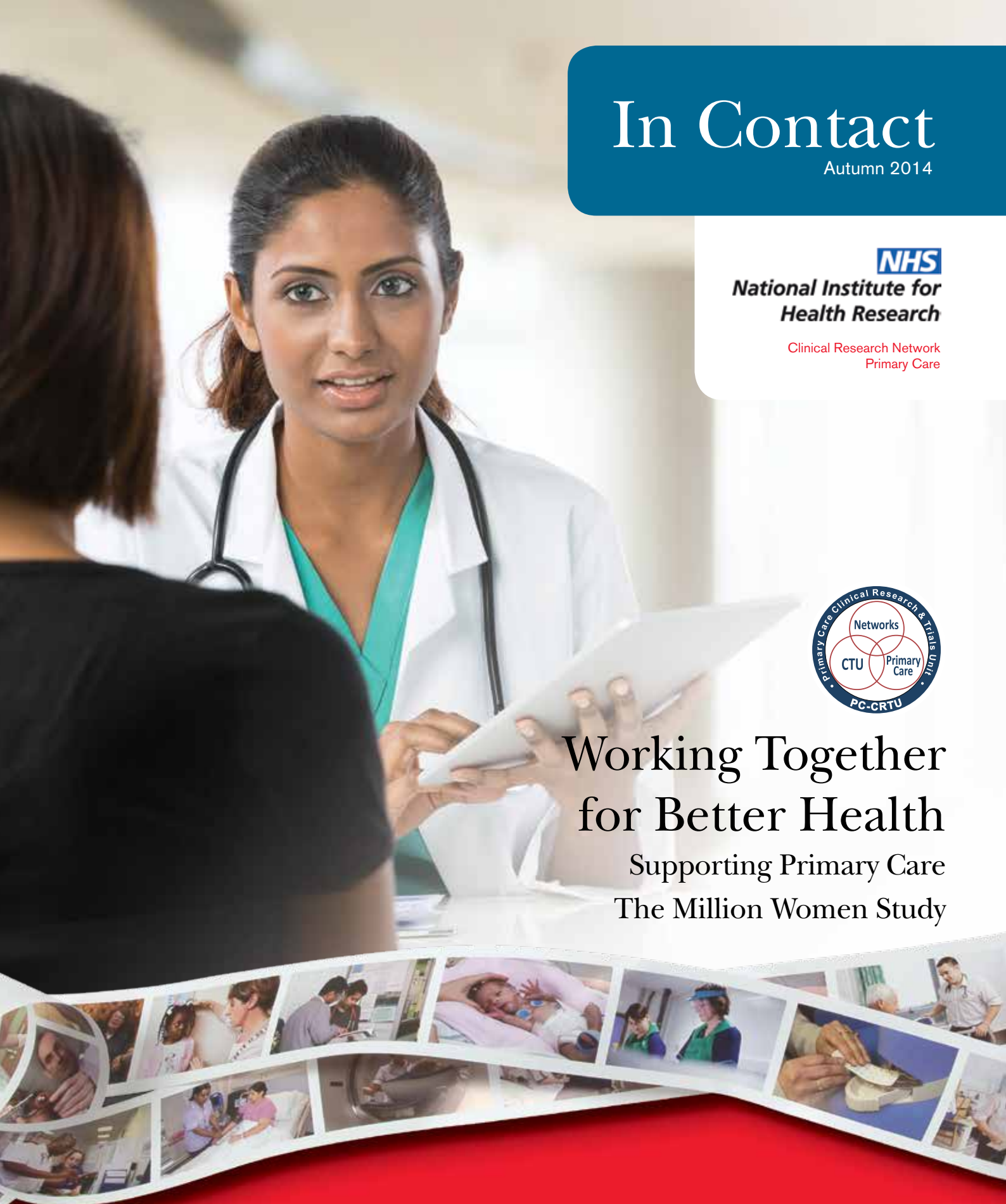

In Contact

Autumn 2014

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

Supporting Primary Care
The Million Women Study

Delivering research to make patients, and the NHS, better

NHS National Institute for Health Research

Clinical Research Network
Primary Care

Welcome

Dear Colleagues,

I would like to introduce myself. I am a Clinical Lecturer and GP in Primary Care Clinical Sciences and have recently taken over from Dr Paramjit Gill as Clinical Lead for the West Midlands Clinical Research Network Primary Care Speciality Group in Birmingham. I am sure you will all join me in thanking Paramjit for doing such an excellent job over the past few years and I certainly have a difficult act to follow, but I shall do my best.

Primary care research is such an important area. A huge number of patient contacts take place in primary care. Primary health care teams provide acute medical care but also provide the majority of long-term conditions management. Around 90 per cent of patient interaction is with primary care services so it makes sense to focus research in this setting. Traditionally, secondary care research has been dominant but is often not appropriate or relevant to primary care settings. Much of the clinical work in primary care does not focus on single disease models but considers the whole person physical, psychological and social needs, which is what makes it unique and needing research devoted entirely to this setting.

There are challenges to being involved in research which, as a practising GP, I am well aware of. Therefore, I hope to use this role as an opportunity to facilitate primary care participation in research and ensure primary care research is prioritised within the CCGs. CCGs were created with the specific aim of improving patient outcomes and care. A research active culture within a CCG helps promote this. In addition, research has shown that individuals and organisations involved in research are more likely to implement the findings, so another good reason to be involved. My role, and the role of the West Midlands Clinical Research Network Primary Care Speciality Group, Birmingham, is to promote this culture and support practices to participate in research.

I look forward to working with you

Dr Liz England
Clinical Lead, CRN: Primary Care

Contents

Patient and Public Involvement

Think Corner Event

The Primary Care Speciality Group raised awareness of clinical research with a range of activities in the University of Birmingham's Pop-Up Shop during a three week Patient and Public Involvement (PPI) event. The shop, called the Think Corner, was located in the Pavilions Shopping Centre in Birmingham City Centre and members of the Speciality Group engaged with the public on ground-breaking research being conducted in Primary Care. As you can see from the photos, we measured people's blood pressure to enable them to experience an assessment typically conducted during a Primary Care clinical trial and handed out information leaflets such as 'Ok to ask – about clinical trials'.

We heard many health research related stories from people during the three days we exhibited in the shop. These varied from members of the public telling us how research had positively changed their life because they were offered a new treatment or because symptoms were picked up earlier than usual during a screening visit.

Learn more about PPI
Sarah Hadfield
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Nursing Supporting Primary Care Research

NHS National Institute for Health Research

Clinical Research Network Primary Care

Five years ago the Midlands Research Practices Consortium (MidRec) secured funding to recruit half-time research nurse posts based in local GP research active practices. We hear the experiences from Susan Read Research Nurse, CRN: Primary Care.

I've always been interested in research and was working in a very busy GP surgery at the time, seeing patients every 5 to 10 minutes, with no quality time available to spend with my patients. I thought this job would give me the opportunity to spend more satisfactory time with patients while becoming involved in gathering accurate information to provide evidence based medicine.

I was the first nurse appointed and am now part of a successful team of six nurses, based in our own individual surgeries, overseen by a Lead Research Nurse. Before we started running research studies in our nominated surgeries our Lead Nurse manager ensured that we underwent a programme of mandatory training so we had an understanding of what was required to safely be involved in research.

Gradually the studies came in and I remember being asked by Professor McManus how many studies we were running and I said we were currently running about 20 studies… he was surprised… I think that opened the GP's eyes and they realised the opportunity they had with the support of the nurses.

Many studies are observational where you are looking at and extracting data… We also look at feasibility of studies… so we are contacted by a study manager and asked to find out the number of patients we have… so we can go back to the study team and say these are the numbers for this head of population which we think you will be able to access at these surgeries.

The medical knowledge nurses have comes in useful when running feasibility studies… we can search effectively for eligible patients. There has been discussion whether nurses are expensive… but we significantly help the GPs.

I remember my first patient recruited to a study. I was absolutely thrilled because patients were willing to participate in the study where we were doing near patient testing and baseline health measurements with immediate feedback of results which we then had time to discuss. If necessary, the patients could be referred back to their GP for any concerns that were highlighted.

The patient contact, the communication pathway that opened up in the last five years with the team has given me job satisfaction. We really feel included more so now than ever before. What pleases me the most is that although we are autonomous within our own environment there are five other host nurses… We have this supportive network of research nurses which makes a powerful effective team. We have opened up effective pathways between the university, study teams and other professionals… if they need help or an answer to a query we can normally provide the information quickly and efficiently because we have close contact with the GPs.

If someone is considering a career in research I would say come and join me for a day and see things first hand… Many of the host nurses have come from a Practice Nurse background and have a wide range of knowledge because you can, in any given day, look after babies, give travel jabs, look after women's health to caring for a patient with a chronic condition… over the years our training has covered an enormous remit.

You learn a lot from problems, you have to be pragmatic and always look for solutions. When they set up this scheme, we were a pilot study – would it work? So already we were in a research study in our own right and it was important that we pull together as a team and pass on what we have learnt… The success of the Pilot enabled funding to continue and currently the NIHR fund us through their networks even after MidRec itself came to an end.

Patients deserve the opportunity to be involved in research.

Susan Read
Host Nurse
CRN: Primary Care

The Million Women Study

A national study of women's health
UPDATE

With more than 12 years of follow-up now available, the Million Women Study continues to be an extremely valuable resource for the study of women's health. With a new period of funding recently awarded by the Medical Research Council to support the study until October 2018, we look forward to answering many new questions related to the health of our cohort. We are grateful for the continued support of all our collaborators and study participants.

We have published 23 MWS papers in 2012 and 2013. These include studies of body size, smoking, reproductive factors, alcohol consumption, pet ownership, mobile phone use, genetic and environmental factors, as they relate to cancers at specific sites. We have also looked at some risk factors for coronary heart disease, fractures, and motor neurone disease. All publications are available on the study website: www.millionwomenstudy.org.

Genes, the environment, and breast cancer
We found that *in situ* ductal breast cancers (DCIS) and invasive ductal breast cancers had similar genetic and environmental risk factor profiles, implying that they both share the same aetiology. However, while there was an association between BMI and invasive ductal breast cancer, there was no association of BMI with DCIS. This suggests that BMI may influence disease progression.

Reeves G.K., et al; Comparison of the effects of genetic and environmental risk factors on in situ and invasive ductal breast cancer. International Journal of Cancer 2012; 131:930-937

The 21st century hazards of smoking and benefits of stopping
Women born in developed countries during the early 1940s were the first generation in which a substantial number of women smoked throughout their adult life. We found that long term cigarette smokers lose at least 10 years of their lifespan. However, stopping smoking before the age of 40 years avoids more than 90% of this increased risk of death.

Pirie K, et al; The 21st century hazards of smoking and benefits of stopping: a prospective study of one million women in the UK. Lancet 2013; 381: 133-141.

Blood Samples and the disease susceptibility study
We have been asking more study participants to provide blood samples to help us expand our understanding of the relationship between genetic and biochemical factors, and disease susceptibility. This phase of blood collection is due to be completed by the end of 2014.

4th General follow-up questionnaires
Mailing of the 4th general follow-up questionnaire began in June 2013 and finished in March 2014.

Online diet questionnaire
To date, 27,500 women have completed at least one online 24-hour dietary recall questionnaire.

What do you think of our website?
Please let us know if you have any comments or suggestions.

Learn more
Barbara Crossley
Email: barbara.crossley@ceu.ox.ac.uk

NHS

CANCER RESEARCH UK

MRC Medical Research Council

‘Working Together for Better Health’

NIHR CLAHRC WM Launches New Collaborative Research Project

This year saw a new collaborative research project start its mission to improve patient care by creating lasting and effective partnerships between health providers and researchers. NIHR Collaborations for Leadership in Applied Health Research and Care West Midlands (or CLAHRC WM for short) began a five year programme in 2014, building on the success of the CLAHRC for Birmingham & Black Country pilot.

The project is funded by the National Institute of Health Research (NIHR); this £10million investment is complemented by £20.6million in matched funding from local health and social services to continue evaluating and developing healthcare.

NIHR CLAHRC WM is hosted by University Hospitals Birmingham NHS Foundation Trust with academic partners at the Universities of Birmingham, Warwick and Keele.

Other partners include Clinical Commissioning Groups, acute and community NHS Trusts and local authorities across the region.

Expanding the geographical footprint of the pilot study, the new NIHR CLAHRC WM focuses on four service themes:

- Maternity and Child Health
- Youth Mental Health
- Prevention and Detection of Disease
- Integrating Care for People with Chronic Diseases

Alongside the four service themes, there are also two cross-cutting, supporting themes: Implementation and Organisational Studies, including the capability for ‘off-line testing’ to help identify flaws in the design of innovations and interventions; and a Research Methods theme to ensure studies are designed to adequately answer complex questions.

Research carried out to date includes the TRaCKED Study – ‘Test Result Communications, Knowledge, Evaluation and Development’ – looking at simple steps to improve the communications of blood tests results in primary care. The study has been published in the Oxford University Press journal, Family Practice.

Director of NIHR CLAHRC WM Prof Richard Lilford explained: ‘Our aim is to conduct imaginative, high-quality health service evaluations to improve patient care. In order to achieve this we have created a collaboration of patients and the public, service personnel and applied health researchers to fulfil our mission.

‘We believe NIHR CLAHRC WM can create lasting and effective working relationships and an environment where close collaboration is the rule, not the exception’, added Prof Lilford.

‘Working together we can help give the UK better health, a better prospect of staying healthy, and a health service in which every pound of the public’s contribution goes on services that use the best evidence of what works. By the end of the five year project, our goal is not just to achieve positive service change, but most importantly, to develop a self-sustaining system.’

Learn more

For more information visit the NIHR CLAHRC WM website www.clahrc-wm.nihr.ac.uk/index.html; here you can also subscribe to the fortnightly News Blog or join the mailing list. You can also follow news of NIHR CLAHRC WM on Twitter @CLAHRC_WM.

GO FOR PIC!

We are currently compiling a database of GP practices who wish to be contacted about PIC (Patient Identification Centre) studies for non commercial research.

These studies are usually straightforward and entail the GP practice identifying patients who may be suitable for a particular study and forwarding them the basic information. If interested, the patient will then get in touch with the study team who are based in an alternative setting (usually secondary care). The flow chart outlines your GP practice input into a typical PIC activity.

Practices are reimbursed for the work they do and this varies depending on the type of search, set up required etc.

We are asking GP practices to register their interest if they would like to complete PIC studies. We will then be able to contact your practice as and when these studies arise. They are a good starting point if your practice is interested in becoming research active. PIC studies cover a wide range of research topics within primary care. For examples of PIC please see articles on studies such as EAST , Diabesity, and DAPA.

Learn More

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Research Facilitator, CRN: Primary Care
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Patient identification Centre (PIC) studies

GP interest – study information provided

↓

Search carried out using inclusion/ exclusion criteria provided

↓

GP to review search and remove anyone they feel is inappropriate

↓

Practice forward information onto identified patients

↓

GP practice involvement ends.

Study team will liaise with patients who express an interest in participating in the study

New studies

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 are looking to recruit up to 10 practices through 2014, and 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

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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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Email: brit@contacts.bham.ac.uk

Anu Krishna
Research Facilitator, CRN: Primary Care
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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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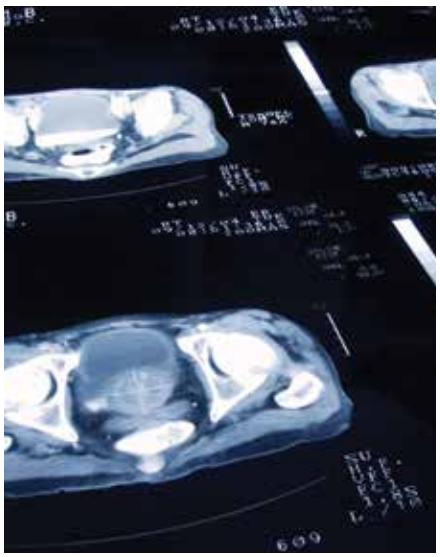
Email: m.g.feltham@bham.ac.uk



New studies

DAPA
(Dementia And Physical Activity)

DOES EXERCISE HELP PEOPLE WITH DEMENTIA?

DAPA is a multi-centre randomised controlled trial comparing an additional structured exercise regimen to best practice usual care. The study aims to establish whether exercise is effective in treating against functional and cognitive decline in community dwelling adults.

Participants who are randomised to the exercise regimen, will attend a group session at the Black Widow Martial Art Academy & Health Club, West Bromwich. It will consist of two 1-hour weekly sessions over 4 months, supplemented with between sessions exercise undertaken at home. This will be conducted by physiotherapists who have specialist expertise in dementia. Each group will also be supported by an exercise assistant. The primary outcome is cognition (as measured by ADAS-COG). The control group will receive usual care.

We are looking to recruit a maximum of 3 patients per practice from within SANDWELL AND WEST BIRMINGHAM CCG.

INCLUSION CRITERIA: People with probable dementia (DSMIV criteria) of mild or moderate severity (MMSE >10), who live in the community and have no contra-indication for exercise and increased physical activity.

EXCLUSION CRITERIA: People with a limited life expectancy (<12 months), severe dementia (MMSE 10 or lower) or who live in care or nursing homes.

PRACTICE INVOLVEMENT:

- Patient search on clinical system to identify patients with mild to moderate dementia.
- GPs will be asked to check the list to confirm eligibility and to approach the patient or carers.
- To send invitation letter on behalf of GPs. Postage costs will be covered by the trial.

REIMBURSEMENT: An estimated NHS Service Support Cost payment of £342 has been calculated for this study. This figure is based upon the information provided by the study team regarding the likely activities to be performed by your Practice; it is an approximation only and may be adjusted in line with the amount of patient recruitment and the level of Clinical Research Network support received.

If your practice is located within Sandwell and West Birmingham CCG and would be interested in finding out more about this study, then please contact:

Learn More
Anu Krishna
Research Facilitator, CRN: Primary Care
Tel: 0121 414 6643
Email: a.t.krishna@bham.ac.uk

Developing and testing accessible web-based support for patient self-management of diabetes

The aim of this study is to develop and trial web-based support suitable for people with lower levels of health literacy. In particular, it will examine the potential for web-based materials and tools to provide enhanced support (compared with standard written materials). We are currently working on phase 2 of this study which comprises a randomised two-arm trial comparing web materials. We will recruit people with Type 2 diabetes from deprived areas to ensure a good representation of people with low health literacy levels.

This is a straightforward study which requires the GP practice to complete a simple search which includes patients who are over 18 years old with Type 2 diabetes. Letters will be sent inviting patients to take part in the study. If they are interested they will visit the website, consent and complete the study requirements online.

Learn More
If your practice is interested in taking part please contact
Sarah Hadfield
Research facilitator, CRN: Primary Care
Tel: 0121 414 8045
Email: s.hadfield@bham.ac.uk

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 fibrilation (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 anti-arrhythmic 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:
Sarah Hadfield
Research Facilitator, CRN: Primary Care
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Email: s.hadfield@bham.ac.uk

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:
Shahnaz Kausar
Research Facilitator, CRN: Primary Care
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A New Study on Autoimmunity in Children with Down's Syndrome

The FADES study (Feeding and Autoimmunity in Down's Syndrome Evaluation Study)

The FADES study is an exciting new study following babies with Down's Syndrome from birth to see how events in their early lives may influence certain autoimmune conditions which children with Down's Syndrome are at increased risk of developing. The study is being undertaken at the University of Bristol but will be recruiting babies under the age of 8 months from across the UK and following them until they are 5 years old.

Autoimmunity and Down's Syndrome

Most babies and children with Down's Syndrome will not develop autoimmune conditions but compared to their peers they are more at risk of developing conditions where the body reacts against its own cells including conditions such as thyroid problems, diabetes and coeliac disease (which causes problems with the gut). If we are able to identify factors that increase the risk of these conditions developing then hopefully in the future we will be able to lower this risk.

What does the study involve?

Thanks to the help and support of the Down's Syndrome Association, Down's Syndrome Scotland and Down's Syndrome Medical Interest Group, the study will be advertised to new parents. If they are interested in taking part, the majority of the study can be done at home and would not require additional appointments. The study includes detailed questionnaires which can be completed online or on paper. These ask about their baby's feeding, the issues that families have with feeding and what support they receive. From this study we may be able to help families in the future by identifying the issues with feeding, dispelling myths and identifying where support could be improved. The questionnaires will also ask about medical conditions, infections and a little bit about family history.

The study will also involve collecting samples including some cells, collected by rubbing the inside of the baby's cheek with a soft swab, these will be used to look at the baby's genes (little packets of information within the cells) especially those we know are associated with autoimmune conditions. We will also collect poo samples to look at the natural bacteria that live in the gut which is considered to have an effect on the development of immunity. Urine samples will be collected to see if there are any signs of any of the babies developing diabetes although we expect that very few will develop diabetes during the 5 years that they are in the study. We will also collect small blood samples from heel pricks which will be used to see if there are any antibodies associated with autoimmune conditions.

A little about the Research Team

The study is being led by Professor Julian Hamilton-Shield, Dr Kathleen Gillespie and Dr Georgina Williams. Professor Hamilton-Shield and Dr Gillespie both have a long standing interest in children with Down's Syndrome and have previously published articles on Down's Syndrome and Diabetes. Dr Georgina Willliams is a paediatrician, this study will form part of her Clinical PhD in Child Health.

The study is sponsored by the University of Bristol and is funded by the National Institute of Health Research, Bristol Biomedical Research Unit in Nutrition.

Learn more

If you are interested in finding out more about this study please contact us at
Tel: 0117 342 1756.
Email: fades-study@bristol.ac.uk

You can also visit our webpage at www.bristolnutritionbru.org.uk and follow the FADES link on the left hand side of the page which will enable you to download a participant information sheet.

New studies

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
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IMPRESS-AF

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

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.

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

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
- Complete a medical history checklist for each patient consenting to participate

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:

Rachel Deller
Project Officer
Tel: 0121 414 3368
Fax: 0121 414 8616
Email: r.deller@bham.ac.uk

BRIEFING NOTE ON PARTNERS2 STUDY (PHASE ONE):

Development and pilot trial of primary care based collaborative care for people with serious mental illness

Project aim:
To enable Primary Care (PC) and community based mental health services to work more closely together and to develop a model of care within which selected individuals with severe mental illness can be managed in primary care with secondary care support. It has the potential for large impact on the care of people with severe mental illness.

Potential benefits to your team of taking part include:

- Research activity at little time or cost to your team
- Opportunity for developing mental health research in your team
- Opportunity to be involved in developing a new type of care for people with schizophrenia or bipolar disorder and to develop your team's skills and knowledge
- Opportunity to be trained by an internationally leading psychiatrist

WHAT'S INVOLVED?

Care pathways study (Starts Spring 2014).
The aim is to describe the process of current care for service users with a diagnosis of schizophrenia or bipolar disorder, and to help us to better target those who could benefit from primary/secondary collaborative care and assess any potential risk and safety issues. The CRN clinical studies officers will liaise with a small number of teams to facilitate a notes review on 100 patients in primary care. If possible we will extract this data electronically but if this is not possible the research assistant will liaise with each team to obtain this data with the support of the MHRN CSOs. There should be minimal input needed from the teams as a major part of data collection work will be carried out by MHRN and CRN CSOs.

We will also conduct focus groups with service users and carers to help us to learn from their experiences of current services and gain their views on how to improve them within a primary care based collaborative care model.

Development of the system of collaborative care (Starts Spring 2015).
In this part of the study, we will work with service users and case managers to organise care more effectively with GPs and other health and social care professionals. We will test a version of collaborative care and ask service users how they felt about the care they received within the model. We will also speak to GPs and other members of the healthcare team about their thoughts on carrying out the care package. The work for this phase will mostly be carried out by the project researchers and research fellow.

Two experienced mental health practitioners with experience of working with people with severe mental illness will be trained in each team to deliver Collaborative Care and take on the role of a case manager working with 12-13 people with schizophrenia or bipolar disorder in each practice. We will use multiple data collection methods so that we can develop manuals for case managers and supervisors.

Learn more

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Dr Humera Khan
PARTNERS2 Programme Manager,
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Chief investigator Professor Max Birchwood

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 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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New 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:
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STAMP-2

Sedentary Time and Metabolic health in people recently diagnosed with, and at risk of, type 2 diabetes – 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 you to mail out a study invitation letter to the participant 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
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Email: s.hinton@bham.ac.uk

Getting to Hospital At a Single Stroke: Free Stroke Training for GP Receptionists Launched

A new, free, training initiative is launched this autumn to help GP receptionists recognise the symptoms of stroke and TIA (transient ischaemic attack).

'Getting to Hospital At a Single Stroke' offers two complimentary and flexible ways to access training: an e-learning module accessed online and a half-day face-to-face training event delivered at venues across the region. The pilot is currently underway in the Telford and Wrekin CCG area with the initiative being rolled out to the wider West Midlands by the end of the year.

Project lead Liz Bates, a GP and NIHR Clinical Lecturer, explains: 'From the second the symptoms appear the clock is ticking: to save lives and minimise long-term damage stroke patients must be diagnosed and treated in just four-and-a-half hours.

'GP Reception Staff are on the front line, we aim to give these staff the confidence to recognise stroke and TIA symptoms as emergencies, and the skills to act quickly and effectively to improve clinical outcomes.'

The training has been developed in response to the RECEPTS study at UoB that revealed 20 per cent of stroke patients called their GP rather than an ambulance at the onset of symptoms.

Based at UoB, 'Getting to Hospital At a Single Stroke' is funded by the West Midlands Academic Health Science Network and operated in partnership with the National Institute for Health Research's CLAHRC (Collaboration for Leadership in Applied Health Research and Care) for the West Midlands.

For more information visit
www.mymds.bham.ac.uk/estroke

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

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 effectiveness 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

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.

It will ascertain which digital blood pressure monitors are currently used by patients, how well they perform, and whether there is any evidence of decreasing accuracy over time or with greater usage.

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)
- Mail a study invitation letter
- Receipt of monitors (frontline staff)
- Room hire

Learn more

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Project Officer
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Current studies

A Great Big Thank You from the ACQUATIK (Acute Care QUAliTy in chronic Kidney disease) Study Team

Dear Colleagues

A few months ago many of you will have received an e-mail containing details of the ACQUATIK study. Needless to say, with the constant and vast torrent of mail that we all continuously receive, it may have gone either totally unnoticed, or indeed, actively ignored by many. This is especially true in todays NHS, when we are all being asked to do more and more with less and less. Although this appears to apply with alternating emphasis to primary and secondary care, it is probably fair to say that primary care has been getting the lion's share of demands of late. It is at times like this when activities such as research tend to be consigned to the dustbin of non-essential activities. Understandable when we are all struggling just to get through the day ensuring that patient care is not compromised. I would, however, argue that it is at times like this that health services research becomes more important than ever. Indeed, how many of us have been given targets to achieve knowing full well that the evidence that achieving these will improve patient care is often poor and sometimes even non-existent? Unfortunately the barriers to good quality research are immense, not least because of its demands on time and resource.

The ACQUATIK study aims to minimize the resources and effort that are required to conduct good quality research at the interface of primary and secondary care. Furthermore, it also aims to greatly reduce the burden on our patients who totally altruistically agree to participate in research. We have been using routinely electronically held records (EHR), in both primary and secondary care, and combining them to form a dataset with which to examine joined-up patient journeys through primary and secondary care. Patients are approached and consented in hospital by a secondary care team and asked a handful of very basic demographic questions and information that is not usually routinely recorded. Pre-admission data is collected from primary care EHR, admission data is collected from hospital EHR and long-term follow-up data is prospectively collected from the Hospital Episodes Statistics database. Extraction of primary care data relies on insertion of a specially commissioned READ code, which will have been sent along with a signed patient consent form.

ACQUATIK is the first phase in a process. It is an observational study in 4000 patients to be recruited over a 2-year period. So far recruitment is ahead of schedule with 2400 patients recruited in the first year from both the Queen Elizabeth and Birmingham Heartlands Hospitals. As we collate the data we intend to make sure that the processes and systems in place are robust enough and comply with all the necessary governance that would be needed for an interventional trial. We also need to ensure that the methodology is acceptable to all stakeholders. The response so far from patients has been phenomenal with the vast majority wondering why they had to give consent when they already assumed that this kind of data sharing was already happening automatically. So far, most of the response from primary care has also been very positive. In fact, the main phone calls we have been getting are to ensure that this study really is that simple and that nothing else is required.

I am keen to make ACQUATIK a success. As such I am keen to get as much feedback and criticism as possible. I am also very keen to get ideas and suggestions for a future interventional trial that is not necessarily related to kidney disease. We owe it to our patients and ourselves that meaningful and high-quality research be conducted in a resource efficient manner.

Learn more
Email: charles.ferro@uhb.nhs.uk
ACQUATIK helpline 0121-6978450

RESEARCH NURSE SUPPORT IS NOW AVAILABLE TO START THE STUDY OFF IN YOUR PRACTICE AND IS AVAILABLE ON A FIRST COME FIRST SERVED BASIS

Benefits of Aldosterone Receptor Antagonism in Chronic Disease Trial

Objectives
To determine whether the addition of an aldosterone receptor antagonist (ARA) in patients with moderate Chronic Kidney Disease (CKD):

- Reduces death
- Reduces onset, or progression of cardiovascular disease
- Improves measures of vascular resistance
- Improves left ventricular function
- Reduces decline in renal function

Background
Better treatment options providing protection from vascular events or delaying progression of CKD are urgently needed.

There are limited therapeutic options to reduce overall cardiovascular risk in CKD.

Accumulating data suggest ARAs may offer cardio-protection and delay renal impairment in some patients.

BARACK D is the only current large prospective randomised open blinded endpoint trial (PROBE) focussing on this theme.

Recruitment
- 120 practices are being recruited nationally.
- 22 practices are needed in the BBC.
- Patients will be identified by their GPs with a diagnosis of CKD stage 3b and will be invited to take part.

Participation
Patients will be followed up for 36 months and will be randomised to either:
a) Treatment plus standard care
b) Standard care alone

Practice remuneration is available.

Learn more
For further information, please contact
Rachel Deller/Helen Duffy
Tel: 0121 414 4839

Birmingham Lung Improvement Studies (BLISS)

As highlighted in the COPD Outcomes Strategy, in response to the increasing burden of COPD in primary care, the University of Birmingham was awarded a 5 year National Institute for Health Research (NIHR) Programme Grant for Applied Research programme. BLISS consists of three studies:

1. The Birmingham COPD Cohort Study – aiming to study prognosis in >2000 patients and create a primary-care based prognostic index.

2. A Randomised Controlled Trial of Targeted Case Finding for COPD versus Routine Practice in Primary Care (TargetCOPD).

3. An occupational study to examine the effect of COPD on work (COPE).

Professor Peymane Adab and Professor David Fitzmaurice are Chief Investigators for the BLISS Programme. Dr Rachel Jordan, Senior Lecturer at the University of Birmingham is co-Chief investigator for TargetCOPD Case finding trial.

The BLISS programme is currently active in 71 GP practices in the West Midlands and has recruited over 2,300 Patients to the Birmingham COPD Cohort Study, which is composed of patients with existing disease and newly diagnosed patients, invited through the TargetCOPD case-finding trial. We are also following a subgroup of patients who report respiratory symptoms with normal lung function test results. The Birmingham Cohort Study has a 3 year patient follow-up assessment, which will commence in April 2015.

The TargetCOPD project is in the final write-up phase. We have screened more than 7,500 patients and performed over 2,600 spirometries, which have been fed back to GPs to identify new cases.

The occupational study has been a great success, with 343 patients currently participating in the project. Our novel occupational intervention feasibility study began in March with 32 patients receiving a personalised occupational intervention plan.

We would like to give a warm Thank you to all those practices who have taken part in the BLISS programme, your partnership has made the programme a success.

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CANDID

CANcer DIagnosis Decision rules

The CRN: Primary Care is looking for expressions of interest from GP practices to be involved in this national non-commercial study. This is an extremely important piece of work and an opportunity for both patients and doctors to be involved in research to look at the way clinical decisions are made for lung and colorectal cancers. Key areas of concern for both doctors and patients in primary care, when suspecting a patient has cancer, are preventing delays in diagnosis, getting high risk patients referred first and keeping unnecessary investigations to a minimum.

CANDID is an observational cohort study recruiting patients opportunistically via GP consultation and, in addition, undertaking a monthly MIQUEST search.

We are looking to recruit a total of 70 practices across Birmingham and the Black Country. Currently 36 GP practices have expressed an interest of which 22 practices are actively participating. Nationally the study is hoping to recruit 10,000 patients for each condition and our recruitment target for Birmingham and the Black Country is 2,500. The study will be recruiting participants until September 2015 with a short notes review 2 years following recruitment. Practices undertaking the study will be eligible to receive payment via service support costs to cover their time spent recruiting patients. As well as GPs, potentially this is an ideal study for trainee GPs in your practice to be involved in research. Additional payments will be made for any blood samples taken.

The study team aim to minimise the work load for practices. The following support is available if required:

Research Nurse – to support clinic visits: take consent, complete the non-examination section of the CRFs, take samples and set up the study at practice level and to provide study specific training to practice staff.

Technical Support – to set up MIQUEST and run the monthly searches. Alternatively, if you prefer to run the searches yourself, telephone support is available to answer any procedural issues or queries.

Learn more

For further information or to express an interest in taking part in this study please contact:

Marie Crook
Research Coordinator
University of Birmingham
Tel: 0121 414 8593
Email: m.e.crook@bham.ac.uk

Current studies

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 post codes.

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 CRN: Primary Care 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:

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ExACT

Extended anticoagulation treatment for VTE: a randomised trial

Funded as part of an NIHR programme grant

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.

We still need your help! To recruit patients, aged over 18, with a first unprovoked VTE from both primary care and secondary care anticoagulation clinics.

To date, 249 patients have been enrolled into the trial.

Recruitment will continue until 28th February 2015, and patient follow up will continue until February 2017.

Although recruitment is well under way we still need more patients and help from GPs.

We are in touch with GPs in your area asking for help with confirmation of patient's eligibility for inclusion into the study and provision of a room for the 2 year follow up.

There is a reimbursement for these services. If you are already involved please don't forget to let us know if an ExACT patient experiences any adverse events.

Trial Intervention: Patients receive brief information about the study and are given a postcard to return to the research team if willing to take part. Patients are randomised to either continue or discontinue 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

In addition if you are interested in getting more involved or require further information then please contact:

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

Global Anticoagulant Registry in the FIELD

GARFIELD-AF (Global Anticoagulation Registry in the FIELD) is an observational, multicentre, international registry of newly diagnosed atrial fibrillation patients with at least one additional 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 will take place in five independent, sequential cohorts and patients will be followed up for a minimum of two years. Enrolment to the fourth cohort is ongoing and in the UK, GARFIELD-AF is currently active in 136 practices in England, Wales, Northern Ireland and Scotland.

We have recruited 2209 patients to the registry so far. Thank you to all the practices participating in GARFIELD.

Learn more

If you would like further information about the study please contact:
Patricia Apenteng
Research Fellow
Tel: 0121 414 8579
Email: p.n.k.apenteng@bham.ac.uk

Patient self-management in primary care patients with COPD – a randomised controlled trial

PSM-COPD is funded by the National Institute for Health Research, School for Primary Care Research. It is a multi-centre study that is taking place across 4 UK Centres including; Birmingham, Oxford, Manchester and Keele. To date 18 practices have been recruited across Birmingham and the Black Country. The study will be recruiting until September 2015 and the study team is still looking to recruit additional practices.

Why is this research being carried out?

There is an absence of research evidence regarding the effectiveness of self-management interventions in primary care for people who report only mild symptoms of their COPD. Recent interest in COPD case finding in primary care, driven by the new National Clinical Outcomes Strategy for COPD, will result in identified patients who are not eligible for pulmonary rehabilitation. This study aims to inform care for this patient group and potentially slow the progression of their condition by advising lifestyle changes.

Aim of the study

The research aims to determine whether a telephone-based self-care intervention for people with COPD who display symptoms of mild dyspnoea, improves health-related quality of life and health behaviours at 12 months follow-up, compared to people allocated to usual primary care.

Practice involvement

- Conduct practice database search to identify potentially eligible patients
- GP to check list and prescribe bronchodilator used for spirometry
- Send out postal invitations to identified patients; materials and costs associated with this will be provided
- Provide a room and facilities for research clinics
- Please note that practice staff WILL NOT have to administer any questionnaires, book appointments for study clinics or train patients in self-management

Benefits to the practice in taking part

- The study will assist with COPD QOF targets (COPD002, COPD003, and COPD004)
- Spirometry assessment for your patients who are MRC1 and 2
- Updated BMI for your patients according to NICE guidelines
- All costs will be reimbursed in the usual way, according to the level of involvement of the practice.

Learn more

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HELICOBACTER ERADICATION ASPIRIN TRIAL

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

Principal Investigator Birmingham Region: Prof Richard Hobbs

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

Enrolment Period: 2012–2014

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

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

Use of aspirin for cardiovascular prophylaxis is widespread and increasing. The main hazard is ulcer bleeding. This is usually associated with *H. pylori* infection. It is important to determine whether this can be reduced or prevented by *H. pylori* eradication. The trial hypothesis is that aspirin does not itself cause peptic ulcers, but that it promotes bleeding of ulcers caused by *H. pylori.* Given the scale of aspirin use, its continuing increase and its contribution to ulcer bleeding, how to deal with this problem is arguably the most important question with regard to current iatrogenic medicine.

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

Learn more

If you would like to find out more, please contact the Trial Manager for your region,
Rachel Iles
Tel: 0121 414 2691
Email: r.iles@bham.ac.uk

Current studies

REVISE-Diabesity

Effective treatment options for combined diabetes and obesity, sometimes called 'diabesity', are fairly limited

REVISE-Diabesity aims to evaluate, in an NHS Secondary Care setting, the metabolic effectiveness of Endobarrier alone versus combined Endobarrier-Liraglutide therapy in patients with obesity and type 2 diabetes mellitus who remain overweight and with sub-optimal glycaemic control despite Liraglutide treatment.

The Endobarrier is a new device for diabetes, which mimics the 'bypass' aspect of gastric bypass surgery using an endoscopic approach. There will be a 1 year treatment period with an additional 12 month follow-up period.

We are asking practices in Birmingham to act as Patient Identification Centres (PICs) for this study.

Learn more
Sarah Hadfield
Research Facilitator, CRN: Primary Care
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Email: s.hadfield@bham.ac.uk

TIRCON

A randomised, double blind, placebo-controlled trial of deferiprone in patients with pantothenate kinase-associated neurodegeneation (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, Newcastle University. 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 Centre (PIC) sites 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 on site.

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 opportunity of having these weekly tests 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 the Primary Care Research Network (PCRN). It will be recruiting 8 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 happening off the GP practice premises.

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

TASMINH 4

Telemonitoring And/or Self-Monitoring IN Hypertension

What is the TASMINH 4 trial?

This research is a patient randomised controlled trial to 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 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

Study findings

Active Women Study: Is exercise an effective treatment for vasomotor menopausal symptoms?

Many perimenopausal and postmenopausal women experience hot flushes/night sweats that negatively impact on their health and quality of life. Hormone therapy (HT) is an effective treatment and, until recently, popular among patients and doctors. Research and media scares however have raised questions about the safety of HT. Many women are now reluctant to consider HT as treatment and doctors more cautious about prescribing it. As many women are choosing to avoid HT it is increasingly important to identify other evidence-based interventions. One possible treatment option is exercise, and the Scientific Advisory Committee of The Royal College of Obstetricians and Gynaecologists, and their Patient Information Committee, have already advised that regular sustained aerobic exercise (eg, running and swimming) may be an effective intervention. Likewise, The North American Menopause Society states that women who are overweight (most menopausal women) have more hot flushes so it is important for them to maintain a healthy weight and exercise regularly to decrease bothersome hot flushes.

Whilst exercise has been recommended as treatment for hot flushes/flushes/night sweats available evidence is inconclusive. The recent Cochrane review of exercise for the management of vasomotor menopausal symptoms in symptomatic women concluded that existing evidence suggests exercise is not an effective treatment for vasomotor menopausal symptoms but a definitive statement could not be made until more evidence was available.

The Active Women Study aimed to investigate the effectiveness of exercise as treatment for vasomotor menopausal symptoms. We wanted to find out whether exercise would reduce the number of hot flushes women experienced each day/week. We randomly allocated participants to three groups:

Group 1: Did not receive an intervention and continued with usual care

Group 2: Received an exercise intervention that involved two exercise consultations with a health advisor and invitations to participate in social support groups in the community to encourage women to increase their exercise levels.

Group 3: Received an exercise intervention that involved two exercise consultations with a health advisor and a DVD and information booklets to encourage more exercise. In total 261 women (87 in each group) were recruited to the study from 23 general practices across the West Midlands. Only women who were experiencing at least five hot flushes/night sweats per day and had not taken hormone therapy in previous three months were eligible to take part.

Neither of the exercise intervention groups reported significantly less frequent hot flushes/ night sweats per week compared to the usual care group. The exercise plus social support group experienced significantly less aches and pains, anxiety, slept better at night and participated in more vigorous exercise than the usual care group.

Contrary to current clinical guidance, we have concluded from this study that exercise is not an effective treatment for reducing the frequency of hot flushes/ night sweats, but it does help with improving other aspects of women's health around the time of menopause.

This study will be published in the British Journal of Obstetrics and Gynaecology later in the year.

We would like to thank all the practices who took part in this study and helped to make it a success.

Chief Investigator: **Dr Amanda Daley** (a.daley@bham.ac.uk).

Study findings

CLAHRC BITE

Brokering Innovation Through Evidence

A bite-sized summary of a piece of research supported by NIHR CLAHRC West Midlands

TRaCKED Study – Test Result Communication, Knowledge, Evaluation and Development

Background and introduction to study: 'I've had a terrible time getting my test results. One doctor told me to make an appointment just to get the results, implying that I wouldn't get them otherwise. In another case I was told that since the results weren't in my file they must have been posted meaning they were normal. Nothing came in the post.'

There are currently no clear guidelines in place for the communication of test results to patients in general practice. Audits have shown that current systems are fallible, with patients failing to receive results. A literature review revealed little existing research.

The variation in how test results are communicated can lead to confusion and failure to give proper care. In addition, some steps in communicating results waste time and resources.

The TRaCKED study gathered data from a series of focus group discussions with patients and staff, to assess strengths and weaknesses of current systems, and to identify areas and strategies for improvement that account for patient preference, staff capabilities, and logistical feasibility.

New systems were introduced at participating practices and evaluated using focus groups and questionnaires.

Current methods to communicate blood test results to patients are haphazard and can be improved by a few simple steps

Findings

Six key areas and strategies for improvement were determined:

1 Reduce delay in blood sample being taken – a wait of a week is common before sampling, leading to anxiety for patients and usually necessitating a return trip to the surgery. Additional phlebotomy appointments have been introduced at two practices.

2 Introduce failsafe – there is currently no mechanism in place for ensuring test results have been returned to practices by the laboratory, or have reached patients. Further work is required in this area.

3 Routine communication of (normal) results – patients were interested in use of modern technologies to standardise communication of normal results. One practice has introduced SMS messaging for normal results

4 Improvement of default system – patients had difficulty getting through to practices by telephone for blood test results. Call waiting was introduced at one practice.

5 Training for non-clinical staff – patients expressed concern about reception staff communicating sensitive information in public areas and being unable to answer further questions about results. A follow-up study is in the application phase.

6 Unambiguous protocol for result communication – no clear protocol was in place at any of the practices. Patient information leaflets were introduced at two practices specifying the blood test ordered, explaining how to retrieve results, outlining the protocol employed by their practice for communicating results, and providing an electronic link to an existing source of information about blood tests.

What is NIHR CLAHRC West Midlands?

The Collaborations for Leadership in Applied Health Research and Care (CLAHRC) is a partnership between universities (Birmingham, Warwick and Keele) and a number of health and social care organisations in the West Midlands. We are funded by the National Institute for Health Research with a mission to undertake high-quality applied health research focused on the needs of patients to improve health services locally and beyond.
For further information, visit:
www.clahrc-wm.nihr.ac.uk

The research was funded by the National Institute for Health Research. The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health.

Recommendations for practice
Communication of blood test results in primary care can be improved by practices providing clear information, reducing delays and being open to adopting new technologies.

References

Litchfield IJ, Bentham LM, Lilford RJ, Greenfield SM. Test result communication in primary care: clinical and office staff perspectives. *Fam Pract.* 2014; pii:cmu041. [Epub ahead of print].

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.



What's new in CPD this coming year at University of Birmingham?

Ongoing Courses 2014–15

PGT MSc 10 or 20 credits

Management of Hypertension in primary care

9 – 11 February

This three day module is suitable for GP's, nurses and other health care professionals aiming to acquire specialised skills and qualifications in hypertension management with primary and community care.

Other modules available 2014 / 2015

- Anticoagulation management in primary care
- Management of Heart Failure in primary care
- Management of Gynaecology in the community
- Atrial Fibrillation Management and Stroke Prevention
- Mental Health Care in the Community

Details of all modules and CPD courses are available on our website:
www.birmingham.ac.uk/anticoagulation

For further details please contact
Amy Partleton
Postgraduate Course Administrator
Tel: 0121 414 2677
Email a.partleton@bham.ac.uk

Continuing Professional Development

An Introduction to Oral Anticoagulation Management

2 March 2015; 18 May 2015

This one day course for practice nurses and GPs aims to provide an overview of the management of oral anticoagulation.

Diagnosis and Management of Common Neurological Disorders in Primary Care

6 February 2015

This one day course aims to provide an evidence-based approach to the diagnosis and management of common neurological problems, from headache and stroke, through to Parkinson's disease and multiple sclerosis. It provides a unique opportunity to interact with the experts on a wide range of neurological conditions.

Management of DVT and Pulmonary Embolism within primary care

11 February 2015

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

Oral Anticoagulation Management for Health Care Assistants and Assistant Practitioners

4 March 2015; 1 July 2015

A very popular one day course aimed at health care assistants and assistant practitioners working within anticoagulation clinics. We provide a basic knowledge of safety issues in anticoagulation management, INR testing technique, quality control and patient education.

Update on Respiratory Disease

3 February 2015

This one day course, suitable for respiratory nurses and physiotherapists, community matrons and GPs with an interest in respiratory medicine, aims to cover how to diagnose and manage asthma, COPD, bronchiectasis and some allergic disease relevant to the lung through a combination of lectures and small group work. Lectures will also include managing exacerbations and diagnostic dilemmas, such as asthma-COPD overlap, and will be focused toward primary care. It may be combined with a second day which covers more advanced respiratory care in the community.

Advanced Respiratory Care

4 February 2015

This one day course, suitable for respiratory nurses and physiotherapists, community matrons and GPs with an interest in respiratory medicine, follows on from 'An Update in Respiratory Disease' and aims to provide basic knowledge of more complex respiratory problems encountered in primary care. This includes pulmonary fibrosis, respiratory failure and obstructive sleep apnoea (OSA). The day will comprise a mixture of lectures and hands-on sessions with relevant equipment, such as oxygen concentrators and non-invasive ventilation (NIV) machines.

Patient self-monitoring of Oral Anticoagulation

24 February; 10 March; 12 March 2015

This one day course aims to provide an education framework for health professionals requiring the tools for training patients in self-testing or management of oral anticoagulation.

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 pccrtu@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

NHS
National Institute for Health Research

Clinical Research Network
Primary Care

The Clinical Research Network (CRN): Primary Care is rolling out a new initiative in the Birmingham and Black Country area called the Research Sites Initiative (RSI). This new annual initiative aims to strengthen the research infrastructure and the CRN: Primary Care would like to invite you and your practice to participate.

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
- Participate in **a minimum** of 2 CRN: Primary Care BBC Portfolio studies (SSC's will continue to be paid)

Level 2 – Remuneration £2000
- Same as Level 1 and
- Participate in **a minimum** of 3 CRN: Primary Care 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
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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