Can Research survive in the new world?
Research Sites Initiative
Studies in your area
I recently became the Research Manager for the Primary Care Research Network (PCRN) in Birmingham and Black Country (BBC). I am delighted to take this opportunity to introduce myself and explain to you about the different ways the PCRN can facilitate your engagement with research activity.

My background is in human movement sciences and I have a particular research interest in community based rehabilitation in children with cerebral palsy and adults who survived a stroke. I have a proven track record in publishing research papers and securing funding for fundamental research and randomised controlled trials. Furthermore, I have been a research participant for several studies, so I feel I am ideally suited to advise on ways to facilitate primary care research.

As you may know, the PCRN is part of the National Institute for Health Research and in the BBC area it builds on the track record established by the MidReC practices. We act as intermediary between the research and clinical teams to foster the implementation of research in primary care during the early stages. In the BBC area, we currently support over 100 research studies, which include, but not limited to, patients with chronic obstructive pulmonary disease, chronic kidney disease and atrial fibrillation.

The PCRN provides support, funding and infrastructure for local GP practices to engage in research. We will help you to select studies that are right for you and your practice. For instance, dedicated research nurses and GP research champions can advise you on the feasibility and practicalities of hosting research in your practice. Last year we helped to recruit over 6,500 patients, so we are well placed to get you started on identifying suitable research participants. My team of committed research facilitators and administrators can support you and your practice by:

- Explaining the needs of studies, so that you feel confident about contributing to them
- Providing hands-on support to contact patients and to obtain patient consent
- Helping you access NHS Service Support resources to cover staff time and involvement in research
- Accessing free Good Clinical Practice (GCP) training developed for primary care

This year we are rolling out a new initiative in the BBC area called the Research Sites Initiative (RSI) Scheme. Your practice will receive core funding to establish and maintain the ability to deliver NIHR Portfolio research in addition to NHS support costs. Accreditation to the scheme will help your practice meet the most up-to-date research standards and provide research teams with reassurance that research is conducted in accredited practices. The scheme will make a difference to support high quality research for the benefit of patients and the NHS. More information about the RSI Scheme is available in this issue of In Contact.

As you can see, there are many different ways the PCRN can facilitate research and I look forward to discussing with you how we can support you and your practice to engage in research activity.

Dr Max Feltham
Research Manager
Birmingham and Black Country
Primary Care Research Network Central England

To register your interest please contact us on: 0121 414 2845 or pcctru@contacts.bham.ac.uk
Can Research survive in the new world?

Many of us are exhausted by the constant change happening in the NHS. But sometimes, change can be good.

For the Primary Care Research Network the closure of the Primary Care Trusts represented a big threat.

The PCTs acted as the vehicle to ensure that support funds could flow to GP and other primary care providers, to enable them to participate in research projects. The PCTs were the bodies that ensured all the appropriate research governance and quality checks had been completed on a research study, to provide primary care providers with the reassurance that a study was safe and feasible to be carried out in their surgeries and that the research staff coming into their premises were trained to do their work in the primary care setting.

So we are delighted to let you know that GP leadership in the Area Team and the Clinical Commissioning Groups, and the strong commitment to primary care within the Clinical Research Network, means that these assurance mechanisms, the support funding and the strong infrastructure in place to enable clinicians and patients in primary care to participate in research, will continue under the new arrangements.

As you can see from this newsletter, the Primary Care Research Network in partnership with local GPs and community services, is going from strength to strength. We can now offer clinicians and patients a much broader range of studies to take part in and the research studies all offer real opportunities to improve clinical services and outcomes for patients.

Our aim is make sure that the support you receive from the Primary Care Research Network makes it easier and more cost-effective for you to take part in research, and that the research studies we can offer you and your patients address important topics, and lead to service improvements and better patient outcomes.

Thank you for your support in making this increase in research opportunities possible.

Rhian Hughes
Executive Director, PCRN
New studies

CANDID
CANcer Diagnosis Decision rules

The PCRN is looking for Expressions of Interest from GP practices to be involved in this non-commercial study, which is new to the BBC area.

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. There have been few valid studies to assist decision-making in primary care, either to get a patient referred quickly or to assist in making sure an anxious patient is effectively reassured.

What is the CANDID TRIAL?
This research is about finding which symptoms and examination findings are most accurate for early identification of lung and colorectal cancer. The study aims to develop clinical decision rules to help identify those primary care patients at increased risk of cancer early on. It is funded by the National Institute for Health Research (NIHR) National School of Primary Care Research (NSPCR).

20,000 people with lung and colorectal symptoms will be asked to take part in this research, half with lung and half with colorectal symptoms. This is a multi-centre study and will be coordinated from the University of Southampton by a team led by Professor Paul Little.

WE ARE LOOKING TO START RECRUITING 50 PRACTICES ACROSS BIRMINGHAM AND THE BLACK COUNTRY THIS AUTUMN.

What is involved for Practices?
This is an observational cohort study with GPs providing patient care as usual.

Practices will identify potential participants in 2 ways:
1. Opportunistically by the GP during consultation
2. Mail out monthly letters of invitation from a search of the practice database

GPs will be asked to:
- Obtain informed consent
- Collect clinical information using an online proforma
- Ask participants to complete a lifestyle questionnaire at home
- Obtain blood/saliva samples from willing participants (equipment will be provided)
- Fax consent form to the research team

Undertake a medical notes review of consented patients two years following recruitment.

Practices undertaking this study will be eligible to receive payment via service support costs to cover the time spent recruiting patients. Additional payment will be made for each blood sample.

Learn more
Sarah Campbell
Senior Facilitator, PCRN-CE
(Birmingham and Black Country Spoke)
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OSAC

OSAC (Oral Steroids for Acute Cough) Trial

The PCRN is looking for Expressions of Interest from GP practices to be involved in this non-commercial study, which is new to the BBC area.

OSAC is a randomised controlled clinical trial to find out whether oral steroids could be a better treatment than prescribing antibiotics, which contribute to the rise of serious hospital infections like MRSA. OSAC is funded by the NIHR and has received NHS ethical approval. The study is being run by the Universities of Bristol, Oxford, Nottingham and Southampton.

We will ask each GP practice to recruit at least 13 patients over the next two winters. Service support costs will be reimbursed to cover the time spent recruiting the patients.

The OSAC trial will test whether 40mg of oral Prednisolone daily for 5 days will reduce the duration and severity of moderately bad (or worse) symptoms associated with acute chest infections by at least 20%, compared to placebo. With the help of GPs and Nurse Practitioners across Birmingham and the Black Country, we will randomise at least 100 non-asthmatic adults presenting with an acute cough (≤28 days) into this trial.

Trial participation involves:
- Identification and screening of eligible patients
- Obtaining written informed consent
- Issuing trial prescription
- Clinical management of participant
- Completion of Case Report Forms
- Primary care notes review

The OSAC trial team provides training for all recruiting GP sites, and the PCRN will be able to advise you about ICH-GCP training.

The findings of this study will help to provide clinicians with a new treatment option that could substantially improve patient’s health and reduce the prescribing of antibiotics. Furthermore, it will contribute to a growing body of research investigating the effects of steroids on the undesirable inflammatory symptoms associated with infection.

Learn more

Saif Uddin
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(Birmingham and Black Country Spoke)
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PSM COPD

Patient Self-Management in primary care patients with Chronic Obstructive Pulmonary Disease (PSM-COPD)

A randomised controlled trial of a telephone-based self-management intervention for patients with mild dyspnoea.

The PSM-COPD trial is a NIHR funded study that aims to assess the effectiveness of a telephone-based self-management intervention as a treatment for patients with COPD who have mild dyspnoea compared to usual care.

Patients will be recruited across four sites (Birmingham, Keele, Manchester, and Oxford). Eligible patients will be randomised to receive the telephone-based self-management care that is delivered by a study research nurse or they will be randomised to usual care. The telephone calls will cover the areas of: smoking cessation advice; encouragement to become physically active; support for medication adherence; and action planning. At present, we are undertaking a feasibility study along with focus groups to assess the acceptability of the intervention. The main trial will begin in January 2014 and we expect patient recruitment to last for eight months.

Therefore, we would like to invite interested GP practices to contact us to take part in our trial. The additional workload, if you decide to take part, is minimal. We will ask you to generate a list of patients who have mild dyspnoea (MRC grades 1 and 2) and mail a study invitation letter. Those patients wishing to take part in our study will be asked to return a reply slip or contact the University of Birmingham research team. Practices will need to provide clinic space so our research nurse can confirm eligibility and take consent from patients. We will pay a set-up fee and reimburse practices for additional activities completed as part of our trial.

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

Dr Manbinder Sidhu
Research Fellow
Tel: 0121 414 7895
Email m.s.sidhu@bham.ac.uk

Principal Investigator: Professor Kate Jolly
The Preloading Trial

Help your patients to quit smoking.

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

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

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

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

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

Therefore practices taking part will be required to write to their list of registered smokers to invite them to the study and provide a room for use by our researchers one day (or morning/afternoon) a week. All of your costs in taking part will be covered, and the study could help your patients to give up smoking. Therefore if you are based in the West Midlands and would like to be involved then please contact:

Learn more
Shahnaz Kauser
Trial Administrator
Tel: 0121 415 8019
Email: s.khan.6@bham.ac.uk

The PMR Study

Polymyalgia rheumatica (PMR) is the commonest inflammatory rheumatic disease seen in older adults. In the UK the majority of diagnosis and management of PMR is mainly done in primary care. However, very limited research has been conducted for this condition in the primary care settings, as the majority of the research has been carried out on patients in secondary care.

The PMR study is a cohort study trying to recruit GP diagnosed new patients. This study is funded by Arthritis Research UK and the research team is led by Professor Christian Mallen, an academic GP based at Arthritis Research UK Primary Care Centre, Keele University. The overall aim of the study is to assess the epidemiology of PMR in general practice.

Eligible patients are identified during consultation. A prompt will appear on your computer system (if it is an EMIS practice) or a paper based reminder will remind the GP about the study. The GP will then need to give the patient a postcard about the study, request a blood test in line with best practice guidance and send the fax referral form to the research centre. At the end of the study, electronic downloads of medical records for consented patients will be requested. The study has so far recruited 23 practices in Birmingham. For further information please contact research facilitators.

Learn more
Anu Krishna
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Fax: 0121 414 6597
Email: a.t.krishna@bham.ac.uk
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


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 bleeding of ulcers. 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 bleeding of ulcers, how to deal with this problem is arguably the most important question with regard to current iatrogenic medicine.

A prominent reason why elderly people have weakened immune systems, and therefore fail to respond adequately to the flu vaccine, is that chronic viral infections accumulate throughout life. Our immune systems display ‘frailty’ because they are diverting a lot of resources towards fighting these viruses instead of new infections. One such virus type is cytomegalovirus (CMV), a herpesvirus carried by the majority of the UK population that can never be cleared from the host.

This study funded by the Medical Research Council is a randomised clinical trial to investigate whether suppressing the CMV load in the body will allow elderly peoples’ immune systems to achieve an enhanced protective response to flu vaccination. The antiviral Valaciclovir will be used to reduce the viral load.

We are currently recruiting primary care health centres across Birmingham and the Black Country. Healthy people aged over 65 are screened for eligibility, randomised to a drug dosage, and then attend monthly appointments for 6 months (and follow-ups at 9 and 12 months). Blood and urine samples are taken at these appointments to monitor safety and collect outcome data.

This trial is led by Professor Paul Moss (School of Cancer Sciences, University of Birmingham) and Professor Richard McManus (Department of Primary Health Care Sciences, University of Oxford). If you are interested in participating in the trial, or would like further information, please contact:

Dr. Odette Chagoury
Senior Trials Manager
Tel: 0121 414 9116
Email: aspire@contacts.bham.ac.uk

A Study Promoting the Influenza Response in the Elderly (ASPIRE)

The flu vaccination, offered to all over-65 year olds, is surprisingly ineffective in a lot of people. 60% of elderly individuals fail to achieve a protective immune response. This fact, coupled with the recent emergence of new influenza strains increasing the risk of a new pandemic, emphasises the need for improved vaccination efficacy.

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Senior Trials Manager
Tel: 0121 414 9116
Email: aspire@contacts.bham.ac.uk
3C Cough Complications Cohort Study

The 3C study has now ended and the national target of 30,000 patients has been met. In Birmingham and the Black Country (BBC) we recruited a total of 1,068 patients which is just over 3.5% of the national figure!

We wanted to personally take this opportunity to thank all the practices that took part for all their hard work and time. It has been a pleasure to work closely with all our community GP’s and nurses and we look forward to our next challenge together, once again thank you!

The following 3 practices were our top recruiters here in the BBC during the duration of the study and we would like to acknowledge their continued support; in order of most recruited. These practices are as follows:

1. Maypole Health Centre
2. Eve Hill Medical Practice
3. Woodgate Valley Health Centre

If you are interested in further studies of a similar nature, two new national studies, OSAC (Oral Steroids for Acute Cough trial) and CANDID (CANcer Diagnosis Decision rules) are due to start very soon, please look out for the articles available in this edition of In-Contact.

Learn more
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Super EDEN
Sustaining Positive Engagement and Recovery

The NIHR funded Super EDEN Programme is the next step after Early Intervention for Psychosis.

Because this study is a follow up to the DoH National EDEN project, our aim was to re-contact all those people (n=1027 across the country) who were a part of the National EDEN study and invite them to take part in the Super EDEN study which is focussed on determining the trajectories and outcome of these clients post Early Intervention Services; identify discharge destinations and explore predictors of change.

Over the past year we have been contacting GP surgeries to help us locate and invite clients to take part in this follow up study. We have now finished recruitment and are delighted to say that 169 clients in the Birmingham and Solihull area consented to take part (Nationally we have re-consented 519 out of a possible 1027?). We are now in a 2 year follow up phase and hope to get initial findings out by the end of 2015.

I would like to take this opportunity to thank everyone involved in helping make this study a success, from GPs to practice managers to the helpful reception staff — we couldn’t have done it without you!

If anyone would like any further information, please do not hesitate to contact:

Linda Everard
linda.everard@bsmhft.nhs.uk
West Midlands
Research Design Service

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

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

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.

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

Understanding Haematology tests – when to refer
Tuesday 11 February 2014

This one day course aims to cover the following areas of haematology: red cells and haemoglobin, white cells, platelets and coagulation, the common laboratory tests used, how to interpret them and parameters at which referral to a haematologist is indicated.

Atrial Fibrillation Management and Stroke Prevention
10–13 March 2014

This four day module will provide theoretical and practical knowledge of the condition of Atrial Fibrillation. Diagnosis will be examined, treatment (both surgical and medical) explained and evidence based management to include anticoagulation for stroke prevention.

Ongoing Courses 2013/2014
PGT MSc 10 or 20 credits

Management of Heart Failure in primary care
27–30 January 2014

A four day module suitable for GPs, nurses and other health care professionals aiming to acquire specialised skills and qualifications in heart failure management within primary and community care.

Management of Hypertension in primary care
10–13 February 2014

A four day module suitable for GPs, nurses and other health care professionals aiming to acquire specialised skills and qualifications in hypertension management within primary and community care.

Anticoagulation management in primary care
7–9 April, 18–20 June, 15–17 September, 1–3 December 2014

This three day module aims to ensure safe practice managing with both fundamental and more complex problems of oral anticoagulation management.

Management of Gynaecology in the community
24–26 March 2014

This three day module is aimed at GP’s and practice nurses working in the community who wish to develop competencies in the management of gynaecological disorders to an advanced level.

Continuing Professional Development

Liver disease in primary care
28–29 November 2013

This two day mini conference is organised in conjunction with Dr Phil Newsome, Hon Consultant Hepatologist, Queen Elizabeth Hospital Birmingham and other national leaders in Liver disease care. The course aims to provide both theoretical and practical knowledge of liver disease and how to manage within a primary care setting e.g. alcohol use and common liver disorders.

Oral Anticoagulation Management for Health Care Assistants and Assistant Practitioners
5 March, 11 June, 15 October 2014

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.

Diagnosis and management of peripheral arterial and venous disease in primary care: implementing NICE guidelines
Wednesday 12 February 2014

This one day course will allow participants to understand the epidemiology, diagnosis and management of peripheral arterial and venous disease so that they can meet the recommendations contained within recent published NICE guidelines.

An Introduction to Oral Anticoagulation Management
17 March, 9 June, 8 September, 17 November 2014

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

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

Tamara Ball
CPD Course Administrator
Tel: 0121 414 3281
Email: t.c.ball@bham.ac.uk
Interested in taking part in research? We’d like to hear from you.
- You will always be able to choose your practice’s level of involvement.
- You will be remunerated for practice time spent on research.

Contact details:

Name: 
Job title: 
Practice address: 
Postcode: 
Practice code: 
Email: 

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

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

You can:
- Fax back this form to 0121 414 2282 or
- Email the details above to pccrtu@contacts.bham.ac.uk or
- Phone us on 0121 414 8843 for further information.

Alternatively, send the completed form to our postal address, as detailed on the back page.
The PCRN 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 PCRN would like to invite you and your practice to participate.

**What is RSI?**
The RCGP and the PCRN 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.

**Is RSI the same as Research Ready?**
No, the Research Ready Scheme is an arm of the RSI, which will eventually be phased out.

**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 PCRN 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 PCRN BBC 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.

**Saif Uddin**
Research Facilitator
Tel: 0121 414 8614
Email: s.uddin@bham.ac.uk

**Sarah Campbell**
Senior Facilitator
Tel: 0121 414 3168
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