In Contact

Spring 2015

NHS
National Institute for Health Research

Clinical Research Network
Primary Care

Primary Care Clinical Research & Trials Unit
Networks
CTU
Primary Care
PC-CRTU

Working Together for Better Health

Time Hypertensive Study
TASMINH-4
CANDID

Delivering research to make patients, and the NHS, better

NHS National Institute for Health Research

Clinical Research Network
Primary Care

Welcome

Dear Colleagues,

As interim Head of Department of Primary Care here at The University of Birmingham, I thought this latest edition of In Contact was an opportune time to say a sincere 'thank you' to all of you who are actively engaged with Primary Care research via the Primary Care Clinical Research Trials Unit (PC-CRTU) and Clinical Research Network: West Midlands (CRN:WM).

We are proud of our network of research active practices, one of the longest running and largest such groups in the world and, if you have any suggestions of how we can communicate and work better with you, we would be delighted to hear from you via email on **crn-wm@contacts.bham.ac.uk**. If you have friends or colleagues in practices that are not research active currently, please do encourage them to make contact with us as we are keen to engage with all practices.

At a time when General Practice is under huge pressure to meet rising clinical demands in a climate of falling resources, I would urge you to keep engaging with research as it is only through our joint efforts in providing the data to make evidence based improvements in care, that Primary Care will keep moving forward. It is also fascinating to be part of for patients and staff, in my experience.

You can be assured that any invitations to participate in research that you receive from us have been scrutinised and reviewed carefully to ensure that they meet the highest standards of research governance and patient safety, but if you are ever confused by an invitation, or have any questions, please do not hesitate to get in touch.

Finally, thank you for your help and support.

Best wishes
Helen

Dr Helen Stokes-Lampard PhD FRCGP
Head of Department of Primary Care,
University of Birmingham

Contents

Continuous Improvement

Dear colleagues,

As some of you may know, the Primary Care Research Network went through transition during 2013/14 to become part of the larger Clinical Research Network (CRN). The aim of the transition is to integrate the different areas of medicine, so we can keep improving our service and make it easier for our clinical teams, study teams and funders to work with us.

A year after the transition, we can now look at some of the changes that have taken place and reflect on how the CRN: Primary Care provides support, funding and infrastructure for local GP practices to engage in research. We are continuously looking to improve our offer to you and your practice and one of our latest developments is the launch of our new website. It provides information about studies that are being offered to GP practices across the Birmingham and Black Country area. The website also contains information on who we are and what we do. Please visit us and provide us with your feedback on: www.birmingham.ac.uk/crn-wm

In addition, we are developing communication pathways on social media, which we hope will increase our outreach and engagement with Primary Healthcare Providers. We will keep you tweeted and posted when these pathways have gone live.

Research Sites Initiative (RSI) scheme

One of the most exciting opportunities has been the expansion of the Research Sites Initiative (RSI) scheme. The aim of the scheme is to strengthen the research infrastructure within your practice. A key requirement for anyone involved in the conduct of clinical research is Good Clinical Practice (GCP) training. GCP is the ethical and practical standard to which all clinical research is conducted. Through the RSI scheme, the CRN will help you and your practice to access the GCP training, which increases the likelihood that your practice is selected by study teams as a research site. In return, the CRN asks you to recruit to a minimum of number of NIHR adopted studies and complete the RCGP Research Ready accreditation process. Supporting studies offered to you through the CRN, you and your practice have reassurance that a (non-)commercial study has received the appropriate NHS ethical and assurance reviews. Furthermore, your practice

will continue to receive the service support costs for conducted research activity. To date we have expanded the scheme to include fifty practices. For further information on this scheme and how to apply, please see the back page of this issue.

RSI for Community Pharmacy

In addition to expanding the RSI scheme for GP practices, we now have 53 Community Pharmacies enrolled in the scheme. The Community Pharmacies are located across Birmingham and The Black Country and have been signposting patients to four studies during the financial year 2014/15. This activity is referred to as PIC activity. For further information on PIC activity please see our website. The first PIC study to 'go live' in Community Pharmacy was the Preloading Trial; a randomised controlled trial of nicotine patch preloading for smoking cessation. The PIC activity resulted in over 25% recruitment through this pathway. The study has reached its national recruitment target of 1,786 participants. The study team will be busy following up the participants and analysing the results. Furthermore, a number of our PIC Community Pharmacies from the West Midlands were selected to participate in a recent commercial study. We hope this demonstrates the commitment of the CRN to include all Primary Healthcare Providers across the region and how your practice or pharmacy can contribute to research by acting as a PIC.

PINK is for PIC

At the CRN, we have observed a recent trend where Secondary Care study teams are inviting Primary Care to conduct PIC activity. In essence, your practice will be identifying and informing your patients about a trial taking place in Secondary Care. It is for your patient to decide if they present at the other organisation conducting the research activity. Your practice is not responsible for the subsequent assessment of potential patients and their possible recruitment into the trial or for the delivery of procedures specified in the research protocol. To streamline the process of raising awareness of PIC activity, we will send your practice an Expression of Interest (EoI) form on pink paper. Remember PINK is for PIC! We will continue to send EoI forms for research site studies on yellow paper.

Research Champions

In the last year, we have been able to welcome four new GP Research Champions and a Community Pharmacy Research Champion in addition to our two existing GP Research Champions. We are working with each CCG in the Black Country, Birmingham and Solihull area to establish links and raise awareness of NIHR portfolio research. Information about your local CCG Research Champion can be found on our website. Please look out for the Research Champions at your forthcoming local CCG events. Research champions can offer you advice on how you and your practice can be involved in research. Some of the Research Champions attended the regional Society for Academic Primary Care conference, which is held annually and this year was hosted in Birmingham. Over 160 Primary Care academics from across the Midlands and South West presented their recent research findings around the theme of the conference: 'Meeting the Challenges of Modern Primary Care'.

Clinical Lead

In the previous edition of In Contact we reported that Dr Liz England took over from Dr Paramjit Gill as the Clinical Lead for the central delivery team. Dr England joins the other Clinical Leads in West Midlands North and South (Dr Mark Porcheret and Dr Jeremy Dale). Dr England says:

'I am really pleased to have this opportunity to contribute to developing research in primary care. Research has often been seen as the remit of secondary care services but this does not reflect the patterns of how people consult and where people are seen. We see many patients in our surgeries but are often relying on evidence derived from secondary care, which can limit its usefulness and fail to reflect the true Primary Care experience. I now have the opportunity to help shape the research agenda and ensure primary care is fully able to contribute and develop this area.'

The CRN: Primary Care aims to continually improve how we can support you and your practices to participate in research. The CRN works with a wide range of primary care practitioners such as GPs, practice nurses, pharmacists and dentists, to support and oversee research in areas which Primary Care Practitioners have particular responsibility. These areas include health promotion and prevention, screening and the management of common and long-term conditions, amongst many others. Research is vitally important to all parts of the NHS but even more so in primary care. We know that about 90 per cent of people's contact with the NHS is in primary care and primary care remains the first point of contact for the majority of people. It, therefore, makes sense that more research should be taking place in a primary care setting to ensure that the outcomes and findings are relevant to how we work. We hope that you have found this information useful and would welcome your feedback on what you would like to see included in the next In Contact.

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Dr Liz England
Clinical Research Speciality Lead – Primary Care
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Top recruiting practice

Hobs Moat Medical Practice

Top Recruiter 2014–15

Congratulations go to Hobs Moat Medical Practices who are the Top Recruiting GP practice for 2014–15. The surgery in Solihull CCG recruited 189 patients to three studies during the last financial year. The studies included the Prevention of Fall Injury Trial (PreFIT), the COPD Screener study and the Million Women Study. In second place was Three Villages Medical Practice who narrowly missed out on the top spot by nine patients. The surgery based in Dudley CCG recruited 180 patients to Prevention of Fall Injury Trial (PreFIT), Patient self-management in primary care patients with COPD (PSM-COPD) and the Preloading Trial. In third place was Greenridge Surgery who recruited 69 patients to five studies, which included Development of the Patient Safety Toolkit for general practices, TASMINH-4, TRaCKED, the COPD Screener study and TIME.

Max Feltham, Research Manager at Clinical Research Network: Primary Care, said: 'Congratulations to our three practices on their achievement and thank you to all our Primary Care sites for supporting the NIHR's Primary Care research portfolio this year.' The Clinical Research Network: Primary Care supported 50 research studies, which recruited from 185 Primary Care sites. Max Feltham added: 'Whilst these figures are impressive, they are only one part of the picture. They do not reflect the incredible work that has taken place in practices to identify patients for the 17 studies running in secondary care studies or the follow-up activity conducted by GP practices for patients enrolled into research studies from previous years.'

Dr Liz England, Clinical Research Speciality Lead for Primary Care in Birmingham and the Black Country, added: 'The Clinical Research Network offers a range of studies to all our GP practices, which include ageing, COPD, cancer, cardiovascular disease, mental health and smoking cessation. As GPs we are specialists in 'Generalism' and so the variety of studies we are involved in reflects our actual day to day work. Research in GP practices and primary care is vital as it gives us another opportunity to engage with our patients and helps to improve patient outcome and care in a meaningful and relevant way that is primary care focused.'

Payment of service support costs

IMPORTANT NOTICE FOR PRACTICE AND BUSINESS MANAGERS

In order to process service support costs for studies, the University of Birmingham **now requires a Practice or Business Manager's email address**. Please can you ensure that the facilitation team is advised of your email address so that payments can be made in good time to your practice.

Alternatively, please contact **Hilary Percival, Finance Facilitator (h.percival@bham.ac.uk)**.

Many thanks for all your help and support with primary care research.

New studies

Rehabilitation Enablement in Chronic Heart Failure: REACH-HF

REACH-HF is a multi-centre randomised controlled trial which aims to develop and test a new self-help manual ('the HF Manual') for people with heart failure and for the family and friends that help them to manage the condition to improve quality of life. We will also measure hospital re-admission rates and the cost-effectiveness of the intervention.

The HF Manual comprises a self-help manual which patients will work through by a specially trained facilitator over a period of 12 weeks. The topics covered include a structured exercise programme, monitoring for fluid build-up, stress management, medication management and monitoring and managing heart failure. If the patient has identified a family member or friend who provides unpaid support that they couldn't manage without (ie, a caregiver) and they consent to take part, they will receive the 'caregiver resource element' of the HF manual.

This is an important study sponsored by the Royal Cornwall Hospitals NHS Trust which requires only a relatively small amount of work from practices within Sandwell and West Birmingham CCG. Once patients have been identified from primary care, the rest of the work will be taken up by the research team based at the University of Birmingham and Sandwell and West Birmingham NHS Trust led by Dr Russell Davis. Service Support costs are payable at the usual Network rate.

If your practice is located within Sandwell and West Birmingham CCG and would like to find out more, please contact:

Learn More

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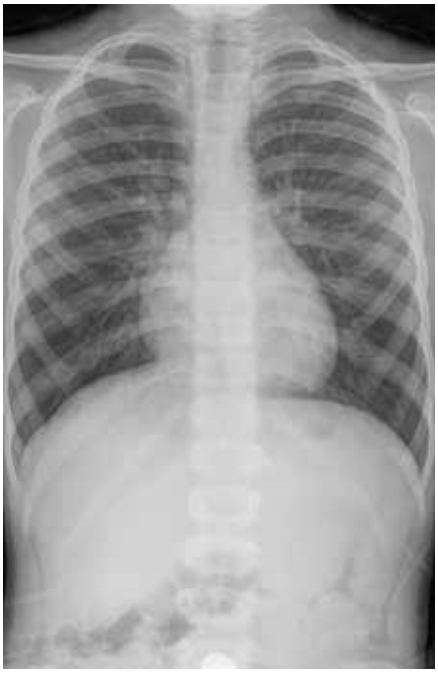
REACH-HF is an independent research programme funded by the National Institute for Health Research (NIHR)



TIME Hypertensive Study

The Treatment In Morning versus Evening (TIME) Study is funded by the British Heart Foundation. The main objective is to determine whether anti-hypertensive therapy taken in the evening has improved cardiovascular outcome compared with more conventional morning dosing. The study is trying to recruit approximately 10,000 patients from across the UK in order to find an answer to this clinically important question. Patients diagnosed and treated for hypertension (all forms) with at least one antihypertensive drug, aged ≥18 years and having an valid email address, are randomised into two groups with one group taking the treatment in the morning and the other group in the evening. Moreover, the study also regularly monitors and records the number of heart-attacks, strokes and vascular death from each group.

Practices will be asked to conduct a search to identify potentially eligible patients and the patient list will be checked by the GP for exclusions. Patient invitation letters will be sent out using DOCMAIL. There are study posters available in order to bring it to the attention of anti-hypertensive patients. Interested patients register themselves on the study secure website – www.timestudy.co.uk. They will confirm their consent and enter their personal details. All study management is done by emails between the study team and the patient, with information being updated online.
The study documents are available on the TIME website: www.timestudy.co.uk/GPRegistration.aspx

Learn More

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New studies

Do you treat patients with Complex Regional Pain Syndrome (CRPS)?

LIPS

The Low dose Intravenous Immunoglobulin in Complex Regional Pain SyndromeTrial

The National Institute for Health Research (NIHR) has been awarded funding via the Efficacy and Mechanism Evaluation programme (EME) to the University of Liverpool, to conduct a randomised controlled trial to explore the effectiveness of low dose Intravenous Immunoglobulin (IVIg) therapy in reducing pain in patients with moderate to severe Complex Regional Pain Syndrome (CRPS). The study is recruiting 108 patients over a 2.5 year period across seven specialist Pain Centres in Leicester, Liverpool, London, Cambridge, Bath, Norwich and Glasgow. Recruitment is expected to finish in December 2015.

What is the purpose of the study?

Complex Regional Pain Syndrome (CRPS) is often a distressing condition, which in many cases is difficult to treat. Many of these patients have tried numerous pain medications and treatments with little benefit to their health. Intravenous immunoglobulin (IVIG) has recently been researched as a treatment for CRSP pain. It is hypothesised that IVIG may be effective in CRPS because IVIG affects the immune system and we know that the immune system is involved in CRPS pain.

Our aim is to investigate if intravenous immunoglobulin can relieve chronic pain against a placebo infusion.

What does the study involve?

- Patients are randomised to receive either two blinded IVIg or placebo infusions three weeks apart
- All patients can consent to take part in the optional open label phase of the trial so that they receive 2 additional non-blinded IVIg drug infusions
- All patients have the option to receive the trial drug
- Patients are required to document daily pain scores within paper pain diaries for the duration of the trial

Who can be considered for participation?

- Patients with a diagnosis of complex regional pain syndrome I or II according to Budapest criteria (if you are uncertain please contact us to discuss)
- 1–5 years disease duration
- Moderate or severe pain
- Aged 18 years and above, with disease duration of between 1-5 years
- Willing and able to travel to a recruiting site (listed below)

Location of study centres?

- Patients can attend any of the seven study centres across the UK, however, Leicester is the closest centre for the Black Country Region
- All travel expenses and, if required, overnight accommodation, can be arranged and reimbursed to the patient

Andreas Goebel
The Walton Centre NHS Trust, Liverpool

Karim Shoukrey
University Hospitals of Leicester

- **Nick Padfield**
  Guy's and St Thomas' Hospital, London
- **Nicholas Shenker**
  Addenbrookes Hospital Cambridge
- **Mark Sanders**
  Norfolk and Norwich University Hospital, Norwich
- **Candida McCabe**
  Royal National Hospital for Rheumatic Diseases, Bath
- **Mick Serpell**
  Gartnavel General Hospital, Glasgow

The Low dose Intravenous Immunoglobulin in Complex Regional Pain Syndrome (LIPS) Trial is led by Dr Andreas Goebel, Consultant in Pain Medicine, Walton Centre NHS Trust and supported by the UKCRC registered King's Clinical Trials Unit in London.

Learn More

For a referral onto the study, or to find out more information, please contact
Jatinder Bisla
LIPS Trial Manager
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Email: jatinder.bisla@kcl.ac.uk

LIPS Study
UNIVERSITY OF LIVERPOOL
UKCRC Registered Clinical Trials Units
The Walton Centre NHS Foundation Trust
NHS National Institute for Health Research

Current studies

CANDID

CANcer DIagnosis Decision rules

Study aims:
An observational study aiming to identify which symptoms and examination findings are most accurate for early identification of lung or colorectal cancer and to develop clinical decision rules for the early identification of Primary Care patients at increased risk of cancer.

What GPs will be asked to do?

- Opportunistically recruit participants during consultation (based on literature, it is assumed GPs will see approx. 1–2 cases per month).
- Collect clinical information using a standardised internet-based form.
- Ask willing participants to provide a blood or saliva sample.
- Ask willing participants to complete a lifestyle questionnaire (paper or online version available).
- Two years after recruitment we will ask you to carry out a notes review of the participants consented.

Support is available if required:
Research Nurse to support clinic visits: take consent, complete the non-examination section of the CRF and take samples.

In addition to opportunistic recruitment we use an electronic patient records search (MIQUEST Query) to identify patients who meet recruitment criteria and send out invitation letters on a monthly basis. Technical support is available to set up and run the monthly searches.

We currently have 52 GP Practices participating in this study.

Learn More
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Research Coordinator
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Validation of home blood pressure monitors in patients with atrial fibrillation

This research aims to determine if automatic blood pressure (BP) monitors, already independently validated to take measurements in the home environment and shown to be amongst the most accurate in the general population, can be reliably used in patients with Atrial Fibrillation (AF).

No automatic BP monitors are currently validated for use in AF. If monitors are shown to take accurate blood pressure readings in patients with AF, the use of home BP monitoring could be recommended in this high risk group to improve the effectiveness of hypertension diagnosis and management. Home BP monitoring allows many more BP readings to be taken, and therefore might help provide a more accurate picture of the true underlying BP levels in AF patients.

The proposed research will assess the potential of home BP monitoring in AF. Validation studies of different home BP monitors in patients with AF will assess their accuracy in this population. This will include analysis of the minimum number of measurements required before we can be confident in the accuracy of the obtained BP values for AF patients. Devices will be validated against standardised protocols to ensure consistent and reliable assessment.

Eligible patients, recorded as having permanent chronic AF, will be invited to participate. The validation studies will follow the standard British Hypertension Society (BHS) and European Society of Hypertension International Protocol (ESH-IP) protocols, and will take place in the NIHR Wellcome Trust Clinical Research Facility in Birmingham, which is accredited by the BHS as a site for monitor validation, and where validation studies are regularly conducted.

We would like to invite interested practices to contact us to take part or for further information. The additional workload is minimal and service support costs to cover time recruiting patients will be reimbursed.

Study participation involves: Identification and screening of eligible patients and mailout of study invitation letter

Learn More
Dr James Hodgkinson
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Current studies

CAP

Cluster randomised triAl of PSA testing for Prostate cancer

Screening for prostate cancer continues to cause controversy because of concerns about over-diagnosis and unnecessary treatment. The aim of this study is to help policy makers decide whether Prostate-Specific Antigen (PSA) testing for prostate cancer should be introduced. We will evaluate the effectiveness of PSA testing in reducing prostate cancer mortality (ie, the number of deaths), and its cost-effectiveness (ie, comparing the health-related costs in combination with the effectiveness of PSA testing), in order to assist policy makers in their decisions about how to achieve the best use of resources. This national study is led by Prof. Richard Martin, funded by Cancer Research UK and sponsored by the University of Bristol. The study is recruiting men aged 50–69 years from over 570 GP practices in eight UK centres (incl. Birmingham).

Practice involvement

Your practice might be contacted if a patient registered with your practice has been identified to the study team based in Bristol by the Cancer Registries as having prostate cancer. The study team will seek your permission to contact the patient to ask for their consent to extract data from their medical records (principally the hospital records), so detailed research can be conducted. Your practice will be asked if the identified patient is well enough to be approached for consent – ie, they are not terminally ill or temporarily too ill. If they are well enough to be approached, the study team would like your practice to send the patient a letter and information sheet on their behalf. In this letter, the patient is asked if they will give consent for this research by post or whether they would like an appointment to discuss the study.

Reimbursement

Your practice will receive £30 per patient contacted. If the patient opts for a face-to-face consent, the study will compensate your practice for the additional GP or nurse time according to Clinical Research Network nationally agreed fees.

Learn More

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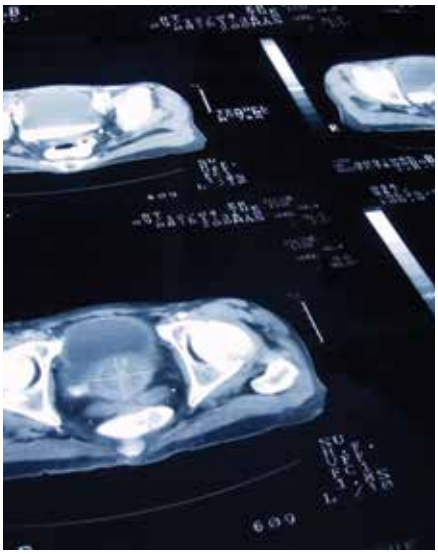

CPRD

Major new national research programme –Your participation invited

The CRN: Primary Care is fully committed to inviting all practices to join the Clinical Practice Research Datalink (CPRD), a secure, world-class, e-health research system jointly funded by the National Institute for Health Research (NIHR) and the Medicines and Healthcare products Regulatory Agency (MHRA) and we ask you to fully support this important initiative by enabling access to your practices' anonymised data for research.

Data Security and governance

Data security together with patient and practice confidentiality is of paramount concern to everyone and is CPRD's number one priority. CPRD uses the very highest standards of data security with robust information governance processes to ensure that patient confidentiality is maintained and data kept safe and secure at all times.

Sir Bruce Keogh, NHS Medical Director, and Sir Kent Woods, MHRA Chief Executive Officer who are the Caldicott Guardians of the NHS and MHRA respectively have both fully endorsed CPRD's data security arrangements.

What data is collected?

CPRD collects all coded data (diagnoses, treatments, referrals, lab results, demographics) against a CPRD identifier. CPRD **does not** receive NHS Numbers, names, addresses or postcodes.

Data Downloads & Your Practice

CPRD is working with the major GP IT systems (Vision, EMIS, TPP) on data collection. The process of downloading data to CPRD is easy and will not interfere with existing systems or the normal day to day running of a practice. Data collections will happen automatically, requiring very little input from practice staff after the initial set up. The practice will not need to add any software to its systems.

Future Developments

The CRN: Primary Care are working with CPRD to help bring online a range of innovative software tools to support the increased efficiency of clinical trials. One such tool is a programme to help recruit patients onto clinical trials from Primary Care more quickly, easily and securely, designed specifically to increase the efficiency of clinical trials and to help the CRN: Primary Care and UK as a whole remain at the forefront of medical research. Therefore, we would like all of the practices in our network to sign up to CPRD as soon as possible so Clinical Research Network: West Midlands can be at the forefront of research in primary care and joining CPRD can help do that.

Learn more

To sign up or to ask additional questions please contact:

Lucy Hughes
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Current studies

EAST

Early treatment of Atrial fibrillation for Stroke Trial

We would like to invite you to take part in an exciting new European study which is seeking to improve cardiovascular outcomes for patients with newly diagnosed atrial fibrillation (AF).

This is a **Patient Identification Centre (PIC) study** so we are simply inviting you to identify potential patients who can be invited to take part in the study. In Birmingham, the study is based around 3 secondary care sites: Heartlands Hospital, City Hospital and Sandwell Hospital. Professor Paulas Kirchof, Chair in Cardiovascular Medicine, Clinical and Experimental Medicine, University of Birmingham, is the International Principal Investigator.

The study will compare the usual treatment of AF with a management that uses early rhythm control therapy on top of usual care to explore whether earlier rhythm control has the potential to prevent strokes and other cardiovascular complications. Earlier treatment may involve the use of antiarrhythmic medicines as well as AF ablation. All treatments selected will comply with usual NHS guidance/technology appraisals and patient preferences will be discussed and agreed.

Patients will be randomly assigned to receive either usual care or early rhythm control, and followed up for a minimum of 3 years. Participants will have their travel expenses reimbursed. Recruitment to the study is currently due to end in July 2015.

Practices will be remunerated for their involvement in the study.

Learn More

If you would like to find out more about the study please contact:

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Brains in Transition (BrIT)

It is possible to identify young people at risk for psychotic illnesses such as schizophrenia through a combination of symptoms and personal or family history. Around 20% of such people develop psychosis within 12 months of being identified. There are differences in the brains of at risk cases when compared to similar participants not at risk and these differences get greater with the onset of psychotic illness. We don't yet know, however, when in the progression these changes occur. They may come before (and somehow cause) the increase in symptoms, implying that trying to prevent these brain changes could prevent the illness. The Brains in Transition (BrIT) study (funded by the Medical Research Council) will investigate the course of brain changes across the transition from being at risk for psychosis to the development of a psychotic illness, and determine if those changes can be used to predict outcome and improve early detection.

Participation in the study involves assessments of symptoms and functioning, as well as brain scans (MRI). Participants are followed for one year and receive £20 in recognition of their time and expenses each time they take part.

GP practices taking part will be eligible to receive payment via service support costs to cover the time spent identifying and mailing out to eligible patients. GP practices will be informed in writing of a patient's participation in the study.

Learn more

Brains in Transition (BrIT) team
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Current studies

EVRA

Early Venous Reflux Ablation Ulcer Trial

Simple study – ideal for novice practices!

Background:

The Clinical Research Network: Primary Care is working in collaboration with the Imperial College of Science, Technology and Medicine to assist with recruitment of patients to the EVRA study. This is a multi-centred, randomised control trial to determine the clinical and cost-effectiveness of early endovenous treatment of superficial venous reflux in patients with chronic venous ulceration. Chronic venous ulceration is a major cause of severe underlying dysfunction to the patient which results in high healthcare costs.

Recruitment:

Patients will be randomised from secondary care into 1 of 2 treatment arms to either:

- Standard therapy, consisting of multilayer elastic compression bandaging/stockings with deferred treatment of superficial reflux or
- Early endovenous treatment of superficial venous reflux (within 2 weeks) in addition to standard therapy.

All patients are seen in an out-patient clinic at 6 weeks and examined, in addition to monthly telephone follow-ups to document resource use for the health economic analysis and monitor patient safety. Four weekly ulcer healing verification visits are performed upon notification of healing. These will be performed by the secondary care research staff. The trial aims to recruit **500 patients by January 2016**.

Practice Involvement:

Practices will be asked to display posters and distribute leaflets for the EVRA study to patients with leg ulcers between 6 weeks and 6 months duration.

We are particularly interested if your practice refers leg ulcer patients to either:

- University Hospital Birmingham NHS Trust
- The Dudley Group NHS Trust (Corbett, Guest & Russells Hall hospitals)

Learn More:

If you are interested in taking part, please contact:
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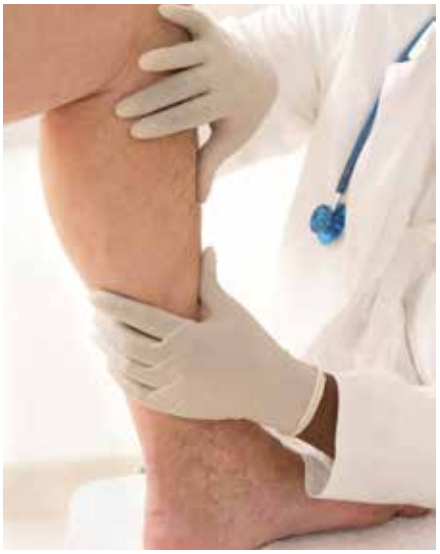
Research Facilitator, CRN: Primary Care
Tel: 0121 414 8072
Email: s.khan.6@bham.ac.uk



Current studies

Pre-conception Care for Women with Diabetes

Local Investigator
Dr Paramjit Gill, Reader in Primary Care

Diabetes is a global health problem and is one of the most common medical complications in pregnancy. Rates of diabetes in pregnancy are rapidly increasing, especially due to the projected growth in the number of women who are obese or overweight. Obesity can increase the risk of getting type 2 diabetes but both forms of pre-existing diabetes, type 1 and type 2, can lead to serious abnormality and stillbirth. These risks to health can be modified and pre-conception care is known to make a difference. Pre-conception care has been listed as a NICE quality standard and has several components including the optimising of blood glucose control, folic acid supplementation and supported lifestyle changes. However, the uptake of pre-conception care is often low and it remains unclear. This study will answer this.

We are looking for 20 white British and 20 Pakistani women with pre-existing Type 1 and Type 2 diabetes, between 16–45 years of age, registered with a practice in Sandwell and West Birmingham CCG. The women will be interviewed by the research nurse, either at home or at the Health Centre.

Learn more
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Global Anticoagulant Registry in the FIELD

GARFIELD-AF (Global Anticoagulation Registry in the FIELD) is an ongoing observational, multicentre, international registry of newly diagnosed atrial fibrillation patients with at least one additional, investigator determined risk factor for stroke. The aim of the study 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 is taking place in five independent, sequential cohorts and patients are followed up for a minimum of two years.

In the UK, participants are recruited in primary care with the University of Birmingham as the recruiting centre. Enrolment to the fourth cohort is ongoing and GARFIELD-AF is currently active in 133 practices in England, Wales, Northern Ireland and Scotland.

The UK is currently the fourth highest recruiting country with 2634 patients enrolled to date.

Learn more
If you would like further information about the study please contact:
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Current studies

Helicobacter Eradication Aspirin Trial

HEAT

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, Sussex & Surrey, Nottingham, Durham, Southampton and Oxford.

Enrolment Period: 2012 – June 2016

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.

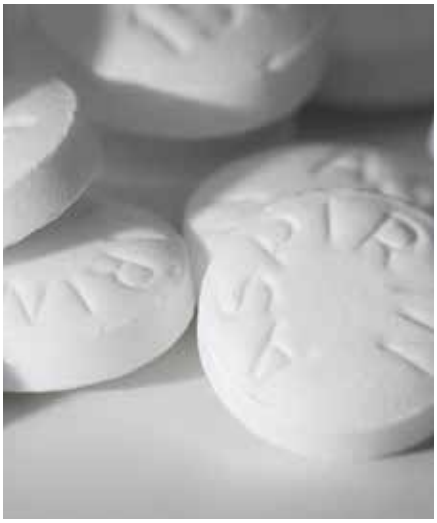
Use of aspirin for cardiovascular prophylaxis is widespread and increasing. The main hazard is ulcer bleeding. This is usually associated with H. pylori infection. It is important to determine whether this can be reduced or prevented by H. pylori eradication. The trial hypothesis is that aspirin does 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.

Learn more

If you would like to find out more, please contact the Trial Manager for your region,

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



ACCU-RATE

How accurate are home blood pressure monitors used by patients?

'Accu-rate' is a NIHR funded cross-sectional survey that aims to determine whether patients' own blood pressure monitoring equipment is sufficiently accurate to be integrated into daily practice.

We would like to invite interested practices to contact us to take part. The additional workload is minimal. Service support costs will be reimbursed to cover recruitment. Patients will be recruited from 8 practices across Birmingham.

Eligible patients on the hypertension register, who currently self monitor with either a wrist or upper arm blood pressure monitor, will be invited to attend device accuracy sessions at their own practices. Using standard calibration equipment and following a standard testing procedure as recommended by the British Hypertension Society, each monitor will be tested over a range of pressures. Machines with a difference in pressure of ≤3mmHg at all levels will pass. Each patient will receive individual feedback for their monitor.

Trial participation involves:

- Identification and screening of eligible patients using the hypertension register (health care professional)
- Mailing of a study invitation letter
- Receipt of monitors (frontline staff)
- Room hire

Learn more

Siobhan Milner
Project Officer
Tel: 0121 414 2954
Fax: 0121 414 8616
Email: s.l.milner@bham.ac.uk

Current studies

IMPRESS-AF

Improved exercise tolerance in participants with preserved ejection fraction by spironolactone on myocardial fibrosis in atrial fibrillation

WE ARE LOOKING TO RECRUIT 64 PRACTICES ACROSS THE BIRMINGHAM AREA.

What is the IMPRESS-AF trial?

This research is a double-blinded randomised controlled trial to determine whether the aldosterone antagonist, spironolactone improves exercise tolerance and quality of life compared to placebo in patients who have permanent atrial fibrillation with normal brain natriuretic peptide levels.

Why is this study important?

The trial will provide data on the clinical effectiveness of a readily available treatment in symptomatic participants with AF and normal BNP levels. This large population of patients suffers markedly from reduced quality of life and is in need of additional therapies to improve their management. Data collected from this trial will inform future guidance on the usefulness of spironolactone in this patient population.

What is involved for Practices?

Participating practices will:

- Carry out electronic searches to identify potential participants
- Generate and send invitation letters and reminder invitation letters

Practices are Patient Identification Centres for the trial. All research activity will take place at City Hospital.

Participating practices will be eligible to receive payment via service support costs and will receive support from the research team.

Learn more

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

Fiona McRonald
Trial Manager
Tel: 0121 414 4839
Fax: 0121 414 3050
Email: f.e.mcronald@bham.ac.uk

FAST

Febuxostat versus Allopurinol Streamlined Trial

The trial will evaluate the long-term cardiovascular safety profile of febuxostat in comparison with allopurinol in patients aged 60 years or older, with chronic hyperuricaemia in conditions where urate disposition has already occurred. Eligible patients will be randomly allocated to either febuxostat or allopurinol treatment. The study research nurses, or local network nurses, will follow-up the patients for an average of 3 years. The trial aims to recruit 5,706 patients by April 2016.

Practice Involvement

Practices will be asked to:

- Nominate a Lead GP to undertake Good Clinical Practice Training (can be provided as part of the trial)
- Search GP database for eligible patients
- Nominate Lead GP to review the patient list and remove unsuitable patients
- Nominated Lead GP to report any Serious Adverse Events via the FAST Web portal or by contacting the study centre

It is expected that each participating GP Practice will recruit a minimum of 6 patients per practice.

Practice Remuneration

Each practice will receive £500 search fee for the initial practice database search, plus £5 per month per patient for follow-up data.

Learn More:

If you are interested in taking part, please contact:

Shahnaz Kausar
Research Facilitator, CRN: Primary Care
Tel: 0121 414 8072
Email: s.khan.6@bham.ac.uk

Current studies

Prove

(Physiotherapy Rehabilitation of Osteoporotic Vertebral)

The objective of the study is to assess and compare the effects of physiotherapy intervention on the quality of life of patients with symptomatic vertebral osteoporosis.

This is a study about how best to treat patients with osteoporosis. The PROVE team have been funded to investigate different types of physiotherapy treatments comparing exercise, 'hands on' manual therapy and advice, to find out which type of physiotherapy is the most beneficial to offer people with osteoporosis who have a vertebral fracture.

The aim of the study is to compare three types of physiotherapy treatment for people with osteoporosis of the spine, to see which treatment helps to improve people's symptoms and daily function. The results of the study will be used to guide future treatment for this condition.

The results will be used to write a report and health journal articles so that health care professionals can use the results to help other patients in the future.

We are recruiting patients:

- With BACK PAIN due to osteoporosis who have had at least one vertebral (bone in the spine) fracture.
- Willing to be treated by either 'Hands on' physiotherapy OR Exercise physiotherapy OR Usual care (a computer will randomly choose treatment type).

Learn more

For more information please contact:
Saif Uddin
Research Facilitator, CRN: Primary Care
Tel: 0121 414 8614
Email: s.uddin@bham.ac.uk

STAMP-2

Sedentary Time and Metabolic health in people recently diagnosed with, and at risk of, type 2 diabetes – STAMP-2

The STAMP-2 study is recruiting two groups of participants: those diagnosed with Type 2 Diabetes Mellitus (T2DM) in the past 6 months and those at high risk of developing T2DM. Participants are being recruited from three sites, two in Bristol and one in Birmingham, led by Dr Parth Narendran at University Hospitals Birmingham Foundation Trust.

This important new study is going to look at patterns of physical activity, sedentary behaviour and diet and how these relate to measures of health in people who are newly diagnosed with T2DM and those at risk of developing T2DM.

We would like to invite interested GP practices to contact us. We will ask you to generate a list of patients who fall into the category of diagnosed with T2DM in the past 6 months and at risk of developing T2DM. We then ask for you to mail out a study invitation letter to the participants and those wishing to take part will be asked to contact the study team directly. We will pay a set-up fee and additional costs per patient contacted.

Learn more

If you would like to take part or would like more information please contact:
Sarah Hinton
Research Facilitator, CRN: Primary Care
Tel: 0121 414 8593
Email: s.hinton@bham.ac.uk

Current studies

TASMINH 4

Telemonitoring And/or Self-Monitoring IN Hypertension

What is the TASMINH 4 trial?
This research is a patient randomised controlled trial. It will evaluate the management of hypertension in primary care using self monitored blood pressure values, with or without tele-monitoring, compared to that using clinic monitored blood pressure. It will also consider the effect of self-monitoring and tele-monitoring on adherence, side effects, quality of life, adverse events and costs. This study is being run by the Universities of Birmingham and Oxford underpinning key work from previous blood pressure surveys and TASMINH trials (TASMINH, TASMINH2, TASMIN-SR).

WE ARE LOOKING TO RECRUIT APPROXIMATELY 30 PRACTICES ACROSS THE WEST MIDLANDS

What is involved for Practices?

- Practices will be asked to identify potential participants (patients with coded hypertension with a BP ≥140 (systolic) and/or 90 (diastolic) mmHg)
- Room hire for holding baseline and follow-up clinics (6 and 12 months)
- Mail study invitation letters to trial participants

Full training will be provided.

Practices undertaking this study will be eligible to receive payment via service support costs to cover the time spent recruiting patients.

Learn More
If your practice would like to take part, or would like more information, please contact:
Mrs Siobhan Milner
Project Officer
Tel: 0121 414 2954
Fax: 0121 414 8616
Email: s.l.milner@bham.ac.uk

Would you like to take part in National Research into COPD?

TWICS
Theophylline with Inhaled Corticosteroids

A randomised, double-blind placebo controlled trial of the effectiveness of low dose oral theophylline as an adjunct to inhaled corticosteroids (ICS) in preventing exacerbations of chronic obstructive pulmonary disease (COPD).

The study is trying to determine the clinical and cost effectiveness of adding low dose theophylline to ICS therapy in patients with COPD. Its objective is to improve the quality of life of COPD patients and to reduce the burden of COPD on the NHS.

Practices will be asked to conduct a search to identify potentially eligible patients and the patient list will be checked by the GP for any exclusions. Patient invitation letters will then be sent out from the practice inviting eligible patients to take part in the study. There are study posters available to display in your practice to provide information about the study to patients.

Patients who agree to take part in the study will attend 3 research clinics at the Queen Elizabeth Hospital, Birmingham (their travel expenses will be reimbursed at £10 per visit). They will also receive 3 telephone contacts from the study team and be asked to complete some questionnaires.

Participating patients may benefit from a possible reduction in COPD exacerbations and reduced hospital admissions as well as receiving assessments (health outcome and spirometry) by a hospital based specialist respiratory team. Practices will benefit from receiving study and spirometry data for any of their patients taking part in the study which can be used to meet QOF targets.

Learn more
We would be very grateful for your support and involvement in this study. Should you wish to find out more, please contact
Anu Krishna
Research Facilitator, CRN: Primary Care
Tel: 0121 414 6643
Email: a.t.krishna@bham.ac.uk

Current studies

TIRCON

A randomised, double blind, placebo-controlled trial of deferiprone in patients with pantothenate kinase-associated neurodegeneration (PKAN)

The TIRCON study is a non-commercial study funded by the European Commission and ApoPharma (drug provision only). The Chief Investigator is Professor Patrick Chinnery, University of Newcastle. The study will be investigating Panthothenate Kinase Associated Neurodegeneration (PKAN) and how to best treat the condition. It is commonly thought that the best way of treating the condition is to prevent the build up of iron within the brain; however the drugs available have been ineffective in achieving this. The aim of the study is to determine whether giving patients with PKAN the drug Deferiprone over an 18 month period can improve the symptoms and reduce the level of iron in the brain.

The main research site, Newcastle-upon-Tyne Hospitals NHS Foundation Trust, along with other Patient Identification Centres (PICs) across the country, will be identifying and recruiting patients aged 4 years to adult diagnosed with PKAN disease to participate in the study. They will consent all participants and randomise them to either receive a placebo or the study medication Deferiprone, which will be administered in secondary care.

Participants will require a weekly blood test to check haematological side effects of the drug. To minimise the inconvenience for patients they will be offered the option of having these weekly tests undertaken at their local GP practice if they do not live near Newcastle. Birmingham Children's Hospital NHS Foundation Trust will be identifying potential participants who may be patients of GP practices in the Birmingham and Black Country area. These GP Practices will then be informed in writing and asked to act as Research Follow-Up Sites to undertake the participant's weekly blood tests.

This is a Medicines for Children Research Network (MCRN) study that has been co-adopted by Primary Care. It will be recruiting 90 participants across the UK (who are likely to be children).

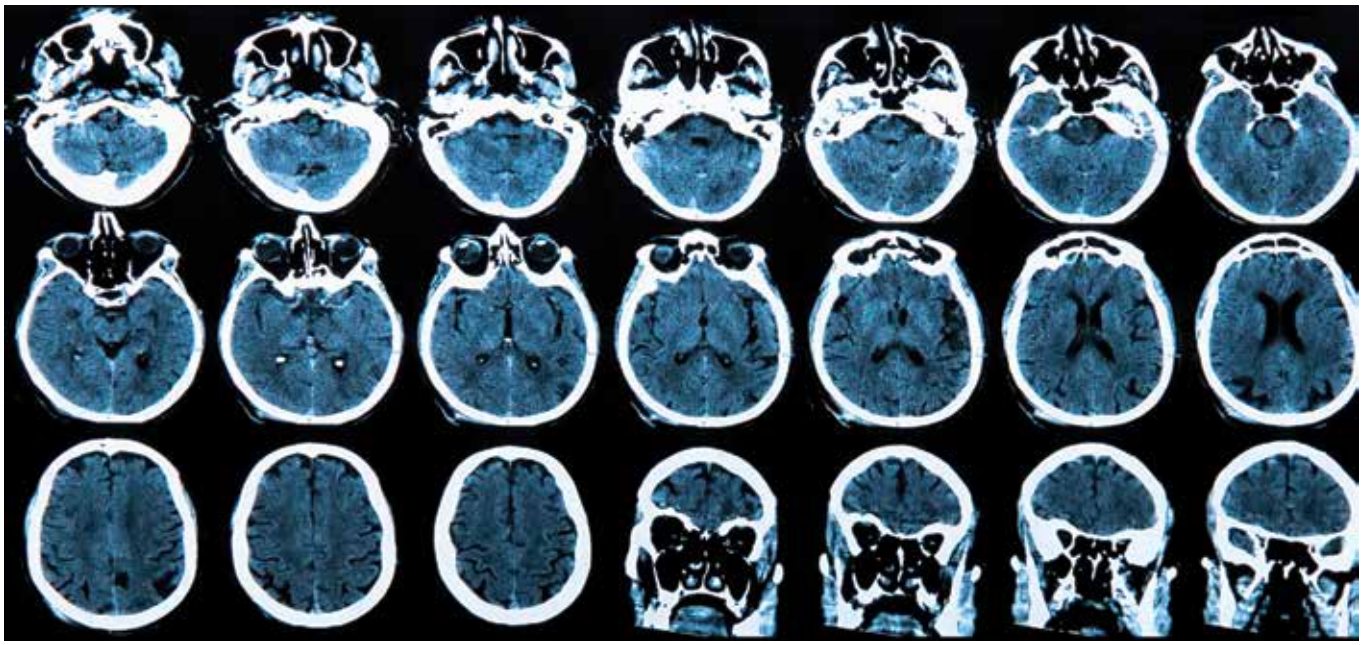
As part of the safety monitoring for the study the participants will be required to provide weekly bloods for a period of 18 months.

Once the participants have been approached there is a window of 60 days from the baseline assessment to the first safety blood sample being required to be taken. All other research activities will be in secondary care. The blood samples will need to be taken by a suitably qualified person at the practice (GP, practice nurse or healthcare assistant) and this will take approximately 15 minutes. The blood samples will then be posted by the GP practice to the Royal Victoria Infirmary, Newcastle upon Tyne for processing in packs supplied by the research team.

GP practices will be informed in writing that a patient will be participating in the study. The practice will receive £5.40 for every blood sample obtained.

Learn More

Max Feltham
Research Manager, CRN: Primary Care
Tel: 0121 414 7557
Email: m.g.feltham@bham.ac.uk



In follow up

ExACT

Extended anticoagulation treatment for VTE: a randomised trial

Funded as part of an NIHR programme grant

Recruitment to the ExACT study has now finished. The study team would like to say a big Thank You to Doctors and Staff at all the practices that have helped to recruit patients and make the study such a success.

In total, 281 patients have been recruited to the study and patient follow-up continues until February 2017.

Background to trial: Venous thromboembolism (VTE) 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). The annual recurrence rate following a first VTE is approximately 10% per annum irrespective of the duration of anticoagulation therapy.

This suggests that some patients should continue anticoagulation long-term. However, currently we are unable to identify this population.

Aim of trial: To investigate whether extending anticoagulation treatment beyond 3-6 months, for patients with a first unprovoked proximal DVT or PE reduces the recurrence rate.

For those of you who are already involved:

- We will be in contact as usual to organise rooms for follow up visits.
- Please contact the study team on 0121 414 3354 if an ExACT patient experiences any adverse events.

There is a reimbursement for these services.

Trial Intervention: Patients are randomised to either continue or discontinue oral anticoagulation and will be followed up every six months for two years. We will be looking at D-dimer levels (a product present in the blood after a blood clot), the development of PTS and associated quality of life. We are also looking at the cost effectiveness of continuing oral anticoagulation treatment for these patients.

Learn more

If you require further information please contact:

Sheriden Bevan
Tel: 0121 414 3354
Email: s.bevan@bham.ac.uk

Study findings

Important findings from the CREDIBLE study

A big thank you to all the GPs, Practice Nurses, Practice Managers and other staff who took part in the CREDIBLE (ColoRectal Early Diagnosis an Information Based Local Evaluation) study. This study investigated the feasibility of using software to flag up patients with symptoms and signs of suspected colorectal cancer in general practice. Using a query incorporated into MSDi Clinical Manager software we searched electronic medical records to identify patients who met NICE urgent referral criteria for suspected colorectal cancer. The list of patients identified was then provided to the practice for them to take appropriate action. Between January 2012 and March 2014 we searched 19,580 records of patients aged 60 to 79 years in 20 general practices. 809 patients met NICE urgent referral criteria. Around a third of these (34%) were invited for further review by their GPs. The study is now complete. We have published preliminary findings in the British Journal of Cancer and we are also providing individual feedback to all the participating general practices.

Findings

1. Electronic searching of medical records can be used to flag up patients who need investigation
   Undiagnosed colon cancer was found in 10/809 (1.2%) flagged up patients and polyps in a further 28/809 (3.5%). Of the 10 cancers, only 5 had already been referred at the time of the electronic search. However, many practices struggle to find time to consistently review lists of flagged up patients.

2. In some GP practices, signs of potential bowel cancer are not acted on
   Anaemia and diarrhoea were the risk factors least likely to be referred, and took the longest times to be investigated. Anaemia was the earliest symptom in 6 of the 10 cancer cases we flagged up. Cause of anaemia in the over-60's needs to be investigated.

3. Sub-optimal referral pathways
   We noted considerable variation in referral pathways. Some patients eligible for 2 Week Wait urgent referral were not referred, were referred first to general Gastroenterology or for upper GI investigation, or were not referred using the 2 Week Wait form. This delayed diagnosis.

'Some colon cancer deaths may have been avoidable if they had been diagnosed earlier. Iron deficiency anaemia is a more common clinical sign of colorectal cancer than is generally appreciated. We saw that it was under-investigated in some general practices. So we have a real potential to reduce deaths from bowel cancer if we treat anaemia with suspicion – please don't wait for other symptoms to appear – refer all unexplained iron deficiency for lower GI investigation straight away'

Professor Tom Marshall
Principal Investigator for the study

NHS
National Institute for Health Research

West Midlands
Research Design Service

What is the RDS?

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

Who can use the RDS?

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

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

www.rds-wm.nihr.ac.uk

How can the RDS help me?

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

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

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

NHS
National Institute for Health Research

Clinical Research Network
Primary Care

Keep *In Contact*

Primary Care Clinical Research & Trials Unit
Networks
CTU
Primary Care
PC-CRTU

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 and Trials Unit, Clinical Research Network: Primary Care and Primary Care Clinical Sciences Department.

The Primary Care Clinical Research and Trials Unit (PC-CRTU) works in conjunction with the Clinical Research Network: Primary Care, part of the National Institute for Health Research (NIHR). Only studies which have been independently peer-reviewed and funded through national competition; and commercial research asking relevant questions will be adopted onto the NIHR Portfolio of studies.

You can:

Fax back this form to **0121 414 2282** or
Email the details above to crn-wm@contacts.bham.ac.uk or
Phone us on **0800 085 4229** for further information.

Alternatively, send the completed form to our postal address, as detailed on the back page.

Funding available for you and your GP practice to support the Research Sites Initiative

The Clinical Research Network: Primary Care is pleased to announce that practices within Birmingham and the Black Country have the chance to participate in the Research Site Initiative (RSI) Scheme.

NHS
National Institute for Health Research

Clinical Research Network
Primary Care

What is RSI?
The RCGP and the CRN: Primary Care have developed the Research Sites Initiative (RSI) which is open to all practices. This is a standardised pathway, which makes funding available to you and your GP practice. It will establish and maintain capacity and capability for you and your practice to contribute to NIHR portfolio research.

How it works
You are invited to apply for membership and, if successful, you and your practice will be allocated funding to cover research infrastructure costs in addition to service support costs (SSC). In return for this support your practice will need to meet specific research-related requirements such as Good Clinical Practice (GCP) training, RCGP Research Ready accreditation and contributing to a minimum number of portfolio and commercial studies. The RSI offers two levels of involvement:

Practice levels and Remuneration
There are two levels of RSI to match your practice's research experience

Level 1 – Remuneration £1000
- Complete the online Research Ready accreditation
- Meet the specific research requirements (GCP)
- Attendance at an annual Network meeting
- Recruit to **a minimum** of 2 different CRN/NIHR Portfolio studies (SSC's will continue to be paid)

Level 2 – Remuneration £2000
- Same as Level 1 and
- Recruit to **a minimum** of 3 different CRN/NIHR Portfolio studies (SSC's will continue to be paid)

Support Costs
NHS service support costs will continue to be paid to cover all agreed research activity you and your practice contribute towards NIHR portfolio research.

If you and your practice would like to apply for this new initiative or would like further information please contact or email us on the details below.

Sheila Bailey
Research Facilitator, CRN: Primary Care
Tel: 0121 414 7956
Email: s.m.bailey.20@bham.ac.uk

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Visit our website
www.birmingham.ac.uk/crn-wm

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 414 8532