

The group of interest are adult patients who are suffering from chronic diseases caused or exacerbated by smoking, as defined in the quality and outcomes framework (QOF). The conditions of interest are: ischaemic heart disease, hypertension, diabetes mellitus, stroke, asthma, COPD, chronic kidney disease, schizophrenia, bipolar disorder, and other psychoses.

Two general practices will be randomised to intervention and two to control. Control practices will advise abrupt cessation as normal. Intervention practices will advise smoking reduction and offer pharmacotherapy and behavioural support for smoking reduction. General practices are asked to record the number of populations of interest that are offered smoking reduction programmes, the number that take up the offer, the number of behavioural support visits made and the number that complete reduction programmes.

The trial is funded by the Heart of Birmingham PCT. We have now recruited our sites and the trial will commence shortly.

For more information about the trial please contact:

Taina Taskila
Chief Investigator
Tel: 0121 414 8580
Email: t.k.taskila@bham.ac.uk

Completed studies

PRISM II

Recruitment for Phase II of the PRISM study came to a close on the 15 April 2011. This randomised controlled trial sought to ascertain whether using rapid near-patient throat swabs to detect bacterial infection was the best way of deciding which patients would benefit from antibiotics. This was compared with using a clinical score to determine antibiotic prescription or delaying a prescription for five days (for collection if symptoms did not settle). Once assigned to a treatment arm, patients were asked to complete a diary over the duration of their illness: notes reviews were also carried out to provide the data required.

A big Thank You to all the practices who took part in PRISM II for their time and commitment which has resulted in the study being such a success.

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
13–15 July, 12–14 September or 28–30 November 2011

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.

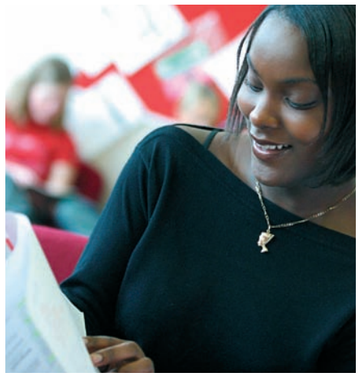
Management of Gynaecology in the community
8–10 June 2011

This three-day CPD-accredited module is aimed at general practitioners and practice nurses working in the community who are required to develop competencies in the management of gynaecological disorders to an advanced level.

Faculty includes: Professor Janesh Gupta, Dr Jennifer Byrom and Dr Eki Sangha

Learning outcomes:

- Demonstrate systematic understanding of the theory and demonstrate ability to deal with complex issues underpinning gynaecological disease, prevention and management



- Demonstrate knowledge of the aetiology, pathophysiology and presentation of gynaecological disorders
- Evaluate critically the management of gynaecological disease and prevention of long-term complications according to current guidelines
- Explain the roles of the multidisciplinary team in gynaecological disease care to improve health outcomes
- Manage gynaecological disorders in the community safely and effectively
- Demonstrate an understanding of the requirements of clinical governance for gynaecological conditions, their management, developing audit tools and performance indicators to ensure services are being delivered to an acceptable standard.

Prescribing: scientific principles and practice
2011–12 dates TBC

This 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 for those who do not necessarily prescribe but are involved with a medicines management process.

Faculty includes: Professor John Marriott and Professor David Fitzmaurice

CPD Courses

Anticoagulation in Practice 2011 conference
26–27 May 2011

GPs, practice nurses, biomedical scientists, pharmacists and patients are all invited to attend Anticoagulation in Practice 2011 at the Wolfson Centre, the Medical School, University of Birmingham. The programme has been designed to present the latest developments in haemostasis and thrombosis.

Oral Anticoagulation Management for Health Care Assistants and Assistant Practitioners
18 May, 21 September or 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
27 June 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
11–12 July 2011

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

Faculty includes: Professor David Fitzmaurice, Mrs Rachel Iles, Dr Chris Arden and Dr Andreas Wolff

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

Liver disease in primary care
13–14 October 2011

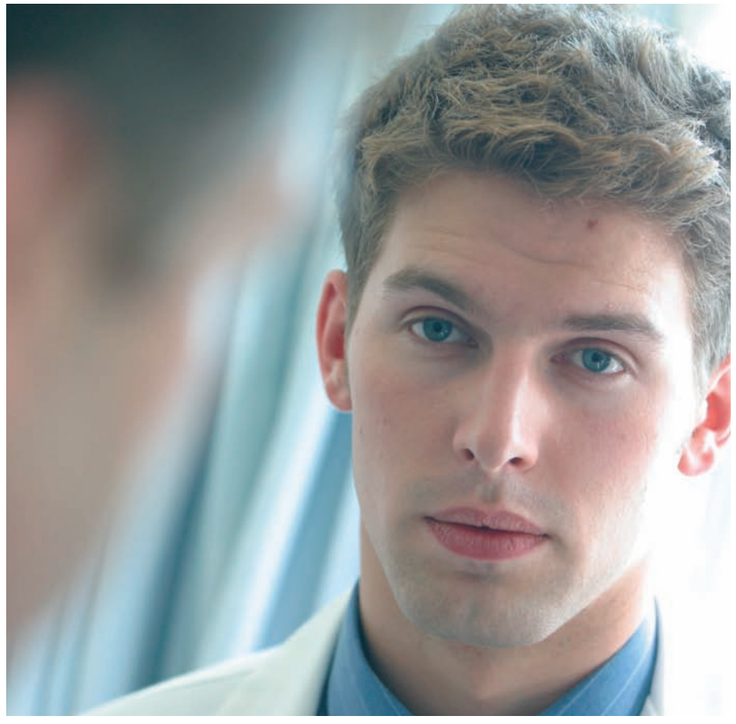
A two-day mini-conference organised in conjunction with Dr Phil Newsome, Senior Lecturer in Hepatology, University of Birmingham and Honorary Consultant Hepatologist, QE Hospital Birmingham.

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

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



Do you want to take part in research coordinated by Birmingham, Keele or Warwick Universities? Let us know by completing the form below.

Reply slip

Birmingham, Keele and Warwick Primary Care Research networks are now working in conjunction with the Primary Care Research Network for Central England (PCRN-CE). If you or your practice is interested in taking part in supported, remunerated, relevant research in Primary Care, please complete and return the form below. PCRN-CE is working with the following Topic Specific Networks. Please tick if you have a particular research interest in any of the following:

- ☐ Cancer
- ☐ Medicines for Children
- ☐ Mental Health
- ☐ Primary Care
- ☐ Obesity
- ☐ Stroke
- ☐ All of the above
- ☐ Other

Please let us know if you have a particular research interest not listed above.

Name: Practice code:

Practice address:

Postcode:

Please note: You will always be able to choose the level of involvement your practice would like to undertake. Only studies which have been independently peer reviewed and funded through national competition and commercial research asking relevant questions will be adopted by the PCRN-UK.

Please fax back to: 0121 414 2282

or post to: Suki Candler
Primary Care Clinical Sciences
Primary Care Clinical Sciences Building
University of Birmingham
Edgbaston
Birmingham, B15 2TT

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

Contact: Suki Candler, Secretary

Primary Care Clinical Sciences
University of Birmingham
Primary Care Clinical Sciences Building
Edgbaston, Birmingham B15 2TT
Tel: 0121 414 8843
Fax: 0121 414 2282
www.haps.bham.ac.uk/primarycare/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